RESEARCH ON HEALTH EFFECTS OF NONIONIZING RADIATION

HEARING

BEFORE THE

SUBCOMMITTEE ON NATURAL RESOURCES AND ENVIRONMENT

OF THE

COMMITTEE ON SCIENCE AND TECHNOLOGY U.S. HOUSE OF REPRESENTATIVES

NINETY-SIXTH CONGRESS

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COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES
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WASHINGTON, D.C. 20515

January 23, 1980

Hon. Don Fuqua, Chairman
Committee on Science and Technology
Washington, D. C. 20515

Dear Mr. Chairman:

I am transmitting herewith the record of hearings on research on the health effects of nonionizing radiation held before the Subcommittee on Natural Resources and Environment.

In partial preparation for the hearings we prepared a "charter" to outline the issues which we felt should be addressed. The charter is reprinted following this letter, and can serve as a brief introduction to the testimony.

Mr. Chairman, I commend this record to you and the other Members of the Committee.

Yours sincerely,

JEROME A. AMBRO, Chairman
Subcommittee on Natural
Resources and Environment

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RESEARCH ON HEALTH EFFECTS OF NONIONIZING RADIATION

THURSDAY, JULY 12, 1979

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
SUBCOMMITTEE ON NATURAL RESOURCES AND ENVIRONMENT,
Washington, D.C.

The subcommittee met, pursuant to call, at 10:05 a.m., in room 2325, Rayburn House Office Building, Hon. Jerome Ambro, Chairman of the subcommittee, presiding.

Present: Representatives Ambro and Walker.

Mr. AMBRO. The subcommittee will be in order. I was hoping Congresswoman Holtzman would be here by now. She is on her way. Maybe she will get here while I go through this opening statement and we will call her as the first witness. If not, we will proceed with our other witnesses.

The Subcommittee on Natural Resources and Environment has a continuing responsibility for oversight of Federal environmental research programs. The question before us today is whether Federal research efforts are adequate to determine the public health impacts of our increasing exposure to electromagnetic radiation.

The members of this subcommittee are aware that, along with persons in every other industrialized society, Americans are increasingly exposed to nonionizing radiation from sources as diverse as television, microwave ovens, radars, and high voltage electricity transmission lines.

Numerous research reports have suggested that over a wide range of exposure levels, adverse, and potentially adverse health effects occur. At the highest levels, tissues are damaged by the heating of cells, while at lower levels of exposure, some research suggests that neurological damage can occur.

However, the existing research results are often contradictory and inconclusive. There is a need for a well-planned and coordinated research program to identify and clear up the uncertainties which exist and to finally establish exposure tolerances for the various levels of nonionizing radiation.

We are aware of the difficulties faced by diverse Federal agencies in planning, coordinating and carrying out research programs spread over a number of agencies. The purpose of this hearing is to identify the problems of research into nonionizing radiation and to seek ways to mount a comprehensive program which will lead to the development of efficacious regulatory decisions.

In today's economy we have limited Federal dollars for a wide variety of research and development problems. It is therefore be-

coming increasingly important that funds be applied to real problems of the most serious nature. Concern over nonionizing radiation covers a wide range of exposure levels. We hope here to establish for the record what ranges of exposure must be the focus of current and future research program.

As I said at the outset I was prepared to have Congresswoman Holtzman who has been a leader motivating Congress in this area testify first, but since she is not here I would like to call up Mr. Howard Johnson, staff vice president for product safety, RCA Corp., and chairman of the RF Radiation Committee of the Electronic Industries Association.

At the outset, I assure you that your entire statement will be included in the record and you may proceed.

[The full statement of Mr. Johnson follows:]

STATEMENT OF HOWARD W. JOHNSON
BEFORE THE SUBCOMMITTEE ON
NATURAL RESOURCES AND THE ENVIRONMENT OF
THE HOUSE SCIENCE COMMITTEE

July 12, 1979

Mr. Chairman, thank you for your invitation to participate in your hearings today.

I am Howard Johnson, Staff Vice President, Product Safety, for the RCA Corporation. I am here today in my capacity as the Chairman of the RF Radiation Committee of the Electronic Industries Association.

The Communications Division of the Electronic Industries Association represents most of the major manufacturers of electronic equipment and systems in the United States used for government, commercial, and private communications services.

In June 1977, I was in the audience during five days of hearings on Radiation Health and Safety conducted by two subcommittees of the Senate Committee On Commerce, Science, and Transportation.

When the Staff report of those hearings was released, I responded to Senator Cannon's invitation for comments with a few recommendations. I have been requested to make those recommendations here today.

During the Senate hearings, Senator Stevenson observed that he had never got into a subject where there was so much information and so little knowledge. We believe that the "so much information" resulted from the attempt to cover the safety and health effects of the whole radiation spectrum. For this reason, the plans for consideration of these problems by the 96th Congress should provide separate sessions on ionizing radiation and separate sessions on nonionizing radiation. The problems and health effects, while never very clear in the public's perception, have become blurred together under one misunderstanding of radiation. Congress can help Science and Industry educate the public by always making the distinction clear, and you are to be congratulated for restricting this hearing to only the one subject, nonionizing radiation.

Although there are more than 5000 published reports of animal experiments in the field of bioeffects of nonionizing radiation, there is a paucity of data on the adverse effects to humans at low levels of exposure. The lack of Federal standards is interpreted by some to be lethargic inaction and ineptitude on the part of the responsible Federal agencies. By others, it is construed to be a tribute to the intellectual honesty of American science that the absence of Federal standards reflects the lack of human data and a demonstrated need. Although some European countries have established standards, and Canada is in the final stages of doing so, it is possible that our great country has not established them because no one has reported irreversible harmful effects to humans from nonionizing radiation at power densities of 10 mW/cm^2 or less.

However, there have been a number of significant events that have occurred since the 1977 Senate Subcommittee hearings that suggest a possible need for standards for other than health and safety reasons. Oversight review, audits, and criticism by other Congressional committees, the General Accounting Office, and the news media have generated much nonproductive time in discussing and defending the lack of action of Federal agencies for not establishing safe exposure standards. The unjust accusations of a cover-up by Government and Industry of potential health hazards have been renewable grist for the popular press. The absence of Federal standards is one reason given by the New York City Board of Health to justify amending its Health Code by proposing an exposure standard far more restrictive than anything supportable in the literature, or suggested by U.S. agencies. Important radar installations, telecommunications links, and security systems have been delayed by an uninformed, but aroused, public. One U.S. company in its annual report recently reported a downturn in microwave oven sales in Great Britain "because of publicity over alleged dangers from various sources of radiation, ranging from microwave cooking to microwave communications equipment."

I have attached as an appendix to these remarks two newspaper reports in The Philadelphia Inquirer of June 19 and June 21, 1979, concerning a microwave telecommunications tower. Such reports are appearing more frequently and reflect local government and industry problems of assuring the public of the safety of microwave communication systems.

These developments have created an unnecessary fear in the public mind and have added another area of adversary government through conflicting claims and rebuttals.

The need for Federal exposure standards is no longer a domestic, scientific curiosity which may take twenty more years to understand, but it has developed into a national and an international problem requiring a political solution. I stress the need for a political solution.

For this reason we are in agreement with the recommendations in the Senate report under the headings of "Fundamental Research Needs" and "Jurisdictional Issues." Coordination of the Federal research programs at an executive-level position within the Executive Office of the President is necessary if there is ever to be scientifically developed data in a reasonable time frame to establish Federal standards. The proposed organization also should be directed to primarily concern itself only with stimulating research programs by the various agencies which show promise of demonstrating the need, or its absence, for Federal standards of safe levels of exposure. I believe the interagency task force on Biological Effects of Nonionizing Electromagnetic Radiation, known by its acronym BENER, recently established by the Department of Commerce, meets the requirement for better coordination of the Federal research programs, but BENER would better meet the jurisdictional issues if it were part of the Executive Office of the President, rather than in a lower level of the Department of Commerce.

The knowledge of what biological effects in humans may be produced by long-term, low-level exposure to nonionizing radiation is a problem that infers a need for urgent answers. However, the records to develop good epidemiological studies may not exist. The daily mobility of our society in an invisible and undetectable environment of nonionizing radiation indicates a wide variation of unrecorded exposure that may occur to any two people who work side by side together or live in the same domicile.

For this reason the recommendations in the Senate report for action by the National Bureau of Standards listed under "Exposure to Nonionizing Radiation" should include direction to establish a research and development program to produce as quickly as possible a satisfactory personal dosimeter for nonionizing radiation so that an inexpensive unit will be available for occupational and general population use in the same manner that ionizing radiation dosimeters are used for determining exposure over a long period of time.

OSHA had a nonionizing radiation exposure standard which it believed was mandatory, but the standard was declared unenforceable and only advisory by Occupational Safety and Health Review Commission Judge James P. O'Connell on 31 December 1975.

The mandatory aspect of the OSHA standard was overturned by one company which would not accept a citation for a non-serious, no penalty violation of employee exposure to nonionizing radiation. It will be no simple task now for OSHA to convert "the present voluntary standard to a mandatory standard on an interim basis," while conducting a review and promulgating a mandatory standard, as recommended in the Senate report under the heading "Exposure to Nonionizing Radiation." The lack of evidence of harmful effects to humans from low-level radiation will make it a difficult task to provide a defensible standard which will hold up in judicial review.

We are in agreement with the Senate report that the Office of Technology Assessment should research the impact of emerging technologies on the environment and assess the economic and functional impact of imposing upper limits on radiation. The intricate problems of enforcement of a nonionizing radiation standard are staggering and such a standard can dislocate the planned services of many industries, to say nothing of the millions of dollars of cost to Government and Industry in litigation which is sure to result if there is no more evidence of harm to human health than exists today. For example, in a multi-source area where the total ambient level of radiation is found to exceed a future standard, which licensed emitter will be judged to have exceeded the limit?

I believe that a study by the Office of Technology Assessment may show that product performance standards limiting the amount of leakage of nonionizing radiation permitted from specific products, such as the present microwave oven standard, is the most effective way to go at the present time.

Although coordination of Federal research is necessary, there is no indication that a scientific breakthrough will occur in the next few years and be helpful in establishing defensible safe exposure standards. Furthermore, the time required for any Federal agency to promulgate the appropriate data and proposed regulations in the Federal Register, solicit comments, hold public hearings, and publish final regulations, will add several years to the process. The average time for rule making by the EPA is four years.

For any agency to publish proposed regulations and safe exposure standards based upon information available today on the adverse effects on humans and without a clearly demonstrated need for the standard, would be counter-productive. One can predict the outcome of such an endeavor by relating to similar safety standards established by the Consumer Product Safety Commission which were made non-effective by court action primarily because of a lack of a demonstrated need for portions of the standards.

Although the continual re-establishment of the public's faith in its Government and the relief of unnecessary anxiety exists, it is also appropriate to recognize that nonionizing radiation has a low priority in regulatory agency budgets because the agencies do not perceive it to have imminent harmful effects as do other items of higher priority. The efforts to control inflation suggest that this is an area where Government spending can continue to be controlled. It will serve little purpose for the Congress to urge the regulatory agencies to spend more money in endeavoring to speed up answers in an area where the public health need is so obscure and satisfactory progress is being made.

The compromise answer to this dilemma is a political solution which lies in Congressional action similar to that taken by the Consumer Subcommittee of the Senate Committee on Commerce, Science, and Transportation, which resulted in the passage of the bill S2401 and established the flammability standard for cellulose insulation.

When faced with the long delays which would be experienced by regulatory agency procedures, the Congress solved that problem in one day and adopted the GSA standard as an interim Federal mandatory standard for cellulose insulation. Congress can do it again and resolve the problem by adopting the present voluntary standard as an interim, Federal standard. The American National Standards Institute ANSI C95.1 "Safety Levels of Electromagnetic Radiation with Respect to Personnel" (and its proposed 1979 reaffirmation or revision) is representative of the consensus of American scientific thought and we recommend that it be adopted by Congress as an interim, mandatory Federal standard. Once this stake is driven, we will have a rallying point from which research and regulation can progress in a more orderly and less-pressured fashion without unreasonable risk to the public.

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THE PHILADELPHIA INQUIRER

Tuesday, 19 June 1979

Microwave towers safe, PUC told

Two witnesses for the Bell Telephone Co. of Pennsylvania testified yesterday at a Public Utility Commission hearing in Norristown that radiation from two proposed microwave towers in Montgomery County would be well below danger levels.

The 120-foot towers, which would be in Lower Providence and Limerick townships, are being opposed by the supervisors of both townships and local residents, who fear that the radiation might be harmful.

The towers would be used to complete a relay system between Wayne and Allentown for telephone subscribers in Montgomery, Bucks, Lehigh and Northampton counties.

Dr. Herman P. Schwan, professor of bioengineering at the University of Pennsylvania, testified that microwave levels near the towers would be comparable to, or lower than, levels in a kitchen with a microwave oven.

He added that the microwaves generated by the towers would be 100,000 times lower than microwaves, such as X-rays, used in routine medical practice.

"The frequency (on which the towers would operate) has much less potential effect on man than lower frequencies, such as those used for FM or citizen's band radio and television transmission," Dr. Schwan said. He added that microwave levels in both townships would conform to national and international safety standards.

The other witness, Dr. Herbert Pollack, professor emeritus of clinical medicine at George Washington University, testified that after a Soviet electronic eavesdropping operation was uncovered in 1976, he coordinated a medical investigation of U.S. Embassy personnel in Moscow who had been subjected to microwaves.

He said the study found no medical abnormalities among the embassy personnel.

Bell Telephone plans to present five other witnesses at the hearings, which are expected to last for two more days.

PHILADELPHIA INQUIRER
Thursday, 21 June 1979

Bell's assurances rejected at microwave tower sites

By Robert McSherry
Special to The Inquirer

"Why tamper with our lives?" Mrs. Lucy Lindsay asks. "Life is too short. Today, we already have enough things to hurt our health."

Lucy Lindsay is far from impressed by Bell of Pennsylvania experts who say there will be no danger to residents living near a proposed microwave tower site in her neighborhood.

Mrs. Lindsay, 59, of Eagleville, who, with her husband, lives in a four-bedroom home 1,000 feet from the proposed tower, has been fighting it five months.

"To me, that paperwork and that talk means nothing," she said of recent testimony by Bell's expert witnesses, who, during a series of state's Public Utility Commission (PUC) hearings in Norristown earlier this week, contended the tower was safe.

Mrs. Lindsay said she did not care that Bell's two biggest witnesses, Dr. Herman R. Schwan of the University of Pennsylvania and Dr. Herbert Pollack of George Washington University, testified that the microwaves emitted by the tower would be harmless. She said she still felt they would be dangerous to her health.

"Why tamper with our lives?" Mrs. Lindsay asked. "Life is too short. Today, we already have enough things to hurt our health."

The proposed 120-foot tower in Lower Providence Township is one of two that Bell wants to construct as part of a $2.4 million relay system for telephone service between Wayne and Allentown. The other tower would be built in Limerick Township.

During the hearings, Ronald H. Reynier, solicitor for Limerick Township, said the proposed tower site at Ryanford Road near Gerloff Road was only 2½ miles from the Limerick nuclear power plant, currently under construction. He said local residents, already worried about radiation from the power plant, were also concerned about microwave radiation.

Bell witnesses assured him that the microwave radiation would be at levels too low to be harmful.

In Lower Providence Township, the supervisors approved the microwave tower in March 1978. But a month later they revoked their approval because of fears of health hazards from microwave radiation.

According to J. Scott Miller, township manager, Bell then tried an end run by filing an application with the PUC to build the tower. He said the PUC had authority to approve the tower over the protests of the township supervisors.

Miller said that about 40 or 50 families lived in the Adele Lane and Wilson Boulevard area of the township, where the tower would be built. He said many of the residents were retired couples who feared that their health would be affected by the microwaves.

According to Carl Buchenauer, chairman of the Lower Providence Township supervisors, a report made for the township by Rob Smith Associates of Norristown stated that the microwave tower would be harmless if built to Bell of Pennsylvania specifications. Buchenauer added, however, that the supervisors wanted the microwaves to be monitored to make sure radiation did not increase to dangerous proportions.

"We (supervisors) all were opposed to it in the beginning. That's why we had Rob Smith Associates check it out," Buchenauer said. "Then when he came back with his report stating it was not harmful if built according to specifications, we felt that someone should monitor it to see that it stays within allowable limits ... I can't see any way we can oppose it when all the experts say it is not harmful."

Buchenauer said that most residents were afraid of the microwave tower because of news reports several years ago about the Soviet use of "microwaves" against the U.S. Embassy in Moscow during an electronic eavesdropping operation.

During PUC testimony, Dr. Pollack said he had examined the medical records of 1,800 persons who worked at the embassy between 1953 and 1976, when the microwave beams were revealed. He testified that the microwave bombardment had not affected the health of the employes.

Philadelphia Inquirer / MICHAEL VIOLA

Mrs. Joelma Thomas of Eagleville points to one of phone company's tower sites near her home

95th Congress
2d Session

COMMITTEE PRINT

REPORT ON RADIATION HEALTH AND SAFETY

PREPARED AT THE REQUEST OF

HON. HOWARD W. CANNON, *Chairman*
COMMITTEE ON COMMERCE,
SCIENCE, AND TRANSPORTATION
UNITED STATES SENATE

DECEMBER 1978

Printed for the use of the
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LETTER OF TRANSMITTAL

U.S. SENATE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
December 1, 1978.

DEAR COLLEAGUE: Many persons in the Government, the health sciences community, industry, academia, and the general public are interested in the possible effect of many forms of ionizing and nonionizing radiation on public health and safety. In recognition of that interest, the Committee on Commerce, Science, and Transportation conducted extensive public hearings in June 1977 to receive the viewpoint of all interested persons and organizations which would permit adequate evaluation of this important issue. The complete record of those hearings was printed and released as publication Serial No. 95–49.

On September 21, 1978, in executive session, committee members recognized that the extensiveness and complexity of this 1,224-page record required thorough analysis and supplemental study and accordingly directed the staff to publish the findings and recommendations of its study for subsequent review by the committee, as well as for the information and guidance of many persons with varying degrees of responsibility and interest in this matter.

This document has been prepared in accordance with that directive. Although this report has been neither approved, disapproved, or considered by the Committee on Commerce, Science, and Transportation, I believe it will prove important and useful to many recipients in their understanding of the effects of all forms of radiation on public health and safety, and in future actions taken with respect to these problems.

Sincerely,

HOWARD W. CANNON, *Chairman.*

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APPENDICES

INTRODUCTION

In June 1977, the U.S. Senate Committee on Commerce, Science, and Transportation conducted 5 days of comprehensive oversight hearings on the subject of radiation health and safety. This document—prepared by the committee staff—provides a summary of the testimony, a report of findings and conclusions, and recommendations for future action.

The hearings were conducted for two principal reasons. First, the committee was concerned with the increasing number of radiation emitting sources to which the public is exposed. It has long been known that ionizing radiation can cause biological and genetic damage (e.g. production of leukemia or short-limbed dwarfism). Furthermore, experts have raised unanswered questions about the effects of nonionizing radiation. Since every person is exposed daily to some level of both ionizing and nonionizing radiation from manmade and natural sources, the Government has an obligation to determine what potential health hazards may exist and to provide safeguards to minimize their effect. Second, the committee played a major role in enacting the Radiation Control for Health and Safety Act of 1968. As a consequence, the committee was interested in determining how the act has been implemented. In addition, under the reorganization of Senate committees, the Committee on Commerce, Science, and Transportation has comprehensive oversight jurisdiction over policy matters relating to science, engineering and technology research and development.

The committee planned a comprehensive review of health and safety concerns related to ionizing and nonionizing radiation. In its preparatory work, the committee solicited data from 32 Federal agencies relative to their radiation research and regulatory efforts. It also requested the opinions of experts from the private sector on the adequacy of present Federal efforts in this area. A careful examination of data submitted prior to the hearing indicated the likelihood of confusion resulting from voids in and duplication of effort at the Federal level in both research and regulation. Therefore, the committee was interested in learning what might be done to coordinate or clarify those responsibilities to protect the public interest more effectively. In addition, the committee was aware of the public's concern over news reports, factual and speculative, concerning the harmful effects of radiation—for example, the controversy surrounding mammography, the microwave irradiation of the Moscow Embassy, and the Navy's proposed Project Seafarer.

The hearing developed a large body of scientific and technical opinion, which was divided on issues bearing directly on safety. Most of this information has been included in the committee's printed hearing record, serial No. 95–49. This present report presents findings and recommendations based upon study and evaluation of that record by the committee staff.

Testimony indicated that medical radiation accounts for more than 90 percent of all manmade ionizing radiation received by Americans, and that nearly one-third of all X-rays (i.e., 70 million to 90 million) may be unnecessary, contributing an estimated $2 billion each year to the Nation's medical bill. Many of these unnecessary X-rays appear to result from the lack of agreement among medical practitioners on criteria for determining when a specific X-ray procedure is needed and the lack of guidance available to the general public for balancing the risks and benefits of these exposures. In addition, testimony indicated that approximately 50 percent of the practicing radiologic technologists have had no formal training nor have they met any Federal, State, local, or professional certification requirements. Furthermore, the health hazards of persons (such as nuclear facility employees) subjected over long periods to low levels of ionizing radiation have not been adequately evaluated and that exposure limits for protection therefrom may not presently be adequate. This information indicates that the public is not adequately protected from the dangers of unnecessary exposure to ionizing radiation.

In the area of nonionizing radiation, witnesses testified that there are no mandatory limits for occupational exposure to nonionizing radiation and that the present voluntary system, in some cases, may not be adequate for employee safety. For example, a National Institute for Occupational Safety and Health (NIOSH) survey discovered that 75 percent of the equipment used for radio frequency (RF) sealing and heating purposes exceeded recommended exposure standards. Many of the affected employees do not realize that they are using RF radiation. It is therefore recommended that the Occupational Safety and Health Administration (OSHA) take prompt action to develop an adequate mandatory standard. Additionally, there are no standards to limit the exposure of the general population to microwaves and other nonionizing radiation produced by a growing number of industrial, military and consumer broadcast sources. An Environmental Protection Agency (EPA) response is clearly required.

To date, U.S. research on the biological effects of nonionizing electromagnetic radiation has identified no positive evidence of harmful effects to humans at the levels of exposure normally encountered by the general population. Nevertheless, because electromagnetic technology continues to pervade modern society, an accelerated program of research is required to determine what power levels, what exposure times, what frequencies and what modulation characteristics may be harmful.

Fragmentation of responsibility among the many Federal agencies involved in various aspects of radiation safety and control indicates the need for more effective direction and coordination.

The testimony revealed several areas where additional information was needed. Accordingly, the committee staff conducted supplemental studies of those issues. One, dealing with irradiation of the Moscow Embassy, will be the subject of a separate report. Three others dealing with (1) current X-ray diagnostic equipment available for reduction of dosage, (2) issues involved in reducing unnecessary diagnostic X-rays, and (3) current availability to the general public of equipment or services for checking microwave exposure levels in the home—particularly with reference to microwave ovens—are covered in appendices to this report. A fourth appendix provided by the Bureau of

Radiological Health, gives a detailed explanation of its estimate that 30 percent of all X-rays are unnecessary.

The following section of this report provides recommendations on actions to alleviate known radiation safety hazards and to provide the scientific base for resolving remaining unanswered questions of radiation safety.

RECOMMENDATIONS

Fundamental Research Needs

A coordinated program of federally sponsored research should be established which would include:

1. Experimental and epidemiological studies to determine the biological and/or behavioral effects of long-term exposure to low-levels of all forms of radiation to which significant segments of the U.S. population are subject. (I.B. p. 10; I.C. p. 11; II.A.3. p. 17; II.B. p. 18; III.A.2. p. 20; III.B.2. p. 23; III.C.1. p. 25; III.C.3. p. 28; and III.D. p. 29) [1]
2. Basic research into the physiological mechanisms by which biological and/or behavioral effects of exposure to nonionizing electromagnetic radiation may occur, with emphasis on developing principles for extrapolation of research findings from laboratory animals to humans. (I.C. p. 11; II.A.3. p. 17; III.A.2. p. 20; III.C.1. p. 25; III.C.3. p. 28; and III.D. p. 29)
3. Previously planned joint US/USSR experiments on the biological effects of long-term, low-level microwave exposure which have not yet begun. (The committee should review the overall mechanism for planning, conducting and managing joint studies of this type.) (III.C.3. p. 28)

Recommendations for the implementation of those actions which require multiagency participation will be found under the heading Jurisdictional Issues.

Medical Uses of Ionizing Radiation

An important step in eliminating unnecessary X-rays will be the establishment of criteria for determining whether a specific examination is or is not required. To this end the Bureau of Radiological Health (BRH), in conjunction with the American College of Radiology, the American Medical Association, the American Dental Association, as well as competent representatives of public and professional groups, should accelerate current efforts to develop and support adoption of criteria for deciding when X-rays are needed for a broad range of diagnostic applications. These criteria should also point toward elimination of certain routine uses of X-rays where no other evidence indicates the need, such as pre-employment physicals, hospital's pre-admission procedures, mammography for certain age groups and semi-annual dental exams. These criteria should consider the problems associated with the use of X-rays to guard against malpractice suits. Concurrent with these activities, the BRH should assist the public in understanding how to balance the risks and benefits of X-ray use. (II.A.2.b. p. 13)

[1] Numbers in parentheses identify the location in the Principal Findings of information which prompted these recommendations.

One of the principal means for guarding against excessive exposure to X-rays is to assure the competence of medical and dental X-ray operators. In this connection the Bureau of Radiological Health, working with professional organizations such as the American Society of Radiologic Technologists, the Conference of Radiation Control Program Directors, and the American College of Radiology, should develop and encourage the adoption by the States of standards for the accreditation of X-ray machine operators and institutions conducting educational programs in radiologic services.[2] (II.A.2.c. p. 14)

To further assist in improving the medical applications of radiation:

1. The Department of Health, Education, and Welfare (DHEW) should increase and stabilize funding for needed expansion and continuity of current BRH cooperative programs with State health departments involving inspection of newly installed X-ray equipment and quality assurance programs for existing X-ray systems; (II.A.2.d. p. 15)

2. The BRH, working with insurers, health maintenance groups, professional organizations, and consumer groups active in public health issues, should promote broader use of its wallet-size individual X-ray and vaccination record; and (II.A.2.b. p. 13)

3. DHEW should conduct a study of the extent to which the principal users of medical X-ray systems are adopting or converting to equipment which can provide adequate diagnostic information with minimum radiation exposure to the subjects at reasonable costs. DHEW should report its findings to the Congress with recommendations, if necessary, for appropriate regulatory or legislative action. (II.A.2.d. p. 15)

Occupational Exposure to Ionizing Radiation

A coordinated Federal program should be established to determine the extent to which occupational exposure to low-levels of nuclear radiation may be a causal factor in subsequent health problems. This program should provide a basis to assess, and if necessary, to alter present standards for occupational exposure to ionizing radiation. (II.B. p. 18)

A coordinated Federal program should be estabilshed to identify, assess and, if necessary, regulate the exposure hazard from any radioactive materials (such as those produced by cyclotrons), or radiation emitting equipment which are not within the jurisdicton of the NRC or other Federal agencies. (IV.A. p. 30)

Congressional committees with oversight or legislative jurisdiction over the Occupational Safety and Health Administration should examine the adequacy of funding and priority assigned by OSHA for protecting workers from excessive ionizing radiation exposure. (II.B. p. 18)

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[2] Voluntary and mandatory approaches for implementation of such standards are contained in Part III of S. 3290, the Consumer Patient Radiation Health and Safety Act of 1978, and in S. 1695, the Radiation Health and Safety Act of 1977.

Exposure to Nonionizing Radiation

The OSHA, in cooperation with other responsible organizations and Federal agencies, should give priority to a review of the adequacy of its present voluntary standard for occupational exposure to nonionizing radiation. After making any necessary changes, OSHA should promulgate a mandatory standard. While conducting this review, OSHA should consider converting the present voluntary standard to a mandatory standard on an interim basis. (II.B.2. p. 23)

The Office of Technology Assessment (OTA) should conduct a study (1) to project the impact of emerging technologies on the levels of nonionizing electromagnetic radiation in the environment and (2) to assess the economic and functional impact of imposing an upper limit on such radiation. (The committee should request authorization of such a study by the Technology Assessment Board of the OTA). (III.A.2. p. 20)

The National Bureau of Standards (NBS) should intensify its efforts to provide the physical measurement standards, calibration services, and standardized measurement techniques necessary for research and regulatory activities relating to nonionizing radiation. (III.C.1. p. 25) Additionally, NBS in conjunction with the Conference of Radiation Control Program Directors, should prepare for the committee on Commerce, Science, and Transportation a review of the need for an intermediate level of calibration services, such as regional facilities to better couple NBS laboratories with State and industrial needs. (IV.A. p. 30)

After completion of its current national survey of ambient nonionizing radiation, EPA should determine whether a mandatory upper limit is needed. (III.A.2. p. 20)

OSHA, in cooperation with NIOSH, should assess the need for standards to control occupational exposure to ultrasound, and BRH should assess the need for standards to control medical uses of ultrasound. (III.D. p. 29)

Jurisdictional Issues

Several committees of the Senate and House have been examining the adequacy of organization and coordination of Federal programs in radiation protection and research. Given the complexity of existing organizational problems, it will be difficult to develop a solution that is totally satisfactory to all parties. Information developed in these hearings and in subsequent staff investigations, suggests that three actions are fundamental to correct the present organizational deficiencies:

1. The President should resolve at the earliest practical date the jurisdictional ambiguities in Federal agency responsibilities which prevent a coordinated approach to radiation research and regulation. This effort should be coordinated with those committees of the Congress which have legislative and oversight jurisdiction over these activities. (IV.A. p. 30 and IV.C. p. 37)

2. The President should establish an executive-level position within the Executive Office of the President with the sole responsibility of

providing sustained coordination of the multiagency radiation research and regulatory effort. While we do not intend to indicate the detailed support structure for this position, it is essential that it have the following capabilites:

Authority to decide among competing jurisdictional and regulatory activities of the various agencies;

Authority to involve representatives of affected agencies on a regular basis;

Direct access to the President in implementing decisions regarding agency roles and responsibilities; and

Adequate staff to carry out these responsibilities.

This coordinating mechanism should provide for Presidential-level review of agency performance and direction of agency responsibilities, priorities, and funding levels. It is essential that the present situation of jurisdictional ambiguity and overlapping not be permitted to recur once the existing problems have been rectified. (IV.B. p. 37 and IV.C. p. 37)

3. The coordinating mechanism established above should make extensive use of existing advisory bodies—specifically the National Academy of Sciences/National Research Council's Committee on Biological Effects of Ionizing Radiation and the Department of Commerce's Electromagnetic Radiation Management Advisory Council. These panels can assist in evaluating present research activities and in establishing priorities among those areas of research which need additional attention. In addition, medical and industrial users of radiation, electronic product manufacturers, the nuclear industry, employee representatives, the radiation research community, and members of the affected public should be consulted in reviewing the radiation protection performance of Federal agencies, and in assigning agency responsibilities and priorities. (IV.C. p. 37)

STATEMENT OF HOWARD JOHNSON, STAFF VICE PRESIDENT FOR PRODUCT SAFETY, RCA CORP., AND CHAIRMAN OF THE RF RADIATION COMMITTEE OF THE ELECTRONIC INDUSTRIES ASSOCIATION

Mr. JOHNSON. Thank you, Mr. Ambro.

Mr. Chairman, thank you for your invitation to participate in your hearing today.

I am Howard Johnson, staff vice president, product safety, for the RCA Corp.

I am here today in my capacity as the chairman of the RF Radiation Committee of the Electronic Industries Association.

The Communications Division of the Electronic Industries Association represents most of the major manufacturers of electronic equipment and systems in the United States used for Government, commercial, and private communications services.

In June 1977, I was in the audience during 5 days of hearings on radiation health and safety conducted by two subcommittees of the Senate Committee on Commerce, Science, and Transportation.

When the staff report on radiation and health was released by the Senate Committee on Commerce, Science, and Transportation, I responded to Senator Cannon's invitation for comments with a few recommendations. I have been requested to make those recommendations here today. My oral remarks will highlight my previously submitted written statement.

Although there are more than 5,000 published reports of animal experiments in the field of bioeffects of nonionizing radiation, there is a paucity of data on the adverse effects to humans at low levels of exposure.

Mr. AMBRO. Mr. Johnson, Congresswoman Holtzman is here now and if you will suspend, I would like to ask her to come up now and ask you to come back when she is finished.

We are pleased now to have with us Congresswoman Elizabeth Holtzman of New York who is not only a good friend, but has been a leader in Congress in bringing to the attention of the American people the potential health problems resulting from our increasing exposure to nonionizing radiation. I would like to welcome you and say that I can assure you that your entire statement will be included in the record and you can proceed in any way you wish.

STATEMENT OF HON. ELIZABETH HOLTZMAN, A U.S. REPRESENTATIVE IN CONGRESS FROM NEW YORK

Ms. HOLTZMAN. Thank you very much, Mr. Chairman.

Mr. Chairman, it is a special privilege to appear before you and before this very distinguished subcommittee.

The problem of nonionizing radiation has not achieved much publicity compared with the problems of ionizing radiation, but it is quite clear that in terms of health effects the potential problem of nonionizing radiation to the American public could be devastating. One report estimates that 21 million workers are currently exposed to nonionizing radiation. There is no enforceable standard to protect workers in the workplace. On March 29, 1978 the GAO reported that there is no standard for protecting the general public

from nonionizing radiation. One of the main problems is an absence of research as to what standards provide safety.

What, indeed, is a standard that will protect the public?

What is a standard that would protect people in the workplace?

There are no clear answers. The voluntary standard was developed many years ago. Data appearing in a report and Toby Moffet requested from the Comptroller General dated November 30, 1978, stated that more protection for microwave hazards is needed. The report suggests that there is substantial research showing adverse physiological effects at levels of exposure less than those that are set in the standard.

As far as I am able to determine, and I do not pretend to be a scientist, the basic way in which we have arrived at the present voluntary standard really has nothing to do with empirical science. What happens is that some level of radiation, let us say 100 millowatts, is determined to be dangerous, so they take a fraction of that and then claim that it is safe. The theory is that if 100 millowats will kill you, one will not. Clearly, the logic would not even have saved Aristotle. We need to engage in a much more intensive effort to determine a safe standard, especially because of the increasing use of microwaves and therefore the increased hazards.

I believe we ought to be concerned about how the research is conducted by Government. It is my understanding that close to 60 percent of the research on microwaves is done by the Department of Defense. This raises some question about the integrity of the product. I think we all agree that the agency basically responsible for the research should have no vested interest in the outcome of the research. The Department of Defense has a vested interest in the outcome and so does the Department of Energy. The research should be in the hands of someone who does not have a conflict of interest. That has not happened.

I think we also should be developing more inhouse capability so that much of the research that is done by NIOSH and OSHA and EPA and others, inadequate as it is, is not contracted out. I believe that there is not enough inhouse capability even to evaluate the quality of the contracted-out work.

I want to compliment you very much for your concern about this matter. I think it shows a good degree of presence and talent because this is a problem that has not been commonly understood, yet it is a problem that could effect the health and well-being of millions of Americans.

Mr. AMBRO. I would like to once more thank you and compliment you, too. I would just like to read into the record at this point the summary of the report that you cite which, indeed, you had the Comptroller General compile. That report says:

Products, such as microwave ovens, medical diathermy equipment, and certain alarm systems, emit microwave radiation. Concern over the safety of exposure to such radiation is increasing because of a new awareness of its potentially dangerous health effects and the growing use of microwave-emitting products.

Food and Drug Administration efforts to regulate these products need strengthening. The Administration has not (1) issued a performance standard, which it has determined is needed, for diathermy equipment, (2) always reviewed manufacturers' reports promptly so that problems could receive early attention, and (3) developed

material for use in training diathermy equipment operators, which would help to minimize patient and operator exposure to unnecessary radiation.

Moreover, since there are no mandatory Federal standards concerning safe levels of exposure to microwave radiation, the Government should establish them to protect the general public and workers from the radiation's potential hazards.

Having read that, I have no questions other than to say that I think you put these hearings in perspective. Some of the witnesses that we have will talk either directly or generally to the points you raise so that we can possibly put together a program which brings together a number of diverse Federal agencies concentrating on this and hopefully, a program which will provide us with the kinds of protection you seek.

Ms. HOLTZMAN. If I might add one final word, even though the state of the art may not be at this point perfect, I would say it is an art rather than a science. It is not as developed as it should be; there is a lack of a labeling and of warnings to workers and the public. You cannot feel microwaves and there is no way of protecting yourself. Right now there are thousands of workers, mostly women, working on RF sealers which emit microwave radiation well in excess of any generally accepted standard. The people who use those machines do not know they are dangerous. In other words, the manufacturers who have the machines in the shops are not aware of any danger; the workers are unaware that they are being exposed to enormous levels of radiation.

Mr. Chairman, these kinds of hearings can alert the public and help require some kind of labeling with regard to the fact that machines of various kinds do emit radiation and some caution should be exercised with regard to exposure.

Mr. AMBRO. I will ask that your entire statement be printed in the record at this point and then ask if you would like to join us up here if you have the time and move on to our other witnesses and request that if you have any questions, please ask them.

Without objection, and as I said, your entire statement will be printed in the record at this point.

[The full prepared statement of Ms. Holtzman follows:]

STATEMENT OF CONGRESSWOMAN ELIZABETH HOLTZMAN BEFORE
THE SUBCOMMITTEE ON NATURAL RESOURCES AND ENVIRONMENT
OF THE COMMITTEE ON SCIENCE AND TECHNOLOGY

JULY 12, 1979

I want to thank Chairman Ambro for the opportunity to testify this morning on the potential critical health threat posed by non-ionizing radiation.

Evidence is mounting that non-ionizing radiation poses a serious health threat to the American public yet in spite of this fact standards to protect workers or to protect the general public have not been issued.

There has been tremendous concern recently, as evidenced by almost daily press reports, of the dangers posed by exposure to low levels of ionizing radiation, such as X-rays and radiation from nuclear power plants. At the same time however, non-ionizing radiation, which is even more widely used in industry, has been largely neglected. The number of workers exposed to radiofrequency and microwave radiation is huge. One report estimates 21 million workers are currently exposed to non-ionizing radiation. Non-ionizin radiation occurs in the auto industry in numerous sealing and heating processes, in the food industry in melting chocolate and drying baked goods, in the furniture industry for laminating wood, in the manufacturing of everything from checkbook covers to plastic wrappings, and in the airline industry for pilots, air traffic controllers and flight attendants.

This hearing addresses the vital issue of what additional research is needed on what levels of microwave radiation people can be exposed to safely and how this research should be structured.

There is a desperate need for more basic research in this area and a particularly urgent need for further epidemiological studies. A recent General Accounting Office report on efforts by the Environmental Protection Agency to protect the public from effects of non-ioninzing radiation concluded that sufficient numbers of research programs had not been developed, that delay and personnel reductions were effecting morale and that additional epidemiological and clinical studies were needed. The call for more research has been echoed by other reports including an ad hoc working group of the Office of Science and Technology and by numerous witnesses in testimony before U.S. Senate Committee on Commerce Science and Transportation.

I am also concerned about the integrity of research currently being conducted. We must see to it that research is conducted by individuals who do not have excessive ties to users. In the past much of the research has been conducted by firms with numerous Defense Department or industry contracts. In some cases this may create a conflict among researchers who fear that advocating standards the industry opposes may effect future contracts with those industries.

We must develop a greater expertise in this area in those agencies such as Food and Drug, Occupational Safety and Health Administration and the National Institute of Occupational Safety and Health who are responsible for standard formulation. Too much basic research is farmed out to private contracts. This may create conflicts of interest and agencies without expertise cannot properly evaluate the quality of the work done. The lack of adequate agency expertise in this area is the result of the low priority which this matter is given.

Even though we need more research on microwave safety, I am convinced that there is currently sufficient data to justify newer and more stringent emission standards.

At present the only standard in effect is a voluntary OSHA standard adopted in 1974. This standard (10 mW/cm^2) is one which the military has been using without change since 1957, even though it was based in part on a purely physiological consideration of the amount of heat that the human body can absorb and ignored the harmful nonthermal effect which have been reported in the applicable literature. Furthermore, OSHA embraces this standard even though companies such as General Electric and Bell Telephone Laboratories adopted much stricter standards for employees working in their laboratories. In 1960, Bell Laboratories reported that power levels in excess of the standard are potentially hazardous and personnel must not be permitted to enter areas where major parts of the body may be exposed. They noted that radiation levels as low as 1/10 of the standard are to be considered safe only for incidental, occasional, or casual exposure, but are not permissible for extended exposure.

Reported adverse health effects in individuals exposed to non-ionizing radiation have included headaches, vomiting, skin burns, visual damage, potential fetal damage as well as stress syndrome and other adverse behavioral reactions. I believe that sufficient information currently exists to establish a non-ionizing radiation safety standard. My office has been provided with a draft of a NIOSH study which recommends levels well below the current voluntary standards. OSHA must respond quickly and must establish an enforceable standard as soon as possible. We must

see to it that industry recognizes the health danger and responds to it. Warnings, similar to those required for ionizing radiation, must be posted on machines and in the workplace. All new and present employees should be informed of the possible danger they face. Shielding and other safety equipment must be installed and monitoring equipment must be in place to detect any abnormal radiation leakage.

Workers who are exposed to non-ionizing radiation should be examined and tested frequently. Medical records should be kept and retained for the expected life of the worker.

On March 20th of this year, I introduced H.R. 3132 which would require the Secretary of Labor to issue emergency standards to protect workers from the dangers of certain non-ionizing radiation. My bill would require the Secretary of Labor, in addition to issuing emergency standards for industrial heating devices, to publish a proposed rule within 60 days to protect all workers from the dangers of non-ionizing radiation.

My bill requires the establishment of emergency standards, effective upon publication,to protect employees from radiation from RF sealers - - that is industrial heating devices. I have done this because many operators of the Radio Frequency (RF) Sealers are facing an immediate and serious health threat. RF sealers are used in the manufacturing industry for bonding plastics and wood. Many of the thousands of workers who operate the approximately 15,000 RF sealers in use are being exposed to levels of radiation which are in some cases as much as 180 times the present voluntary standards. Many of the operators of these machines are women of child-bearing age for whom the dangers are doubly great. This

situation is all the more inexcusable since protective shielding is commercially available and are in fact installed in RF sealers which are sold by U.S. companies to Eastern Bloc countries. Neither the Occupational Safety and Health Administration nor the Food and Drug Administration, both of whom have jurisdiction in this area, has taken any action in spite of the fact that they are aware of the enormous health risks posed by this equipment. OSHA has not revised its outdated standard and FDA has not fulfilled its responsibility under the Radiation Control for Health and Safety Act to establish an electronic product radiation control program.

Earlier this year the National Institute for Occupational Safety and Health visited the sites of 82 RF sealers. They found that 60 percent of the sealers emitted radiation in excess of the current voluntary standard for magnetic fields. Although the machines have been surveyed, no one has informed the operators of the possible health effects, nor have they been given medical exams.

My bill would force immediate protection for those untold number of workers. RF sealers should be labeled as potentially hazardous and should be shielded. Standards for worker exposure should be adopted. Our knowledge of the health dangers from non-ionizing radiation is rapidly increasing and the standards established today may need to be revised upward or downward as our knowledge increases. We do, however, have sufficient data to set much stricter and sounder standards then those that currently exist. We must act now to assure that our citizens are protected from any possible health threat posed by non-ionizing radiation.

Ms. HOLTZMAN. Thank you, very much, Mr. Chairman. I have another amendment to make on the floor, but I will be happy to sit with you.

Mr. AMBRO. Mr. Johnson, sorry to interrupt your statement. We were to the point where you were talking about the fact that we have more than 5,000 published reports of animal experiments and the like, and if you can pick up at that point we would appreciate it.

Mr. JOHNSON. Although there are more than 5,000 published reports of animal experiments in the field of bioeffects of nonionizing radiation, there is a paucity of data on the adverse effects to humans at low levels of exposure.

Despite the fact that some European countries have established exposure standards, and Canada is in the final stages of doing so, it is a tribute to the intellectual honesty of American science that the absence of Federal standards reflects the lack of human data and a demonstrated need.

However, there have been a number of significant events that have occurred since the 1977 Senate subcommittee hearings that suggest a possible need for standards for other than health and safety reasons.

The absence of Federal standards is one reason given by the New York City Board of Health to justify amending its health code by proposing an exposure standard far more restrictive than anything supportable in the literature, or suggested by U.S. agencies.

Important radar installations, telecommunications links, and security systems have been delayed by an uniformed, but aroused, public.

News reports of these delays are appearing more frequently and reflect local government and industry problems of assuring the public of the safety of microwave communication systems.

The need for Federal exposure standards is no longer a domestic, scientific curiosity which may take 20 more years to understand, but it has developed into a national and an international problem requiring a political solution.

I stress the need for a political solution.

OSHA had a nonionizing radiation exposure standard which it believed was mandatory, but the standard was declared unenforceable on December 31, 1975.

The mandatory aspect of the OSHA standard was overturned by one company which would not accept a citation for a nonserious, no penalty violation of employee exposure to nonionizing radiation.

The lack of evidence of harmful effects to humans from low-level radiation will make it a difficult task for OSHA to provide a defensible standard which will hold up in a judicial review.

Although coordination of Federal research is necessary, there is no indication that a scientific breakthrough will occur in the next few years and be helpful in establishing defensible safe exposure standards.

Furthermore, the time required for any Federal agency to publish final regulations will add several years to the process.

The average time for rulemaking by the EPA is 4 years.

For any agency to publish proposed regulations and safe exposure standards based upon information available today on the ad-

verse effects on humans and without a clearly demonstrated need for the standard will be counterproductive.

One can predict the outcome of such an endeavor by relating to similar safety standards established by the Consumer Product Safety Commission which were made noneffective by court action primarily because of a lack of a demonstrated need for portions of the standards.

It is also appropriate to recognize that nonionizing radiation has a low priority in regulatory agency budgets because the agencies do not perceive it to have imminent harmful effects as do other items of higher priority.

It will serve little purpose for the Congress to urge the regulatory agencies to spend more money in endeavoring to speed up answers in an area where the public health need is so obscure and satisfactory progress is being made.

The compromise answer to this dilemma is a political solution which lies in congressional action similar to that taken by the Consumer Subcommittee of the Senate Committee on Commerce, Science, and Transportation which resulted in the passage of the bill S. 2401 and established the flammability standard for cellulose insulation.

When faced with the long delays which would be experienced by regulatory agency procedures, the Congress solved that problem in 1 day and adopted the GSA standard as an interim, Federal mandatory standard for cellulose insulation.

Congress can do it again and resolve the problem of a standard for safe exposure levels of nonionizing radiation by adopting the present voluntary standard as an interim, Federal mandatory standard.

The American National Standards Institute ANSI C95.1 "Safety Levels of Electromagnetic Radiation with Respect to Personnel"—and its proposed 1979 reaffirmation or revision—is representative of the consensus of American scientific thought and we recommend that it be adopted by Congress as an interim, mandatory, Federal standard.

Once this stake is driven, we will have a rallying point from which research and regulation can progress in a more orderly and less-pressured fashion without unreasonable risk to the public.

Thank you, very much.

Mr. AMBRO. Thank you, Mr. Johnson.

I cannot at all determine whether or not the Senate bill S. 2401 which established the flammability standards for cellulose insulation is directly on target, but as I recall there were good reasons why the court initially threw out the OSHA standard and that had to do with the lack of reliability in the data, is that correct?

Mr. JOHNSON. No; it was because under the original act the standard was required to be adopted but Judge O'Connor, I believe was the administrative law judge, determined that the language was advisory and not mandatory in nature and therefore, it had to be an advisory type of standard.

Mr. AMBRO. So that was the basis for it?

Mr. JOHNSON. Yes. Swim Line Corp. was the company involved.

Mr. AMBRO. Then it might be possible to accept your recommendation as a starting point and a jumping-off place. That is most interesting and I appreciate the comment and the thought.

On page 8 of your testimony you use the term, "we recommend." Who is the we? Is it the electronics industry that supports your proposal, or does that depend on the nature of the ANSI standard?

Mr. JOHNSON. I am sure that the industry would support the current standard because they have in the past. The present revision will be issued and determined in November I believe of this year. It will be my job to discuss that with the industry and get their position because I will be voting on the standard for the industry and although I anticipate some problems, I do not think there will be any great ones.

Mr. AMBRO. Let us try this as a small one. The ANSI standard is written as a voluntary standard. It says that the RF protection guide should not be exceeded without careful consideration of the reasons for doing so. You say that the standard should be mandatory. Do you mean the prescribed standard must not be exceeded, or do you merely mean careful consideration is to be mandatory?

Mr. JOHNSON. Well, when I said mandatory I mean to be used by all agencies as well as everyone that uses the energy and I presume that in the final provisions there would have to be some give and take in it. I really had not considered that point. I know it is written as a guideline. Maybe that is the best way to go at the present time, but the big thing you need is something that both the public and local governments can point to as being the guideline. Currently, there is not anything.

Mr. AMBRO. You say as well on page 7:

> It will serve little purpose for the Congress to urge the regulatory agencies to spend more money in endeavoring to speed up answers in an area where the public health need is so obscure and satisfactory progress is being made.

Does that refer to regulatory and research and development programs or just regulatory?

Mr. JOHNSON. I am referring to research programs, but I believe the Interregulatory Task Force known as BENER is doing a good job of bringing all the research together and trying to get a defensible standard.

Mr. AMBRO. I think you also suggested that you believe the OTA study may show that product standards limiting leakage are the most effective way to go at the present time. Is that correct?

Mr. JOHNSON. Yes; I think so. If you follow the microwave oven standard you will find one that is working very well and when you attempt to regulate you have to get back to a product. So, if you are dealing with a microwave oven you get the product and you make sure the design takes care of the problem.

Mr. AMBRO. Well, are you suggesting as well that the greatest potential exposure results from unintentional leakage rather than intentional sources such as microwave telecommunications towers and aircraft control equipment?

Mr. JOHNSON. Are you talking general population?

Mr. AMBRO. Yes.

Mr. JOHNSON. I think the risk would be in unsuspected leakage.

Mr. AMBRO. And with respect to workers?

Mr. JOHNSON. Yes.

Mr. AMBRO. Well, I would like to thank you, very much, and ask my colleague Congresswoman Holtzman if she has any questions.

Ms. HOLTZMAN. Did you say you would support as a mandatory basis the setting of the present standard as 10mW/cm²?

Mr. JOHNSON. Sorry—I did not understand you.

Ms. HOLTZMAN. You are asking for the Congress to set as a mandatory standard the present standard, is that correct?

Mr. JOHNSON. Yes.

Ms. HOLTZMAN. Are you aware of a report by the GAO dated November 30, 1978, and I quote:

> Also because a number of reports have indicated that exposure to microwave radiation at 10mW/cm² effects in humans * * * the safety of exposure at that level seems questionable.

Mr. JOHNSON. That can be questionable.

Ms. HOLTZMAN. And you want to set that as the present standard?

Mr. JOHNSON. I can also tell you the present discussion within the ANSI subcommittee is going for revision in that area.

Ms. HOLTZMAN. And is it not true that this standard of 10mW/cm² was developed in 1957?

Mr. JOHNSON. If you are looking at the triservice agreement, yes. The present ANSI standard, I believe the committee was formed in 1960 and the first standard was published in 1966 and the current one was revised in 1974.

There is an ANSI requirement of reaffirmation or revision every 5 years.

Ms. HOLTZMAN. And was there not a proposal by this organization ANSI that the standard ought to be one-tenth of that?

Mr. JOHNSON. No. I think Dr. Guy will be testifying here and will give you more information, but it has a frequency dependency and time dependency that is different from the current standard. That is the proposed one. You go through a peer review.

Ms. HOLTZMAN. But despite the fact that the proposal will be a drastic change from the present voluntary standard you nonetheless are urging the Congress to adopt as a mandatory standard one that was developed in 1957 and one that is being abandoned in a proposed draft by this ANSI organization.

Mr. JOHNSON. I am not saying it is being abandoned, perhaps revised before the end of the year. It has to be revised before the end of 1979.

Ms. HOLTZMAN. Thank you, Mr. Chairman.

Mr. AMBRO. Thank you, very much, Mr. Johnson.

I will now call up as a panel Dr. Arthur W. Guy, Department of Rehabilitation Medicine, University Hospital, University of Washington, Seattle, Wash., and Dr. Don R. Justesen, Director of the Neuropsychology and Behavioral Radiology Laboratories, U.S Veterans' Administration Medical Center, Kansas City, Mo.

Gentlemen, I welcome you and will tell you as I have told other witnesses, we shall incorporate your statement into the record and ask you to proceed in any way you choose.

[The full prepared statement of Dr. Guy is as follows:]

STATEMENT OF DR. ARTHUR W. GUY, BIOELECTROMAGNETICS RESEARCH LABORATORY, DEPARTMENT OF REHABILITATION MEDICINE, SCHOOL OF MEDICINE, UNIVERSITY OF WASHINGTON, SEATTLE, WASH.

For the hearing on Non-ionizing Radiation of the Subcommittee on Natural Resources and Environment, Committee on Science and Technology, U.S. House of Representatives, July 12, 1979.

1. INTRODUCTION

I would like to thank the Chairman and the Subcommittee for inviting me to testify at this hearing on non-ionizing radiation. My name is Arthur W. Guy. I am a graduate of and have a doctorate from the University of Washington. I have been a member of the Medical School faculty at the University of Washington since 1966. My academic training has been in the area of electrical engineering, with emphasis on electromagnetic fields and wave propagation. Following my appointment with the Medical School at the University of Washington, I have been carrying out studies and research on the biological effects of electromagnetic fields and am Director of the Bioelectromagnetics Research Laboratory in the Department of Rehabilitation Medicine. I am also a member of a number of national and international committees involved with various aspects of the biological effects of electromagnetic fields.

As Chairman of the American National Standards Institute (ANSI) Subcommittee C95.4 on RF radiation hazards with respect to personnel and Chairman of the National Council on Radiation Protection and Measurements (NCRP) Committee SC 53 on biological effects and exposure criteria for radiofrequency electromagnetic radiation, I will provide you with a brief report on the goals, status, and activities of each committee and address the needs for research on the health effects of non-ionizing radiation which have become apparent through the work of these committees. I will first discuss the activities of the ANSI C95.4 Subcommittee, then the activities of the NCRP SC53 Committee, and finally the problems that were defined from these activities.

2. ROLE AND ACTIVITIES OF THE ANSI C95.4 SUBCOMMITTEE

(a) Past work

The American National Standards Institute (ANSI) is the national clearinghouse and coordinating body for voluntary standards in the United States. It is a non-profit federation of consumer groups, trade associations, technical and professional societies, government agencies, and over 2,000 companies. The main functions of ANSI are as follows:

(1) Provide for the systematic development, use, and coordination of American national standards.

(2) Approve American national standards which are set by consensus of all concerned national groups.

(3) Serve as a clearinghouse for information on American and foreign standards.

(4) Represent American interests in international standardization activities.

The standards come into existence through several methods, one of which is the "standards committee method". Under this method, a committee is formed to develop and review standards intended for approval as American national standards under an assigned scope. The committee normally comprises accredited representatives of various organized groups and societies concerned with the project, and, when desirable, companies, agencies, and specifically qualified individuals interested in the subject. The committee within ANSI charged with developing standards relating to radiofrequency radiation hazards is designated the C95 Committee. The C95 Committee is charged with "the preparation of standards for terminology and units of measurement for the radiofrequency radiation hazards in the areas of biological organisms, flammable materials, and eletroexplosive devices". This work is carried out by a number of subcommittees. Subcommittee C95.4 is responsible for the establishment of safety levels and/or tolerances with respect to personnel. The first standard developed by the Subcommittee was approved as USAS C95.1-1966, "Safety Level of Electromagnetic Radiation with Respect to Personnel", in 1966, and reaffirmed with minor modifications in 1974 as ANSI C95.1-1974, with the same title. The standards were based on the following conditions:

(1) Frequency range of 10 MHz-100 GHz.

(2) All possible sources of electromagnetic radiation in the above range.

(3) Continous and/or intermittent radiation.

(4) Normal or moderate environmental conditions.

(5) Whole body and partial body exposure.
(6) Not applicable to the deliberate exposure of patients.

The 1966 and 1974 ANSI standards were based on the best experimental evidence available at the time as judged by a cross-section of scientists, many of whom are recognized as international authorities on the subject. I should be noted, however, that due to the lack of suitable experimental and theoretical data in the literature, the early standards had many weaknesses. They did not specify how the standard should be modified as a result of different environmental conditions or health conditions of the exposed individuals. They also were not specified as a function of frequency, modulation, and other parameters, nor did they take into account the reported effects due to low level exposure so prevalent in Soviet and East European literature.

(b) New work

A number of working groups were set up to review both the old and the new literature and make recommendations for improvement of the guide at the end of the 5-year valid period of the 1974 Standard. The goals and conclusions reached by each working group are as follows:

Working Group I.—Peak power effects

Goal: Determine how the Standard should account for possible effects due to exposure to pulsed fields of low duty cycle in contrast to those due to exposure to CW fields of the same average power.

Conclusion: It was concluded that there was insufficient information in the scientific literature to help formulate a standard that would recommend the treatment of pulse fields of low duty cycle any differently than CW fields of the same average power. It was recognized that two investigators in the United States observed enhanced biological effects from radiofrequency fields with modulation frequencies corresponding closely to the natural EEG frequencies of the brain. At this time, however, these effects are not well enough understood nor quantifiable to the point necessary for basing standards on them. There was discussion of the possibility of limiting the exposures to pulse sources such that the peak energy per pulse did not exceed the threshold level of 40 $\mu J/cm^2$ for the so-called microwave hearing effect. Since this level was measured accurately only over a limited band width of about .8–3 GHz, and there was no evidence that the effect was hazardous, it was felt that it was inappropriate to base a standard on the phenomenon.

Working Group II.—Low-level effects

Goal: Determine how the Standard should take into account the many types of low level effects reported in the literature.

Conclusion: A number of papers alluding to low level effects were analyzed. Most of them were found in Soviet and East European publications and related to biological effects due to long-term chronic exposure to low-level fields. A limited number of publications originated in the United States. There were considerable differences, however, among the various reports concerning the threshold level where biological effects take place, varying from as low as 10 $\mu W/cm^2$ to as high as 20 mW/cm^2 for similar effects. It can be concluded from the literature search that there is a scarcity of scientific information concerning low-level effects that is sufficiently quantified, replicated, and consistent to be suitable for setting standards.

Working Group III.—High-frequency effects

Goal: Determine how the Standard should account for the sharp variation of power absorption and the relationship between absorption and field impedance with frequency in the high frequency band.

Conclusion: The working group was able to collect a considerable amount of information useful for modification of the standard in terms of the sharp variation of the rate of energy absorption with exposure frequency. The group collected considerable material from the scientific literature that allows determination of the relationship between absorption and incident power density as a function of frequency in the high-frequency band.

Working Group IV.—Surveillance and reliability assessment of literature

Goal: Develop a system for the assessment of all available literature pertaining to the biological effects of electromagnetic fields in terms of basic scientific and practical value in standards setting by the C95.4 Subcommittee.

Conclusion: The group was able to assemble more than 1,700 references and abstracts for use by the various Working Groups. The Committee also set up criteria

for the Working Groups to follow in the selection of the material in terms of basic scientific and practical value in the setting of standards.

Working Group V.—Occupational exposure standards

Goal: Determine how the Standard should differentiate between certain occupational exposures and exposure of the general population.

Conclusion: The working group surveyed the more serious and potentially hazardous occupational exposures that are experienced by the working population of the U.S. The group felt that the ANSI standard probably should not attempt to differentiate between certain occupational exposures and exposure of the general population. If such differentiations were made, however, the standard could probably be made less conservative for the occupationally exposed without any additional health risk over that of the general population simply from a better control of the exposure conditions. For example, for a general population one must assume worst cases, such as the exposure of children and infants, as well as large adults standing on metallic ground planes. In some occupational settings, where such worst case exposure conditions do not exist, exposure levels over certain parts of the radiofrequency spectrum could be higher than those recommended for uncontrolled exposure of the general population.

Working Group VI.—Dosimetry

Goal: Determine how the various radiation conditions specified in the scientific literature considered by the Subcommittee can be converted to a common base for intercomparison and extrapolation to man, taking into account variations of coupling with frequency, subject size, and source configuration.

Conclusion: The working group was able to take advantage of the many engineering developments over the past several years for determining the rate of energy in test animals exposed under typical laboratory conditions and in man exposed to uniform electromagnetic fields. The working group developed criteria for utilizing this information for formulating a whole-body exposure criteria for man as a function of frequency.

The 1700 references specified by Working Group V were reviewed by the other Working Groups and the ones most pertinent or applicable to developing standard-setting criteria were specified. In its new work, the Subcommittee especially wanted to make use of the engineering advances made over the last several years that could be used to more accurately extrapolate laboratory data from test animals for recommending maximum incident power density or electromagnetic field strength for human exposure. In most of the world, non-ionizing radiation safety standards today do not take into account this extrapolation process and, as a result, many are too conservative over some portions of the spectrum and not conservative enough over other portions. In order to properly extrapolate the laboratory results, it is necessary to convert electromagnetic field exposure level information used for laboratory experiments into the rate of energy absorption in the bodies of the exposed test animals. In addition, it is also necessary to relate human exposure under various levels and conditions to the rate of energy absorption or specific absorption rate (SAR) in the tissues. SAR is the quantity most directly related to the biological effect in the tissues of exposed subjects, rather than the exposure field. Engineering work over the past several years allows easy calculation and prediction of the average SAR in man and animals exposed under various conditions and, in many cases, the actual SAR distribution over the entire body may be quantifiable.

(c) Analysis of international standards

It is interesting to analyze the current standards of other countries in terms of the highest SAR allowed in the tissue of exposed humans. Table I (Attachment 1) illustrates the worst-case exposures allowed by various standards of the world in terms of average and peak SAR in the exposed tissues. The first column identifies the country, the second the frequency, the third the worst-case exposure level, and the fourth the average SAR as calculated from the literature (Ref. 1 in Attachment). The fifth column is the estimated maximum SAR based on reports in the literature (Ref. 2,3 in Attachment). The sixth column is the calculated maximum electric field strength in the tissue, and the last column is the maximum allowable exposure level of electric field strength.

In examining Table I, we note that the Swedish occupational standard would allow a maximum power density of 5mW/cm^2 over a frequency range of 100–300 MHz. Maximum absorption would occur near 70 MHz, resulting in an average SAR greater than 1.75 W/kg with a maximum SAR of approximately 6.25 W/kg. On the other hand, from the Soviet occupational standard, with the worst case exposure occurring at 50 MHz where a magnetic field strength of .3 amps/meter is allowed,

we could calculate an average SAR of .046 W/kg and a maximum SAR of 0.59 W/kg. The worst case for the Czechoslovakian occupational standard occurs at 30 MHz. This exposure limit of 50 volts/meter would produce an average SAR of 0.105 W/kg and a maximum level of 0.335 W/kg. The Polish occupational standard, on the other hand, has a worst case exposure at 10 MHz, allowing a maximum H field of 2 amps/meter in the unlimited safe zone corresponding to an average SAR of 0.0745 and a maximum SAR of 1.05 W/kg. The 10 amps/meter allowed during a working day in Poland, however, corresponds to an average SAR of 1.86 W/kg and a maximum of 26.3 W/kg. In addition, the Polish standard permits exposures as high as 250 amps/meter for a period of 20 minutes or less corresponding to an average SAR of 1,660 W/kg and a maximum SAR of 16,400 W/kg, which would result in rapid death for human whole-body exposure conditions. Finally, we see that the proposed Canadian occupational standard and the proposed ANSI standard, with the worst case occurring near 70 MHz, would permit an average SAR of 0.35 W/kg and a maximum value of 1.25 W/kg.

It appears that, in terms of maximum allowable average SAR corresponding to at least one or more frequencies in the spectrum, all of the standards agree more closely in terms of the worst case for continuous exposure than one would expect based on the allowable power density levels. It is also significant to note that the Polish standard allows average SAR's that are equal to or greatly exceed those allowed by the standards of other countries, reaching levels that could be fatal to exposed humans. Finally, from the last two columns in Table I, one may make the interesting observation that the Polish and the Soviet standards restrict the exposure levels of electric fields to values less than that produced in the tissues due to magnetic field exposure allowed by their standards. Also, it is clear that the 3.6 W/kg or total whole-body power loading of 250 watts allowed by the U.S. standard is excessive.

(d) Development of new standard

In order to make a final review and develop a standard, a three-day meeting was held at the University of Washington from February 28–March 2, 1979, with the Chairman of the various Working Groups and a limited number of ANSI C95–4 members who had the expertise to help the Working Group Chairmen and who could conveniently travel to Seattle (Attachment 2). In general, the meeting followed the agenda given in Attachment 3. The overall plan of action was to complete the review and ranking of the scientific literature and, based on the literature, develop criteria for setting a standard which could then be used to establish a new human exposure guide. In addition to the material from the literature survey, the group considered the most recent literature reviews.

The Subcommittee members agreed to the following approach in formulating a standard:

(1) Select most pertinent literature reporting biological effects in terms of quantitative information.

(2) Determine from literature directly or through calculation the average SAR in the exposed subjects where effects were noted.

(3) Based on the selected literature and corresponding average SAR, select a maximum allowable SAR for human exposure.

(4) Determine maximum allowable whole-body human exposure levels of power density and field strengths to limit SAR to the selected maximum as a function of frequency.

(5) Develop criteria for partial-body exposures.

The Subcommittee members attending the Seattle meeting were divided into two groups, one heavily weighted by background on the engineering side and the other heavily weighted in expertise toward the life sciences aspects of the problem in order to make the final evaluation of the papers and to decide how they could be used in developing criteria for a new standard. The engineering group identified the sources that could be best used for extrapolating exposure levels to the average and peak SAR produced in exposed animals as well as man. The life sciences group evaluated the literature at hand and identified that most pertinent for developing a criteria for setting the standard.

The engineering group especially noted the incident power density (in mW/cm^2) required to limit total human body average SAR to a constant level, in order to provide a specification as to the frequency dependence of the standard to account for changes in coupling under worst-case coupling conditions where the electric field vector is parallel to the long axis of the body. Based on the relationship between incident power density and the total body average SAR which is provided on the curve shown in Attachment 4, the engineers formulated a frequency dependence criteria for the standard in terms of a fixed maximum allowed average SAR. The

engineering group felt that the standard should be specified in terms of constant power density over the region where maximum coupling (body resonance) would occur for a wide range of different body sizes from an exposed infant in free-space (highest frequency resonance condition) to a full-sized man standing on a ground plane (lowest frequency resonance condition). The group also felt that the standard should be increased with the inverse square of frequency below this range and directly with frequency above the range. It was felt, however, that in the upper range the standard should not be allowed to reach a level any higher than five times that allowed over the range of constant value, in order not to exceed the SAR allowed at body resonance.

The life sciences group, through a careful selection process, identified some 28 papers covering various biological effects that contained sufficient information to quantify the average SAR and sometimes the peak SAR developed in the test animals used in the reported work. These papers are listed in Attachment 5.

The engineering group then, through the Dosimetry Handbook (1) and the information in each paper, tabulated the exposure parameters and calculated the average SAR as given in Attachment 6. Attachment 7 shows the SAR values as plotted for the 28 references, spanning a range of values from .002–20 W/kg.

The entire group than discussed and evaluated the work based on reliability and importance in terms of hazards. The committee analyzed the papers based on thresholds for effects or hazards in terms of agreement with others, replication of other researchers, and confounding factors. It was noted that there was general agreement among many of the papers reporting effects at 0.5 W/kg of averge SAR and above. On the other hand, the thresholds for effects occurring below 0.5 W/kg varied over a wide range with no general agreement between papers concerning a level that would constitute a hazard. The group felt that the reported effects that were hazardous occurred at whole-body average SAR levels of 4 W/kg and above. After considerable discussion, it was felt that a decrement in working ability by test animals began to occur when animals were subjected to average SAR levels of 4–10 W/kg. There was unanimous agreement within the group, with the exception of one abstention, that the average SAR allowed for human exposure should be at least an order of magnitude below the threshold level of the most replicated and noncontroversial deleterious effects on the animals. This corresponds to a whole-body average SAR of approximately .36 W/kg. This was later rounded off to one significant figure, or .4 W/kg. The group then adopted the proposal of the engineers to set allowable exposure levels to values that would prevent the average SAR in an exposed human from exceeding .4 W/kg. This resulted in the exposure criteria shown in Attachment 8 with the proposed standard of 1 mW/cm^2 over the frequency range of 30–300 MHz. At frequencies below 30 MHz, the exposure level is allowed to rise as the square frequency by the formula shown on the chart up to 100 mW/cm^2 at a frequency of 300 kHz. From this frequency down to 300 kHz it was proposed to limit the exposure level to 100 mW/cm^2. At frequencies above 300 MHz, the exposure standard was allowed to rise with frequency according to the formula given on the chart until it reached a level of 5 mW/cm^2 at 1500 MHz. At frequencies above 1500 MHz, the allowed exposure level was held constant at 5 mW/cm^2 up to a frequency of 300 GHz.

A major problem facing the group, however, was how to handle partial-body exposures. The criteria discussed up to this point were based on whole-body exposure to a plane-wave field. Thus, in terms of a stated maximum power density, the standard should be relaxed for partial-body exposures to account for the large decrease in energy absorbed by the body tissues under such exposure conditions. This could be accounted for all allowing the peak or maximum SAR (hot spots) to increase in magnitude for decreasing average SAR. It certainly doesn't make sense to set a 1 mW/cm^2, or for that matter a 5mW/cm^2, partiall-body exposure standard, since it would be more conservative than the whole-body exposure standard and unnecessarily restrict the use of many hand-held, mobile, and marine radios used in everyday life, especially for vital public safety services. It is also clear that restrictions without a scienfitic basis placed on millions of citizens using citizens-band radios would be difficult, if not impossible, to implement or enforce, based on the past failure of the FCC to enforce their regulations on this group. The total output power for most of these devices is far less than that which the body would absorb under plane-wave exposure conditions, but the local electric and magnetic field strength and "apparent" power densities could greatly exceed those specified in standards based on whole-body exposure conditions.

For example, consider Attachment 9, which is a map of the field strengths and power densities that would be measured in the vicinity of a quarter-wave grounded antenna energized with an input power of 2 W at a frequency of 150 MHz. Such an

antenna would be typical of many hand-held radio transceivers. The antenna is drawn to scale with a calculated electric field strength (V/m), the magnetic field strength (A/m), and the "apparent" power density in mW/cm^2 calculated for each of the points as shown. The power density is based on the equivalent value for a plane-wave with the same electric and magnetic field strength. The field strength (E or H) that provides the largest power density is used in the calculation. Note that the "apparent" power density calculated at a position more than 20 cm from the base of the antenna exceeds 1 mW/cm^2. One may also note on Attachment 10 that similar calculations made for a 30 MHz quarter-wave antenna show that the power density would exceed 1 mW/cm^2 at distances greater than 1.5 m from the base of the antenna with an antenna input power of 100 W typical of many mobile antennas operating in the high frequency band. For these near-zone exposure conditions, the power coupled to the human body would be far less than that for plane-wave with the same incident power density. It is therefore essential that the standard should account for such exposure conditions to insure proper trade-off between benefits, public acceptance, and real health hazards. With a hand-held 2 W radio transceiver, with fields as illustrated in Attachment 9, the total coupled energy or the body would be a fraction of a watt, even though the peak SAR would exceed 5, 10, or even 100 W/kg depending on the distance between the tissue and the antenna.

Thus, any criteria based on limiting peak SAR in the body would be difficult to formulate with any reasonable scientific basis. With the exception of experiments on cataractogenes involving the localized exposure of the eyes of test animals, most of the experiments reported in the literature are based on the whole body exposure of test animals. There is insufficient information in the literature to assess the maximum allowable localized SAR in the tissues of exposed man. This matter was not resolved at the Seattle meeting.

Another problem discussed was the possible limitation of the peak power or the peak energy per pulse for pulse type sources. There were proposals for limiting the peak energy per pulse to the threshold level for the so-called microwave hearing effect corresponding to approximately 40 $\mu J/cm^2$. Since this level was based on experiments conducted over a limited frequency range, and it was felt that the effect was not hazardous, the proposal was not accepted. After the Seattle meeting, I made the suggestion that the partial body exposure problem be handled by allowing the whole body exposure protection guides to be exceeded for partial body human exposure if the average rate of energy absorption in the whole body is less than 7 watts over the frequency range of 300 kHz–1.5 GHz. This is based on the following considerations:

(1) Seven watts absorption is substantially less than that allowed by the standards for whole body exposure, and under most of the foreseeable exposure conditions involving reasonably finite volumes of tissue that level of total absorption would not result in maximum SAR levels exceeding those allowed by the Standard based on whole body exposure criteria. Such an exposure guide can reasonably be used for low-power devices such as hand-held, mobile, and marine radio transceivers. These devices may emit localized fields exceeding the whole body protection guide, but will result in significantly less energy absorption than allowed for the whole body. The technical problems associated with control of such devices would be significantly reduced since any device with seven watts or less output power would be exempt from the standard. Devices with greater output power would require a case-by-case analysis to insure that the protection guide was not exceeded.

The entire proposed standard developed by the Working Group Chairmen and their consultants was presented to the full ANSI C95.4 Subcommittee at the meeting in Seattle on June 17, 1979. A major concern was that the upper frequency limit for the partial body exposure limit of 7 watts rate of absorbed energy was too low and should be extended to 5 GHz so that the ANSI Standard for partial body exposure would not be in contradiction with the HEW Oven Performance Standard. The latter does not limit the power density for distances closer than 5 cm from an oven leak while the former, as originally worded, would limit exposure to 5 mW/cm^2 regardless of the distance from an oven leak. With this modification, and other minor modifications of the Standard proposed by the Working Group Chairman, the Standard as written in Attachment 11 was unanimously accepted by the full C95.4 Subcommittee. A supporting document is now being written to accompany the proposed Standard when it is submitted to the parent C95 Committee in the Fall of this year.

3. NCRP SC 53 COMMITTEE

The National Council on Radiation Protection and Measurements (NCRP), the successor to the National Committee on Radiation Protection and Measurements, is a non-profit corporation chartered by Congress. The members of the Council are

nationally recognized scientific experts on radiation problems, working on a volunteer basis in the national interest. The objectives of the Council are to collect, analyze, and disseminate information and recommendations about radiation protection and measurements, and to stimulate exchange of ideas and promote cooperation among organizations concerned with radiation problems. On a national scale, the Council's recommendations provide the scientific basis for radiation control in industry, medicine, public health, and government, and on an international scale, they form a firm foundation for U.S. efforts in international radiation protection and measurements activities. Based on knowledge produced by the scientific and technical community, NCRP Scientific Committees draft basic recommendations which are reviewed by the Board of Directors before they are published and disseminated. Up until 1972, the Council was involved only with problems relating to ionizing radiation. After that date, however, with increasing concern in the country relating to non-ionizing radiation problems, NCRP set up Scientific Committee 39, which began to work on the non-ionizing radiation problem, ultimately resulting in the drafting of a report on physical aspects including the definition of quantities and units relating to non-ionizing radiation. In 1977, a second committee, NCRP SC 53, was set up under my chairmanship to study and draft a report on the biological effects and exposure criteria for radiofrequency electromagnetic radiation. The general goals of the Committee are to provide a substantive general outline of the scientific basis for understanding of the effects of microwave radiation, and based on this to proceed to risk assessment and finally develop exposure criteria. The Committee report will include: a) a technical overview of the long-term and acute effects of microwave radiation, as well as it is known, with a substantive discussion of the areas of scientific doubt where data is so sketchy as not to permit any reasonable firm conclusions. These would include chapters on the effect of non-ionizing radiation on a) the brain and special senses, b) performance and behavior, c) lenticular tisssues, d) the immune system, and e) cardiovascular system. Also, chapters would be included on hyperthermia at the cellular and organismic level, as well as the relationship between microwave exposure and carcinogenesis, metabolic effects, reproduction, growth, and development. At the present time, the Committee is in the final stages of developing the chapters for the technical overview. The drafts for this section are expected to be completed at the end of the next meeting, scheduled for October, 1979.

4. RECOMMENDATIONS FOR FUTURE RESEARCH NEEDED TO IMPROVE THE STANDARDS

In the work of modifying and updating the exposure guide, the ANSI C95.4 Subcommittee was confronted with some difficult problems that point to the urgent need for additional research. They include:

(a) Development of partial-body exposure criteria

There is insufficient engineering and biological information in the literature to allow the formulation of realistic partial body exposure standards. Most reported research results on animals are based on whole-body exposures, and therefore can be extrapolated only to aid in the development of whole-body exposure criteria for man. Actually, however, the most common exposure conditions of any significance for man occur for example in the operation of industrial RF heaters, the maintenance of radiating antennas, the use and operation of hand-held and mobile radios, the operation of diathermy equipment, and similar activities which involve exposure of only portions of the body at significant levels of electromagnetic fields. Biological data from whole-body exposure of animals and engineering data specify whole-body exposure energy absorption patterns in man cannot be used to quantify the hazards or to help formulate safety levels for partial-body exposures. Research is urgently needed on the thresholds for biological effects due to localized exposure of critical organs of the body, such as the brain, the testicles, and the eyes, as well as noncritical tissues such as muscle, bone, subcutaneous fat, and connective tissue in the fingers, hands, and legs. Also urgently needed are the characterization of SAR patterns induced in the tissues of man under the common, everyday exposure conditions alluded to above.

(b) Peak power and modulation effects

The ANSI C95.4 Subcommittee could not find sufficient information in the literature to warrant any limitation of peak power other than through the 6 minute averaging criteria. There has been much concern expressed over the fact that the ANSI standard does not limit the peak power exposure of man to low duty cycle pulsed sources. In fact, based on the 6 minute averaging, the previous as well as the new proposed ANSI standard allows the exposure of man to pulses with energy

density levels as high as 3.6 J/cm², which is approximately 100,000 times greater than the threshold for microwave hearing. There is an urgent need for a scientific basis for limiting (or not limiting) the peak energy or peak power per pulse for such exposures. There is some evidence in this country that indicates that certain modulation frequencies and other characteristics are more effective than others in producing biological effects. Research is required to provide more quantitative information on these phenomena so that the effects can be accounted for in the formulation of safety standards.

(c) Low-Level effects

Considerable more work is needed in this country to determine the biological effects of low-level fields, especially those arising from long-term chronic exposure conditions. Most of the scientific data base on this subject is derived from the Soviet and East European literature, and has not been quantified, nor is it consistent to the point necessary for the formulation of practical safety standards where the trade-off between risk and benefit is clearly known. There is a need for expanded research in this area with the aim of ultimately using the results for the formulation of safety standards that are acceptable by all groups. Limited work of this type is now taking place in the United States, some of which is under the USA–USSR Cooperative Program on Environmental Health. Work of this type should be expanded to involve more of the key scientists of the country. Especially desirable is promotion of additional cooperative programs between the Soviet Union and the United States with the aim of involving the best scientists of both countries in conducting more quantitative work and the understanding of the mechanisms involved in low-level effects. The latter is needed to determine whether such effects, either directly or indirectly, are injurious to the health, and, if so, what are the thresholds as related to human exposure. The current USA–USSR Cooperative Program on Environmental Health is a first step in this direction, but it somewhat limited in scope and should be supplemented with other cooperative programs, especially between the Academy of Sciences of the two countries. This would insure the involvement of the necessary scientific laboratories and talent to resolve the problem.

TABLE 1. HIGHEST AVERAGE SAR, MAXIMUM SAR AND ELECTRIC FIELD STRENGTH IN TISSUE ALLOWED BY VARIOUS HUMAN EXPOSURE STANDARDS

COUNTRY	FREQUENCY (MHz)	EXPOSURE LEVEL	AVERAGE SAR[1] (W/kg)	MAXIMUM SAR[2,3] (W/kg)	MAXIMUM E (V/cm) in tissue	MAXIMUM E (V/cm) allowed in air
Poland (unrestricted)	10 MHz	2 A/m	0.0745	1.05	0.500	0.200
Poland (working day)	10 MHz	10 A/m	1.86	26.3	2.52	0.700
Poland (time limit 20 minutes)	10 MHz	250 A/m	1,660	16,400	63.0	10.0
U.S.A. (ANSI)	70-200 MHz	10 mW/cm^2	3.5	12.5	1.58	1.94
U.S.A. (others?)	70-200 MHz	1 mW/cm^2	0.35	1.25	0.500	0.614
Sweden	70-200 MHz	5 mW/cm^2	1.75	6.25	1.12	1.37
Canada	70-200 MHz	1 mW/cm^2	0.35	1.25	0.500	0.614
U.S.S.R.	50 MHz	0.3 A/m	0.046	0.59	0.366	0.100
Czechoslovakia	30 MHz	50 V/m	0.105	0.335	0.276	0.500

1. Durney, C.H., et al., Radiofrequency Radiation Dosimetry Handbook, 2nd Ed., Report SAM-TR-78-22, May, 1978.

2. Guy, A.W., M.D. Webb, and C.C. Sorenson, "Determination of power absorption in man exposed to high frequency electromagnetic fields by thermographic measurements on scale models", IEEE Transactions on Biomedical Engineering, BME-23:361-371, 1976.

3. Guy, A.W., et al., "Measurement of Power Distribution at Resonant and Nonresonant Frequencies in Experimental Animals and Models". Prepared for: USAF School of Aerospace Medicine, Aerospace Medical Division (AFSC), Brooks Air Force Base, TX 78235, Contract No. F41609-76-C-0032, Final Report, March, 1978.

Attachment 2

ATTENDEES OF MEETING OF ANSI C95.4 SUBCOMMITTEE
WORKING GROUP CHAIRMEN ON MODIFICATION OF HUMAN EM FIELD EXPOSURE GUIDE
February 28 - March 2, 1979

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Attachment 3

AGENDA FOR MEETING OF ANSI C95.4 SUBCOMMITTEE
WORKING GROUP CHAIRMEN ON MODIFICATION OF HUMAN EM FIELD EXPOSURE GUIDE

February 28 - March 2, 1979
South Campus Center, University of Washington
Seattle, Washington

Wednesday, February 28

0830 I. DISCUSSION OF OVERALL PLAN OF ACTION
- A. Review and ranking of scientific literature
- B. Develop criteria for setting standard
- C. Establish exposure limits

0930 II. REPORTS FROM WORKING GROUPS AND DISCUSSION OF REPORTS
- A. WG 1 Peak Power Effects (Chairman, Fred Cain)
- B. WG 2 Low-Level Effects (Acting Chairman, Joe Elder)
- C. WG 3 High Frequency Effects (Chairman, Om Gandhi)
- D. WG 5 Occupational Exposure Standards (Acting Chairman, Zory Glaser)
- E. WG 6 Dosimetry (Chairman, James Lin)
- F. WG 4 Surveillance and Reliability Assessment of Literature (Chairman, Ed Hunt)

1330 III. FINAL REVIEW BY THE ENTIRE COMMITTEE OF SELECTED PAPERS
- A. Specification of average and peak SAR and modulation characteristics for occurrence of effects as function of frequency 10 MHz - 100 GHz
- B. Ranking according to scientific quality (biological)
- C. Ranking according to scientific quality (physical and dosimetry)

Thursday, March 1

0830 III. FINAL REVIEW BY ENTIRE COMMITTEE OF SELECTED PAPERS (continued)

1330 IV. DEVELOPMENT OF CRITERIA FOR SETTING STANDARD
- A. SAR allowed by other standard-setting groups
  1. USSR and East Bloc Countries
  2. Sweden
  3. Canada
  4. Finland
  5. USA - NIOSH, NY State DOD, Bell Labs, etc.
- B. Maximum allowable average SAR for continuous exposure
- C. Maximum allowable peak SAR for continuous exposure
- D. Maximum average SAR, peak SAR, and energy per exposure period for short exposures (less than 6 minutes, less than 100 μs)

Friday, March 2

0830 V. ESTABLISH EXPOSURE STANDARDS BASED ON ABOVE
- A. Whole body
- B. Partial body
  1. Hand held transceivers
  2. Mobile and marine transceivers
  3. Other sources

1600 VI. ASSIGNMENTS FOR WRITING FIRST DRAFT OF REPORT AND PROPOSED STANDARD

1700 VII. ADJOURN

ATTACHMENT 4

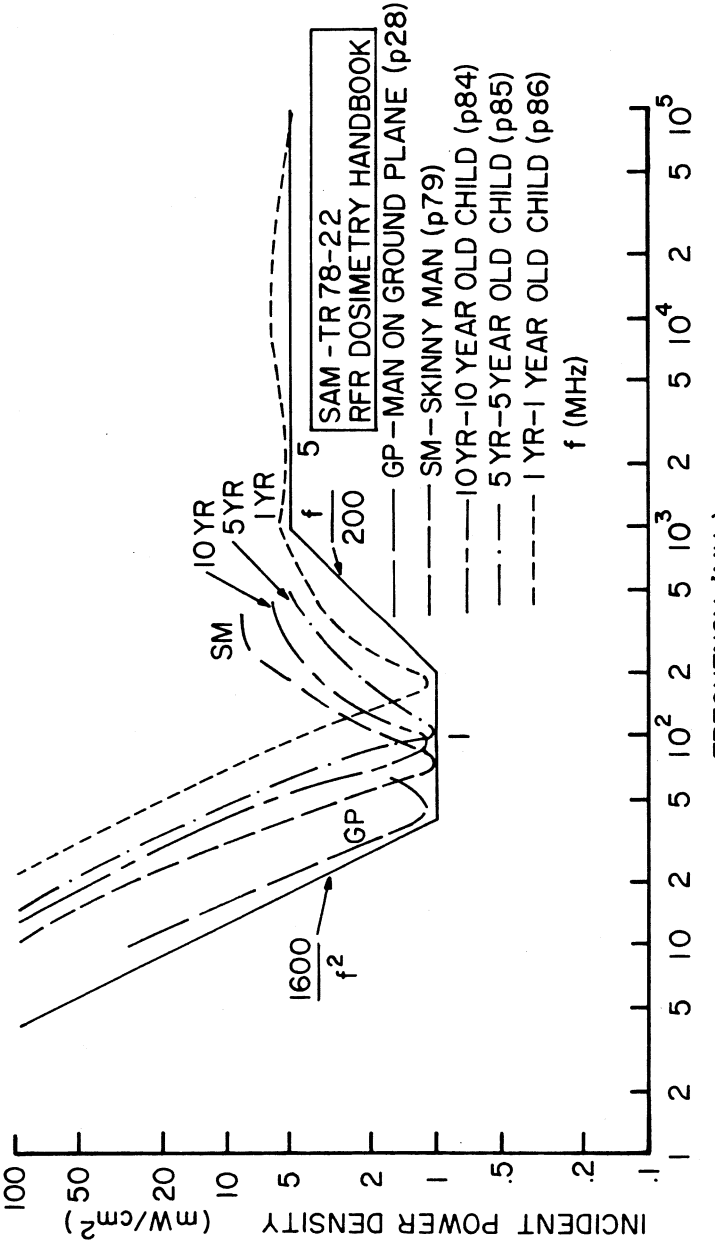

FIGURE 1 Incident Power Density (mW/cm^2) Which Limits Total Body SAR To 0.35 W/kg (Adults And Children)

Attachment 5

BIO-EFFECTS LITERATURE
ANSI C95.4 COMMITTEE MEETING

University of Washington
February 28 - March 2, 1979

1. Environmental Factors

a. Shandala, M.G., M.I. Rudnev, and M.A. Navakatian, Patterns of change in behavioral reactions to low power densities of microwaves. In Abstracts of 1977 International Symposium on the Biological Effects of Electromagnetic Waves, Airlie, VA, Oct. 30-Nov. 4, p. 88.

b. Johnson, R.B., S. Mizumori, R.H. Lovely, and A.W. Guy, Adaptations to microwave exposure as a function of power density and ambient temperature in the rat. In Abstracts of 1978 Symposium on Electromagnetic Fields in Biological Systems, Ottawa, Canada, June 27-30, p. 30.

c. Monahan, J.C., and H.S. Ho, Microwave induced avoidance behavior in the mouse. In Biological Effects of Electromagnetic Waves, C.C. Johnson and M.L. Shore, eds., HEW Publication (FDA) 77-8010, Vol. I, 274-283, 1976.

2. Behavior and Physiology

a. D'Andrea, L.A., O.P. Gandhi, and J.L. Lords, Behavioral and thermal effects of microwave radiation at resonant and nonresonant wavelengths. Radio Science 12(6S):251-256, 1977.

b. Thomas, J.R., E.D. Finch, D.W. Fulk, and L.S. Burch, Effects of low-level microwave radiation on behavioral baselines. Ann. N. Y. Acad. Sci. 247:425-431, 1975.

c. Frey, A.H., Behavioral effects of electromagnetic energy. In Biological Effects and Measurement of Radio Frequency/Microwaves, D.G. Hazzard, ed., HEW Publication (FDA) 77-8026, 11-22, 1977.

d. King, N.W., D.R. Justesen, and R.L. Clarke, Behavioral sensitivity to microwave irradiation. Science 172:398-401, 1971.

e. Frey, A.H., S.R. Feld, and B. Frey, Neural function and behavior: Defining the relationship. Ann. N. Y. Acad. Sci. 247:433-438, 1975.

f. Lin, J.C., A.W. Guy, and L.R. Caldwell, Thermographic and behavioral studies of rats in the near field of 918-MHz radiation. IEEE Trans. on Microwave Theory and Techniques MTT-25:833-836, 1977.

3. Immunology

   a. Shandala, M.G., M.I. Rudnev, G.K. Vinogradov, N.G. Belonozhiko, and N.M. Gonchar, Immunological and hematological effects of microwaves at low power densities. In Abstracts of 1977 International Symposium on the Biological Effects of Electromagnetic Waves, Airlie, VA, Oct. 30-Nov. 4, p. 85.

   b. Czerski, P., Microwave effects on the blood-forming system with particular reference to the lymphocyte. Ann. N.Y. Acad. Sci. 247:232-241, 1975.

   c. Huang, A.T., M.E. Engle, J.A. Elder, J.B. Kinn, and T.R. Ward, The effects of microwave radiation (2450 MHz) on the morphology and chromosomes of lymphocytes. Radio Science 12 (6S):173-177, 1977.

   d. Smialowiz, R.J., J.B. Kinn, and J.A. Elder, Exposure of rats in utero through early life to 2450 MHz (CW) microwave radiation: Effects on lymphocytes. Radio Science 14/S, 1979, in press.

   e. Smialowiz, R.J., C.M. Weil, J.B. Kinn, and J.A. Elder, Exposure of rats to 425 (CW) microwave radiation: Effects on lymphocytes. J. Microwave Power, in press.

4. Teratology

   a. Berman, E., J.B. Kinn, and H.B. Carter, Observations of mouse fetuses after irradiation with 2.45 GHz microwaves. Health Physics 35:791-801, 1978.

5. Central Nervous System/Blood-Brain-Barrier

   a. Bawin, S.M., L.K. Kaymarck, and W.R. Adey, Effects of modulated VHF fields on the central nervous system. Ann. N.Y. Acad. Sci. 247:74-80, 1975.

   b. Blackman, C.F., J.A. Elder, C.M. Weil, S.G. Boname, D.C. Eichinger, and D.E. House. Induction of calcium in efflux from brain tissue by radio-frequency radiation: Effects of modulation-frequency and field-strength. Radio Science 14/S, 1979, in press.

   c. Frey, A.H., S.R. Feld, and B. Frey, Neural function and behavior: Defining the relationship. Ann. N.Y. Acad. Sci. 247:433-438, 1975.

   d. Albert, E.N., Light and electron microscope observations on the blood-brain barrier after microwave irradiation. In Biological Effects and Measurement of Radio Frequency/Microwaves, D.G. Hazzard, ed., HEW Publication (FDA) 77-8026, 294-304, 1977.

6. Cataracts: None $\leq$ 10 mW/cm^2

7. Genetics: None $\leq$ 10 mW/cm^2

8. Human Studies: None

9. Thermoregulation and Metabolism

a. Lovely, R.H., D.E. Myers, and A.W. Guy, Irradiation of rats by 918 MHz microwaves at 2.5 mW/cm^2: Delineating the dose-response relationship. Radio Science 12(6S):139-146, 1977.

b. Stern, S., L. Margolin, B. Weiss, and S.-T. Lu, Microwaves affect thermoregulatory behavior in rats. Abstract, Bioelectromagnetics Symposium, Seattle, WA, June 18-22, 1979.

c. Adair, E.R., Microwave modification of thermoregulatory behavior: Threshold and suprathreshold effects. Abstract, Bioelectromagnetics Symposium, Seattle, WA, June 18-22, 1979.

d. De Lorge, J.O., Operant behavior and colonic temperature of squirrel monkeys (Saimiri sciureus) during microwave irradiation. NTIS Document No. AD A043706, 33 pp., 1977.

e. Lu, S.-T., N. Lebda, and S.M. Michaelson, Effects of microwave radiation on the rats' pituitary-thyroid axis. Radio Science 14/S, 1979, in press.

10. Biorhythms

a. Lu, S.-T., N. Lebda, and S.M. Michaelson, Effects of microwave radiation on the rats' pituitary-thyroid axis. Radio Science 14/S, 1979, in press.

11. Endocrinology

a. Lovely, R.H., A.W. Guy, R.B. Johnson, and M. Mathews, Alterations of behavioral and biochemical parameters during and consequent to 500 μW/cm^2 chronic 2450 MHz microwave exposure. In Abstracts of 1978 Symposium on Electromagnetic Fields in Biological Systems, Ottawa, Canada, June 27-30, p. 34.

b. Travers, W.D., Low intensity microwave effects on the synthesis of thyroid hormones and serum proteins, Health Physics 33(6):662, 1978.

12. Development

a. Michaelson, S.M., R. Guillet, and F.W. Heggeness, The influence of microwaves on development of the rat. Radio Science 14/S, 1979, in press.

b. McRee, D.I., and P.E. Hamrick, Exposures of Japanese quail embryos to 2.45 GHz microwave radiation during development. Radiation Research 71(2):355-366, 1977.

c. Johnson, R.B., S. Mizumori, and R.H. Lovely, Adult behavioral deficit in rats exposed prenatally to 918 MHz microwaves. In Developmental Toxicology of Energy Related Pollutants, M. Sikov and D. Malum, eds., 17th Hanford Symposium, DOE, GPO, pp. 281-299, 1979.

13. RF Hearing

14. Hematology

a. Mitchell, D.S., W.G. Switzer, and E.L. Bronaugh, Hyperactivity and disruption of operant behavior in rats after multiple exposures to microwave radiation. Radio Sciences 12(6S):263-271, 1977.

b. Miro, L., R. Loubiere, and A. Pfister, Effects of microwaves on the cell metabolism of the reticulo-historytic system. In Biologic Effects and Health Hazards of Microwave Radiation, P. Czerski, K. Ostrowski, M.L. Shore, C. Silverman, M.J. Suess, and B. Weldeskoz, eds., Polish Medical Publishers, Warsaw, pp. 89-97, 1974.

15. Cardiovascular

a. Reed, J.R., J.L. Lords, and C.H. Durney, Microwave irradiations of the isolated rat heart after treatment with ANS blocking agents. Radio Science 12(6S):161-165, 1977.

TABLE 2

CALCULATION OF SAR IN ANIMALS USED TO OBTAIN RESEARCH RESULTS SELECTED BY ANSI C95.4 SUBCOMMITTEE

RESEARCH PAPER		SUBJECT & SIZE	ORIENTATION WITH E FIELD	FREQUENCY (MHz)	SAR PER mW/cm^2	MODULATION	AVG. POWER DENSITY mW/cm^2	PEAK POWER DENSITY mW/cm^2	DURATION OF EXPOSURE	AVG SAR W/kg
Berman, et al.	4a	Mice (25-33g)	Dorsal Multiple	2450	0.8	CW	28		100 min/day for 1-17 d	22.2
Bawin, et al.	5a	Chick Brain	Parallel plate in vitro	147		AM (0.5-32 Hz)	<1		20 min	0.003
Blackman, et al.	5b	Chick Brain	Crawford cell in vitro	147		AM (0, 3, 9, 16, 30 Hz)	0.75		20 min	0.0023
Frey, et al.	5c	Rats (225g)	Head positions varied	1200	0.30	P	0.2	2.1	30 min	0.06
						CW	2.4		30 min	0.72
Albert, E.	5d	Chinese Hamsters (=35g)	---	2450	1.0	CW	10		2 or 8 hr for 1 day	10
Lovely, et al.	9a	Rats (316-388g)	Waveguide	918	0.36	CW	2.5		8 hr/day for 13 wks	0.9
Stearn, et al.	9b	Rats (325-400g)	Dorsal	2450	0.18	CW	5		15 min intermittent	0.9
Adair, E.	9c	Squirrel monkey (~1 kg)	---	2450	0.13	CW	6		15 min intermittent for 3 hrs	0.78
DeLorge, E.	9d	Squirrel monkey		2450	0.13	AM (120 Hz)	50 mW/cm^2		30-60 min	6.5
Lu, et al.	9e, 10a	Rat (150g)		2450	0.36	CW	1 mW/cm^2		8 hr	0.36
Lovely, et al.	11a	Rats (300-350g)		2450	0.21	CW	0.5		7 hrs/day for 3 mo.	0.11 (1.1 peak)
Travers, W.	11b	Rat		2450	0.21	CW	8		8 hrs/day 0, 7, 14 or 21 days	1.68
Michaelson, et al.	12a	Rats (neonatal) (10-25g)		2450	1.3	CW	10		1 hr	13
McRee, et al.	12b	Japanese quail embryo (10g)		2450	0.8	CW	5		12 days	4
Johnson, et al.	12c	Rats (200-300g)	Waveguide	918	0.5	CW	5		20 hrs/day for 19 days	2.5
Mitchell, et al.	14a	Rats (307g)	15/group cavity	2450	0.5	CW	2.3		1 hr & 5 hr/d 110 days	1.2
Miro, et al.	14b	Large mouse (26-30g)	Horizontal	3105		Pulsed 5 Hz-1ms	2 mW/cm^2		145 hr	1.8
Reed, et al	15a	Isolated rat heart		960		CW			10 m	1.5

TABLE 2

CALCULATION OF SAR IN ANIMALS USED TO OBTAIN RESEARCH RESULTS SELECTED BY ANSI C95.4 SUBCOMMITTEE

RESEARCH PAPER	SUBJECT & SIZE	ORIENTATION WITH E FIELD	FREQUENCY (GHz)	SAR PER mW/cm^2	MODULATION	AVG. POWER DENSITY mW/cm^2	PEAK POWER DENSITY mW/cm^2	DURATION OF EXPOSURE	AVG. SAR W/kg
M. Shandala, et al. 1a	Rats (310 g)	---	2.375	0.21 (med. rat)	CW	10-50	---	7 hrs/day 90 days	.0021-.0105
B. Johnson, et al. 1b	Rat embryo in mother (448 g)	---	.918	0.30 (large rat)	CW	5	---	380 hours	1.5
Ho and Monahan 1c	Mouse (30-34 g)	---	2.45	waveguide SAR measured by author	CW		---		9.0 @ 35 °C
D'Andrea, et al. 2a	Rat (420-450 g)	Long axis // to E	.600	0.61 (large rat)	CW	10	---	---	6.1
Thomas, et al. 2b	Rat	?	2.86 and 9.6	0.20 - 0.16	Pulse	5	?	1 hour	1.0 Far Field 0.8
Frey 2c	Rat (250 g)	Horizontal	1.3	0.36 (med. rat)	0.5 ms wide 1000 pps	.65	1.3 mW/cm^2	---	Avg: 0.23 Peak:0.47
King, et al. 2d	Rat (400 g)	Cavity	2.45	0.22 (med. rat)	CW		---	<60 sec.	0.6 W/kg
Frey, et al. 2e	Rat (med.)	?	1.2	0.36	Pulsed and CW	.2	2.1 mW/cm^2 2.4 mW/cm^2	--- ---	Avg: .07 Peak:.076 0.86
M. Shandala, et al. 3a	Rat (med.)		2.375	0.21	CW	10^{-2}	---	90 days	.0021
Czerski, P. 3b	Mouse (20 g)	Group Exp. Far Field	2.950	1.1	1 μs 1200 pps	0.5	---	6-12 wks	0.55
Huang, et al. 3c	Hamster (35g)	Dorsal Group Exp. Far Field	2.45	1.1	CW.	5	---	15 min/day for 5 days	5.5
Smialowicz, et al. 3d	Neonatal Rats (50-90g)	Dorsal Individual	2.45	0.7-4.7	CW	5		60 days	0.7-4.7
Smialowicz, et al. 3e	Rats (8-180g)	Crawford Cell	.425	measured by author	CW	10	---	40 days	4

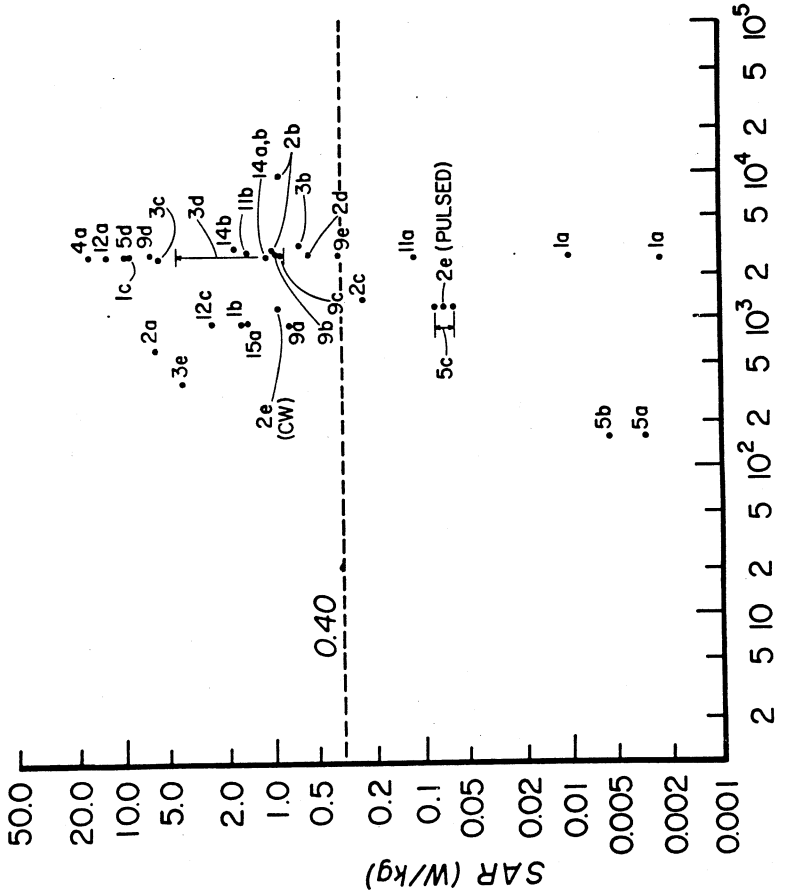

FIGURE 3. Average whole body SAR corresponding to biological effects reported in various references

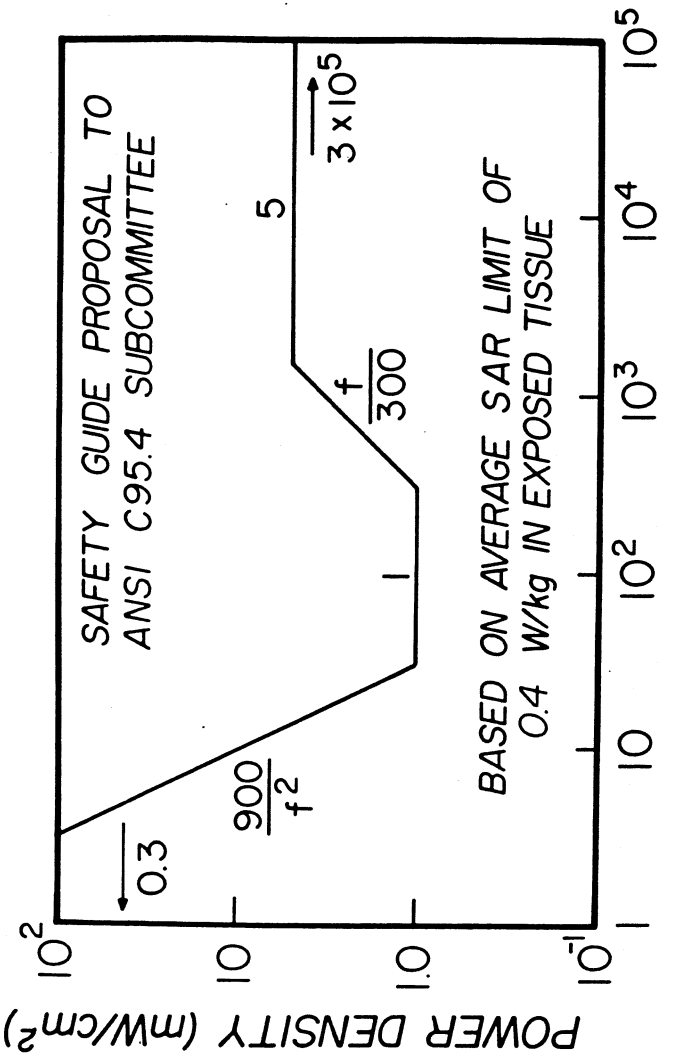

FIGURE 4. Safety guide proposal to ANSI C95.4 Subcommittee

TABLE 3. FIELD STRENGTH AND POWER DENSITY IN VICINITY OF RADIATING MONOPOLE ANTENNA

FREQ = 150 MHz, INPUT POWER = 2 W, INPUT Z = 36 Ω

64.3	48.7	32.7	24.2	19.3
0.00	0.0217	0.0310	0.0341	0.0348
1.10	0.628	0.287	0.156	0.0985
*	*	*	*	*
	95.1	45.7	29.8	22.4
	0.0524	0.0524	0.0489	0.0456
	2.40	0.553	0.236	0.133
*	*	*	*	*
	121	53.4	33.3	24.5
	0.136	0.0856	0.0682	0.0533
	3.88	0.757	0.295	0.159
	*	*	*	*
	110	51.7	33.3	25.0
	0.229	0.124	0.089	0.0716
	3.72	0.708	0.300	0.193
	*	*	*	*
	83.6	43.0	30.2	24.1
	0.306	0.157	0.108	0.0531
	3.54	0.931	0.437	0.261
←10cm→	*	*	*	*
	50.1	32.0	26.2	22.7
	0.358	0.180	0.120	0.0910
	4.82	1.22	0.548	0.312
	*	*	*	*
	27.7	26.3	24.3	E= 22.1 V/M
~	0.375	0.188	0.125	H=0.0938 A/M
	5.31	1.33	0.589	PD=0.332 mW/cm^2
*	*	*	*	*

Attachment 10

TABLE 4. FIELD STRENGTH AND POWER DENSITY IN VICINITY OF RADIATING MONOPOLE ANTENNA

FREQ = 30 MHz, INPUT POWER = 100 W, INPUT IMPEDANCE = 36 Ω

90.9	68.8	46.5	34.3	27.3
0.00	0.0307	0.0465	0.0483	0.0992
2.19	1.26	0.574	0.311	0.197
*	*	*	*	*
	135	64.6	42.2	31.7
	0.0789	0.074	0.0692	0.0644
	4.81	1.11	0.472	0.267
*	*	*	*	*
	171	75.6	47.1	34.7
	0.192	0.121	0.0965	0.0825
	7.75	1.51	0.589	0.319
	*	*	*	*
	156	73.1	47.0	35.4
	0.323	0.175	0.126	0.101
	6.44	1.42	0.601	0.386
	*	*	*	*
	188	60.7	42.6	34.1
	0.434	0.222	0.153	0.118
	7.08	1.86	0.878	0.54
← 0.5 m →	*	*	*	*
	70.9	45.2	37.0	32.1
	0.506	0.254	0.171	0.129
	9.64	2.43	1.10	0.624
	*	*	*	*
	39.2	37.139	34.3	F=31.2 V/M
~	0.531	0.265	0.177	H=0.133 A/M
	10.6	2.65	1.18	PD=0.663 MW/CM^2
*	*	*	*	*

Attachment 11

ANSI C95.4 Fifth Draft 6/17/79

SAFETY LEVEL WITH RESPECT TO HUMAN EXPOSURE TO RADIOFREQUENCY ELECTROMAGNETIC FIELDS (300 KHz-300 GHz)

1. SCOPE AND PURPOSE

Recommendations are made to prevent possible harmful effects on mankind resulting from exposure to electromagnetic fields in the frequency range from 300 KHz to 300 GHz. They apply to all exposures within this frequency range originating from radio and television stations, radar equipment, and other possible sources of electromagnetic fields such as used for communication, radio-navigation, industrial and scientific purposes, and household appliances and other consumer items.

These recommendations are not intended to apply to the purposeful exposure of patients by or under the direction of practitioners of the healing arts.

2. DEFINITIONS

Partial body exposure. Pertains to the case in which substantially less than the entire body is exposed to the incident electromagnetic energy.

Radiofrequency protection guide. Level of radiofrequency field strength or equivalent power density which should not be exceeded without (1) careful consideration of the reasons for doing so, (2) careful estimation of the increased energy deposition in the human body, and (3) careful consideration of the increased risk of unwanted biological effects or stress.

Whole body exposure. Pertains to the case in which the entire body or a substantial part of the body is exposed to the incident electromagnetic energy.

3. RECOMMENDATIONS

For whole body human exposure to electromagnetic energy of radiofrequencies from 300 KHz to 300 GHz, the radiofrequency protection guides, in terms of equivalent plane wave free space power density, and in terms of the mean squared electric and magnetic field strengths as a function of frequency, are given in Table 1.

TABLE 1
WHOLE BODY RADIOFREQUENCY PROTECTION GUIDES

(1) Frequency Range MHz	(2) Power Density mW/cm^2	(3) E^2 V^2/m^2	(4) H^2 A^2/m^2
0.3 - 3	100	400,000	2.5
3 - 30	$900/f^2$	4,000 $(900/f^2)$	0.025 $(900/f^2)$
30 - 300	1.0	4,000	0.025
300 - 1500	f/300	4,000 (f/300)	0.025 (f/300)
1500 - 300,000	5	20,000	0.125

Note: f is the frequency, in MHz

For near field exposure, the only applicable radiofrequency protection guides are the mean squared electric and magnetic field strengths given in Table 1, columns (3) and (4).

For partial body human exposure at frequencies between 300 KHz and 5 GHz the protection guides in Table 1 may be exceeded if the averaged rate of energy absorption in the whole body is less than 7 watts. The protection guides for exposures at frequencies above 5 GHz are the same as those given in Table 1.

For both pulsed and non-pulsed fields, the power density and the mean squares of the field strengths, as applicable, are averaged over any 0.1 hour period and should not exceed the values given in Table 1, except as noted for partial body exposure.

For mixed or broadband fields consisting of a number of frequencies for which there are different values of radiofrequency protection guide, the fraction of the radiofrequency protection guide incurred within each frequency interval should be determined, and the sum of all such fractions should not exceed unity.

4. EXPLANATION

Exposure to electromagnetic fields in the frequency range under consideration is but one of the several sources of energy input into the body, which requires wide ranges of energy production and dissipation in order to function. For situations involving exposure of the whole body, the radiofrequency protection guide is believed to result in energy deposition averaged over the entire body mass for any 0.1 hour period of about 144 joules per kilogram (J/kg) or less. This is equivalent to a specific absorption rate (SAR) of about 0.40 watts per kilogram (W/kg) spatially and temporally averaged over the entire body mass.

The partial body exposure guide can be used for low power devices such as hand-held, mobile, and marine radio transceivers. These devices may emit localized fields exceeding the whole body protection guide, but will result in significantly less energy absorption than allowed for the whole body. Thus, most devices with less than 7 watts output power would not be restricted.

Devices with greater output power would require a case-by-case analysis to insure that the protection guide was not exceeded.

Biological effects data applicable to humans, for all possible combinations of frequency and modulation, are currently not available. The radiofrequency protection guide, therefore, has been based on the best available interpretations of the literature; it is intended to reduce possible stress on the functioning of the human body to a practical minimum, and in most foreseeable circumstances such stress should be reduced to undetectable levels.

Exposures slightly in excess of the radiofrequency protection guide are not necessarily harmful. However, they are not desirable and should be prevented wherever possible. Especially where exposure conditions are not precisely known or controlled, and particularly where large numbers of persons may be involved, exposure reduction should be accomplished by reliable means to values as low as reasonably achievable.

STATEMENTS OF A PANEL CONSISTING OF DR. ARTHUR W. GUY, DEPARTMENT OF REHABILITATION MEDICINE, UNIVERSITY HOSPITAL, SEATTLE, WASH., AND DR. DON JUSTESEN, DIRECTOR OF THE NEUROPSYCHOLOGY AND BEHAVIORAL RADIOLOGY LABORATORIES, U.S. VETERANS' ADMINISTRATION MEDICAL CENTER, KANSAS CITY, MO., AND ALSO WITH THE UNIVERSITY OF KANSAS MEDICAL SCHOOL

Dr. GUY. I would like to thank the chairman and the subcommittee for inviting me to testify at this hearing on nonionizing radiation. My name is Arthur W. Guy. I have been a member of the Medical School faculty at the University of Washington since 1966. My academic training has been in the area of electrical engineering, with emphasis on electromagnetic fields and wave propagation.

As chairman of the American National Standards Institute—ANSI—subcommittee C95.4 on RF radiation hazards with respect to personnel, and as chairman of the National Council on Radiation Protection and Measurements—NCRP—Scientific Committee SC 53 on biological effects and exposure criteria for radiofrequency electromagnetic radiation, I shall provide you with a brief report on the goals, status, and activities of each committee and address needs for research on health effects of nonionizing radiation that have become apparent through the work of these committees.

The American National Standards Institute is the national clearinghouse and coordinating body for voluntary standards in the United States. It is a nonprofit federation of consumer groups, trade associations, technical and professional societies, Government agencies, and over 2,000 companies. The main functions of ANSI are as follows:

One, to provide for the systematic development, use, and coordination of American national standards;

Two, to approve American national standards that are set by consensus of all concerned national groups;

Three, to serve as a clearinghouse for information on American and foreign standards; and

Four, to represent American interests in international standardization activities.

Standards come into existence through several methods, one of which is the standards' committee method.

By this method, a committee is formed to develop and review standards, intended for approval as American national standards under an assigned scope. The committee normally comprises accredited representatives of various organized groups and societies concerned with the project, and, when desirable, companies, agencies, and specifically qualified individuals who are interested in the subject.

The committee within ANSI charged with developing standards relating to radiofrequency radiation hazards is designated the C95 committee.

The C95 committee is charged with:

The preparation of standards for terminology and units of measurement for the radiofrequency (RF) radiation hazards in the areas of biological organisms, flammable materials, and electroexplosive devices.

This work is carried out by a number of subcommittees. Subcommittee C95.4 is responsible for the establishment of RF radiation safety levels and/or tolerances with respect to personnel. The standard developed by the subcommittee was first approved in 1966 and was reaffirmed with minor modifications in 1974.

The 1966 and 1974 ANSI standards were based on the best experimental evidence available at the time as judged by a cross-section of scientists, many of whom are recognized as international authorities on the subject.

It should be noted, however, that due to the lack of suitable experimental and theoretical data in the literature, the early standards had weaknesses. They did not specify how exposure conditions should be modified under different environmental conditions or in relation to health status of exposed individuals. They also were not specified as a function of frequency, modulation, and other parameters, nor did they take into account the reported effects from exposure to low-level radiation, which are prevalent in Soviet and East European literature.

A number of working groups was set up to review both the older and the newer literature and to make recommendations for improvement of the guide at the end of the 5-year valid period of the 1974 standard.

Seventeen-hundred references from a total exceeding 4,000 in the literature were reviewed by the working groups and the ones most pertinent or applicable to developing standard-setting criteria were specified.

In its new work, the subcommittee especially wanted to make use of the engineering and scientific advances made over the last several years that could be used more accurately to extrapolate laboratory data from test animals for use in recommending maxi-

mal incident power densities or electromagnetic field strengths for human exposure. In most of the world today, nonionizing-radiation safety standards do not take this extrapolation into account and, as a result, many are too conservative over some portions of the spectrum but are not conservative enough over other portions.

In order properly to extrapolate results from the laboratory, it is necessary to convert data on electromagnetic field intensity into rates of energy absorption by bodies of exposed animals. In addition, it is also necessary to relate human exposure under various levels and conditions to the whole-body rate of energy absorption, or to the specific absorption rate (SAR), which is the dose rate or mass-normalized rate of energy absorption, in the tissues. The SAR is more directly related to biological effects in exposed subjects than is the intensity of the incident field. Engineering and analytical work over the past several years has yielded equations that allow easy calculation and prediction of the average whole-body SAR in man and animals exposed under various conditions and, in many cases, the actual distribution of SAR's over the entire body may be quantified.

A number of key subcommittee members attending a recent meeting in Seattle agreed to the following approach in formulating a standard:

One, to select the most pertinent literature on biological effects in terms of establishing quantitative information.

Two, to determine from the literature directly or through calculation the average whole-body SAR in the exposed subjects where effects were noted.

Three, to select a maximal allowable SAR for human exposure based on the selected literature and corresponding SAR's.

Four, to determine maximal allowable whole-body human-exposure levels of power density or field strengths by which to limit SAR to the prescribed maximum as a function of frequency, and

Five, to develop criteria for partial-body exposure.

The subcommittee members were divided into two groups, one heavily weighted by background in the engineering and physical sciences, and the other heavily weighted in expertness in the life sciences, in order to make the final evaluation of the papers and to decide how they could be used to develop criteria for a new standard.

The life-sciences group, through a careful selection process, identified some 28 papers covering various biological effects, which contained sufficient information to quantify the average SAR and sometimes the peak SAR developed in the test animals that were used in the reported work.

The engineering group from the information in each paper then tabulated exposure parameters and calculated average whole-body SAR's as given in attachment 7 to my statement [slides—figures 1 and 2] which shows SAR values as plotted for the 28 references, and spans a range of values from 0.002 to 20 W/kg.

The entire group then discussed and evaluated the work based on reliability and importance in terms of hazards. The committee analyzed the reports based on thresholds for effects or hazards in terms of agreement with other reports, replication by other researchers, and confounding factors. The group felt that the report-

ed effects that were implicative of hazard occur at whole-body average SAR, of four watts per kilogram (W/kg) and above.

There was unanimous agreement within the group, with the exception of one abstaining member, that the average SAR allowed for human exposure should be at least one order of magnitude below the threshold level associated with confirmed deleterious effects in animals.

This conservative dose rate corresponds to a whole body average SAR of approximately 0.4 W/kg. The group then adopted the proposal of the engineers to set allowable exposure levels to values that would prevent the average SAR in an exposed human being from exceeding .04 W/kg. This rational resulted in the exposure guide shown in the attached document [figure 3] with the proposed standard of 1 mW/cm^2 over the frequency range of 30–300 MHz.

At frequencies below 30 MHz, the power density of incident radiation is allowed to rise as the inverse square of frequency—according to the formula shown in figure 3—to a maximum of mW/cm^2 at a frequency of 3 MHz. From 3 MHz down to 300 kHz, it was proposed to limit the power density to 100 mW/cm^2.

At frequencies above 300 MHz, the power density is allowed to rise with frequency—according to the formula given in figure 3—until it reaches a level of 5 mW/cm^2 at 1,500 MHz. At frequencies above 1500 MHz, the allowed power density is held constant at 5 mW/cm^2 to a frequency of 300 GHz, the upper limit of the microwave spectrum.

A major problem facing the group was that of partial-body exposures. The criteria discussed to this point are based on whole body exposure to a uniform electromagnetic field. Thus, in terms of a stated maximal power density, the standard should be relaxed for partial body exposures to account for the large decrease in energy absorbed by the body under such exposure conditions. This relaxation could be accomplished by allowing the peak or maximal SAR—hot spots—to increase in magnitude for decreasing average SAR.

It certainly does not make sense to set a 1 mW/cm^2, or for that matter a 5 mW/cm^2 partial body exposure standard, since it would be more conservative than the whole body exposure standard and unnecessarily restrict the operation of many hand-held, mobile, and marine radios used in everyday life, especially for vital public safety services. The maximal output power of most of these devices is far less than the rate of energy that the body would absorb in a 1-mW/cm^2 field under plane-wave exposure conditions, but the local electric and magnetic field strengths and the apparent power densities could greatly exceed those specified in standards based on whole body exposure conditions.

The subcommittee agreed that the partial body exposure problem could be handled by allowing the whole-body-exposure protection guides to be exceeded for partial-body human exposure if the averaged rate of energy absorption in the whole body is less than 7 watts over the frequency range of 300 kHz-5GHz. This rationale is based on the following considerations:

Absorption of energy at the rate of 7 watts is substantially less than that allowed by the standards for whole body exposure, and under most of the foreseeable exposure conditions involving reason-

ably finite volumes of tissues, that level of absorption would not result in maximal SAR's exceeding those allowed by the standard based on whole body exposure criteria. Such an exposure guide can reasonably be used for low-power devices such as hand held, mobile, and marine radio transceivers. These devices may generate localized fields that exceed the whole body protection guide, but will result in significantly less energy absorption than allowed for the whole body. The technical problems associated with control of such devices would be significantly reduced since any device with 7 watts or less of output power would be exempt from the standard. Devices with greater output power would require a case-by-case analysis to insure that the protection guide was not exceeded.

Another problem discussed was the possible limitation on the peak power, or the peak energy per pulse for pulsed sources. There were proposals for limiting the peak energy per pulse to the threshold level for the so-called microwave hearing effect, which corresponds to approxmiately 40 $\mu J/cm^2$. This level is based on experiments conducted over a limited frequency range, however; moreover it was felt that the effect was not hazardous so the proposal was not accepted.

Now I shall briefly discuss the role and activities of the National Council on Radiation Protection and Measurements, or NCRP. NCRP is a nonprofit corporation chartered by the U.S. Congress. The members of the council are nationally recognized scientific experts on radiation problems, who work on a volunteer basis in the national interest.

The objectives of this council are to collect, analyze, and disseminate information and recommendations about radiation protection and measurements, to stimulate exchange of ideas, and to promote cooperation among organizations concerned with radiation problems. Until 1972, the council was involved only with problems relating to ionizing radiation. In 1977, scientific committee 53—(NCRP SC-53)—was set up under my chairmanship to study and draft a report on biological effects and exposure criteria for microwave radiation. The general goals of scientific committee 53 are to provide a substantive general outline of the scientific basis for understanding effects of microwave radiation and, based on this, to proceed to risk assessment and, finally, to develop exposure criteria.

The SC-53 report will include a technical overview of the acute and long-term effects of radiofrequency radiation, as well as it is known, with a substantive discussion of the areas of scientific doubt where the data are so sketchy as not to permit any reasonably firm conclusions.

The technical overview of the committee is now nearly complete with a first draft of all chapters expected to be completed in the fall of 1979.

In the work of modifying and updating the exposure guide, the ANSI C95.4 subcommittee was confronted with some difficult problems that point to the urgent need for additional research. They include:

One. Development of a rational and a data base to formulate criteria for partial-body exposures

Two. Development of a rationale and a data base for handling biological effects that are related to peakpower and modulation.

Three. Improvement of our knowledge of low-level effects that might occur over the ultra-long term, that is over the life spans of species.

In regard to the latter, considerably more work is needed in this country to determine the biological response to chronic low-level irradiation.

Most of the scientific data on the subject of RF radiation are derived from the Soviet and other Eastern European literatures, and have not been quantified, nor are these data consistent to the point necessary for the formulation of practical safety standards where the tradeoff between risk and benefit is clearly known. The current U.S.-U.S.S.R. Cooperative Program on Environmental Health is a first step in this direction, but it is somewhat limited in scope and should be supplemented with other cooperative programs, especially between the Academy of Sciences of the two countries.

Thank you, Mr. Chairman.

Mr. AMBRO. Thank you, very much.

Dr. Justesen, we will hear from you now.

Dr. JUSTESEN. Mr. Chairman, I have been asked to make a statement about the goals, purposes, and activities of the committee on man and radiation of COMAR, of which I am chairman, and also to address problems associated with research on hygienic implications of radiofrequency—including microwave—radiations.

Mr. Chairman, your invitation to testify did not reach me until July 3. There was not sufficient time to secure a review of my written testimony by the membership of COMAR and by the technical activities board of IEEE, of which COMAR is a function. I must therefore stipulate my testimony as expressive of my views, although I believe I speak from consensus. It is my good fortune to be associated with one or the better collegia of biomedical investigators in these United States—the basic scientists and physicians of the Medical Research Service in the Kansas City Veterans' Administration Medical Center—but I must also indicate that I do not speak for that service or for any entity of the Veterans' Administration. Since I am a tenured professor of psychiatry in the school of medicine of the University of Kansas, I do not disclaim the university and, indeed, recognize that the blessing and the blight of tenure are the freedom to speak with impunity and the obligation to speak with candor. I shall honor my obligation.

The working membership of COMAR currently comprises more than 30 engineers, physicists, physicians, and biological scientists, all unpaid volunteers, who represent vocationally every important sector—public and private, academic and industrial—identified with research, development, and application of radiofrequency—RF—radiation. The requirement of members is expertness in some facet of the radiobiology of RF radiations; their charge is evaluation, interpretation, and dissemination of information; and their purpose is to educate and enlighten, not only the 190,000 members of IEEE, but the general public as well.

The composition, charge, and activities of COMAR have been detailed in two papers, one recently published and one in press, both of which are appended to my statement.

Mr. AMBRO. We will insert the papers in our record.

[The papers referred to are included as appendices 2 and 3.]

Dr. JUSTESEN. I think it accurate to state that this volunteer assembly, COMAR, has no equal anywhere with respect to its collective depth and breadth of expertness and to its grasp of data and theory that bear on the biological response to RF radiations.

The members of COMAR recognize two categorical problems associated with RF radiations: excessive exposure and misinformation. The industrial setting serves as an example of the first category of concern. Since RF radiations ordinarily have no sensory signature save that from warming of tissues, and since the human sensory apparatus is notoriously poor in discriminating pervasive and deeply penetrating sources of heating, there is concern for the thousands of technically unsophisticated operators of highpower RF heaters and sealers in the plastics, leather, and lumber industries, most of whom are women of child-bearing age. This is not to say that there is a widespread problem in industry, only that the potential for injury does exist, that proper engineering and surveillance are needed to prevent injury, and that COMAR has an express concern that compliance and safety are industrial watchwords.

Misinformation about RF radiation abounds and, in my opinion, presently constitutes a greater hazard for greater numbers of people than do the electrical machines such as electronic ovens and microwave TV and telephone relays that so often are the targets of inexpert invective. If faith can move mountains, false beliefs can mount movements in which the shared illusion of danger creates psychological and even somatic disabilities in sensitive individuals. A case in point is the video-display terminal—VDT—which was accused of emitting microwaves that were being blamed for induction of cataracts and birth defects until extensive studies revealed that the only measurable radiations from VDT's are those of visible light.

The false belief that low levels of microwave radiation and of ionizing radiations such as X-rays have the same destructive affinity for biological systems is widespread and has been fostered and perpetuated by accounts in the popular media. Recent examples are stories published in Time—April 9, 1979—and U.S. News and World Report—April 16, 1979—in both accounts, which were prompted by the accident at the Three Mile Island nuclear reactor, the domestic microwave oven was erroneously listed as a source of ionizing radiation. Members of COMAR frequently make written responses to such accounts, but the hope of rectification is usually met with silence and sometimes with an avowed indifference. Witness this recent response by an editor of Time, who received a letter from Prof. Arthur W. Guy in reaction to the allegation that microwave ovens are emitters of ionizing radiation:

Dear Dr. Guy: Our box How much—ionizing radiation—is too much? was a general discussion of what is known and what is not known about radiation and its biological effects. Necessarily, we had to simplify what is for laymen an extremely

complicated subject, and we did not think it necessary on this occasion to distinguish between ionizing and nonionizing radiation. * * *

I wrote to the editor who wrote this letter over a month ago to point out that, by analogy, she might as well tell a child that there is no difference between a sleeping kitten and a rabid tomcat. So far, no reply.

It would be unfair to condemn the media en bloc. The misleading accounts in Time and U.S. News & World Report stand in marked contrast to the reasoned and technically competent coverage recently provided by Newsweek. The Boston Globe is also worthy of positive mention as a newspaper committed by policy and practice to straighten a distorted record.

I shall turn now from COMAR's activities to problems associated with biological research on RF radiations.

A persistent problem of ever-increasing severity is the gap of knowledge—the epistemic distance if you will—between the citizen and the scientist. The public doesn't understand the scientist, and the scientist, while aware of the gap of understanding, has done little to repair it. The problem is general to every sector of science but presents in the arena of RF radiations a curious inversion in the perception of risks and hazards. Low-level radiations—man-made RF fields at intensities well below those that induce a measurable rise of body temperature—are feared by many citizens—who mistakenly equate them with ionizing radiations—while there is little anxiety about the highly intense fields that are capable of inducing severe thermal damage. The layman's belief is that low-level radiations will insidiously cumulate over a long period of time to produce insult ranging from birth defects and cataracts to cancer, heart disease, and death. High-intensity radiations are not feared, apparently out of the mistaken belief that elevation of body temperature will warn the individual to make a timely retreat from the field. In points of fact, there is:

One, no consensus among experts that weak RF—fields—circa 10 Mw/cm^2—produce physical morbidity and,

Two, several recent studies of small animals have shown that highly intense, deeply penetrating RF fields that result in excessive heating may overcome the victim with little evidence that warning signals of pain occur or that the source of the heating is identifiable. Indeed, there is a vast reservoir of anecdotal and medical evidence that diffuse, part or whole body heating by intense RF fields or by conventional means has analgesic properties. One recalls in this connection the retired naval officer and his wife who recently died in Ventura, Calif., as they relaxed at 110 degrees Fahrenheit in their hot water spa.

Mr. AMBRO. What did they die from?

Dr. JUSTESEN. They died from hyperpyrexia. They died from excessive elevation of body temperature.

Mr. AMBRO. Caused by the high temperature of the water?

Dr. JUSTESEN. Yes. Permit me to point out that the Great Engineer who designed man and the other mammals was concerned with the potential for excessive exposure of the body to the natural nonionizing electromagnetic radiations of infrared and visible light. The wavelengths of these radiations are very short, and consequently their depth of penetration into the skin is very limited.

The thermal receptors whose activation results in the sensory witness of pain are accordingly located near the external surface of the body. Deep, diffuse heating by longer wavelength RF radiations—or by hot water surrounding a body that convectively disperses the thermal energy via the circulatory system—can be lethal without being painful. The pain sensors that tell us we are recipients of dangerous quantities of thermalizing energy are not activated until they reach a temperature between 45° C and 46° C—113° F to 115° F. Mammalian cells begin to die within a few minutes at a temperature of 43° C—109° F. This is a curious inversion of adaptive and destructive thresholds and probably accounts for the death of the Ventura couple.

I do not fault the Great Engineer's design, because it works quite well in the natural scheme of things in which ambient energy levels of deeply penetrating nonionizing radiations are extremely low. Also, the human brain, possibly the greatest accomplishment of the Great Engineer, is quite capable of devising means to protect the species from insult by manmade RF radiations. Since the backyard bathtubs called spas are also instruments of mortality, they, too, should be engineered to prevent thermal injury.

Mr. AMBRO. Thank you.

Dr. JUSTESEN. There are no simple solutions to the epistemic gap, but a basis for building bridges of understanding lies in the dialogs between scientist and elected representative, which are exemplified by this hearing and by the annual Technological Policy Conferences in Washington under sponsorship of IEEE. I shall draw from the proceedings of the 1978 conference in suggesting concrete proposals for resolving and anticipating problems in the area of RF radiations.

Two important distinctions should be made at the outset. The first is the dichotomy of present and future. The second is the difference between acute—something that occurs briefly or momentarily—and chronic—something that occurs continuously or intermittently over a long period of time. There is no objective evidence of a clear and present danger for the general population from acute or chronic exposure to RF radiation at current environmental levels. Intensive surveys in heavily populated areas by engineers of the EPA have revealed that ambient levels of RF radiation with minor exception are well below even the most restictive exposure limits of Eastern Europe. The potential for danger is associated with specific subpopulations such as engineers, industrial workers, and patients, who may be chronically or acutely, inadvertently or therapeutically exposed to intense fields.

The future, perhaps within the decade, will bring technological advances that could radically increase ambient levels of RF radiation, at least in certain areas. Dwindling supplies of oil are producing a frenetic search for alternate sources of energy, among them solar energy that may be brought to Earth from satellites through the agency of microwave radiation. More powerlines of ever-increasing voltage, electrical-current storage systems, and magneto-hydrodynamic facilities are all in the offing—all would increase the environmental complement of longwave or shortwave RF radiations.

To cope with the present and to prepare for the future, well-conceived programs of research are needed. The most notable organizational needs within the Federal scientific establishment arise from the paucity of extramural programs of grant-supported research, and the absence of an effective mechanism for oversight and coordination of in-house and extramural research.

Three mistakes have been made or perpetuated by past and present administrations that should be rectified by the Congress. The first mistake was Caspar Weinberger's dissolution of the FDA's study panel on radiological health. This panel was the solely constituted, fully representative body of experts on ultrasonic, RF, and ionizing radiations capable of evaluating grant proposals in the area of investigative medicine. It is ironic that the primary source of injury by ionizing radiation tc the general public derives from medical diagnosis and therapy—ironic because medical diagnosis and adjuvant treatments by RF radiations hold the greatest promise for reducing the citizen's burden of medically incurred ionizing radiation.

The second mistake was to transfer responsibility for evaluation of RF-related grant proposals to the RAD study section of NIH. This study panel is largely composed of experts on ionizing radiation; a lesser number of specialists in ultrasound and a token representative of RF radiation have characterized its membership since dissolution of the FDA's study panel. One cannot fault, and indeed, one sympathizes with the members of this study panel, who have been required to pass judgment on proposals the technology and scientific content of which lay without their sphere of training and expertness. In effect, the ionizing cat was forced to watch the nonionizing mouse. For this reason and others, the total extramural program of grant-supported research on biological effects of RF radiations is very small and is woefully inadequate.

The third mistake was associated with the disolution by the present administration of the Office of Telecommunications Policy (OTP). An important element of OTP, the Electromagnetic Radiation Management Advisory Council, or ERMAC, was a baby thrown out with the bath. Charged with responsibility to coordinate Federal in-house research on RF radiation, but armed with no authority save its erstwhile association with the Executive Office of the President, ERMAC is now a subaltern advisory group associated with the Department of Commerce. I think it unlikely that a dozen Federal entities with agency-specific missions of research on RF radiation will be maximally responsive to the dictates of a low-echelon advisory group. From personal contact, I know that many of the members of ERMAC believe the Council has been emasculated.

Increased support of basic and medical research on biological effects of RF radiation is needed, but equally important is redress of the mistakes mentioned earlier. A strong program of extramural grat-supported research is an imperative because:

One. The present heavy emphasis on contracts favors the older, well-established investigator and thereby precludes the fresh input and innovations of the youthful, university affiliated engineer, scientist, and physician; and,

Two. The requisite cadre of young investigators is not being developed to help society anticipate and cope with tomorrow's problems.

Accordingly, the Congress is urged to enact legislation that would result in:

One. Restoration of FDA's study panel on radiological health with sufficient earmarking of grant funds to support medical research, especially on conjoint utilization of ionizing, nonionizing, and ultrasonic radiations in therapy and diagnosis.

Two. Institution of a basic-science study panel within NIH that provides full representation of physics, engineering, and biological disciplines of relevance to RF radiation. Emphasis should be focused on evaluation of ultra-long-term exposures to RF fields of the sort that are highly likely to be encountered by civil and working populations as a byproduct of emerging electrical technologies.

Three. Restoration of ERMAC to the Executive Office of the President—a proposal favored by officials and scientists of virtually every agency within the federal system that conducts in-house programs of research on RF radiations.

I also want to voice the need for continued support of the NIEHS-based programs of scientific exchange on RF radiations between the United States and the Soviet Union. Also, additional exchange programs through establishment of linkage between U.S. scientists and those of the U.S.S.R. Academy of Sciences, which houses some of the world's most capable theoretical and biological physicists, is highly desirable. The resulting pooling of knowledge and resources, and an international program of cooperative evaluation of alternate sources of energy, such as the solar-powered satellite, would require a modest investment that has a potentiality for a tremendous return.

I shall conclude my prepared testimony by noting that the physical welfare and economic health of the American public are closely interwoven. The energy crisis should and can be resolved by technological advance, but ours will be a Pyrrhic victory indeed if a triumph of machines is achieved at the expense of human well-being. Hand in hand with innovations and applications of RF technology must be a critical and credible scientific assessment of their biological and social impacts.

Thank you, Mr. Chairman.

Mr. AMBRO. Thank you very much, Dr. Justesen and Dr. Guy. I would like to compliment you both on the comprehensiveness and relevance and the candor of your testimonies.

I might say at the outset, if there are any representatives of Time and U.S. News & World Report in the audience, that the views of the witnesses are theirs and not necessarily those of this committee.

To be fair, I must say I chaired hearings on low-level ionizing radiation and environmental hearings at Three Mile Island and bear witness to the fact that a little knowledge is harmful.

I might say, too, that related to the rather frightening fact you gave concerning the body sensors not picking up heat; that the reason for the heat in here is because we decided symbolically to do something about the energy crisis. The speaker went running around turning up the thermostats to 78° because of our depend-

ence on oil. Nobody told him that the electricity provided to this place was from coal-fired generators, so if you want to take your jackets off, be my guest.

Dr. Guy, when you talked about specific absorption rates (SAR) in the tissues, you used the phrase "whole body average." What does that mean? I think you can probably differentiate between or among infants, grown men, and small girls, but can you distinguish different organs of the human body in any way?

Dr. GUY. The only relatively complete information available to the ANSI subcommittee was from experiments on whole-body exposures so the only thing that could really be quantified was the total energy absorbed by the body and the average specific absorption rate, the average rate of energy absorption divided by the mass of the animal.

There was considerable discussion about what to do about hotspots and their distribution in the body. Relatively little quantitative work has been done on absorbed energy distributions in the human body and, indeed, this is part of my concern about partial body exposures as they may relate to RF energy absorption by certain organs.

Under conditions of whole-body exposure, hotspots appear in certain regions of the body. In some regions there is hardly any energy absorbed at all. The only firm guideline we had to go by was the whole-body average. When an animal is exposed to electromagnetic energy, there are localized regions of high SAR throughout the body; probably, in a similar manner, hotspots will occur in the human being.

We felt that if we established an average SAR for the animal, it possibly may hold for the human being, too. The hotspots in the human being may be of the same magnitude.

Mr. AMBRO. Well, it is interesting because if we know there are hotspots in the body and we do not know there are different organ sensitivities, or do we know that? Do we know if the brain might be more sensitive than the liver or other organs or tissues to these impacts?

Dr. GUY. Well, the eyes—the lens of the eyes are more vulnerable than most other parts of the body.

Mr. AMBRO. What I am driving at is the question you raise of a relaxed standard for partial-body exposures. How do you get into that in a reasonable way in the absence of specific knowledge about the sensitivity of different parts of the body under an SAR concept that deals with the whole body average?

Dr. GUY. Well, there is really no good quantitative way of getting at this. What the ANSI subcommittee was suggesting was to limit partial-body exposures to a level of about one-fourth that for the whole body with the understanding that many whole-body exposures could have resulted in regional incorporation of energy at a rate of 7 watts.

Mr. AMBRO. Well, I do not subscribe to Congresswoman Holtzman's analysis of the bullets, but is it possible to limit exposures, if they are quantifiable and identifiable, to the most sensitive parts of the body. Is that not a reasonable approach?

Dr. GUY. Yes.

Mr. AMBRO. The trouble is we do not know which part of the body is the most sensitive.

Dr. GUY. We know the central nervous system is more sensitive to exposure than, say, the arm or leg.

Dr. JUSTESEN. Radio-frequency radiation, even in a highly uniform field, is never uniformly absorbed. The RF fields in the tissues are distributed in intensity, and it is, so to speak, the sum of the hotter and the colder spots that yields a whole-body average. To a great extent, the whole-body SAR, which is the average, mass-normalized rate of energy absorption and is expressed in units of watts per kilogram (W/kg), contains the hot spots.

Studies have been performed on small animals in which both averaged and peak SAR's have been determined. Peak SAR's as much as three orders of magnitude above the average have been observed. Since whole-body averaged SAR thresholds of behavioral and physiological disruption are based on exposures that produce the extreme peaks, the hotspot phenomenon is largely contained—is taken into account.

Before passing from the topic of SAR's. I think it important to note that there are two classes of hotspots, electrical and thermal. The SAR is an electrical measure; it is an index of the strength of the RF fields in tissues. When live animals are immobilized during irradiation there doubtless are continuous concentrations of fields in some parts of the body that are much stronger than the average field strength. However, these electrical hotspots are not the same as thermal hotspots, since the flow of blood in the circulatory system will rapidly transfer and to some extent equilibrate the thermalized energy by convection. The distribution of SAR's in a body—that is, the distribution of electrical hotspots—will therefore be much more widely ranging in intensity than the resulting distribution of thermal hotspots.

Mr. AMBRO. Dr. Justesen, is the whole-body SAR an effective way to go?

Dr. JUSTESEN. I think so. Let me stipulate for the record that your line of questioning has caught Dr. Guy in the middle of his modesty. Not one to put his own achievements up front, he hasn't told you but I will tell you that he has done more to advance the methodology of distributive dosimetry than anyone on this great green globe. There is very much a concern for the distribution of energy dosing, and Dr. Guy's innovations involving thermographic analyses of electrical hotspots in bodies of irradiated animals represent the most advanced efforts to achieve a distributive dosimetry. He is indeed the pioneer in the quantitation of hotspots.

Dr. GUY. I am glad you said that.

Mr. AMBRO. I am glad Dr. Justesen said it for you, Dr. Guy. I have a eulogy for you, Dr. Justesen, but I will not read it. I will leave that for Dr. Guy.

I just have one more question for Dr. Guy. How do you know the substantive results of the NCRP SC 53 committee will not disagree with the conclusions embodied in the ANSI standard?

In other words, how do you know that the two programs fit?

Dr. GUY. Well, to a certain extent the ANSI and NCRP committees have the same members. Unfortunately, most of the people working in this area are overburdened by the number of their

committee and subcommittee assignments, and you will see many of the same faces showing up, but there is nonoverlapping membership on the NCRP and ANSI committees, and there are disagreements.

Hopefully, we will work out the disagreements, in the deliberations of the two committees.

Mr. AMBRO. With respect to you Dr. Justesen, you call for increased support of basic and medical research that includes a strong program of extramural grants for research.

Dr. JUSTESEN. Would you like me to comment on that?

Mr. AMBRO. Do you propose study panels at FDA and NIH?

Dr. JUSTESEN. Yes. There are two distinct needs that are not being met. One relates to investigative medicine and to the combined application of RF, sonic, and ionizing radiations in diagnosis and therapy. The other need relates to basic studies in which the biological response to RF radiations is studies in its own right.

The Bureau of Radiological Health of the FDA is the appropriate base for a medically oriented program. Indeed, before Mr. Weinberger's abolition of the radiological health study panel, a symbolic gesture that saved a few dollars but wasted untold thousands in retarding development of life-saving therapies and diagnostic devices, the FDA was the administrative and evaluative locus of an extramural grant program. The administrative talent, the congressional charge, and the machinery for reestablishing a study panel in FDA are all there. I urge an initiative by the Members of Congress in reestablishing the study panel and in providing a level of funding commensurate with its task. Quite literally, the lives you save by such an initiative may be your own.

As to specific level of funding of an FDA grant program, that should be studied and recommended by ERMAC, which alone has the broad scientific vision and the knowledge of resources by which to assess priorities and the slicing of the fiscal pie.

A basic-science study panel would suffice two related ends, discovery of mechanisms of interaction of RF fields in biological systems—the better to predict long-term effects of chronic irradiation—and training of a cadre of young scientists for the next generation. NIH is the appropriate locus for such a study panel, but current plans to assemble a single panel with experts on both ionizing and nonionizing radiations are, in my judgment, neither fiscally nor scientifically sound. Beyond the area of medicine, both forms of radiation are too important and too disparate in their implications for the public health to be treated as a common entity. Competition for a given pool of funds would inevitably result. Moreover, the size of a single study panel would be inordinately large if truely representative of each of the many disciplines involved in all areas of concern.

Once again, ERMAC's expertness and broad vision should be the avenue for reckoning and recommending a level of funding.

To advocate the need for medically and basic-science oriented study panels is to advocate grant-supported research is to acknowledge an imbalance in the present division of contracted and grant-supported study of RF radiations. While I have no hard numbers, I probably err on the conservative side in estimating that for every

dollar of grant support for study of RF radiation, 25 are going into contracted research.

I do not disparage the raison d'etre of the research contract and recognize that it is a useful means to short-term resolution of problems faced by agency management. When used as a near-exclusive instrumentality, the contract does have undesirable by-products. It focuses on the narrow and immediate interests of the agency, which may or may not mesh with the interests and innovative capabilities of the contractor. Moreover, precisely because the contract will be and should be awarded to the established and materially well-disposed investigator, it will not be awarded to the young and aspiring scientist. The rich, so to speak, get richer, and the young scientist unless apprenticed to the savant with the contracts will in these times grow old without giving society the products of his or her creative zeal.

Innovation, our greatest need, is the possession of youth—and the dearth of grant support is starving our most promising source of innovation.

If the young scientists in general are faced with problems of opportunity and support, those who attempt to play the most dangerous game of interdisciplinary research are maximally disadvantaged. It is difficult for the specialist in physics, chemistry, or biology, to obtain support; only a fraction of peer-approved research proposals is being funded by NIH at the present time. Given this competition, the scientist who attempts to embrace two or more disciplines—as is necessary for those who study the biological response to RF radiation—faces bleak binominal odds. If the odds of being funded are 1 in 10 for a physical scientist and are 1 in 10 for a biological scientist, they are 1 in 100 for the interdisciplinary aspirant. As a result, the interdisciplinary researcher, particularly in the sphere of medicine, is an endangered species.

I think it appropriate that the members of the Subcommittee on Natural Resources and Environment consider well-constituted study panels and well-funded programs of extramural, grant-supported research as means to prevent the extinction of a valuable species. I am not pleading for protection of a snail darter. History since the time of the Renaissance has shown that science is a goose that lays golden eggs.

Sadly enough, OMB and some Members of the Congress have embraced the tragic and contradictory conviction that starving the goose is a means of conserving the Nation's treasure.

Mr. AMBRO. Well, from my limited observation it seems, regardless of the field you are in, if you went to MIT you would get the contract.

Dr. JUSTESEN. Harvard and the University of Washington do very well, too.

Mr. AMBRO. That is no reflection of course, on MIT.

Well, both of you talk somewhat about the U.S.S.R. and the scientific exchange program between them and this country. Do you think these programs have led to a better understanding of the differences in the research programs? Do you think we have good answers for why their standards are 1,000 times lower?

Dr. JUSTESEN. I would like to refer this question to Dr. Guy because he has been in this program and I have not.

Dr. GUY. I have been involved in the program since the microwave component was introduced into it in 1974. More recently, the high-voltage powerline problem was introduced. The program is working both ways. We are finding more about how the Soviets have conducted their research in the past to get the type of answers they have obtained.

Mr. AMBRO. I do not want to interrupt, but just on that point, have we not been singularly unsuccessful in duplicating the kind of research that they have done at very low levels?

Dr. GUY. Before the exchange program was developed, researchers in the United States tried to duplicate their experiments, which was very difficult because their papers did not have enough methodological detail, but more recently, based on information and the exchange program, there are some replications based on very limited experimentation that should be expanded.

But, on the other hand, the Soviets are learning some of our techniques and they are redoing some of their earlier work in which they reported low-level effects; now, they are not so sure of earlier findings. They are concerned about artifacts. A most dramatic example of what is happening occurred early last year when the high-voltage powerline problem was introduced into the exchange program. One of the U.S. participants in the program, Battelle Pacific Northwest Laboratories, designed and constructed a very good experimental setup for exposing test animals. The system was observed by engineers of the Soviet group. The system was designed to eliminate many of the problems known to produce artifactual research data which have frequently been reported in the literature.

Not too many months after the visit of the Soviet scientists, we visited a laboratory in the Soviet Union and noted that the engineers there had assembled an identical system. Common facilities and methodologies are going to give a better convergence of results between the two countries. Rest assured that we are not going to end up with standards that are a thousand times different.

Mr. AMBRO. Well, I wonder if either of you would mind if I ask you to permit us to hold the hearing record open so that if we have further questions we could ask you those questions in writing and you could respond to us.

Dr. JUSTESEN. Be glad to.

Dr. GUY. Yes.

Mr. AMBRO. Since you agree to that, I would like to thank you very much for attending these hearings and contributing so much to them.

We have another witness after Dr. Guy and Dr. Justesen, but we also have a couple of bells on the floor, so I would like to recess for a couple of minutes, maybe 5 to 10, and come back and ask Dr. Louis Slesin of the Natural Resources Defense Council to testify.

We will recess for about 10 minutes.

[Brief recess.]

Mr. AMBRO. The subcommittee will resume its hearing.

Let us now call up Dr. Louis Slesin of the Natural Resources Defense Council. Welcome, Dr. Slesin. Proceed in any way you choose.

STATEMENT OF DR. LOUIS SLESIN, NATIONAL RESOURCES DEFENSE COUNCIL

Dr. SLESIN. My name is Louis Slesin. I am a senior research associate with the National Resources Defense Council, a national, not-for-profit environmental group supported by 45,000 members throughout the country. The NRDC has been involved in issues related to public health for the last 10 years. As its representative, I wish to thank the subcommittee for the opportunity to testify before you this morning.

My background is in chemical physics and I recently received a doctorate in environmental policy from MIT. Over the last decade, I have worked on a large number of health and environmental issues. Because of the NRDC's increasing concern over the potential long-term, chronic health effects of nonionizing radiation, I have devoted a major portion of my time to this subject during the last year. First and foremost, I would like to impress upon the subcommittee my own belief that there is an urgent need for more research in this area. Health studies should begin as soon as possible, and should be coordinated and funded by the EPA and other Federal agencies specifically charged by Congress with the protection of public health.

I believe this increased research is urgent because of the scope of the nonionizing problem. For instance, a recent report[1] by a working group for the President's Office of Science and Technology Policy (OSTP) found that the use of nonionizing radiation has grown enormously and has become an integral part of modern society. Specifically, the reported noted:

> The current U.S. Government depreciated capital investment in electronics is $67 billion and is expected to grow to $99 billion in 1986. (The private sector investment is approximately the same.)
>
> There are over 35 million industrial radiofrequency sources in use.
>
> The FCC, as of 1977, had authorized 9 million transmitters.
>
> As of May 1978, there were 369 UHF-TV and 624 VHF-TV stations, 4,524 AM stations and 3,975 FM stations.
>
> There are some 30 million CB radios now in use.
>
> In 1976, some 1.6 million microwave ovens were sold. (More than 10 percent of U.S. homes now own microwave ovens, and industry planners believe this may rise to over 40 percent in a few years. ["Money," December 1978]).

In addition, there are the radiation emissions and exposures associated with radars at airports and military installations, and the miles upon miles of point-to-point communications and high-voltage energy transmission lines.

The OSTP working group urged, and I quote:

> It is in the national interest that sufficient resources be made available to conduct the research needed to develop a sound scientific basis for national guidelines for exposure to—nonionizing radiation. This requires effective central coordination of agency programs, supported by adequate budgets for research, and development of additional research facilities that might be required.

Impartial research would define the nature and degree of the possible health hazards associated with nonionizing radiation, presently the subject of considerable controversy. The findings that are available indicate that low-level exposure to this type of radiation can have adverse effects on the fetus, the blood-brain barrier, the

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[1] "A Technical Review of the Biological Effects of Nonionizing Radiation," A Report Prepared for the Office of Science and Technology Policy by an ad hoc Working Group, May 15, 1978.

central nervous system, and information transfer in the brain. Some of these biophysical effects may one day explain the long history of reports that low-levels of nonionizing radiation cause a host of behavioral effects including dizziness, headaches, nausea, depression, irritability, fatigue, and memory loss.

However, at this time we really do not know what long-term effects exposure to nonionizing radiation may have. The studies simply have not been done. Given the long leadtimes necessary to do this research, the time to begin is now.

EPIDEMIOLOGY

The need for more funds for research is best exemplified by the current state of epidemiological research. At present, only three epidemiological studies are in progress:

1. The Bureau of Radiological Health (BRH) within the FDA has contracted a study by the National Academy of Sciences to investigate the long-term effects of nonionizing radiation on radar operators. A pilot study done in 1970–71 showed that the full study would be very expensive, so the protocols were modified, but even the $400,000—over a 4-year period—for the smaller study could not be raised. The study was scaled down further, and in 1974 BRH allocated $150,000 to do the epidemiology. The results will be out soon, but due to the constraints placed on the study, their utility will be very limited. To do the study properly would cost an additional $500,000, and that money is simply unavailable at the present time. Thus, nearly 10 years after the study was first conceived, we still know very little about the effects of microwaves on radar operators.

2. The second study in progress, also funded by BRH, is of diathermy workers. This study has also been unduly circumscribed. For some reaons, only male therapists were surveyed; no female workers were included. Given the risks of teratogenic—fetus-deforming—effects associated with nonionizing radiation, it is a great pity that women were not included.

3. The third study is just getting underway. It is being set up by the National Institute for Occupational Safety and Health—NIOSH—and is designed to study people who work with radiofrequency—RF—sealers. This is a high-risk group and the study is most important, but it will be years before it is completed.

Past epidemiological efforts such as the Moscow Embassy study and the study of congenital anomalies in children born at Fort Rucker were no different. They, too, left many unanswered questions. Under the best of circumstances, epidemiological studies are extremely difficult to do. When the agencies are strapped for funds and the research designs become cramped, the results may generate as much uncertainty as they were designed to resolve.

Members of the EPA staff have told me that they have identified a particular group of MIT radar operators who could be studied. In addition, they would like to identify other populations for which epidemiological studies could be carried out at a later date. I urge you to encourage this work, and not let it be diluted so as to undermine its future utility.

The status of animal studies for chronic exposures to nonionizing radiation is no better. To my knowledge, only one laboratory in the country is equipped to do this research. Other labs must have the capability to do these experiments, and the research must go on.

The funds for the three ongoing epidemiological studies total less than half a million dollars—spread out over a number of years. Surely we can afford more money to assess a technology which reaches into every part of American industry and or our daily lives, and which, by the end of the 1980's, will no doubt represent a total capital investment of over a quarter of a trillion dollars.

INSTITUTIONAL ARRANGEMENTS

Of course, more money, in itself, is not enough. The Congress must make sure that the institutional arrangements are in order so the money is well spent.

Some progress has been made toward this goal by the establishment of the task force on Biological Effects of Nonionizing Electromagnetic Radiation—BENER—within the National Telecommunications and Information Administration—NTIA—in the Department of Commerce, and by the formation of a radiofrequency and microwave committee at the Interagency Regulatory Liaison Group—IRLG. More steps must be taken however. The Congress must insure that the research is geared to the needs of the regulatory agencies and that both the research and the regulatory agencies are free of any adverse influence from the user agencies, such as the Departments of Defense, Energy, and Commerce.

It is important for the subcommittee to realize that the Department of Defense controls more than 63 percent of the research funds devoted to the study of the bioeffects of nonionizing radiation. In fiscal year 1978, the combined Army, Air Force, and Navy budgets were $6.35 million out of a total of $10.1 million.

We must not repeat the sad history of ionizing radiation bioeffects research which has been controlled by the Atomic Energy Commission, the Department of Energy, and the Department of Defense. As Peter Libassi's work group on institutional arrangements for ionizing radiation recommended in its draft report:

> The lead responsibility for coordinating a radiation health effects research program should be exercised by an agency that specializes in health-related research.[1]

I am appending a letter I wrote to Mr. Libassi last May asking him to include nonionizing radiation in the new institutional arrangements for ionizing radiation. This task force had its hands full with ionizing radiation, and so no action was taken on nonionizing radiation. The ionizing radiation task force issued its final report in June and designated the National Institute of Health—NIH—to chair an interagency research committee.[2] While the committee could perform the same function for nonionizing radiation, others have suggested that the Office of Science and Technology Policy—OSTP—within the Executive Office of the President should coordinate this work. Indeed, it is ironic that the present chairman of the BENER task force, Dr. Howard Clark, made precisely this

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[1] Draft Report of the Interagency Task Force on Ionizing Radiation on Institutional Arrangements, April 17, 1979, p. 10.

[2] "Report of the Interagency Task Force on the Health Effects of Ionizing Radiation," HEW, June 1979.

latter recommendation when he worked for the Senate Commerce Committee.[3]

I believe it is very important for there to be no appearances of any conflict of interest in research on and regulation of nonionizing radiation. The only way this can be accomplished is by moving the BENER task force out of NTIA. The task force should not be located in an agency which has the responsibility for setting the Nation's communications policy. This dual function of developing and controlling telecommunications technology can create unnecessary conflicts of interest. Similarly, the Electromagnetic Radiation Management Advisory Council—ERMAC—an advisory committee to the Secretary of Commerce and NTIA on the potential biological effects of nonionizing radiation, should also be relocated to a nonuser agency.

In addition, I recommend that the research and regulatory arms of the Federal Government be supported in their efforts to build up their expertise on this very complex subject. There is a learning curve at work: It will take time for the agencies to develop their knowledge. EPA has announced that it will soon issue a guidance for population exposure to nonionizing radiation. Any such guidance, and future ambient standard, are bound to be controversial. The agency must have the expertise to back up its determinations.

The NIOSH criteria document on radiofrequency and microwave radiation, which was recently issued for external review, illustrates what can happen when this expertise is lacking. I have sent Dr. Robbins of NIOSH a long letter describing the deficiencies of this document, and with your permission I would like to place a copy of the letter in the hearing record. The NIOSH document, I believe, is confused and understates the risks associated with occupational exposure to nonionizing radiation. If NIOSH had more people and funds to spend on health research, I am sure that a much better document would have been written.

In conclusion, I urge the subcommittee to encourage work in this area. I would say that research on the bioeffects of nonionizing radiation is at the same stage of development as the research on ionizing radiation was in the early 1950's. We must not wait 20 years before finding out what the biological effects of nonionizing radiation might be.

I thank the subcommittee for the chance to make this statement, and I am prepared to answer any questions, you may have.

Mr. AMBRO. Thank you, Dr. Slesin. The letter of May 15, 1979, addressed to F. Peter Libassi and the letter of July 11, 1979, addressed to Dr. Anthony Robbins will be placed in our record at this point.

[The letters referred to follow:]

[3] "Report on Radiation Health and Safety," pp. 7–8.

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May 15, 1979

F. Peter Libassi
Interagency Task Force on Ionizing Radiation
Office of the General Counsel, DHEW
Room 712-E, HHH Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Libassi:

In response to your request for comment on the "Report of the Interagency Task Force on Ionizing Radiation on Institutional Arrangements," I urge you to expand the purview of the Task Force in order to address the issue of non-ionizing radiation.

The review of the institutional arrangements for research and regulation of ionizing radiation presents an ideal chance to take up the related problems of non-ionizing radiation. The parallels between the two types of radiation suggest that, unless this opportunity is taken, the federal government may be doomed to repeat the sorry history of ionizing radiation all over again. By acting now, you can avoid reorganizing non-ionizing radiation regulation and research in a climate of controversy similar to that which pervades the on-going work on ionizing radiation.

From an institutional and policy perspective, the similarities between ionizing and non-ionizing radiation are compelling:

Research on Biological Effects

Research on the biological effects of non-ionizing radiation is still in its infancy, especially with respect to low-level chronic exposures. The many uncertainties are similar to those which dominated research on the health effects of ionizing radiation in the 1950's. In 1977, only $8.5 million was spent on non-ionizing radiation research. This small sum was divided among a large number of federal agencies, including the Army, Air Force, Navy, BRH, NIEHS, NIOSH, EPA, NBS, NSF, VA, and CIA. The Department of Defense had control of 63.4% of these biomedical research funds. Moreover, biological effects research is being coordinated by the National Telecommunications and Information Agency (NTIA) in the Department of Commerce, with the advice of

the Electromagnetic Radiation Management Advisory Council (ERMAC).

This current situation is contrary to the Task Force's recommendation:

> The lead responsibility for coordinating a radiation health effects research program should be exercised by an agency that specializes in health-related research. (p. 10)

Because the lion's share of the research funding is coming from DOD which has a strong interest in the continued free use of non-ionizing radiation, and the research is being coordinated by NTIA, an agency whose mission is the promotion and maintenance of the nation's communication system, DOD and NTIA are in a "position of apparent conflict of interest such as to cast doubt on the objectivity or credibility of the research results." (p. 21)

If, as the Task Force proposes, primary responsibility for radiation research is given to NIH, I strongly suggest that the equivalent authority be given to NIH for research on non-ionizing radiation.

Radiation Protection

Reports from the General Accounting Office [1/] and another [2/] from the Senate Committee on Commerce, Science, and Transportation have recommended greater protection for non-ionizing radiation. Some of the reasons for this concern are:

- In 1977 the old Office of Telecommunications Policy estimated that by 1986, the federal government's depreciated capital investment in electronics will be $99 billion. The private sector investment is about the same.

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1. The Environmental Protection Agency Needs Congressional Guidance and Support to Guard the Public in a Period of Radiation Proliferation, January 20, 1978; Efforts by the Environmental Protection Agency to Protect the Public from Environmental Nonionizing Radiation Exposure, March 29, 1978; and More Protection from Microwave Radiation Hazards Needed, November 30, 1978.

2. Report on Radiation Health and Safety, December 1978.

- In a time of proliferating sources, there is no general population standard for exposure to non-ionizing radiation.
- Up to 20 million Americans are being exposed to non-ionizing radiation on the job. At this time, there is no enforceable standard to protect them, and the BRH within FDA had found that the OSHA guideline was set arbitrarily and that it fails to protect workers' health. Even this arbitrary and unprotective standard is routinely exceeded, sometimes by up to a factor of 26.
- Adequate monitoring equipment to measure non-ionizing radiation has not been developed; there is an especially urgent need for portable detectors to gauge exposures to radiofrequency radiation in the near field.
- As in the case of ionizing radiation, the regulation of non-ionizing radiation is plagued with jurisdictional problems: a host of federal agencies have fragmented and overlapping authorities.

Non-ionizing radiation research and regulation has been neglected for too long. New institutional arrangements are desperately needed. Whatever specific reorganizational plan the Task Force selects for ionizing radiation, the same plan would also vastly improve the government's non-ionizing radiation program. I hope you will not miss this opportunity to restructure work on non-ionizing radiation.

If you or the other members of the Task Force have any questions about this matter, I would be happy to help answer them.

Sincerely,

Louis Slesin, Ph.D.
Senior Research Associate

cc: David Hawkins, EPA
Donald Fredrickson, NIH
John Villforth, BRH

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July 11, 1979

Dr. Anthony Robbins
Director
NIOSH
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Robbins:

The purpose of this letter is to urge you to withdraw the draft NIOSH Criteria Document on Radiofrequency and Microwave Radiation, and to commission a new occupational health study. In the interim, NIOSH and OSHA should begin procedures for promulgating either a new occupational exposure standard or an emergency temporary standard for radiofrequency and microwave (RF/MW) radiation before the end of the year.

The Natural Resources Defense Council (NRDC) is concerned about the potential health effects of RF/MW radiation. We welcomed NIOSH's initiative in preparing this criteria document, but we are distressed to find it so seriously flawed. The present draft misstates and understates the risks of RF/MW radiation to occupationally exposed workers. The document fails to provide a scientifically and medically sound standard: it admits the existence of many low-level effects, but does not set a standard to protect workers from them. As a result, the document's proposed standards have been set arbitrarily, and will result in significant risks to occupationally exposed populations. In addition, the procedures followed by NIOSH and its contractor were seriously flawed -- raising substantial questions about the objectivity of the document. These problems are too basic and too comprehensive to allow for correction by modifying the existing draft. The draft RF/MW criteria document must be rewritten. In the paragraphs below, I shall outline specific objections, both substantive and procedural, to the document.

I. The Document's Scientific and Medical Inadequacies

The document's 500 annotated pages look impressive, but upon close reading, it is apparent that the criteria document lacks a reasoned and balanced appraisal of the risks associated with RF/MW radiation. There is no synthesis or interpretation to guide the reader through the mass of uncoordinated facts. Studies are cited without any discussion of their relative importance or relevance.

A number of crucial facts and studies are not cited. For example, in a table of workers potentially exposed to RF/MW radiation, more than a page is devoted to listing all the different types of plastics which are sealed with this radiation (pp. 27-29). Yet, the same table neglects some of the most important categories of occupationally exposed workers, including air traffic controllers, radio operators, and radar and microwave oven repairmen. The writers of the document must have been aware of these job categories for each is the subject of health studies cited elsewhere (e.g., pp. 39, 40, 57, 92). Also, ten pages of the document describe some 15 studies which show the obvious: that at very high levels (above 100 mw/cm^2), RF/MW radiation is lethal to experimental animals. Yet the document fails to even mention most of Dr. Ross Adey's work on the effects of low-levels of RF/MW radiation on brain chemistry. The only citation to Dr. Adey's research is to a paper published in 1973. The last six years of his research are ignored.

(1) A Host of Studies Show Low-Level Effects

The document cites many studies which indicate that RF/MW radiation can have effects at power densities at 1-5 mw/cm^2 or below (note the proposed standard is 1 mw/cm^2 between 10-500 MHz and 5 mw/cm^2 between 500-300,000 MHz). All of the following effects are presented in summary form on p. 389 of the NIOSH document, and discussed in detail in previous sections:

- Between 10 and 500 MHz reports of "increased urinary secretion of 17-ketosteroids; alterations in EEG patterns and conditioned reflex behavior; and decreased leukocyte count, blood cholinesterase, and phagocytic activity" have been published by Russian scientists at levels below 0.01 mw/cm^2. (p. 386).

° Above 500 MHz, a large number of animal studies on experimental animals are reported.1/

-- alterations in certain neuroendocrine functions at 0.01-18 mw/cm^2.

-- microscopic changes in central nervous system tissue at 2-10 mw/cm^2.

-- effects on the peripheral nervous system at 1-10 mw/cm^2.

-- changes in the permeability of the blood brain barrier at 0.03-10 mw/cm^2.

-- alterations in EEG at 0.02-5 mw/cm^2.

-- changes in behavioral patterns at 0.1-15 mw/cm^2.

-- changes in cardiac rate at 3-12 mw/cm^2.

-- alterations in various blood and bone marrow parameters at 0.05-10 mw/cm^2.

-- changes in the immunologic system at 0.5-10 mw/cm^2.

Several of these reports merit specific attention:

° Oscar and Hawkins' experiments that show that 1300 MHz radiation can reversibly increase the permeability of a rat's blood brain barrier at average power densities of only 0.03 mw/cm^2 for pulsed and 0.3 mw/cm^2 for continuous wave radiation. (pp. 140-142). These results confirm the previous experimental findings of Frey et al. (pp. 139-140)

° Adey's 1973 experiments using amplitude modulated 147 MHz radiation affected the electrical activity of cats' brains at power levels of 1 mw/cm^2 and below (pp. 155-156). As I noted earlier, an entire body of important

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1/ Small animals are believed to absorb more radiation at higher frequencies, thus many experiments are conducted at above 1000 MHz (1 GHz).

work has been excluded, which shows that calcium binding in cerebral tissue is very sensitive to weak, modulated fields at other frequencies.2/

° Lovely et al. have shown that 0.5 mw/cm^2 2450 MHz fields can induce a reversible decrease in the concentration of blood cholinesterase -- an indication of changes in the functioning of neurotransmitters in the brain. (p. 215-216).

It should be stressed that all these effects are for short-term acute exposures. No one has yet done the research for long-term chronic exposures, those which many workers experience each day, every day for many years while they are on the job. There is the added problem, not considered in the document, that many of the workers are in poor health and may be more susceptible to ill effects.

(2) The Document Proposes a Thermal Standard, Failing to Adequately Address Low-Level Non-Thermal Effects

All of these low-level results taken together support the reports by Russian and East European scientists that low levels of RF/MW radiation can induce a wide range of behavioral abnormalities, including dizziness, headaches, nausea, depression, irritability, fatigue, and memory loss. While many of the physiological and biochemical changes induced by RF/MW radiation in animals cannot yet be associated with gross behavioral effects in humans, it is reasonable to assume that such a connection exists.

Yet, the document fails to interpret the relevance and importance of the studies showing low-level effects. For those low-level effects shown below 500 MHz, the document simply notes: "Whether these effects constitute occupational hazards is not clear." (p. 387). And for

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2/ For example: S.M. Bawin, L.K. Kaczmarek, and W.R. Adey, "Effects of Modulated VHF Fields on the Central Nervous System," Annals of the New York Academy of Sciences, 247, 74-81 (1975), and S.M. Bawin, W.R. Adey, and I.M. Sabbot, "Ionic Factors in Release of 45 Ca 2+ from Chicken Cerebral Tissue by Electromagnetic Fields," Proceedings of the National Academy of Sciences, 75, 6314-6318 (1978).

effects above 500 MHz: "there is not total agreement in the literature on the production of these effects." (p. 390).

The document bases its standards on thermal effects (effects usually associated with radiation heating at higher power levels), and arbitrarily discounts most of the reports of ill effects a low power densities. Thus, the proposed 1 mw/cm^2 standard (for frequencies between 10 and 500 MHz) is selected because it "falls between [the] two extremes" of documented non-thermal effects; (p. 387) the standard provides protection "from excessive thermal loading." (p. 388). Similar reasoning is given for the proposed 5 mw/cm^2 standard. (p. 390).

The use of a thermal loading argument as the basis for the exposure standard is of dubious merit, particularly when one considers that the three specific examples of low-level effects cited above are almost certainly of a non-thermal 3/ type:

- Oscar and Hawkins state: "the possibility of the BBB [blood brain barrier] alteration being caused by direct heating seems remote."4/ A recently published report confirms such a non-thermal mechanism: "It is unlikely that the increased permeability of the blood-brain barrier due to low power density microwaves is a result of increased temperature, in a macroscopic sense."5/

3/ The distinction between "thermal" and "non-thermal" effects may not be a sharp one. For the purposes of the present discussion, a thermal effect is one that entails a net temperature rise. Thus while non-thermal effects may involve similar molecular interactions as thermal effects, they do not entail gross heating of the exposed biological system.

4/ K.J. Oscar and T.D. Hawkins, "Microwave Alteration of the Blood-Brain Barrier System of Rats," Brain Research, 126, 291 (1977).

5/ G. Brainard et al., "The Effects of Low Power Density Microwaves on Rat Hypothalamic Temperatures," Proceedings of the 1978 Symposium on Electromagnetic Fields in Biological Systems, Ottawa, Canada, June 23-30, 1978.

- The criteria document reports on Adey's 1973 experimental results: "Thermal effects were ruled out, since the power densities involved were lower than 10% of accepted thermogenic levels." (p. 156). And, a more complete review of Adey's group's work found that the "effects may be induced at intensities such that thermal stress cannot entirely account for the detected changes."6/

- Lovely's group's results on neurotransmitters led them to conclude that the effects of the weak fields indicate an interaction by a mechanism other than generalized heating of tissues.7/

In addition many of the other low-level effects probably involve non-thermal interactions. For instance, teratogenic (fetus-deforming) effects induced by RF/MW radiation may be due to field interactions at the microstructural level, rather than microwave heating.8/

Therefore, under the proposed standard, workers would be exposed to levels of RF/MW radiation which can cause many non-thermal ill-effects.

(3) The Document Gives an Inadequate Rationale for the 500 MHz Cut-off

The proposed standard provides for a five-fold increase in exposure at frequencies above 500 MHz using a rationale which is also based on a thermal mechanism of interaction. According to the document, the 5 mw/cm^2 standard "was arrived at after considering the lowest range of power densities (0.01-15 mw/cm^2)" at which effects have been reported and "after considering the reduced absorption rate exhibited by humans in this frequency range." (p. 390). As

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6/ S.F. Cleary, "Biological Effects of Microwave and Radiofrequency Radiation," CRC Critical Reviews in Environmental Control, (June 1977), p. 149.

7/ National Research Council, Analysis of the Exposure Levels and Potential Biologic Effects of PAVE PAWS Radar System, (1979), p. 60.

8/ Ibid., p. 67.

noted earlier, the 5 mw/cm^2 standard is arbitrary, having been set at a level for which effects have been documented, rather than at a level known to be without adverse effects.

The experimental evidence which demonstrates that low-level exposures cause non-thermal effects indicates that such biological interactions are frequency dependent. This means that the frequency extrapolation used by NIOSH in its document is invalid. The Air Force School of Aerospace Medicine's Dosimetry Handbook warns:

> When the biological effects are due to heat generated by the radiation, combined power and frequency extrapolation is probably better because it results in a similar distribution of internal fields, which depends strongly on the relationship of absorber size to wavelength. For studying effects that might be strongly frequency dependent, such as molecular resonance of some kind, frequency extrapolation would obviously not be appropriate.9/

One could calculate a relationship between frequency and absorption even for frequency dependent events; however, the theoretical and experimental models which relate energy absorption and frequency dependent phenomena are still in their infancy. In any case, the NIOSH model is inadequate.

Furthermore, it is important to note that the models used for frequency independent absorption are also unsound. In these models, human beings are represented by saline-filled prolate spheroidal bodies.10/ As the Air Force Dosimetry Handbook points out:

> The rigorous analytical treatment of a realistic-shaped inhomogeneous model for humans or experimental animals would be an enormous theoretical task.11/

9/ C.H. Durney et al., Radiofrequency Radiation Dosimetry Handbook, USAF School of Aerospace Medicine, 2nd Edition, May 1978, p. 127. [Emphasis added.]

10/ See O.P. Gandhi, "Conditions of Strongest Electromagnetic Power Deposition in Man and Animals," IEEE Transactions on Microwave Theory and Techniques, MTT-23, 1021-1029 (1975).

11/ Durney, op. cit., p. 7.

And therefore:

> Spheroids, ellipsoids, and block models must be recognized as very crude models of animal and human bodies.12/

The models are too simple to represent the interactions that occur in human beings at the organ and cellular levels. Finally, these models are based on far-field exposures and do not reflect the complex electromagnetic interactions that take place in the near field.

The complexity of the interaction between electromagnetic fields and the human body is illustrated by experiments conducted by Motorola, Inc., and recently reported by the Federal Communications Commission (FCC):

> The results of these experiments...indicated that the maximum power deposition at 840 MHz did not occur immediately below the bone-brain interface, as theoretical calculations predict, but occurred, instead, deeper in the cerebral cortex. These "absorption peaks" were believed to be caused by the focusing of the electromagnetic energy by the curvature of the frontal lobe of the skull. An absorption peak was also located at the surface of the eye.13/

It is ironic that the NIOSH criteria document seeks to minimize the importance of a whole body of work on RF/MW radiation that posits low-level non-thermal effects, and yet to a large extent bases its standards on models which view human beings as balloons filled with salt water.

The new Canadian standard is more protective by placing the cut-off at 1000 MHz (1 GHz) (p. 375) and the Swedish government has promulgated a more stringent standard above 300 MHz than below this frequency (p. 373). This opposite frequency dependency is neither addressed nor explained in the document. Furthermore, as you know, the NIOSH and other "Western" standards are orders of magnitude weaker than those of Poland, Czechoslovakia, and the Soviet Union.

12/ Ibid.

13/ Federal Register, June 25, 1979, p. 37,012.

Given the deficiencies in the absorption models, and given the fact that so many non-thermal effects have been demonstrated, NIOSH should not have a cut-off at 500 MHz.14/ At some future time when basic research increases our understanding of the interaction between biological systems and electric and magnetic fields, a frequency-dependent standard may be desirable. For the present, NIOSH should propose the same standard for frequencies between 10 MHz and 300 GHz.

(For additional comments on the criteria document, please see the Appendix.)

In summary, the document does not reflect an understanding of the significance of the biological effects associated with low-levels of RF/MW radiation. A new, shorter, and more critical document must be developed by NIOSH.15/

II. Procedural Irregularities

On January 17, 1979, NRDC wrote to you requesting permission to review the draft criteria document as soon as it was completed. (See attached correspondence). On January 31, 1979, Frank Mitchell, Acting Director of NIOSH's Division of Criteria Documentation and Standards Development, responded on your behalf, and told us that the document would be available "early in March 1979," and that NIOSH "will be happy to provide a copy to you, and request your comments on the draft." On April 27, 1979, having received no word from NIOSH, NRDC wrote to Frank Mitchell asking him for the new schedule for the release of the criteria document. This letter was never answered.

14/ I have been advised that a later draft of the criteria document will propose a standard which increases with frequency between 300 and 1,000 MHz. Such a standard would still be unacceptable.

15/ For instance, the Canadian Environmental Health Directorate's two-volume report was less than 200 pages long and recommended a more stringent standard than the one now proposed by NIOSH. Health Aspects of Radiofrequency and Microwave Radiation Exposures, Part 1 (1977) and Part 2 (1978).

As you know, the criteria document was released for external review on April 15, 1979. NRDC did not receive a copy at that time. Indeed, we did not even learn that the document was in circulation until May. When we made inquiries about why we had not received it, we were told that NIOSH had decided to delay our participation until June. No reason was given for this change of plan. The removal of NRDC as an official reviewer is difficult to explain given the extensive participation by industry officials and the lack of participation by affected unions in the review process.

Among the professional societies and trade associations who were sent the document in April are: Howard Johnson of RCA, representing the Electronic Industries Association; Jules Cohen, a consulting electronics engineer, representing the TV Broadcasters All Industry Committee; M.J. Maw of Mann-Russell Electronics, Inc., representing the Forest Products Association; and John Osepchuk of Raytheon, representing the Association of Home Appliances Manufacturers.

In contrast to all these industrial reviewers, the record indicates that NIOSH made little effort to involve union representatives. Only one union official was sent the criteria document, Robert Harbrant of the Food and Beverage Trades Department of the AFL-CIO. (This Department represents only a small number of the affected industries in which workers are occupationally exposed to RF/MW radiation.) This Department has rejected the criteria document as inadequate. In a letter to NIOSH dated June 12, 1979, Mr. Harbrant wrote: "we recommend and strongly urge that the [criteria document] be withdrawn and a new effort begun by the Institute." Sheldon Samuels, the Director of Health, Safety and Environment, Industrial Union Department, AFL-CIO, concurred with the view that the document should be withdrawn, and signed the same letter.

Fairness would demand that if industry groups, which would be adversely affected by a new standard, were given the document, then unions and public interest groups, like NRDC, should also have had an equal chance to participate in the review process.

In addition, there are serious questions about the advisability of having asked Equitable Environmental Health (EEH) to be the contractor for the development of the criteria document, and the selection of consultants by EEH.

Over the last few years, EEH and its predecessor Tabershaw-Cooper Associates have been involved in many controversies arising out of its work for NIOSH. EEH has found itself simultaneously working for NIOSH and for corporations that are contesting NIOSH initiatives to protect workers' health.16/ In this case, EEH did not hire a balanced team of consultants. Dr. Sol Michaelson of Rochester University was one of the four consultants to EEH on this criteria document. Dr. Michaelson has often testified as an industry spokesman, and, in our view, has regularly understated the potential health effects of RF/MW radiation.

In 1976, The Bureau of Radiological Health (BRH) had the occasion to review Dr. Michaelson's testimony on behalf of the General Electric Company. After a detailed analysis, BRH concluded that:

> "The evaluation of Dr. Michaelson's testimony indicates that his conclusions are not supported by data," and that "the testimony does not provide the evidence necessary to draw the conclusion that Dr. Michaelson makes regarding the lack of significant risk of injury at microwave exposures. In fact, the data indicate significant effects are possible."17/

It is difficult to see how NIOSH could allow its contractor to hire a consultant whose judgment has been challenged by one of its sister agencies. At a minimum, NIOSH should have insisted that EEH balance this pro-industry view with one that favors protecting workers health. NIOSH should not be releasing a report when the composition of the team is so suspect.

When NIOSH commissions a new criteria document, NIOSH should convene a fair and balanced team of experts to consult with NIOSH on writing and reviewing the new criteria document.

16/ See, for instance, "Conflict-of-Interest Guidelines Are Needed -- Now," Occupational Health and Safety Letter, September 8, 1977.

17/ Attachment E: "Analysis of Written Testimony of Sol M. Michaelson," Letter from John Villforth to Ronald J. Greene in reference to General Electric's Petition for Exemption from Section 359 of Radiation Control for Health and Safety Act, August 13, 1976, pp. 47-48.

III. The Need for Immediate Action

The desperate need for an enforceable and protective occupational standard should not force the premature publication of the RF/MW radiation criteria document. Once finalized, the criteria document will become the official record upon which OSHA will base its standard. To publish the criteria document in its present (or slightly modified) form would unfairly prejudice future OSHA rule-making. Moreover, the criteria document will become one of the basic sources of information on the health effects of RF/MW radiation; as such, it will have a great deal of influence in shaping expert and public opinion about these radiation hazards.

Because a fair and competent study will take time, NRDC urges you to take action on this serious occupational risk now. Under normal circumstances, OSHA would wait for the criteria document to be completed before proposing a new standard. The Occupational Safety and Health Act of 1970 both authorizes OSHA to propose a standard without a completed criteria document and allows OSHA to set an emergency temporary standard. There are enough data in the document to warrant NIOSH and OSHA recommending the equivalent of a 1 mw/cm^2 standard for frequencies between 10 MHz and 300 GHz. We recommend that you and your staff work with Dr. Bingham's staff at OSHA to take one of these actions so that an occupational standard will be in place before the end of the year.

The following statistics should make the case for the standard:

- NIOSH estimates that up to 21 million workers are potentially exposed to RF/MW radiation on the job.
- NIOSH estimates that there are over 35 million RF sources in use in industry today.
- The courts have ruled that the present 10 mw/cm^2 standard is unenforceable, and is therefore voluntary.
- The Bureau of Radiological Health within the Food and Drug Administration has found that the present 10 mw/cm^2 standard was set "arbitrarily," and does not protect public health.
- For radiation exposure in the near field, the present OSHA standard is given in the wrong units. (It

should be in terms of electric and magnetic field strengths, not power density.)

- There is no reliable and easy-to-use monitoring equipment for near field exposures -- especially for frequencies below 300 MHz, where workers may frequently be in the near field.

- Most employees (and many employers) are unaware that there are any radiation exposures associated with these machines.

For one particular class of workers -- those working with RF sealers -- the health risks are extraordinarily great. All of the following statistics are taken from NIOSH sources:

- There are at a minimum 15,000 - 25,000 RF sealers in operation in the United States.

- Workers are routinely exposed to peak values which exceed the arbitrary 10 mw/cm^2 standard by a factor of over a 100.

- Field studies indicate that 75% of workers using RF sealers were exposed to levels higher than the 10 mw/cm^2 standard.

- A majority of those exposed are women of child-bearing age and NIOSH's own research shows that there are potential teratogenic effects associated with RF/MW radiation, and as discussed earlier, such effect may be induced by non-thermal mechanisms.

- Workers do not feel the heating effects of the radiation until the exposure is far in excess of the standard.

We stress that RF sealers operate at frequencies below 300 MHz, frequencies at which the workers are in the near field, that the present standard is given in the wrong units, and that no reliable monitoring equipment is commercially available.

The pressing need for an occupational standard has been voiced by the Congress and the General Accounting Office (GAO). A report by the Senate Commerce Committee found:

> It is clear that OSHA, in cooperation with other responsible organizations and Federal agencies, should give priority to a review of the adequacy of its present voluntary standard for occupational exposure to nonionizing radiation. After making any necessary changes, OSHA should promulgate a mandatory standard. While conducting this review, OSHA should consider converting the present voluntary standard to a mandatory standard on an interim basis.18/

And the GAO has recommended that:

> "the Secretary of Labor direct the Assistant Secretary for Occupational Safety and Health to establish an occupational exposure standard to protect workers from [microwave] hazards."19/

On March 20, 1979, Congresswoman Holtzman introduced special legislation (H.R. 3132) requiring OSHA to set an emergency temporary standard for workers exposed to RF sealers and to propose, within 60 days of enactment, a general RF/MW occupational standard. As Congresswoman Holtzman argued on the floor of the House:

> "It is imperative to develop standards to protect workers from non-ionizing radiation ... the problem of exposure of workers to harmful effects of non-ionizing radiation is too serious to be ignored any longer."20/

Conclusion

In conclusion, NRDC recommends that you immediately take the following actions:

1. Withdraw the draft RF/MW criteria document.
2. Commission a new RF/MW criteria document.

18/ Report on Radiation Health and Safety, December 1978, p. 24.

19/ GAO, More Protection from Microwave Radiation Hazards Needed, November 30, 1978, p. 36.

20/ Congressional Record, March 21, 1979, p. H1573.

3. Hire a balanced team of experts to work with NIOSH in developing a new draft.

4. Set up a balanced group of experts to review the new document.

5. Work with OSHA to propose an occupational safety standard for RF/MW radiation as soon as possible so that it can be in effect by the end of the year. If necessary, an emergency temporary standard should be promulgated. We suggest that the equivalent of a 1 mw/cm^2 standard for 10 MHz to 300 GHz be adopted.

If we can be of any assistance or can provide any additional information to you or your staff, we are most ready to do so.

Sincerely,

Louis Slesin, Ph.D.
Senior Research Associate

LS:wk
Enclosures

cc: Eula Bingham
John Froines
Zory Glaser

APPENDIX: Additional Deficiencies

Although this does not represent an in-depth analysis, a few additional points can be made:

Heat Stress: Many researchers have long recognized that the thermal effects of RF/MW radiation can be aggravated under conditions of heat stress, that is in high temperature and humidity environments.1/ In August 1973, OSHA proposed to make the 10 mw/cm^2 standard dependent on a temperature-humidity index (THI). The standard would be 1 mw/cm^2 if the THI was 79 or more.2/ In commenting on this proposed standard, the Bureau of Radiological Health (BRH) within the FDA agreed that heat stress is "an important consideration," but it found that the use of the THI would be too difficult to apply. However, BRH did recommend that OSHA adopt a 1 mw/cm^2 standard for all RF/MW frequencies between 10 MHz and 100 GHz.3/ Thus, even in 1973 BRH was advocating a more stringent standard than is now being proposed by NIOSH.

Synergistic Effects: The criteria document does not include a special section on the possible synergistic effects between RF/MW and drugs or pathogenic organisms 4/ (in addition to thermal stress cited above). The importance of this type of synergy is emphasized by a recent report that pulsed radiation at 2450 MHz with average power densities of only 1 mw/cm^2 increased the behavioral effects of chlordiazepoxide, better known as Librium.5/ Librium is one of the most commonly prescribed drugs in America.

1/ For instance, see W.W. Mumford, "Heat Stress Due to RF Radiation," Proceedings of the IEEE, 57, 171-178 (1969).

2/ Federal Register, August 28, 1973.

3/ Letter of John Villforth to OSHA, October 19, 1973. In its final rule-making OSHA rejected BRH's recommendation, Federal Register, March 26, 1975.

4/ See Cleary, op. cit., p. 140.

5/ J.R. Thomas, et all., "Microwave Radiation and Chlordiazepoxide: Synergistic Effects on Fixed-Interval Behavior," Science, 203, 1357-1358 (1979).

Pulsed Radiation: The document devotes little direct discussion to the difference in effects between continuous and pulsed radiation. For instance, it simply notes: "Sufficient information is not presently available to base a recommended standard for peak pulsed power." (p. 391). Yet many of the experiments cited in the document report effects at lower power densities when the radiation is pulsed. For example, Oscar and Hawkins found that pulsed radiation affected the permeability of the blood-brain barrier "at an average power density of only 0.03 mw/cm^2 where it took CW [continuous wave] energy of approximately 0.3 mw/cm^2 to cause the same magnitude of change."6/ Thus by pulsing the radiation, a factor of 10 less energy is required to cause the same effect. Also, some of Dr. Adey's work, cited earlier, showed low-level effects using pulsed radiation. While two standards, one for continuous wave and one for pulsed radiation may still be premature, at the very least, the criteria document should address each in separate sections.

Monitoring Methods: The section on monitoring of RF/MW radiation (pp. 303-324) is confusing and sometimes contradictory. The whole section needs to be rewritten.

6/ Oscar and Hawkins, op. cit., p. 289.

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January 17, 1979

Dr. Anthony Robbins
Director
NIOSH
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Robbins:

NIOSH has stated that it intends to release a criteria document on radiofrequency and microwave radiation by early September 1979, and that a draft of this document will be available for external review next month. We at NRDC are very interested in this potentially harmful type of radiation, and request that we be given the opportunity to participate in the review process. We ask you to send us a copy of the draft criteria document as soon as it is completed.

We are encouraged that NIOSH has given this particular criteria document high priority. We trust that all available efforts will be made to keep to the present deadlines.

Sincerely yours,

Louis Slesin, Ph.D.
Senior Research Associate

Karen Massey
Attorney

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January 31, 1979

Dr. Louis Slesin
Natural Resources Defense Council, Inc.
122 E. 42nd St.
New York, N.Y. 10017

Dear Dr. Slesin:

In response to your letter of January 17, 1979 to Dr. Robbins, NIOSH is pleased to receive your comments, and to learn of your interest in our criteria document on radiofrequency and microwave radiation. The document is progressing well, and is on schedule. Present plans are to have a draft of the document available for external review early in March 1979. We will be happy to provide a copy to you, and request your comments on the draft.

Sincerely yours,

Frank L. Mitchell, D.O.
Acting Director
Division of Criteria Documentation
and Standards Development

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April 27, 1979

Frank L. Mitchell, D.O.
Acting Director
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and Standards Development
NIOSH
5600 Fishers Lane
Rockville, Maryland 20852

Dear Mr. Mitchell:

In your letter to me of January 31, 1979, you noted that NRDC would have an opportunity to review the draft criteria document on radiofrequency and microwave radiation, and that the draft would be available for external review in early March 1979.

I appreciate this opportunity to participate in the criteria document development process and thank you for making this possible.

Please let me know the present schedule for releasing the external review draft. I look forward to hearing from you.

Sincerely,

Louis Slesin, Ph.D.
Senior Research Associate

Mr. AMBRO. Thank you again, Dr. Slesin.

Dr. SLESIN. If I my add a few remarks to this morning's discussions I would like to agree with you, Mr. Chairman, about the limits of SAR as a guide for exposure, especially for low-level effects.

The SAR assumes a thermal mechanism of interaction, that is, SAR reflects the potential for a heating effect. There is evidence in the literature to suggest that something else is at work other than direct heating which would indicate that the SAR may not be the sole indicator of hazard.

For example: Oscar and Hawkins state: "The possibility of the BBB—blood-brain barrier—alteration being caused by direct heating seems remote."

A recently published report confirms such a nonthermal mechanism: "It is unlikely that the increased permeability of the blood-brain barrier due to low-power density microwaves is a result of increased temperature, in a macroscopic sense."

Also, hot spots are still very controversial and they should not be used as a definitive guide. As you said, the brain may be one of the most susceptible parts of the body; nonionizing radiation has been implicated in changes in the transfer of information and the permeability of the blood-brain barrier.

One last point, it is worth pointing out that the same people are always on the standards committees—for instance, the NCRP and ANSI. A very small group of experts are writing most of the standards and supporting documents. If you look at the composition of the ANSI and NCRP you will find a subgroup who played an important role in writing the NIOSH criteria document. More money must be channeled into this field so that there is a greater diversity of opinion and expertise; there needs to be more interchange among a larger group of scientists. This is what the scientific enterprise is all about.

I thank you again for the chance to make the statement and I am prepared to answer any questions.

Mr. AMBRO. Thank you, very much. I appreciate your testimony and candor. I have good peripherial vision and I saw Dr. Justesen standing, probably to take issue with some things you have said. I have always found these kinds of hearings less than effective with respect to the kind of controversy that could be generated and the kind of answers that could be developed. Perhaps we will ask Dr. Guy and Dr. Justesen to comment on what you said after I have asked you a couple of questions.

Were you here when Mr. Johnson testified earlier this morning?

Dr. SLESIN. Yes; I was.

Mr. AMBRO. What do you think of his suggestion that Congress legislate a standard?

Dr. SLESIN. The agencies must be given some discretion. I would support Congresswoman Holtzman's bill that a standard be set in the very near future. With respect to occupational exposures there is an urgent need for an enforceable standard which protects human health.

The 10mW/cm^2 standard which was mentioned earlier has been studied by BRH and it found that the standard had been set arbitrarily.

A safe standard, one that is at least an order of magnitude, or 10 times, more stringent is needed. This field is developing quickly and I believe that research in the next few years will show what levels are safe; for Congress to set a number would be a mistake.

It is important for the Congress to tell the agencies to get cracking and to set a standard, but they must have some discretion—discretion to change a standard as more information becomes available.

Mr. AMBRO. Well, let us put that together with the rather general endorsement you have given for increased research in this area. Exposure levels vary greatly.

What exposure levels do you believe research should be focused on?

Dr. SLESIN. Below 1mW/cm^2.

There was testimony earlier this morning indicating that population exposures are extremely low at this time. I would tend to agree for readings taken at ground level; most of the EPA measurements cited to back that statement up were taken on the ground.

When you start going up into tall buildings in dense urban areas, those readings go up by orders of thousands, perhaps 10,000, even sometimes 100,000. EPA has, to my knowledge, made only 5 to 10 measurements in tall buildings compared to hundreds on the ground. There is an urgent need to find out what kind of levels the public is being exposed to in urban centers like New York, Chicago, and Washington.

NIOSH did a survey of radiation emissions from video display terminals and did not find hazardous levels associated with them. But if one reads the report carefully, one discovers that the agency found the equivalent of 1mW/cm^2 background reading for the magnetic field component.

This means that NIOSH found an ambient background reading that is many thousands of times higher than the readings found at ground level. Some peole have said this high reading was anomalous and that it does not mean anything. But no one checked because the money was not available. EPA did not check and consequently we really do not know what population exposures are like at this time above the ground.

Mr. AMBRO. You said that under the best of circumstances epidemiological studies are extremely difficult to do.

Are you saying overall that we need more epidemiological studies?

Dr. SLESIN. Absolutely.

Mr. AMBRO. Do we know enough about past exposure levels to conduct those studies?

Dr. SLESIN. This is one of the problems with the Moscow Embassy study. The levels were very low and the researchers had to guess the levels to which the Embassy employees were exposed.

We now know that we must have accurate exposure data. Epidemiological studies like the radiofrequency-sealer and the diathermy studies will provide us with such data. We have learned to be careful about collecting accurate scientific data. I think we can do the measurements now, and the studies should go on. Simultaneously, basic research should investigate mechanisms of interaction.

There are huge populations of workers out there being exposed to extremely high levels. Everybody talks about the 10mW/cm² standard but NIOSH field studies show that about 70 percent of the time the standard is exceeded by a factor of up to 100.

NIOSH is considering lowering the standard from 10 to 1 milliwatt per square centimeter at same frequencies, but at the same time workers are being exposed to very high levels, and in addition the 10mW/cm² is not being enforced.

I would add that below 300 MHz, the standard is written in the wrong units. This shows you how much attention has been paid to the problem. The NIOSH standard should be in terms of electric and magnetic field components at such frequencies but is instead written in terms of power densities. In addition, no one has developed a good dosimeter. It is hard to go into the field and find out what the workers are being exposed to because the funds have not been available for the development of dosimeters to take measurements in the workplace.

Mr. AMBRO. Staying with epidemiology, do you think we know enough about human health effects to do good epidemiology in this area?

Dr. SLESIN. For subjective factors like behavioral effects, epidemiology is difficult, but for other, more objective end points like harm to the fetus, one can certainly do such studies, for example there is no reason the epidemiology of female operators of radiofrequency sealers cannot be done well. I might add that the diathermy study I mentioned in my prepared testimony, excluded females and I am quite perplexed why women were not part of the study.

Developmental effects are not subjective. A child is born and you can tell what kind of effects have occurred by studying the health of the child, and by watching his or her development. If the fetus is exposed to radiation and then the radiation is continued some ill effects have been shown to occur. But again, such studies have been inconclusive and they have to be repeated.

Mr. Chairman, there is a vicious cycle of inconclusive findings and inconclusive research; this research can be done and it must be done, otherwise we will never progress from our current state of ignorance.

In the 1977 hearings, Senator Stevenson said he had never been so confused by a subject as he was by nonionizing radiation. It is time we started to dispel the confusion with some hard data.

Mr. AMBRO. Well, I think you are right and I think you have stimulated some questions, but maybe we can get some answers from others in the room who heard your statements.

Now, you got into an exchange about SAR's and if you would like to comment, Dr. Guy, I would be happy to have you do that, although I think Dr. Justesen seemed to be more agitated.

Dr. GUY. Thank you, Mr. Chairman, for letting me comment. I was a bit agitated, too.

There is a popular misconception that the SAR is a thermal concept. In reality, it is a measure of the electromagnetic energy entering the body and whether it is converted entirely to thermal energy or partially to some other form is an open question. One has to be able to measure something to be able to relate an effect with some physical quantity in order to set a safe standard.

In the past, this relationship has been related to the intensity of the incident fields and to resulting biological effects, which can lead to all kinds of problems. I recall that, 2 years ago in a Soviet laboratory, a group responsible for the radiation safety of the general population of the Soviet Union said:

> We understand you Americans are using mathematical and modeling techniques for formulating standards, but we feel they are too complex for us to use at this time so we base our standards on the exposure of small laboratory animals. If we see *any* kind of effect we assume it is a hazardous effect and we then apply a certain safety factor.

In basing their standards on such an approach, the Soviets are probably erring on the conservative side. It turns out for the microwave frequency range that it would take a much higher exposure level to produce a given SAR in man than in the small animal.

The SAR is a measure of the amount of absorbed energy, but it is nonetheless a measure of the field. In the body it is a quantity one can most logically relate to an effect. In directly relating the level of incident power density for producing effects in small animals to safe levels for human exposure, the Soviet scientist erred on the conservative side.

Now what about the case where you can err on the nonconservative side?

The present Polish safety standard allows a magnetic field strength of 250 amperes per meter for human exposure for periods to 20 minutes.

Now, I do not know what this limit is based on, but let's consider an experiment with a laboratory animal. If you exposed a small mouse to a magnetic field strength at 250 amperes per meter, it would produce an average SAR near 2 W/kg which probably would not result in a measurable effect. Thus based on the Soviet standards-setting philosophy the level would be assumed to be insignificant. If you exposed a human being at 250 amperes per meter, however, it would produce an SAR of 1,500 watts per kilogram, which can be fatal in a few minutes. If you do not scale appropriately from small animals to man, in some cases the safety standards may be too conservative, but in other cases they could be dangerously high.

The other statement Dr. Slesin made was that the group of scientists working on standards and related activities is too small. I agree with him. I would like nothing better than to cut down on my travel to many meetings by sharing the committee work with other scientists. The group of qualified people that is responsible for making standards and for analysis of the scientific literature is much too small in this country. There are other groups that are trying to do this, but they do not have the training and experience. There is a definite need to train younger scientists, perhaps through an extramural grant program.

Mr. AMBRO. What would be the incentives to young scientists to move into these fields now? How would you attract them?

Dr. GUY. The only mechanism I know of is to introduce more academic training in this area, which we are trying to do at the University of Washington.

The University of Utah has also introduced into its curriculum courses that are relevant to RF radiobiology, but a considerable amount of research experience is still required.

Mr. AMBRO. We tried, for example, and this may be off the target somewhat, to get an epidemiologist in this area for these hearings. There were two or three recognized people in the field but we had trouble getting them. That does not speak well for a nation of this size with respect to this very specific and difficult field. I do not know how we encourage people to move into it. It is a concern which cuts across a variety of R. & D. agencies, a concern about how to attract scientists who will, indeed, move into these fields We seem to have limited success in attracting them.

Dr. GUY. I think some groups like the National Science Foundation have been successful in the past in training young scientists by providing small grants to get them started in a specific area of research. Maybe this sort of funding would help resolve the problem.

Mr. AMBRO. They start. We have some science fellows working for this committee. As soon as they do their time they move on to greener pastures. Any way, that is something else.

I think Dr. Justesen might want to say something now.

Dr. JUSTESEN. Dr. Guy said essentially what I wanted to say but since we have gone into a seminar mode, perhaps I should respond.

Mr. AMBRO. Is that what you call this?

Dr. JUSTESEN. The hearings mode is advocation; the seminar mode is education.

Dr. Slesin holds the view that the SAR is a thermal concept. But to equate the SAR with the process of thermalization is to confuse independent with dependant variable. The SAR is nothing more than an index of the rate at which electromagnetic energy is captured by the body. The units by which this rate is specified are universal within the international and MKS systems in referring to all forms of energy: Potential or kinetic, radiant or electrical, mechanical or thermal. The basic quantity of all these forms of energy is the joule. One joule per second is the watt. And 1 watt per kilogram of body mass is the SAR. To state that a body is absorbing electromagnetic energy at, say 2 watts per kilogram is only to state the quantity of the rate at which electromagnetic fields invest body tissues. Any effect arising from absorption of the RF energy might or might not be thermal; the mechanism of effect is not a matter of presumption but is an empirical question to be solved on a case-by-case basis by experimentation.

The tendency to misinterpret the SAR as a thermal construct has a twofold origin. First of all, metabolic rate—the rate at which the body burns its fuel—is expressed in the international system of units as watts per kilogram. And second, the SAR is often measured calorimetrically via thermographic or discrete temperature measurements in irradiated models or animals. However, one should not confuse the operations of measurement with biological mechanisms of action or reaction. The dose rate of ionizing radiation is also couched in terms of watts per kilogram and can be determined calorimetically, but despite the commonality of units of measurement, the metabolic rate, the SAR, and the ionizing dose

rate have no necessary commonality with respect to mechanisms of action.

The burden of the SAR—or of any energy dose index of RF radiation—is simply prediction. The SAR succeeded power density as the fundamental basis of metering personnel exposure for two related reasons:

One, it is the energy captured by—not that incident on—the organism that generates consequences; and

Two, the SAR is a much better predictor of thresholds of biological responses than is power density. Doubtless there are factors such as modulatory and environmental conditions that can affect the biological response to RF radiation, but the best single predictor to my knowledge is the SAR.

As a final note under the rubric of education, I should emphasize that the SAR can relate to whole body or part body, average or peak rates of energy absorption. Some finite period of irradiation is assumed, of course, since a time rate is meaningless without specification of the time-intensity product that constitutes the biologically operative variable—the energy dose. Given that finite period, I know of no biological response to RF radiation that is not at least partially contained in the sense of threshold predictability by the SAR.

Mr. AMBRO. Dr. Slesin, will you comment?

Dr. SLESIN. I am confused by what Dr. Justesen said. SAR reflects the amount of energy that is going in, and energy and heat are very much related.

SAR sounds very good but it is worth discussing how one gets these SAR's. Allow me to quote from the Air Force dosimetry handbook that describes the models:

> The rigorous analytical treatment of a realistic shaped inhomogeneous model for humans or experimental animals would be an enormous theoretical task.

Basically, the SAR are derived from these spheriodal shaped balloons filled with salt water that do not allow for differences in organs, or in cellular changes within the body. They are a homogeneous bodies and much too crude to be the basis of a human health standard. To do so is, I believe, a great injustice to the people who are exposed to these kinds of electromagnetic fields.

The human body is much more complex than the models from which these SAR's are desired.

A second point I would like to make concerns the extrapolation from animals to man. If one thinks only in terms of thermal effects and one adjusts for the geometric differences between animals and humans, then one is assuming that the frequency of the radiation is unimportant other than in terms of energy of the radiation.

Low-level effects that have been documented in the literature which may, in fact, be frequency dependent. One current proposal is to raise the standard above 300 MHz, and also below 30 MHz. If the effects are frequency dependent, these increases in the standard just do not hold up.

In summary, a study by Motorola, Inc., recently reported by the Federal Communications Commission, illustrates the difficulties associated with predicting the distribution of radiation inside the human body:

The results of these experiments indicated that the maximum power deposition at 840 MHz did not occur immediately below the bone-brain interface, as theoretical calculations predict, but occurred, instead, deeper in the cerebral cortex. These absorption peaks were believed to be caused by the focusing of the electromagnetic energy by the curvature of the frontal lobe of the skull. An absorption peak was also located at the surface of the eye.

These interactions do not show up in phantom models. We are talking about health effects to human beings. We are much more complicated than the models suggest.

Finally, I would like to respond to your question about how to interest people in this field. As an ex-graduate student, I would say that students go to where the money is. When you are writing a doctoral thesis you look for money to support your studies. Graduate school is where the process starts; students then go out and set up their own labs. After all their doctoral research is just like an apprenticeship.

Mr. AMBRO. Well, on that happy note, had you met Dr. Guy or Dr. Justesen before you came in here?

Dr. SLESIN. I had met Dr. Justesen on a couple of occasions.

Mr. AMBRO. Let us recess until 2 o'clock this afternoon in room 2318. This will give all three of you and others a chance to get better acquainted as a result of your testimony.

I would like to really thank you for your statement and the kind of questions you raise. We will see if we can get some better answers this afternoon.

We stand in recess until 2 o'clock this afternoon when we will be in room 2318.

[Whereupon, at 12:20 p.m., the subcommittee recessed until 2 p.m. of the same day.]

AFTERNOON SESSION

Mr. AMBRO. I would like to call the meeting to order.

This morning we had a productive session which focused, I would say, not only on suggestions for legislation but also on problems rather technical in nature.

This afternoon we will hear from a variety of witnesses. Our first witness will be Dr. John M. Richardson, Chief Scientist, National Telecommunications and Information Administration.

I would like to tilt the focus of this afternoon's hearing in the direction of developing both the administrative and funding approaches to the problem. We will ask various representatives of the various departments and agencies how best to go about this after hearing their testimony.

Dr. Richardson, welcome.

Before you proceed with your testimony, I wish to insert in our hearing record a statement of Congressman John G. Fary.

[The statement of Congressman Fary follows:]

Statement of

Congressman John G. Fary

Before the

SUBCOMMITTEE ON NATURAL RESOURCES AND ENVIRONMENT

COMMITTEE ON SCIENCE AND TECHNOLOGY

U. S. HOUSE OF REPRESENTATIVES

JEROME A. AMBRO, CHAIRMAN

JULY 12, 1979

STATEMENT OF CONGRESSMAN JOHN G. FARY
ON
STANDARDS OF SAFE LEVELS OF MICROWAVE RADIATION

Mr. Chairman, my colleagues in the Congress, I am very pleased to have the opportunity to appear before you today. I congratulate you on taking the initiative and holding hearings on an issue which has held increasing significance for many of my constituents: non-ionizing radiation and its effects on human health.

My own interest in this issue has stemmed from a very recent development in my Congressional district. Late last year, a cable TV company applied for and was granted a license by the Federal Communications Commission (FCC) to construct and operate an Earth Station receiver. This receiver is designed to accept signals from a satellite and relay the signals up to the top of an office building in downtown Chicago. Both a ground receiver and a twenty-one (21) foot transmitter are to be located in one of our residential areas.

The equipment was intended to operate in the following fashion: The Earth Station receiver, which has a four and one-half (4 1/2) meter parabolic dish, receives a signal from a satellite orbitting the earth. It then amplifies the signal and filters it through a transmitter. Using a twenty-one (21) foot antenna, the signal is relayed to the top of one of the office buildings in downtown Chicago for use in cable television service for Chicago area subscribers.

The proposed transmitter would sit on a building and would be thirty (30) feet above ground level and would transmit a one-degree beam at 1.5 watts of power. As I understand it, in order to receive the full 1.5 watts, a person would have to climb the antenna and stand in the line of sight transmission path.

A community group, people who live near the proposed site, has sought to block the construction of the transmitter and has asked my office to assist them in this matter. The group, I believe, is genuinely concerned about the effects that the transmitter will have on their health and the health prospects of their children. The zapping of our embassy in Moscow, the controversy which centered on radiation leakage from microwave ovens, and other well-publicized incidents have all served to raise the very

serious question: "How safe is low level non-ionizing radiation?"

Unfortunately, Mr. Chairman, to date there has been no well-publicized answer to this question. In trying to obtain information on this subject, I discovered that no one really knows, or is willing to say, what a safe level of exposure is. The only specific exposure limits set by the federal government were those set in the 1960's which applied only to occupational contact and not to low level exposure over a twenty-four (24) hour period.

The Department of Defense, the Environmental Protection Agency and the Department of Health, Education and Welfare have some small unco-ordinated research efforts in this field. Yet no one has taken the lead on setting an acceptable standard. The Soviets and Eastern Europeans have all done extensive tests and, as a result, have very low standards. Our National Academy of Sciences has done research and is calling for lower standards.

To whom am I to turn for an answer for my constituents? The technicians, the FCC, assure us that we are safe but the groups which share the responsibility for safe-guarding our health tell us they are not sure, or they have not decided.

Mr. Chairman, a health standard must be set in this area. I hope that after reviewing the testimony which will be brought before it that this committee will decide to fight for more cohesive research efforts in this area and, if there is any doubt in the committee's mind, I hope that you will fight for a lower, safer standard. You may count on my support in such an effort.

Thank you again for the opportunity to appear before you today.

STATEMENT OF DR. JOHN M. RICHARDSON

Dr. RICHARDSON. Thank you, Mr. Chairman and members of the subcommittee. My prepared statement has two exhibits and six rather short attachments. I would ask those attachments be included in the record following the presentation of my oral statement.

Mr. AMBRO. Without objection.

Dr. RICHARDSON. Mr. Chairman and members of the subcommittee, I thank you for the opportunity to appear before you today on behalf of Assistant Secretary Geller and to testify on the subject of nonionizing electromagnetic radiation. These hearings are highly important in evaluating the kind and degree of Federal effort that should be devoted to this issue.

You have asked me to summarize the role that the National Telecommunications and Information Administration, or NTIA, plays in this area. In a word, that role is, and has been, the coordination of the Federal research program on the possible health hazards of nonionizing radiation and the factors relating to its control. This coordination is accomplished by:

One. Providing a comprehensive annual data base of Federal project activities and publishing a yearly survey of these and related activities.

Two. Providing, through contract, a compilation of world scientific literature in the field, updated quarterly.

Three. Holding meetings of advisory and working groups to exchange information and assess progress.

Four. Recommending the direction of future program efforts.

The origins of this role lie with our predecessor agencies and their responsibility for allocating and authorizing use of the electromagnetic spectrum by radio stations of the U.S. Government. It was necessary to be sure that such stations operate without hazard to health or environment. A decade ago, little information was available to provide any such assurance, and so a multiagency effort was begun against future need.

NTIA's coordinating role was reaffirmed by Dr. Frank Press, as Science and Technology Adviser to the President, in 1978.

When establishing NTIA, the Secretary of Commerce also delegated authority, under 15 U.S.C. 272 (9), to the Assistant Secretary for Communications and Information, who is also the Administrator of NTIA, "to perform functions which relate to the investigation of nonionizing radiation, its uses, and means of protection of persons from their harmful effects, to the extent appropriate to coordination of research throughout the executive branch."

Now, as to advisory groups. In performing its role NTIA is assisted by the Side Effects Working Group of the Interdepartment Radio Advisory Committee and the Electromagnetic Radiation Management Advisory Council, or ERMAC. The working group helps to provide interagency coordination and a forum for the developement and exchange of information of common interests. The ERMAC provides advice, recommendations, and continuing review of program activities and research progress essential in evaluating technical and policy issues.

The ERMAC was established in 1968 to advise the Director of the Office of Telecommunications Management, later to become the

Office of Telecommunications Policy, or OTP, on undesirable side effects and the adequacy of control of nonionizing electromagnetic radiation associated with the use of the spectrum. The Council is made up of individuals with expertise in various pertinent technical disciplines—biological and physical sciences, engineering, and risk assessment.

Based on a comprehensive assessment of scientific standards, requirements, and research within the Federal Government and scientific community, in their 1971 report, the ERMAC recommended increased budgetary appropriations and comprehensive guidelines for a coordinated program among responsible Government agencies. Its purpose was, as now, to establish a scientific basis for evaluating hazards and developing controls to ensure the safe use of nonionizing radiation.

As a basis for assessing progress and determining future research requirements, the ERMAC continually reviews new developments and individual agency programs and holds seminars on specific research areas which cross agency lines. For example, seminars have been conducted on: Nervous System and Behavioral Effects; Environmental Measurements; Genetic, Hereditary, Growth and Development Effects; and Immunologic Systems and Responses.

Considering the advances since its first report in 1971, ERMAC has begun to assess where we now stand and to develop a broad strategy for the long range, national effort. This examination will complement the far more detailed program development that occurs in the Federal budgetary process.

I would now like to turn to the activities of the Interagency Task Force on the Biological Effects of Nonionizing Electromagnetic Radiation, or the BENER group.

On March 14, 1979 Dr. Frank Press, Director, Office of Science and Technology Policy, or OSTP, wrote to Assistant Secretary Geller to request that NTIA "prepare a detailed plan for a Federal program on understanding the biological effects of nonionizing electromagnetic radiation." In response to that request, Mr. Geller proposed the formation of an interagency task force. This idea was endorsed by Dr. Press, and the BENER task force was born.

The purpose of the task force is to prepare the detailed plan that Dr. Press requested. This plan should provide a more specific definition of the research needs than was identified by the OSTP ad hoc working group in May, 1978. Further, to the maximum extent possible, it should indicate which agencies will do what work, how long it might take, and how much it might cost.

The product of the task force will be twofold—a multiyear planning framework and specific program tasks, within that framework, that should begin in fiscal year 1981. The multiyear plan will necessarily be preliminary because of the task force schedule, but it will be fully adequate for near term planning. Periodic review and improvement, with the advice of the ERMAC, will produce a definitive planning context for future budget years.

The plan will be used to help all of the following:

One. The President in the allocation of resources.

Two. The Congress in its oversight of Federal research and institutional arrangements.

Three. Users of electromagnetic radiation in identifying which agencies have what capabilities.

Four. NTIA in coordinating and evaluating the research program.

I am pleased to report that all relevant agencies are participating in a cooperative and enthusiastic manner. More than 25 people in some 15 agencies have already made substantial contributions to its effort. We are also making use of material development by the ERMAC.

As to accomplishments, the task force has already secured agreement on the overall goal of the Federal program for BENER research. The skeleton of the plan has reached the first draft stage, and participants are now preparing detailed narratives for each of the identified tasks. The task force leader has set September 14, 1979 as the deadline for completion of the plan, and I am sure that the deadline will be met if participants continue to work as they have until now.

Finally, Mr. Chairman, I would like to say that I am encouraged to see the degree of interest that you and Congresswoman Holtzman have expressed in the preparation of a coordinated research plan. Communications such as your May 10, 1979 letter to Mr. Geller are very helpful in assuring a full measure of effort.

Now as to the relationship of NTIA to regulatory agencies: The relationship of NTIA, and its advisory groups, to the regulatory agencies can conveniently be described in the perspective of the entire nonionizing electromagnetic energy problem. Briefly stated, the national goal in this area is to protect human health and environment from hazard while permitting the beneficial use of electromagnetic radiation. Let us now, in a greatly oversimplified way, examine this task in the light of its several component parts.

To begin with, a real and present hazard to health or environment will exist only when two conditions are satisfied. First, there must be some injury that results if a particular level of exposure occurs. The injury level will depend on several other characteristics of the energy source as well as the exposure level. This kind of information has to be provided by biological research on the many effects of electromagnetic energy on living systems—together with judgments as to which effects constitute actual injuries. The second condition for a hazard is the existence of that particular exposure level in the general or occupational environment. Information of this sort has to be provided by research on environmental conditions.

Protection against such a hazard is also two-faceted. The first facet is a quantitative measure of the severity or the hazard, which usually depends on the exposure level and the kind of energy source involved. This measure can sometimes be expressed in terms of illness, disability, lost work, medical care, pain, and other appropriate measures, each of which may or may not be quantifiable or even measurable, let alone convertible into a dollar equivalent. This task falls to those familiar with the methods of risk assessment as already applied to many other areas of health and environmental protection.

One easily sees that controling the exposure level will be the principal means of protecting against the hazard. The second

aspect of protection is assessing the total cost of the control of the exposure that will keep the severity of the hazard within acceptable health and safety limits. This cost must generally be measured both in economic terms, such as the dollar cost of retrofit and more complex equipment design, and in operational terms, such as a lesser quality of television reception or air traffic control, for example. In assessing the various costs of control, it will be desirable, of course, to consult the users of nonionizing electromagnetic energy, such as those operating telecommunications and industrial facilities.

The task of the regulator is to consider the magnitude of the hazard that is avoided by control and the cost or feasibility of that control. The regulator will thus arrive at a degree of protection that is consistent with his legislative mandate and national policy. The final steps are to adopt the necessary controls and look to their enforcement.

We can now return to the relationship of NTIA to the regulatory agencies. That relationship, at present, is to recommend and to coordinate the aggregate Federal program that will provide information on injury, exposures, severity, and control costs. As explained above, NTIA undertook this relationship to the Federal program in the absence of an alternative coordinating mechanism. It is important to stress that the several portions of the Federal program will be performed by the various research, user, and regulatory agencies themselves according to their missions, and not by NTIA. Neither will NTIA arrive at any judgments that the regulatory agencies should make; nor will NTIA have any role in enforcing their decisions, beyond requiring compliance as a part of its own spectrum management function.

With respect to the task force, one of its subgroups is composed of members of the Interagency Regulatory Liaison Group. As such, the regulatory agencies are participants in developing both the preliminary long-range plan and the specific fiscal year 1981 program recommendations of the task force. Therefore, a plan prepared by the task force will reflect the interests of the regulatory agencies and will ultimately serve their needs.

Now as to the overview of the Federal program. The objectives of the program, consistent with the broad goal stated earlier, are as follows:

One. To determine what effects radiofrequency energy has on living organisms under different conditions of exposure—that is, various frequencies, waveforms, energy levels, electric and magnetic field components, and exposure durations.

Two. To determine the health and ecological significance of any effects and to assess any hazards from probable exposure environments.

Three. To characterize actual radiofrequency exposure environments and associated populations.

Four. To establish a scientific basis for evaluating risk.

Five. To develop standards and guidelines for exposure or use of radiofrequency energy with regard for their socio-economic and operational impact.

The research program consists of some 110 to 140 individual projects annually. These projects are being conducted in both Gov-

ernment and nongovernment laboratories. The research deals with various topics and generally concentrates on priorities previously recommended by the ERMAC and others and indicated by the research findings themselves.

Counting separately the three military services and three components of the Department of Health, Education and Welfare involved, there are 14 agencies engaged in this research. Total funding for these activities has been betwen $6 million to $10 million per year over the past 6-year period. For example, funding for fiscal year 1977 and fiscal year 1978 was approximately $7.5 and $10 million respectively. Fiscal 1979 funding is currently estimated to be about $11.5 million.

The majority of the research effort and support is concentrated in the Department of Defense, HEW, and the Environmental Protection Agency, which together account for approximately 95 percent of the total Federal program. My exhibit 1 shows the distribution of funding by agency.

Exhibit 2 shows roughly the amount of attention given by various agencies to the broad topical categories identified by the ad hoc working group of the OSTP. We have added two other categories which we feel are important elements of a comprehensive program, namely:

One. Characterizing actual radiofrequency exposure environments.

Two. Hazard assessment and standards.

The measure of effort in exhibit 2 is the project, whether devoted in whole or in part to a particular area. Thus, there is some multiple counting of projects when they span several topics.

The DOD, HEW and EPA conduct the bulk of the biological effects studies. This category groups research projects which deal with a wide diversity of biological systems and effects—for example, nervous system, embryology, ocular, and ecosystem effects. As is the nature of research, an individual project frequently deals with more than one type of biological effect or system. So, while the numbers of biological effects projects shown here appear modest, they account for a substantial portion of ongoing efforts. The distribution of effort generally follows the two priority groupings of the OSTP ad hoc working group with concentrations of research, for example, on nervous system, developmental, membrane, and cellular level effects and considerably less work on ocular, ecosystem and cardiovascular effects.

A considerable proportion of the program is concerned with instrumentation, studies of absorption, and dosimetry. These topics are essential to the conduct and interpretation of this research, for characterizing radio frequency environments, and for standards compliance activities.

The number of studies concerned with mechanisms of interaction has been increasing recently.

There are still very few studies of humans in radiofrequency environments or large-scale laboratory studies involving truly long term, relatively low-level exposures of animals, that is, 1 year or more—although the number of experiments with exposures up to a few months has been gradually increasing.

There has been very little research on possible effects of radiofrequency radiation in combination with other agents. The Navy has supported some research, in one case involving viral infection and currently on the effects of radio frequency radiation and drugs.

We do not explicitly identify or monitor research to develop beneficial medical applications although we recognize this as an important and valuable area to which the knowledge developed in this program can and has contributed.

After this overview of the magnitude and distribution of program effort, let me now briefly highlight where our knowledge stands.

First I would like to underscore that research to date has not identified any positive evidence of harmful effects to man or public health crises at levels of radiofrequency radiation normally encountered by the general public. However, additional research is needed to develop a better understanding of many current laboratory observations and to insure there are no unknown effects or interactions.

Measurements and calculations of actual radio frequency exposure environments by EPA, the National Institute of Occupational Safety and Health, and others have shown that levels in most environments encountered by the general population are typically very low—for example, more than 99 percent of U.S. citizens are exposed to less than 1 microwatt per square centimeter—as compared to levels associated with harmful effects in research to date. However, higher levels—for example, milliwatts per square centimeter—have been found to occur in some occupational situations; and additional efforts are needed to better characterize potential exposure environments and associated population groups.

Based on experiments to date, most of which involved small laboratory animals and microwave frequencies, some gross generalizations can be made. They are:

One. Exposures greater than 100 milliwatts per square centimeter can produce definite thermal damage, for example, cataracts and tissue injury.

Two. Exposures above 10 milliwatts per square centimeter can produce heating and thermal stress. Developmental anomalies and other effects have been observed in laboratory animals.

Three. In the range of roughly 1–10 milliwatts per square centimeter, effects on behavior, perception of the fields, some blood characteristics, and the immunological system, for example, have been observed under various exposure conditions. This region, therefore, has considerable interest with regard to present considerations of standards.

Four. Below 1 milliwatt per square centimeter, while there are some reports of effects, statistics are lacking and we are at the level of scientific debate as to what has been confirmed and the significance of these observations. At levels of the order of those found in the general environment there are virtually no indications of effects or hazards in the light of the research to date.

To illustrate with a few examples, while cataracts can be induced in experiments at levels of the order of 100 mW/cm^2 or greater, they have not been found in experiments at lower levels—for example, with continuous exposure at 10 mW/cm^2 over a 6-month period. While additional research should be conducted to insure

that there are no more subtle ocular effects, it appears that microwaves at typical general environmental levels are not a significant factor in the formation of cataracts.

Genetic effects in mammalian systems appear to require moderately high levels of exposure in experiments where heating is implicated or cannot be ruled out.

Effects on the immunologic system, which have been reported in the range of 1–20 mW/cm^2, are of particular research interest at present. This is an important area for additional research because changes in the body's immune system could affect man's susceptibility to disease.

Additional information on program content and distribution of effort by topic, frequency, and agency is contained in the fifth report on "Program for Control of Electromagnetic Pollution of the Environment: The Assessment of Biological Hazards of Nonionizing Electromagnetic Radiation," NTIA Report 79–19 dated March, 1979.

There remains a need for additional research on mechanisms of interaction and large scale studies to investigate effects of long term relatively low-level exposures in animals and for well designed studies of carefully selected human populations. Aside from certain other difficulties and limitations, these latter studies require relatively large and stable funding beyond the resources which have been available in the individual agencies to date.

Finally, our present biological knowledge, imperfect as it is, is sufficient for us to step up studies on environmental characterization, risk assessment, and impact of alternative control measures, in the interest of dealing with the total problem.

Looking ahead, it will take a more intensive program of systematic research to develop the reliable information on radiofrequency radiation effects and interactions which will permit informed choices and rational standards in the full public interest.

Mr. Chairman, this concludes my prepared statement. I will be happy to respond to any questions.

Mr. AMBRO. Thank you, Dr. Richardson. The two exhibits and six attachments that appear in your statement will appear in our hearing record at this point.

[The exhibits and attachments referred to follow:]

PROGRAM FUNDING

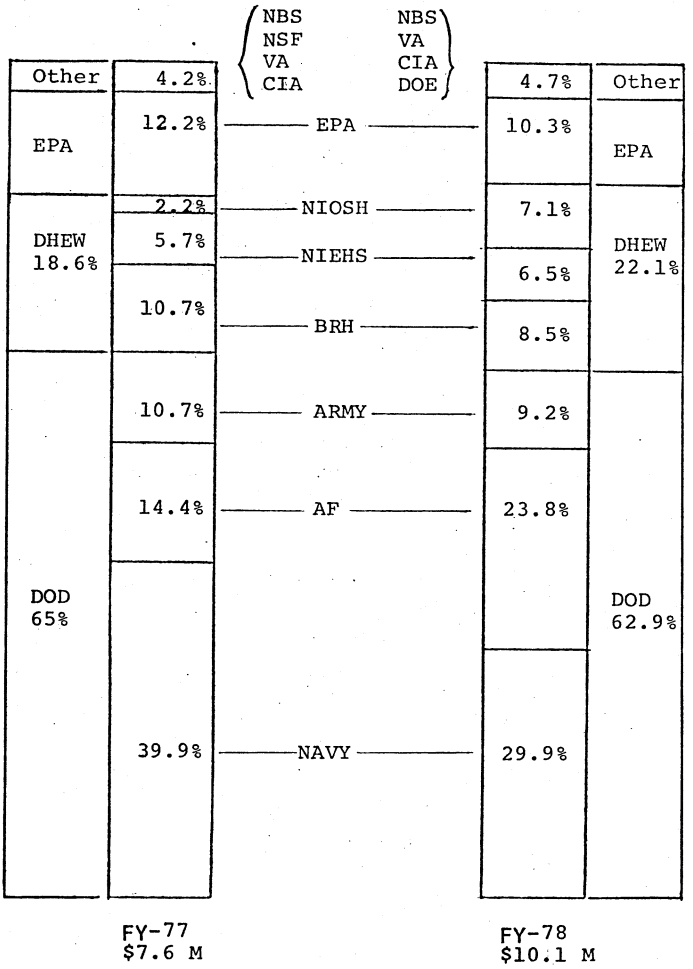

EXHIBIT 1

(Excerpted from Fifth Report on "Program for Control of Electromagnetic Pollution of the Environment: The Assessment of Biological Hazards of Nonionizing Radiation," NTIA Report 79-19 (March 1979)

EXHIBIT 2

NUMBER OF PROJECTS APPLICABLE TO CERTAIN KEY CATEGORIES, BY AGENCY (FY 1978) (a)

AGENCY		NO. OF INDIVIDUAL AGENCY PROJECTS (b)	BIOLOGICAL EFFECTS	HUMAN STUDIES	MECHANISMS	INSTRUMENTATION DOSIMETRY/ABSORPTION	COMBINED FACTORS	LONG-TERM (≥ 6 MOS.) LOW-LEVEL (c) RF ENVIRONMENT	HAZARDS ASSESSMENT/ STANDARDS
HEW	BRH	22	9	2	2	11	1		7
	NIEHS	10	9		5		(d)		
	NIOSH	3	1	1		1		1	1
DOD	ARMY	15	6		1	10	1	(x)	
	NAVY	44	36		18	6	3	2 (x)	
	AF	16	9		4	6	2	1 (x)	1
	EPA	17	14	(e)	4	4	1	1 1	1
	NBS	4				4			
	NSF	4	1		1	4			
	FCC	1						1	
	FAA		(e)						
	VA	2	2			1	1		
	DOE	5	2			1			2
	CIA	1	(Foreign research literature)						

NOTES

(a) This program does not specifically identify projects on beneficial applications. However Army (microwave imaging) and others, such as BRH and VA are involved with this subject.

(b) Projects that deal with more than one category are included in each applicable category. Therefore the row total across the key categories may be greater than the tabulated number of individual agency projects.

Joint or interagency projects are attributed to each applicable agency.

(c) There are also a few 3- to 4-month experiments.

(d) 2 projects in FY 1979.

(e) 1 project in FY 1979.

(x) Also have activities not explicitly identified in this program.

THE WHITE HOUSE

WASHINGTON

MAR 13 1978

Dear Henry:

As Chairman of the Federal Coordinating Council for Science, Engineering and Technology, I am writing to inform you that the new agency which you will head in the Department of Commerce will have the responsibility for coordinating all federally-supported research activities in the wide field of investigation of biological effects of non-ionizing electromagnetic radiation. Research objectives should be consistent with needs the National Telecommunications and Information Administration (NTIA) identifies in the development and regulation of electromagnetic radiation and telecommunications.

You will have the authority to draw together experts from the various agencies of the government and from the outside on interagency committees and panels of your choosing. In a number of ways, OSTP will be able to provide oversight and assistance for your activities, but the responsibility will be lodged clearly with you.

I trust that the ad hoc working group which we have set up will provide you with an up-to-date assessment of research activities and objectives.

Yours sincerely,

Frank Press
Science and Technology
Adviser

Mr. Henry Geller
Office of Telecommunications Policy
Room 770
1800 G Street, N.W.
Washington, D.C. 20550

U.S. DEPARTMENT OF COMMERCE

Charter of

ELECTROMAGNETIC RADIATION MANAGEMENT ADVISORY COUNCIL

ESTABLISHMENT

The Electromagnetic Radiation Management Advisory Council (the Council) was established on December 11, 1968 and provided advice to the Director, Office of Telecommunications Management and his successor, the Director, Office of Telecommunications Policy, Executive Office of the President. The majority of the functions of the latter office (and the Council) were transferred to the Department of Commerce by Executive Order 12046 of March 27, 1978 and are performed by the National Telecommunications and Information Administration.

The Secretary of Commerce having determined after consultation with the General Services Administration that it is in the public interest in connection with performing duties imposed on the Department by law and Executive Order 12046 hereby continues the Electromagnetic Radiation Management Advisory Council pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. (1976).

SCOPE AND OBJECTIVES

The Electromagnetic Radiation Management Advisory Council will advise the Secretary of Commerce on side effects and the adequacy of control of electromagnetic radiations arising from telecommunications activities. It will review, evaluate, and recommend measures to investigate and mitigate potential undesirable effects on the environment. Its objectives include:

(a) the review of Government and non-Government activities bearing upon the adequacy of control of electromagnetic applications which may involve directly or indirectly the production of radiant energy in any portion of the spectrum capable of causing either harmful biological effects, or harm to equipment and material. (The spectrum is presumed to consist of the electromagnetic spectrum range from electrostatic and constant magnetic fields through the radio frequency to the optical spectrum, including the use of coherent optical radiation (lasers), and x-rays produced by electrical or electromagnetic devices).

(b) the review, as required, of matters relating to non-electromagnetic radiation phenomena (such as infrasonic and ultrasonic radiation) which may derive from the use of electronic equipment or be under the purview of those agencies of the Government concerned with the electromagnetic spectrum.

The Council will function solely as an advisory body, in accordance with the provisions of the Federal Advisory Committee Act.

MEMBERS AND CHAIRPERSON

(a) The Council shall consist of no more than fifteen members, as needed, to be appointed by the Assistant Secretary for Communications and Information to assure a balanced representation in such areas as engineering, the physical sciences, biomedical and the health sciences. The members will be appointed for a period of two years and will serve at the discretion of the Secretary. Vacancy appoints shall be for the remainder of the unexpired term of the vacancy.

(b) The Chairperson of the Council is the Assistant Secretary for Communications and Information or designee.

ADMINISTRATIVE PROVISIONS

(a) The Council will report to the Secretary through the Assistant Secretary for Communications and Information.

(b) Members of the Council will not be compensated for their services but will, upon request, be paid travel expenses incurred in the performance of their duties, as authorized by Department of Commerce Travel Regulations.

(c) Administrative support for its activities will be provided by the National Telecommunications and Information Administration and is estimated not to exceed $10,000 annually and one-fourth personyears of effort.

(d) Meetings will be held at approximately three-month intervals at the call, or with the approval of the responsible Departmental official or his representative, and with an agenda formulated and approved by such official. No meeting shall be conducted in the absence of this official.

(e) Detailed minutes of each meeting shall be kept and shall contain a record of the persons present, a complete and accurate description of matters discussed and conclusions reached, and copies of all reports received, issued or approved by the Council. The accuracy of all minutes shall be certified to by the chairperson of the Council.

DURATION

The Electromagnetic Radiation Management Advisory Council shall terminate two years from the date of this charter unless terminated earlier or renewed by proper authority by appropriate action.

12/29/78
Date

Assistant Secretary for Administration

Pursuant to subsection 9 (c) of the Federal Advisory Committee Act, 5 U.S.C. App. (1976), this charter was filed with the Assistant Secretary for Administration on December 29, 1978. On the same date, copies were filed with the following committees of Congress, and a copy was furnished the Library of Congress:

--Senate Committee on Commerce, Science, and Transportation
--House Committee on Interstate and Foreign Commerce

1/2/79
Date

Robert T. Jordan, Chief
Information Management Division
Office of Organization and
Management Systems

ELECTROMAGNETIC RADIATION MANAGEMENT ADVISORY COUNCIL

June 30, 1979

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20500

March 14, 1979

MAR 19 1979

Date Rec'd
Control # 79-03-002
Action by: DARTZ/RUDDS

Copies to:

Suspense Date 4-2-79

Remarks:

Henry Geller
Assistant Secretary
for Communications and Information
Department of Commerce
Washington, D.C. 20230

Dear Henry:

Nearly a year has passed since the transfer of the Office of Telecomunications Policy functions to the Department of Commerce's National Telecommunications and Information Agency and the publication by OSTP of a technical overview of the biological effects of nonionizing electromagnetic radiation (NEMR). While the utilization and expansion of the Electromagnetic Radiation Management Advisory Council is an encouraging sign, on the whole the Government's activity with regard to this area of growing concern is quite disappointing. As I indicated to you and a number of other Government officials last year when transmitting the review prepared at OSTP's request, I expected NTIA to update the "annual" survey (last prepared in June 1976) and to prepare a detail plan for a Federal program on understanding the biological effects of NEMR. Neither of these activities has occurred and we have lost the opportunity to influence FY 1980 budget levels. Unless they are undertaken immediately we will not impact the FY 1981 budget either.

I am willing to seek increased support for R&D in this area, if needed, if there is a Federal program which lays out the research needs in the area along the lines of the priorities recommended by the OSTP working group. Such a program, and related budget requests, must however include all on-going work.

I look forward to hearing from you regarding this matter as soon as possible.

Yours sincerely,

Frank Press

cc: Honorable Juanita M. Kreps
Stuart E. Eizenstat
Honorable James T. McIntyre, Jr.

July 6, 1979

AGENCY PARTICIPANTS ON BENER TASK FORCE

The following individuals have been selected to represent their agencies and/or to assist the BENER Task Force:

BUREAU OF RADIOLOGICAL HEALTH	
* Mr. John Villforth	443-4690
Mr. Mays Swicord	443-3840
Dr. William M. Leach	443-2434
CENTRAL INTELLIGENCE AGENCY	
* Dr. Donald Myers	351-4035
Mr. Dudley Foster	351-6204
Ms. Frances Stephenson	351-6204
DEPARTMENT OF DEFENSE	
* Colonel Philip Winter	697-8535
DEPARTMENT OF ENERGY	
* Dr. Martin L. Minthorn, Jr.	353-3681
Mr. Alec Bulawka	376-4726
Dr. Nathaniel Barr	353-3571
DEPARTMENT OF TRANSPORTATION	
* Mr. Edwin A. Richardson	426-3768
ENVIRONMENTAL PROTECTION AGENCY	
* Dr. George Armstrong	429-2275
Mr. David Janes	427-7604
Dr. Daniel F. Cahil	FTS - 629-2771
Dr. Joseph Elder	FTS - 629-2541
Dr. Carl Blackman	FTS - 629-2541

FEDERAL COMMUNICATIONS COMMISSION

* Mr. Will A. McGibbon 632-7060

NATIONAL BUREAU OF STANDARDS

* Mr. Charles K. S. Miller FTS - 323-3321

Dr. Alvin H. Sher 921-3357

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

* Dr. Donald McCree FTS - 629-3382

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY & HEALTH

Mr. David Conover FTS - 684-8482

* Dr. Wordie Parr FTS - 684-8483

NATIONAL SCIENCE FOUNDATION

* Mr. Norman Caplan 395-3102

NATIONAL TELECOMMUNICATIONS AND INFORMATION ADMINISTRATION

Ms. H. Janet Healer 377-1850

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

* Mr. Robert Curtis FTS - 588-5896

Mr. Frank Tipton 523-7174

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

* Dr. Carl Gerber 456-6272

VETERANS ADMINISTRATION

* Dr. Lawrence Hobson 389-2616

Task Force Leader
Howard E. Clark 377-1850

* Offically designated representative

COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES
SUITE 2321 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, D.C. 20515

May 10, 1979

Date Rec'd
Control #
Action Office Richardson
Copies to: Carrier
Suspense Date
Remarks: Furnished copy to HEC 5/11

Mr. Henry Geller
Assistant Secretary for
Communication and Information
U.S. Department of Commerce
Washington, D.C. 20230

Dear Mr. Geller:

The Subcommittee on Natural Resources and Environment has jurisdiction over environmental research and development and under this jurisdiction authorizes the research programs of the Office of Research and Development at the Environmental Protection Agency. As a result we are aware of the increasing concern over the potential biological effects resulting from exposure to nonionizing radiation. The Subcommittee also has a direct interest in seeing that the total Federal R&D effort is well coordinated and has recognized the difficulty in addressing a research program such as EPA's, which is only part of the total Federal R&D effort. We need to know what other agencies are doing in the area and what their plans are.

During the Floor debate on March 27, 1979, concerning H.R. 2676, the 1980 EPA Authorization Bill, the adequacy of funding for EPA's nonionizing radiation research program was discussed. At the time I recognized the need for the Federal agencies involved to develop a comprehensive plan to attack this most serious problem.

On May 3, 1979, Dr. Howard Clark briefed the Subcommittee staff on the formation of the Biological Effects of Nonionizing Electromagnetic Radiation (BENER) Task Force, an interagency task force now being organized to develop a comprehensive, coherent program plan for Federal R&D on the health effects of nonionizing radiation. I am very encouraged to hear that a coordinated planning effort is being organized within the Executive Branch, and that the effort will encompass the research programs of agencies involved in related coordinating efforts, such as those of the Interagency Regulatory Liaison Group. I am also encouraged to hear that this effort has the endorsemcnt of Dr. Frank Press of the Office of Science and Technology Policy.

We will be following the progress of this effort closely and will be paying particular attention to the recommendations that are made for the FY 1981 budget request and the recommendations that are made in the area of long-term research needs. Again, I am encouraged to hear of the BENER Task Force, I support coordinating planning efforts, and I am looking forward to hearing about how this particular planning effort is proceeding.

Sincerely,

JEROME A. AMBRO, Chairman
Subcommittee on Natural
Resources and Environment

Mr. AMBRO. Dr. Richardson, you say the role of NTIA is coordination. Can that role be characterized as a passive role?

Dr. RICHARDSON. No, Mr. Chairman, I do not think coordination need be a passive role. In order for coordination to work, there needs to be somebody who realizes he has been coordinated and that means persuasion of certain courses of action. It is our objective in playing this role to point out desirable courses of action and persuade other agencies to take action.

Mr. AMBRO. Well, the second part sounds fine but it is not always just the existence of somebody who has been persuaded he is coordinated that makes the role active. There are some cases where you just pull information together and have it sit there.

If coordination is accomplished by recommending the direction of future program efforts, to whom do you make these recommendations?

Dr. RICHARDSON. We make the recommendations to the community of research and regulatory interests that exist now. This community is reasonably well defined by those agencies who are performing projects.

Mr. AMBRO. Well, do the recommendations take into consideration the size of the total research effort and the distribution of funds among different and various agencies?

Dr. RICHARDSON. We expect the product of the task force on the Biological Effects of Nonionizing Radiation to make such recommendations both as to the structure of the total program and the resources required to carry it out.

Mr. AMBRO. You see, Dr. Richardson, I think we are at this point. We have a number of regulatory agencies, the EPA, FDA, OSHA and others, and I think where we are headed, is toward a central reservoir of research and data collection that would be available to the regulatory arms. At the moment the research and data collection activities are so fragmented as not to be able to provide the kind of data that can effectively be used by those regulatory arms.

Suppose, as a hypothetical example, the Subcommittee on Natural Resources and the Environment authorized a funding level and the authority to have the National Institute for Environmental Health Sciences—(NIEHS)—be the lead agency in bringing all of these activities together and then through contracts and funding of

the research required by the mission agencies, provide the data to be used by the regulatory arms. What do you think of the proposal?

Dr. RICHARDSON. NTIA would be very willing to defer to any arrangements that achieve stronger planning direction, sounder budget justifications and more directed implementation of this program.

Mr. AMBRO. Did you read that?

Dr. RICHARDSON. I read it from some notes made in anticipation of such a question.

Mr. AMBRO. I did not have such a question. I just dreamed it up looking at that wall over there.

Dr. RICHARDSON. I figured the question was coming.

Mr. AMBRO. What question do I ask now? [Laughter.]

Well, let me ask you this one. Suppose we did, indeed, accede to the earlier recommendation that we develop legislation for a standard of 10 mW/cm^2 for the present and at the same time say we are going to provide the funding for the research to drop the standard below or elevate the standard above 10 mW/cm^2.

How would you feel about that recommendation and that piece of legislation?

Dr. RICHARDSON. Mr. Chairman, I have to say that I do not think that it would be a good precedent for the Congress to actually set detailed standards.

As I see it, the function of the Congress is to put this burden on the regulatory agencies who will then use the resources and the public processes available to them to carry out the intent of the Congress. In this way, I think that we would achieve a sounder standard than by some quick action by the Congress.

Mr. AMBRO. The difficulty we are in is because of the timeframe it takes to develop a standard by appropriate Federal agencies. Industry may be anxious for standards of their own, which are going to be bombarded by those who believe that their standard is better than the industry standards or those that believe we should have a mandatory standard, whatever it is. Industry says that those who want a tight standard should know better and therefore can rest on that as a way out of their difficulties.

How long will it take, do you think, continuing at this petty pace if you will, with fragmented construction, to develop a standard?

Dr. RICHARDSON. I think it will take a long time at the present pace to develop a standard. The reason it will take a long time is that there will be those who will not want to act until they have exhaustive information at hand. You can pursue this subject too long and too far before acting.

Mr. AMBRO. But how about the proposal that Congress act instead, forgetting about setting a precedent, and go directly to the agencies and the number of existing R. & D. efforts and provide a stronger focus for this problem in order to develop the necessary research so that the various regulatory arms can develop standards as needed.

Dr. RICHARDSON. I think if Congress acted as you suggested, it would certainly get the attention of the agencies. With your permission, I might suggest an alternative.

Mr. AMBRO. I was going to ask you to do that.

Dr. RICHARDSON. Congress could make a finding that a standard was needed, for the reasons you spoke of, by such and such a date—certain. It would then become incumbent upon the agencies to respond to that finding and they would arrive at a result through the usual public policy process that obtains in this regulatory area. It would leave Congress free from having set an unusual precedent.

Mr. AMBRO. Well, if the road to hell is paved with good intentions, then the path to dates—certainly is, in my time in Congress, filled with huge obstacles and impediments which seem to me to never permit us to get there. I could recite a litany. Although I must say this report that was delivered today from the BENER Group comes at a surprisingly efficacious time.

What, by the way is the IRLG group relationship with BENER?

Dr. RICHARDSON. The agencies which belong to the Interagency Regulatory Liaison Group—IRLG—are also members of the BENER task force and these agencies constitute a subgroup of the BENER task force and are working in concert to provide input for the product of the task force.

Mr. AMBRO. I must interrupt. We have a new system here now where we have quorum calls. The votes come 5 minutes immediately after the quorum call so I will have to recess for about 15 minutes and come back and hear from others.

I would like in your case, Dr. Richardson, to thank you very much for your testimony and suggest that we leave the record open for additional written inquiries if needed.

Dr. RICHARDSON. Thank you, very much, Mr. Chairman.

Mr. AMBRO. We will recess for about 15 minutes.

[Brief recess.]

Mr. AMBRO. The subcommittee will reconvene. We now call Mr. Mays Swicord, Bureau of Radiological Health, FDA, to appear as Chairman of the Interagency Regulatory Liaison group Radiofrequency and Microwave Committee.

Mr. Swicord, welcome.

STATEMENT OF MAYS SWICORD, BUREAU OF RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION, APPEARING AS CHAIRMAN OF THE INTERAGENCY REGULATORY LIAISON GROUP, RADIOFREQUENCY AND MICROWAVE COMMITTEE

Mr. SWICORD. Thank you, Mr. Chairman. I am pleased to appear before you this morning as Chairman of the Interagency Regulatory Liaison Group's Radiofrequency and Microwave Committee. I would like to begin by describing the genesis of the IRLG, its mandate, its progress to date, and then address each of the points raised in your letter.

The Interagency Regulatory Liaison Group was formed in October 1977 to coordinate the activities of four regulatory agencies responsible for controlling materials that are hazardous to the public health.

The original agencies, the Consumer Product Safety Commission, the Environmental Protection Agency, the Food and Drug Administration and the Occupational Safety and Health Administration were recently joined by the Food Safety and Quality Service of the

Department of Agriculture to form the present Interagency Regulatory Liaison Group.

In September 1978, the agency heads agreed to extend the area of cooperative concern to cover radiofrequency and microwave radiation.

The three agencies with regulatory responsibilities in this area—EPA, FDA, OSHA—formed the Radiofrequency and Microwave Committee. The National Institute for Occupational Safety and Health, or NIOSH, which has a supportive role to OSHA and the Federal Communications Commission, were subsequently asked to participate.

For purposes of clarification, I would like to define the terms radiofrequency and microwave. Radiofrequency refers to that portion of the electromagnetic spectrum ranging from 10 kilohertz, or KHz to 300 gigahertz, or GHz.

The term microwave refers to a subset of this range extending from about 1 GHz to 300 GHz. Although the term radiofrequency literally applies to the entire range, its common usage refers only to that range below 1 GHz. To avoid confusion, therefore, the Group has chosen to describe itself as the IRLG Radiofrequency and Microwave Committee.

Since its first meeting in October 1978 the committee has convened every 4 to 6 weeks to accomplish the following objectives:

One. Develop a consistent radiation protection philosophy for radiofrequencies and microwaves;

Two. Coordinate the development of a comprehensive biological effects survey report on published experimental and epidemiological studies, considering the efforts of all agencies;

Three. Identify common research needs and coordinate a biological and physical research program;

Four. Identify radiofrequency and microwave emitters and the population exposed. Identify significant sources and categorize them; and,

Five. Develop a coordinated control and corrective action plan in areas of overlapping jurisdictions.

I would like to discuss these objectives in terms of the specific questions identified by the subcommittee. The first and second objectives of the IRLG Committee are the motivating forces for sponsoring the National Academy of Sciences—NAS—study on which your subcommittee requested comment.

The first objective of the committee is to develop a consistent radiation protection philosphy for radiofrequencies and microwaves.

The committee has drafted a philosophical approach to radiation protection entitled, "Radio Frequency and Microwave Radiation Protection: Elements of a Consistent IRLG Philosophy and Approach," a copy of which I am submitting for the record.

[The document referred to follows:]

RADIO FREQUENCY AND MICROWAVE RADIATION PROTECTION:

ELEMENTS OF A CONSISTENT IRLG PHILOSOPHY AND APPROACH*

The Interagency Regulatory Liaison Group (IRLG) was formed in 1977 by the US Consumer Product Safety Commission, the U.S. Environmental Protection Agency, the Food and Drug Administration and the Occupational Safety and Health Administration. Its expressed goals included the initiation of a process by which interagency co-operative efforts can be improved, augmented, or modified as needed. Since its inception, the IRLG has sought to enhance the efficiency of the regulatory process by developing co-ordinated approaches to problems involving its member agencies. The initial meetings of the various work groups have illuminated the importance of practical and usable guidelines, and have clarified the need for a consistent philosophy. This paper develops several considerations engendered by that need. First, several general regulatory issues have been noted. Next, the essential elements of such a regulatory philosophy have been presented with a brief critical discussion. Finally, several specific approaches to the problem of determining acceptable levels of human exposure to potential hazards have been provided.

I. REGULATORY CONSIDERATIONS

Any usable philosophy must recognize not only the member agencies' common goal of protecting our citizens from unnecessarily hazardous levels of biological insults but also the common scientific and ethical considerations which inform each agency's decisions. In fact, these overlapping interests motivate the development of a co-ordinated and consistent approach.

Yet to be realistic such a philosophy must also acknowledge that different agency responsibilities may sometimes necessitate differences in approach. E.g. certain environmentally pervasive sources of potential hazard are difficult or impossible to avoid completely, but certain other types of individual risks (such as some medical or occupational risks) can be acknowledged, and accepted or rejected. It will sometimes be desirable to deal with these in different ways. As a society we generally choose to allow a lesser risk than some individuals may choose to accept; and this arrangement of choice is as it should be. It is clearly important to consider risks not only to the general public, but also for medical and occupational environments. It is equally clear that relevant concerns may differ for each of these populations, both in risk-benefit factors and in the characteristics of the population at risk. Finally, the laws under which the various agencies operate assign to them differences in responsibility and authority.

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It is also important for any philosophy to respect the broad socio-economic nature of the value judgments involved in regulation. E.g., in addressing the problems of RF and microwave radiation exposure, one can reasily recognize a complex constellation of perceived societal "benefits" underlying the common sources of such radiation. Aside from medical and occupational exposure, a recent study has suggested that the principal sources of

pervasive chronic exposure of the general public are FM radio and UHF TV broadcasting (1). Navigational aids, such as radar, constitute another potential source of exposure (2), (3). Acute exposures may be associated with microwave ovens (4), CB radios (5), and other personal and professional communications equipment. The complexity of the social values involved is compounded by the fact that the risks and the benefits associated with such exposures do not always accrue to the same segments of society.

Certain other types of difficulties are almost unavoidable in the regulation of potential health hazards (6). It is well to recognize these and their universality, while resolving not to be crippled by them. Because of the pressing nature of problems requiring regulatory action, the process frequently must proceed in the absence of wholly sufficient data. Further, even without these time-constraints, it is necessary to accept the fact that no finite amount of data could ever categorically establish the "absolutely safe" (i.e., zero possibility of adverse health effect) exposure level. Finally, even in the hypothetical presence of a complete data base, we are still confronted by the problem of interpretation. Data is, of course, simply a collection of facts, not generalizations or scientific conclusions. Extracting these objective conclusions from a set of empirical data invariably leads to uncertainty and multiple points of view.

There is, however, a consideration which is much more important than such technical problems with the data. Even flawless science is insufficient to make the value decisions which determine acceptable levels of risk and uncertainty. Such decisions arise from basic personal beliefs and philosophy; they are ethical questions. In deciding such issues of moral acceptability, scientists and researchers are no better qualified than informed laymen. We are all inclined to see things on two planes: the personal and the societal. They constitute the appropriate realms of feelings and statistics, respectively. Conflict between them is often unavoidable, yet at this level of value judgment, in a democracy they must be reconciled.

Furthermore, since no amount of regulatory activity can ever suffice to establish "absolute safety" (zero risk), it is necessary to determine an acceptable level of regulatory effort. We must seek the best relative distribution of our societal resources to deal with all of our various concerns, including not only regulation but also production, etc. One can readily envision a hypothetical society in which more resources were expended on regulation than on production. Few would be satisfied with such a situation. It is well to remember that every regulatory decision affects this overall determination of the allocation of societal resources.

Finally, it is a familar truism that regulatory action in controversial questions will invariably leave some parties incompletely satisfied, and such action is frequenty contested. It is well to remember that the only apparent alternative is delay and indecision, clearly a less desirable option.

II. A CONSISTENT PHILOSOPHY

A philosophy which may be embraced by each of the IRLG agencies, while still allowing ample recognition of individual differences, contains five key elements. These include commitments to caution in safeguarding the public health, recognition of the special character of unaccepted risk, public involvement in determining acceptable risk, timeliness in decision-making, and a scientific foundation for decisions:

A. Caution in Safeguarding the Public Health. The ethics and the ambiguities which permeate the regulatory process demand a clear commitment to prudence in concerns of public health. One can hardly improve on the admonition of Philip Handler, President of the National Academy of Sciences (6):

> "Regulatory agencies will repeatedly be confronted with the need for decision making with an insufficiency of data. At such times they have no choice; they must then err on the side of conservatism when protection of public health is involved. That is their role in our society, the only choice that is before them. The fact that they cannot always justify those actions fully will rest on that philosophy; it is, in fact, their very business."

To be sure, regulatory cautiousness sometimes develops from undesirable bureaucratic characteristics. For example, it has previously been noted that, from a cost-benefit standpoint, the potential penalties to a regulator who errs due to insufficient caution are rarely balanced by the potential rewards of the reverse (6). Nevertheless, it is frequently necessary to make public health decisions more out of concern for the unknown than in response to the known. That is a responsibility which cannot be avoided, any more than we can avoid the competing societal demands for the benefits of regulation, on the one hand, and production, on the other.

B. The Special Character of Unaccepted Risk. Provided that adequate information is made available, it is possible, in principle, that an informed individual decision may lead to the acceptance of levels of risk greater than those encountered by the general public. For example, this sort of acknowledgement and acceptance of exposure might be associated with certain medical and occupational procedures (though personal economic factors may severely constrain choices in the latter case). In contrast, however, certain types of risk to the general public may be difficult or impossible to avoid altogether. In such cases the idea of acceptance or

rejection of exposure levels has little meaning. Further, unlike some medical and occupational populations, the general population is completely uncontrolled with respect to such variables as health, age, and individual susceptibility. In such cases of unaccepted risk where little choice is possible and few assumptions are justified regarding the population at risk, lower level of permissible exposure should be considered.

C. Public Involvement in Determining Acceptable Risk. The most ideal scientific procedures imaginable can do no more than to evaluate the risks associated with various levels of hazard exposure, and to estimate the uncertainties associated with that evaluation. Scientific data itself cannot make the ethical judgments regarding the levels of risk or uncertainty which are acceptable. Nor can they determine for us the point at which such risks become unacceptable. Such decisions must be based on our personal and societal values; they are not simply matters of technical detail.

For this reason, it is essential to develop such decisions from a broad social base, to involve the public well before decisions are made. The crucial technical function in such a process is to ensure that all parties are well informed of the objective consequences of those decisions. Furthermore, questions involving effective means of disseminating such information are also important ones. It is particularly important to ensure that information reaches the actual users, especially in the medical and occupational fields.

In addition to obtaining a broad-based public participation, it is important to publish a complete record of the decision making process. It has often been said that regulatory agencies, like Caesar's wife, must be above any suspicion of bias. To ensure this, it is necessary to make known the basis for decisions, and the considerations involved.

Another important question is, "Who is the public?" Considerations involving vying claims to represent the public interest are vexing, and include complex questions regarding media treatment of public issues.

Any consideration of public input to regulatory policy also must recognize the varied character of the phenomena which may be vehicles for such input. These may include referenda, participation in hearings, public comments on role-making, and even action in the legal arena.

It is probably too optimistic to expect that active public involvement in decision-making will lead to simple consensus. Yet this involvement is the only way to provide that decisions reflect the true range of societal values, and to assure interested individuals that there is an opportunity to participate and influence the process.

D. Timeliness in Decision-making. It is, of course, important to allow sufficient time to collect and interpret the important factors which

bear on a decision. Yet it is at least as important to avoid the delay and indecision which undermine public confidence. Such equivocation serves only to increase anxiety and confusion on all sides of an issue.

E. Scientific Foundations of Policy. It is of paramount importance that decisions be informed by the best scientific information available. It is also clearly important to recognize the frequent need to encourage and support additional research to illuminate those factors which remain poorly understood. However, such encouragement and support should not be continued indefinitely and uncritically.

Finally, despite every regulated industry's understandable desire for a simple and unchanging set of rules, all decisions need to be reviewed in the light of current scientific information and updated if necessary. This function can be ensured by supplementing such decisions with target dates for re-evaluation.

III. SPECIFIC APPROACHES

The philosophy outlined above provides principles to carry out our specific efforts and sets forth our guiding values. Such general principles, however, still require specific techniques for application to immediate problems. Five particular approaches to the determination of of acceptable risk exposure levels are presented below. It should be borne in mind, however, that encouraging additional research, and soliciting active public involvement should be an integral part of any approach. The approaches discussed below are intended to represent a wide range of alternatives. They are generally not mutually exclusive, and it is possible that a complementary combination of them may lead to convergent results.

A. Accept Existing Standards. Various personnel exposure standards for many hazardous substances are in use around the world. One approach to determining acceptable exposure levels is to accept one of these existing standards (on the basis of its conservatism, or for other reasons), or to attempt to glean a consensus somehow averaged from these various world standards.

This approach is based on the acceptance of a dictum from authority, and has all of the values and flaws of any such argument. It can be accomplished quickly and economically. However, it addresses the scientific questions only very indirectly, through the considerations of the institutions which issued the standards. As such, its scientific defense might be very difficult. The approach is also complicated by differing social values which obtain in different societies.

B. Impanel an Independent Body of Experts. This approach would seek to obtain the consensus of a group of scientists recognized as experts on the hazard to be addressed, supplemented by public representatives. Such a group could be balanced in composition to obtain all points of view.

The group could serve to make recommendations not only on acceptable levels of exposure, but also on specific areas in which further research is needed for the developing regulatory process.

Such an approach would have a more firmly scientific basis than the first, but with more attendant problems. Assuring balanced representation on such a group would be difficult. Nor is it really clear that a consensus is always possible with our present state of knowledge, given the diversity of existing viewpoints. The approach also still retains some of the features of a recourse to authority, since the technical factors addressed would be largely determined by the panel, not the agencies.

C. Determine Lowest Significant Level from Scientific Literature; Add Safety Factor. This empirical approach would review the existing literature to find the lowest level at which an effect (or a hazard) is reported. When lowered by an additional safety factor, these levels would be used to set acceptable human exposure levels.

This is basically a more scientific approach. Its results would take longer and be somewhat more expensive. Several technical difficulties are evident. Not all reported findings result from equally careful research; not all such findings have been reproduced. Projections from experimental animals to humans entail difficulties which have been elaborated at length in the literature. Further, it is sometimes suspected that the degree of hazard associated with a given insult may be dependent upon many subtle secondary characteristics of the insult itself, such as the modulation of radiation; yet there is often a substantial lack of data on the specific significance of these parameters.

This approach illuminates the importance of continuing support for research. The acceptable exposure levels resulting from this approach are visibly tied to identifiable research results. Clearly, if research were to dwindle, subsequent revision of exposure levels could be indefinitely delayed, even if an unresearched biological effect existed and was widely suspected. In particular, the current dearth of usable epidemiological data for some potential hazards is disturbing in this regard.

As the scientific aspect of the approach becomes more explicit, though, so does the non-technical ethical aspect. The selection of safety factors is clearly a value-decision, certain to be strongly dependent on the nature of the low-level effects reported in the literature.

D. Use Specific Interaction Models for Theoretical Projection of Levels. This approach is also essentially scientific but more theoretical in orientation. It seeks to circumvent the lack of biological data at lower exposure levels by postulating theoretical biophysical models to describe the interaction between the insult and the living organisms. These models would be drawn from currently existing experimental observations, and would be used

to project effects at lower levels theoretically. Such an approach could also be used to project results for variants of the insult for which data is lacking. The primary problem clearly lies in the difficulty of formulating adequate models describing the interaction mechanisms.

The difficulties can be illustrated by considering the question of human exposure to RF and microwave energy. In this area the only models which can be considered well-developed at present are those which are thermal in nature, based on tissue-heating. Indeed, the importance and usefulness of these models is considerable. Yet even these are barely able to address all of the relevant thermal concerns, including whole-body versus partial-body exposure and macrothermal versus microthermal heating. Several non-thermal models exist, but are currently in an embryonic state of development; a high priority should be placed on their development. Nevertheless, even existing thermal models can be of substantial value. Since thermal models have historically been associated with higher levels of exposure, one might begin by using their projections (with suitable safety factors) as an absolute upper bound for personnel exposure, to be modified downward as a result of other findings as they develop. [In fact, this is very nearly the current Western position, except that the existing thermal exposure standards have not clearly accounted for all of the most recent thermal-model information.]

E. Use Cost-Benefit or Risk-Benefit Considerations. These are basically products of systems-analysis concepts and are clearly the most sophisticated approach to analyzing the relevant value judgments. While almost unavoidable aspects of any societal decision, they are also extremely difficult to apply in an objective (or quantitative) way.

There are three main reasons for this. First, the risks and benefits surrounding real decisions are often largely unknown, and even more often unquantifiable. Second, even when the risks and benefits can be quantified, they generally appear with incommensurable units. For example, we can compare benefits in dollars with risks in dollars; but how shall we compare benefits in dollars with risks in health? Nor is this difficulty really avoided by trying to force risks or benefits into units which, in truth, will not accomodate them. Finally, it is very often the case that the risks and benefits accrue to different segments of the society.

Such difficulties with cost and risk-benefit analyses have led Philip Handler to observe (6):

> "This is really a facile phrase rather than a reference to a developed science or art. The ground rules for such analyses have not been spelled out, nor am I aware of an important decision outside the military which has really rested on what might be described as a formal, careful cost and risk-benefit analysis."

Still, some assessment of the relative merits and costs of any societal decision is ultimately unavoidable. Furthermore such concepts clearly can be illuminating. They show us, for example, that the idea of limiting human exposure to the lowest level technically feasible is only half an idea. Clearly, the lowest level feasible is a function of the cost one is willing to bear.

In general, the relevant value judgment comparisons may be considered in several ways. Risks may be compared with benefits, or with the risks of background-levels of the insult, or with other risks accepted by society-at-large (e.g., those associated with automobile or tobacco usage). In any case, it is important that we address real, identifiable risks in such a discussion, not chimeras. There is a considerable difference between a risk, and the uncertainty inherent in defining that risk. It is important to address each of these explicitly.

Benefits may be even harder to evaluate. Any meaningful assessment of them must begin from a clear delineation of the common sources of human exposure. In the previously cited example of RF and microwave radiation exposure, the sources include: occupational exposure, medical exposure, TV and radio broadcasting, navigational equipment, microwave ovens, CB and other professional and amateur communications equipment. The scope of societal values emcompassed is awesome. It underscores the importance of broad public participation in determining acceptable risk-benefit tradeoffs.

IV. SUMMARY

While the member agencies of the IRLG must respond to a variety of different issues, there is a large overlap in their goals, and in their scientific and ethical concerns. In their common goal of minimizing human exposure to unnecessarily hazardous levels of biological insults, a consistent philosophy and specific co-ordinated approaches are both clearly desirable and emphatically possible.

Such a regulatory philosophy must embrace unequivocally key concerns in protecting the public interest. These should include commitments to caution in safeguarding the public health, recognition of the special character of unaccepted risk, public involvement in determining acceptable risk, timeliness in decision-making, and a scientific foundation for decisions.

Specific approaches to determining acceptable levels for exposure to potential hazards may include a utilization of existing world standards or the scientific consensus of an independent advisory panel. Alternative (and, perhaps, complementary) approaches could determine exposure limits from the lowest levels currently shown to be biologically effective, or from the theoretical predictions of specific interaction models, incorporating a safety factor in either case. An explicit consideration of risks and benefits seems desirable in any approach.

The number and complexity of the issues involved illuminate with stark clarity the difficulties inherent in the attempt to safeguard the public health from the hazards of our evolving society. Only a dedication to integrity will enable us to confront those difficulties and make that attempt successful.

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(3) Larsen, Ezar B., and John F. Shafer. Surveys of Electromagnetic Field Intensities Near Representative Higher-Power FAA Transmitting Antennas. NBS Report NBSIR-76-849, December 1977.

(4) Seabron, LaVert C. and Lewis Coopersmith. Results of the 1970 Microwave Oven Survey. DHEW Publication No. (FDA) 72-8007, August 1971.

(5) Ruggera, Paul S. "Near-Field Measurements of RF Fields" Symposium on Biological Effects and Measurement of Radio Frequency/Microwaves. HEW Publication (FDA) 77-8026, July 1977.

(6) National Academy of Sciences. How Safe is Safe? The Design of Policy on Drugs and Food Additives, 1974.

This document recognizes the present lack of scientific data on which to establish a basis for common regulatory action. Since an overall approach to radiation protection must span the diverse areas of electronic products, occupational exposure, and radiofrequency levels in the environment, its evolution will depend strongly on a common understanding of the biological effects of exposure.

Such an understanding must be developed in a way that is scientifically credible and impartial to any particular interest group.

The committee concluded that the most efficient and economical way to achieve this objective was to ask the National Academy of Sciences to undertake an objective, comprehensive, critical appraisal of the world literature on the biological effects of radiofrequency waves.

The Academy's efforts would culminate in a document similar to their second report on the Biological Effects of Ionizing Radiation—BEIR—which has been used very successfully by the agencies to develop standards for ionizing radiation.

The NAS study also addresses the second objective of the committee—to coordinate the development of a comprehensive biological effect survey report. The Academy has been suggesting a literature study for about 2 years. In June of 1977 they briefed the Senate Committee on Commerce, Science, and Transportation on the Academy's proposal during oversight hearings on radiation health and safety.

Using the Academy's proposal as a starting point, the IRLG Radiofrequency and Microwave Committee has developed a scope of work, which I am submitting for the record.

[The document referred to follows:]

15 January 1979

DRAFT SCOPE OF WORK

A Critical Appraisal of the Biological Effects Due to Exposure to Radio Frequency Waves Including Microwaves

Purpose

This proposed study is to provide an objective, comprehensive, critical appraisal of the world literature on the biological effects that are due to radio frequency waves (3 kilohertz to 300 gigahertz). The reason for conducting this study is to obtain a summary document for consideration by Federal regulatory agencies (1) in their development and promulgation of radiation protection standards. It is intended that this study will focus on the state of knowledge of the potential health effects of exposure to these electromagnetic radiations, particularly those parameters which influence or might influence the effects produced in the work place and the general environment. Among these parameters are frequency, time duration of exposure, level of exposure, and response differences or expected differences, between study subjects. Excluded from the study are those indirect health effects that may result from "electronic interferences" or cardiac pacemakers, thermometers, etc. It is not intended that the contractor address regulatory decisions or make recommendations of specific standards for human exposure, but rather examine and evaluate the scientific aspects of the information base upon which regulatory decisions may be made. The BEIR (2) report is an example of the format and the nature of the conclusions expected in the final report.

Statement of Work

To perform this study it is desired that the Contractor select a Committee whose membership considers expertise in both the basic and medical sciences (biologists, physiologists, psychologists, geneticists, ecologists, biophysicists, physicists, engineers, medical specialists, epidemiologists, and persons from other scientific disciplines as required) to ensure a balanced scientific review. Consultants to the committee may be used as necessary. In addition to the regular meetings of the committee, public meeting(s), symposia, and conferences may be conducted to meet the goals of this study.

The Committee's study of the literature on the biological effects of exposure to radio frequency waves should include a critical evaluation of experimental protocols and interpretation of the consequences of reported effects in terms of human and environmental risk from exposure to radio frequency waves. For the purposes of this study radio frequency waves are defined as that part of the electromagnetic spectrum with frequencies between 3 kilohertz and 300 gigahertz.

In its review the Committee should consider the effects of exposure to radio frequency waves on man and other biological systems such as laboratory animals, lower animals forms, and plants. The study should include, but not be limited to, the following areas:

1) human studies (epidemiology)
2) special senses (auditory, ocular, etc.)
3) nervous system (neurophysiology, neurochemistry, etc.)
4) behavior
5) endocrinology
6) immunology, hematology
7) biochemistry, physiology
8) genetics, mutagenesis
9) developmental effects (teratology, reproduction, etc.)
10) cellular and subcellular effects
11) ecology
12) life span and carcinogenesis
13) special populations
14) multiple frequency exposures
15) multiple environmental agent interactions

Since the literature on biological responses to thermal stress may aid in the interpretation of the data collected on the effects of exposure to radio frequency waves, the contractor should evaluate the thermal stress literature in the areas listed above. This should be done only for the thermal stress literature directly applicable to the interpretation of the radiofrequency data. Since radiofrequency radiation exposure is likely to be partial-body, special note should be made of parallels in the thermal stress literature. The review of this literature should also be considered by the contractor in evaluating the impact of the interaction of multiple environmental agents.

Phase I

The Committee selected by the Contractor should critically appraise all the pertinent data on the biological effects due to exposure to radiofrequency waves. In order to complete this task the Committee will need to collect literature from both U.S. and foreign sources. There are a number of existing data and information sources which should greatly simplify the gathering of information. Among these are the bibliographies compiled by the Franklin Research Institute [3], the Electromagnetic Radiation Management Advisory Council [4], the National Institute for Occupational Safety and Health [5] and recent biological effects assessment studies sponsored by national and international groups [6]. The data on thermal physiology and stress has been recently summarized by Santo Donato and Bosch [7]. The establishment of liaison with groups such as the American National Standards Institute (ANSI)[8], the National Council for Radiation Protection [9], and involved Federal agencies should prove useful to the Committee in obtaining existing data and information. The critical review will have the maximum impact if it is based on the original scientific papers and on recognized reviews of research when the original work cannot be obtained. In its critical review appraisal of the literature it is desired that the Committee:

1) Review, evaluate and interpret the current state of knowledge on human epidemiological, clinical and case studies.
2) Consider the extent to which animal data is pertinent to estimating effects in human populations.
3) Consider the physical parameters that are necessary for interpreting the effects of exposure to radio frequency and microwave radiation, e.g., field strengths, rates of energy absorption, frequency modulation (including pulsed fields), duration of exposure (including acute versus chronic exposures), temperature, humidity, etc.
4) Consider the effect of:
    a) intermittent versus continuous exposure,
    b) near-field versus far-field exposure,
    c) partial-body versus whole-body exposure, and
    d) transient versus irreversible effects.

5) Indicate where possible the relative sensitivity of various biological systems to radio frequency and microwave radiation.
6) Review, evaluate and interpret the current state of knowledge on the effect of radio frequency and microwave radiation on ecological systems.
7) Include in the final report the criteria used to select the experimental data from the world literature upon which the critical appraisal is based.
   a) submit as a portion of the final report the critical review of all information deemed relevant to an assessment of reported biological effects of radiofrequency waves;
   b) submit a complete bibliography of all articles cited in this review as well as any other materials used in the preparation of this review;
   c) submit as a part of the final report a detailed list of any and all criteria established by the contractor for selection of scientific articles for use in this review including a discussion of the degree of confidence that can be placed in reported exposure values;
   d) submit as part of the final report a detailed list of any and all criteria established by the contractor for assessing the validity of reported results.

Phase II

The Committee should make such recommendations on the potential human and environmental risks from exposure to radio frequency and microwave radiation as it believes are appropriate based on the current state of knowledge. In particular, it is desired that the Committee:
1) Analyze the spectrum of interest into biologically meaningful bands.
2) Identify all known biological effects (generic and specific) associated with any level of exposure in each of those bands.
3) For (each type of effect in) each band quantify four human exposure levels, with commentary on the relevance of amplitude-modulation and the continuousness or intermittency of exposure:
   a) an upper limit which identifies the lowest level clearly demonstrating a significant risk of an adverse health effect

b) the lowest level reported to be associated with each type of effect (with some allowance by the Committee making judgements on credibility)
c) the highest levels at which each type of effect is known not to occur
d) a clear delineation of those effects for which lower limits of exposure have not been identified.

4) The parameters to be considered in risk assessment e.g., environmental factors, exposure durations, co-stressors, physiological and health status, whole-body versus partial-body exposure, and radiation modulation parameters.

5) The Committee shall also identify those frequency ranges between 3 kHz and 300 GHz and the radiation modulation parameters for which insufficient data exists upon which to base risk assessments.

Footnotes

[1] Consumer Product Safety Commission, Environmental Protection Agency, Food and Drug Administration, and Occupational Safety and Health Administration.
[2] Advisory Committee on the Biological Effects of Ionizing Radiations, The Effects on Populations of Exposure to Low Levels of Ionizing Radiation, National Academy of Sciences, Washington, DC, November 1972.
[3] Kleinstein, B.H. and E.P. Sabor (Project Manager and Editor, respectively), "Biological Effects of Nonionizing Electromagnetic Radiation, Volumes I thru III, Franklin Research Institute, Philadelphia, PA.
[4] Electromagnetic Radiation Management Advisory Council, National Telecommunications and Information Administration, Washington, DC.
[5] Federal Register 42: 56799, October 28, 1977.
[6] McRee, D.I., "A Technical Review of the Biological Effects of Non-Ionizing Radiation, Office of Science and Technology Policy, Washington, DC.
Michaelson, S.M. "Microwave and Radiofrequency Radiation," Regional Office for Europe, World Health Organization, Copenhagen (as revised).

[7] Santo Donato, J. and S. Bosch, "Review, Summarization, and Evaluation of Literature to Support the Undate and Revision of Criteria Document XIII, Hot Environments," (NIOSH Contract 210-76-0167) Syracuse Research Corporation, Syracuse, NY, December 1977.
[8] American National Standards Institute Committee on Radio Frequency Radiation Hazards, C95, Chairman, Professor S.W. Rosenthal, Polytechnic Institute of New York, Farmingdale, NY 11735.
[9] National Council on Radiation Protection, Scientific Committee 39, "Microwaves" and Scientific Committee 53, "Biological Effects and Exposure Criteria for Radio Frequency Electromagnetic Radiation," Washington, DC.

Mr. SWICORD. This "scope" is more specific than the original Academy proposal, and its emphasis is on a critical appraisal of the world literature. Although a number of literature surveys are available, those surveys merely report the work of other authors without critically analyzing the protocol and results.

One difficulty of evaluating published research results is the large number of unconfirmed biological effects reported in the literature. These experiments are often extremely complex and require knowledge and techniques derived from the fields of engineering, physics and biology. In fact, radiofrequency and microwave biological effects studies are advancing the state of the art in these disciplines.

For example, the physics of the interaction process of radiofrequency or microwave radiation with biomolecules, membranes or cells have not been thoroughly studied and are not presently understood.

We do, of course, understand the absorption process of microwaves by some molecules such as water, which could lead to a temperature rise in the absorbing medium, but we do not know about other interaction processes.

Also, the biochemical processes, which derive from some physical interaction and eventually result in an observed biological effect, are not understood. This lack of understanding of the fundamental processes makes it difficult to determine the important variables such as exposure conditions, that are critical in confirming the results of other experiments. Such complexities allow investigators to obtain false negative or false positive results, so that repetition of a reported experiment can yield contradictory results and thereby cast doubt on the original reported effects but without conclusively negating them.

An unbiased critical evaluation of both contested and uncontested reported effects is greatly needed in order to establish the data base upon which regulatory actions can be taken. The NAS study will provide such a critical evaluation. It will also guide future research by pointing out areas that are in need of further attention.

Although the NAS study will take approximately 2 years to complete, it is the intent of the IRLG member agencies to proceed with regulatory action on those problems already identified. The insufficiency of data in some areas is recognized and discussed in our draft philosophical approach. I will return to this issue of regulatory action in my discussion of the fifth objective.

The third objective—to identify common research needs and coordinate a biological and physical research program—addresses the first two subcommittee questions concerning the research needs of the regulatory agencies.

The IRLG committee has made considerable progress toward identifying common research needs and has developed a draft document outlining 14 priority areas of concern with specific research needs for each of these areas. The areas of research are not mutually exclusive, but the approach allows for the development of a cohesive plan around each regulatory concern. A copy of this draft, which will be further refined by the committee, is being submitted for your record.

[The document referred to follows:]

Rev. 9 July 1979

PRELIMINARY RESEARCH PLAN ON BIOLOGICAL EFFECTS OF NONIONIZING ELECTROMAGNETIC RADIATION

Interagency Regulatory Liaison Group
Radiofrequency and Microwave Committee

In order to carry out their regulatory mission, the member agencies of the Interagency Regulatory Liaison Group (IRLG), the Food and Drug Administration, the Environmental Protection Agency, the Occupational Safety and Health Administration, and the Consumer Product Safety Commission, formed a committee to coordinate a review and analysis of the available data on radiofrequency and microwave exposure effects and to coordinate activities and responsibilities in this area. The National Institute for Occupational Safety and Health, due to their supportive role to OSHA, and the Federal Communications Commission have been invited to participate on this committee.

One of the stated objectives of this committee is to "identify common research needs and coordinate a biological and physical research program." To that end the committee has developed a list of research areas or questions which demand consideration in order to assure the adequacy of regulations being developed or to be developed. The 14 items listed below are not exhaustive and certainly not mutually exclusive, but they do serve to illustrate the kinds of concerns that must be addressed by regulatory and support agencies.

The areas of concern and their definitions are as follows:

1. Near-field absorption: Characterize the specific absorption rates of biological tissues over the entire range of frequencies when exposure occurs in the near-field of the irradiating element.

2. Partial versus whole-body exposure: How are the biological effects of RFR affected by the percentage of the body that is irradiated? Are they different for different organs or tissues?

3. Maximum versus average dose rate: Whether peak rate of energy transfer or average rate of energy transfer is the appropriate measure of potential hazard due to radiofrequency radiation (RFR) exposure.

4. Intermittent versus continuous exposure: How are the biological effects of RFR affected by the length of exposure period and the number of exposure periods per day and week?

5. Dose rate response: Study of effects of power levels with particular attention to identifying "thresholds" of effects of acute and chronic exposure.

6. Modulation: How are the biological effects of RFR affected by the time-varying radiofrequency field?

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7. Mechanisms of interaction: Define the mechanisms of interaction of RFR with biological systems.

8. Multiple frequency exposures: Determine the combined effect of simultaneously or serially applied exposures at more than one frequency.

9. Induced body currents: Determine the effects of the currents induced in the body structures, especially at lower frequencies.

10. Ambient climate ranges: Determine the influence of ambient environmental conditions on the biological effects of RFR.

11. Relative tissue sensitivity: The relative biological effectiveness of the various RFR frequencies, i.e. variation of effect with frequency.

12. Exposed populations including sensitive populations: Define groups which may be more sensitive to injury by RFR, either naturally or as a result of environmental or occupational factors such as high work rate, drugs, pollution, toxic materials etc.

13. Specification of human exposure: Acurate characterization of exposure fields is required.

14. Control measures for device emission: How can device emission best be controlled?

Any biological research program should contain priorities and coordination directed toward addressing each of these outstanding questions. In the following sections the outline of a research plan which is recommended by the IRLG agencies agencies is presented. Efforts are underway to develop a coordinated plan for the regulatory agencies to address the common research needs under their regulatory mandates.

RESEARCH PLAN OUTLINE

1. Near-field absorption. Most of the exposure to higher levels of RF energy occurs in the reactive near-field, while our understanding of dose-rate distributions is best for far-field exposures. Among other things, one needs to know dose-rate distributions for complex fields and what physical variables (i.e., electric field strength, magnetic field strength, polarization, orientation, etc.) need to be measured in order to predict maximum and average dose rate. This work should devote particular attention to programs in the HF and UHF region.

   1.1 Theoretical dosimetry.

      1.1.1 The theoretical determination of energy deposition, in terms of specific absorption rate and internal E-field distributions, is required for risk determination with

human models in the proximity of various devices. While simple, regular shapes, and block models of men and animals have been analysed for plane wave and simple near-field exposures, techniques are needed for accurate determinations of internal fields induced in realistic, inhomogeneous models in complex fields. This theoretical program should be performed in coordination with the requirements of sections 2 and 3 and so that this model will provide results for a variety of frequencies and conditions of exposure, e.g. (as a limiting case) with and without ground plane, various body orientations (standing, sitting, lying), etc.

1.1.2 Whereas the theoretical work of 1.1 will provide internal energy distributions within a dielectric object exposed to complex specified fields, further theoretical consideration must be given to the interaction of the source and the nearby exposed body. This inductive coupling will effect the exposure field and the amount of energy delivered to the exposed body.

1.2 Experimental dosimetry

1.2.1 Phantom model studies are needed to establish the validity of and give guidance to the theoretical work discussed in 1.1.1. This work could proceed to provide valuable information during development of theoretical procedures and provide results where the theoretical models are limited.

1.2.2 Phantom model studies must also be used to parallel the theoretical work of 1.1.2. The methods used may be different from that of 1.2.1 but the objects will be similar.

1.3 Instrumentation design. In order to perform the experimental work of 1.2 one must utilize methods of themography and electric and magnetic field measurement.

1.3.1 External E- and H- field measurements. Improved external E- and H-field measurement probes should be developed which can handle near-field geometries, including electromagnetic fields which are frequency and amplitude modulated. These instruments should be portable, non-perturbing (possibly using fiber optic readout cables), stable, and simple. They should have wide frequency range (for example 400 kHz to 12 GHz) and a wide dynamic range (for example, 10 to 3000 volts/meter, and 0.05 to 10 amps/meter). The values of the three separate field components should be displayed or recorded along with the resultant field. In order to relate experimental and theoretical work, instruments are needed to provide phase as well as amplitude information.

1.3.2 Internal E- field probes. Systems are needed to measure fields in live, unrestrained animals during exposure to radiofrequency fields. The present small implantable electric field probe is somewhat large for in vivo use. In addition, the single dipole element must be rotated twice by 120° to obtain all three field components. A miniature, three-axis probe should be developed so that internal measurements may be made conveniently and with minimal sample damage. This project is in a study phase through an NSF grant with the University of Virginia, with participation by BRH in the testing and evaluation phase. However, additional funding will be required to produce a probe which is significantly smaller than the present one.

1.4 Phantom material development. Although several types of dielectric materials which simulated the electrical properties of human and animal materials have been developed, these materials are not useful at all frequencies and in all experimental situations. Further material development is needed particularly to address problems in the HF region of the spectrum.

2. Partial versus whole-body exposure. A number of devices produce very nonuniform fields. What considerations for the maximum rate of energy absorption (see 3 below) and relative tissue sensitivity (see 11 below) influence the choice of appropriate exposure values?

2.1 Thermoregulatory and circulatory regulation studies are needed to determine the effects of whole-body versus partial-body heating.

2.1.1 Develop human and animal models for predicting thermal physiological responses resulting from the absorption of radiofrequency energy.

2.1.2 Develop models (incorporating realistic thermal regulatory mechanisms) for determining localized heating patterns. These heating patterns would be the combined result of the absorbed energy distributions described by theoretical and experimental work discussed under 1, and the physiological response of the thermoregulatory system.

2.1.3 Perform animal studies to verify predicted results of model studies.

3. Maximum versus average dose rate. The average dose-rate gives one index of the stress placed upon a dynamic physiological system. It remains to be determined whether limits placed on the average value will also limit maximum values, i.e., hot spots. This involves consideration, among other things, of thermal and circulatory physiology, and absorption patterns in humans exposed to complex electromagnetic fields.

3.1 The theoretical work of 1.1 should provide the average dose-rate and the maximum dose-rate with little or no additional effort. The programs should be utilized to aid in bioeffects studies listed below.

3.1.1 Determine the biological effects of localized heating patterns in animals, with implications for man. Relate an observed biological effect to variations in local hot-spot position, maintaining constant average dose.

3.2 Evaluate the equivalence of circularly polarized, waveguide, cavity and anechoic chamber exposure systems in terms of biological effects, energy deposition, and electric and magnetic fields. These various exposure systems must be thoroughly characterized in terms of the resulting internal field and energy distribution in the exposed subject. Standardization of exposure should proceed from these described internal distributions. In addition development of new systems is needed and should proceed considering the resulting internal field distribution and the biological consequences of such a distribution.

3.3 The field probes proposed for development under 1 will be necessary for this work. The evaluaion of exposure systems will require phantom modeling and measurement.

4. Intermittent versus continuous exposure. Certain devices operate intermittently, for example, microwave ovens; mobile communications equipment; and radiofrequency heat sealers. Research is needed to address the question of what is a biologically meaningful interval over which to the average exposure. If adaptation plays a role in the system's response, is adaptation the same for intermittent and continuous exposure for both high-duty factor devices in the industrial setting (such as radiofrequency heat sealers), and for low duty factor devices (such as mobile radio in the general environment)?

4.1 Study various established biological effects as a function of period of exposure.

4.2 Determine, at least from a thermoregulatory standpoint, what constitutes a biologically meaningful interval over which to average the effects.

5. Dose-rate response. In animal studies and for some endpoints like cataractogenesis there appears to be a time-temperature threshold for the production of an effect. Additional information is needed on the generality of this conclusion for both acute and chronic exposure. Study designs should address this question either by reference to earlier work or by direct experimentation.

5.1 Determine dose-rate responses of observed biological effects.

5.2 Determine the existance of long-term, low-level effects and establish the length of time necessary for onset.

5.3 Develop exposure systems for long-term, low-level studies of animals at frequencies of environmental interest. The design of these systems must consider biological study needs.

6. Modulation. It has been established that pulsed fields can produce at least one effect, the hearing phenomenon, which is not elicited with continuous wave sources. This effect has not been established as a hazard. However, there are at least two quesions that need to be addressed. Are there other receptors that are sensitive to pulsed fields? Can some of the behavioral data be interpreted as a response to an audible cue? For very high peak values one can at least postulate non-linear effects. Does there need to be some limit placed on peak amplitude? Square or rectangular pulsed modulation is only one of a large number of possible modulations. Specific effects due to modulation are subtle ones (e.g., the work of Adey et al., and Blackman et al. at extremely-low-frequency modulations). Therefore, it is unlikely that these effects will be understood in the near future. How should an exposure standard treat this uncertainty?

6.1 Examine biological responses to modulation (both AM and FM)

6.2 Study pulsed versus CW radiation for effects produced at exposure levels which may bring into question a thermal causal mechanism.

6.3 Determine the response of biological systems to extremely high peak fields. A radar may present a low average-power exposure but peak power exposures of killowatts per cm^2 or higher.

7. Mechanisms of interaction. If the mechanisms of interaction of radio-waves with biological systems were understood, then effects under a wide variety of conditions could be predicted. On close examination a large number of effects can be accounted for by assuming that the system is responding to additional heat input though not necessarily to an increased temperature. Experimental design should incorporate credible tests of whether the system is responding to additional heat loads. Only in this way can effects that may be due to other mechanisms be isolated. This involves, among other things, an understanding of both thermal and circulatory physiology. On a continuing basis, experimental and theoretical models of other modes of interaction need to be developed. Theoretical models should be amenable to experimental verification.

7.1 Determine the effects of heat on physiological processes associated with heat loading, including circulatory and hormonial aspects. Although a vast amount of research has been done on thermal physiology very little or none has been directed towards determining a critical localized temperature rise in tissue. The research to date

suggests that a small temperature rise in the body may result in behavioral effects, but a threshold for behavioral effects has not been established, nor has the relationship between other observed biological effects and temperature elevation in various systems. Such research could be done with or without the use of microwave radiation.

7.1.1 Determine the effects of heat as a function of organ and tissue type. This should be quantitated in energy deposited and temperature rise.

7.1.2 Determine the response of the system as a function of energy absorbed.

7.1.3 Expand the work of 2.1.2 so that models will be developed suitable for consideration of this work. These models should consider the dielectric and thermal properties of the norm of study.

7.2 Develop experimental and theoretical studies of other modes of interaction which can be used as screening systems.

7.2.1 Experimental physical interaction studies (e.g. spectroscopy). Develop methods of correlating physical interactions with biological responses. These methods should include dielectric, spectroscopic, and other physical measurements. One purpose of these studies is to identify frequency- and amplitude-specific responses; therefore, the work of section 6 should be considered.

Methods development should be followed by (and in some cases run concurrently with) intensive use of these methods in examining several biological materials. Existing methods for dielectric measurements, as well as newly-developed spectroscopic methods and other methods, should be used to examine simple systems (single molecules), semi-complex systems (such as biological water, i.e. bound water around that molecule), and complex systems (such as cells or membranes).

The established techniques of Raman and Brillouin scattering should be applied to investigations of living cells and biomolecules to better understand interactions in the infrared and millimeter-wave range. This should provide proper guidance to investigations in the radiofrequency and microwave range. These well-established techniques will lead to better theoretical models enabling one to predict and investigate mechanisms in the RF and microwave range. These results may also be directly applicable to microwave bioeffects involving multiple photon absorption.

7.2.2 Experimental biochemical interaction studies. In order to understand the complete mechanism of interaction one must not only understand the physical interaction process (i.e, how the electromagnetic wave interacts with the molecule, membrane, cell or system) but also the biochemical process leading from excitation to observed biological effect.

7.2.3 Develop non-perturbing, implantable physiological probes for monitoring temperature, cardiovascular parameters, brain wave activity, etc., in animals. Ideally, these systems would measure physiological parameters in live, unrestrained animals during exposure to radiofrequency fields.

7.2.4 Determine if interaction of RFR with biological water structure can cause changes in cellular physiology. Perform similar biochemical experiments when indicated.

7.2.5 Experimental biological interaction studies. Determine the mechanism of interaction of reported biological effects of RFR, such as effects on the central nervous system and drug-RFR interactions.

Biological effects which can be correlated with spectroscopic results or other physical measurements will be most important in establishing mechanisms of possible athermal interactions. Biological experiments should be designed to test any interactions which are suggested by the spectroscopic or physical results. Similarly, significant results from biological experiments might be tested by suitable biophysical means.

7.2.6 Theoretical studies of possible mechanisms of interaction. Parallel efforts of theoretical modeling are necessary for giving proper guidance to the experimental efforts discussed above. This work should provide predictions of absorption data for various systems, and provide better explanations of possible membrane or cellular interactions. Models with specific, experimentally verifiable predictions should be emphasized, including theoretical studies which attempt to develop a mechanistic basis for current phenomenological theories.

8. Multiple-frequency exposures. Most, but not all, of the intense exposures will be due to a single frequency or a small band of frequencies. What are the physical and biophysical considerations that need to be specified and what scheme will be used for assessing multiple-frequency exposure situations?

8.1 Perform theoretical calculations which expand the work discussed under 1 to determine the dose-rate and distribution of dose rate due to exposure to multiple frequencies.

8.2 Perform theoretical calculations to determine the modulation characteristics resulting from possible multiple frequency exposures which may be biologically significant (e.g., 16 Hz).

8.3 Perform exposures of biological systems to simulate common, multiple-frequency, field conditions.

9. Induced body currents. Especially for the lower frequencies, the concept of induced body currents may provide a better understanding or an easier way to control exposure. There is a need to relate induced body current, and its distribution, to dose rate.

9.1 Measure induced body currents in humans and human models exposed to radiofrequency fields.

10. Ambient climate ranges. It has been noted that radio waves and microwaves are but one source of heat input and it has been postulated that this heat source is more similar to metabolic heat than to externally applied heat. The interrelationship of these various sources of heat with ambient environmental conditions, e.g., temperature, humidity, air velocity, etc., needs to be characterized.

10.1 Determine, using animal studies, the relationship of an observed biological effect with temperature, humidity, air velocity and heat dissipation.

10.2 Determine, using animal studies, the relationship of an observed biological effect with workload.

10.3 Perform comparison studies of heat dissipation in animals and humans.

11. Relative tissue sensitivity. In the near-term we need information on whether certain tissues or organ systems are more sensitive to radiofrequency fields, either because of their sensitivity to increased temperature or their sensitivity to the dynamic physiological changes the system undergoes. In the long term, information is needed to determine the relative biological effectiveness as a function of frequency.

11.1 Determine the sensitivity of various tissues and organs to the RF fields as a function of exposure level.

11.2 Determine the sensitivity of various tissues and organs to RF fields as a function of frequency.

12. Exposed populations including sensitive populations: The response of the population to additional stress will not be uniform. It will be influenced by other factors such as age, circulatory disorders, state of activity (resting or exercising), and perhaps drugs and other factors. Assessing the impact of these factors may require different

approaches for occupational and nonoccupational settings. What are the factors that characterize specifically susceptible populations? These factors need to be determined.

Ascertainment of adverse effects of RFR seems a much more pressing need than determination of beneficial effects, and delayed adverse effects much more vital than acute adverse effects. Few delayed effects are unique--most have multiple causes. For these and other reasons, epidemiologic methods are needed to identify and quantify causes of such effects. Clinical studies are a desirable adjunct, but are impossible to apply retrospectively.

While experimental studies in man, when ethical, would be of unique value, reported studies are rare. As a consequence, one must resort to studies of real-life exposure ("experiments of nature") which rarely fit an ideal design.

In order to ascertain effects in man, one must combine experimental (mainly in non-human subjects), with case histories and epidemiologic methods.

Studies of human subjects are needed because

a. there are no satisfactory counterparts for some human disorders of major importance, particulary those affecting the psychological quality of life, and

b. the well-known difficulties of extrapolating from animals to man.

12.1. Conduct feasibility studies to determine the human populations exposed to significant levels of radio frequency fields, including Go He fields due to high-voltage electric transmission lines (HVTL).

a. Environmental populations.
b. Occupational populations.
c. Sensitive populations.

12.2. Perform epidemiological studies in those populations which are found to be exposed to significant levels of radio frequency fields, including HVTL fields.

12.3. Conduct prospective clinical studies of radiofrequency exposed workers (e.g., radar technicians, radio tower maintenance and repair workers, diathermy operators, microwave oven operators or repairmen, and RF sealer operators).

12.4 Conduct long-term studies of animals exposed to low-level RFR under conditions which simulate occupational or environmental conditions. Important biological parameters to be measured include effects on the developing embryo, immune defense

and hematopoietic system, central nervous system, behavior, chromosomes and possible cumulative effects on the lens of the eye and on the male reproductive system.

12.5 Conduct studies using animal models of human clinical conditions.

13. Specification of human exposure: Fundamental to any understanding of the potential harm or benefit from exposure to RFR is an accuracte characterization of the exposure fields and conditions.

13.1 Develop instruments for characterizing RF exposure fields for occupational and environmental settings (see 1.3, above).

13.2 Develop instrument calibration procedures and facilities.

13.3 Develop standard survey procedures and monitoring techniques with standardized reporting formats.

13.4 Perform field surveys on RF source emission and personnel exposure.

14. Control measures for device emission: Many sources including plastic sealers, induction welding devices, microwave instrusion detection devices, aircraft and marine radars require investigation via direct measurement of emissions. Also many communication devices, especially hand-held units have the potential for exposing law enforcement officials, security personnel, and the general public to high-level fields.

14.1 Product evaluation. More field surveys must be conducted by qualified laboratory personnel with an emphasis on spectral content, modulation, and polarization.

14.2 Product control. Standardized agency plans should be developed to deal with new or existing products which emit RFR. These plans should cover the agency's handling of a product starting with identification and continuing through evaluation, analysis, and control action. When new or unique exposure conditions require additional information, this fact should be communicated to the appropriate research components of the IRLG agencies.

14.3 Development of radiation suppression technique. The IRLG agencies should cooperate with industry to develop radiation suppression techniques for products with emission problems.

Mr. SWICORD. An explanation and summary of one of these objectives, the description of the "dose" delivered, maximum versus average dose rate to an experimental animal or a human, will exemplify this planning approach.

One of the present controversies surrounding the application of biological effects data from animal experiments to the development of exposure limits for humans is whether the average amount of energy per unit time delivered to the entire animal or the maximum amount of energy per unit time delivered to a selected organ or tissue area of the animal is the important consideration.

A quantity that has been recently introduced and is now being frequently reported in the literature is the specific absorption rate—SAR—an indication of the amount of energy absorbed by the exposed subject. The SAR is a more appropriate measure of exposure than the previous method of reporting the magnitude of the exposure field because the amount of energy absorbed by the subject is dependent on a number of factors, not only the incident field or power density. It also depends on the shape of the animal, its size in relation to the frequency of the radiation field, its orientation in the field, and the electrical properties of the animal tissue.

The absorbed energy is, moreover, not distributed uniformly throughout an exposed subject, and it is possible to have organ or tissue specific variations in absorbed energy throughout the body of several orders of magnitude. These variations and the locations of the maximum absorption will also vary with the parameters of size, shape, and orientation.

The question then is whether an observed and reported biological response is due to the whole body average SAR or is the response of a particular organ or tissue area to the maximum SAR. Answers to this question could result in a difference of a factor of 10 in regulatory standards. Such an issue demands a coordinated plan, which provides theoretical and experimental dosimetry, instrumentation development, development of specific exposure facilities, and the performance of biological experimentation under the specific condition of constant dose rate with special variation of the maximum dose rate. Thus, the plan directs basic and fundamental research towards specific needs.

This planning effort by the IRLG Committee has made clear the necessary qualifications needed for research direction. In order to design and coordinate a responsive research program there must be an understanding of both the standards setting process and the scientific problems of a research program that is responsive to such a process.

Fortunately, this capability does exist within the regulatory agencies, and the management of these programs should proceed in an orderly fashion.

Mr. Chairman, your letter of June 19 specifically requsted information about how the research needs of regulatory agencies differed from those of research institutes and user agencies. The major requirement for research in the area of microwave biological responses stems from the need to determine levels of safe exposure. Other areas such as beneficial applications are far less demanding at present.

Not surprisingly, therefore, the list of research requirements developed by a research agency are essentially the same as those developed by a regulatory agency. Indeed, the regulatory agencies submission to the National Telecommunications Information Agency formed the basis for the research agencies working committees plan with only minor changes.

Certain differences, however, do exist. For example:

The regulatory list will include the need for device emission investigations. The clarification of radiation emissions from products and devices and engineering methods of control are fundamental to the regulatory process. This information also directs us to the priority problem areas not only for regulatory action but for future bioeffects research considerations.

The research agencies want to emphasize the development of beneficial applications of nonionizing radiation. Although regulatory agencies share this concern, their primary interest is in assuring the safe development and use of medical products which may thereby reduce overall radiation exposure, and

The user agencies place greater emphasis on the need for including risk analysis in the research plan.

Prioritization of research needs and coordination of research for specific goals may be very different for different agencies. The coordinated regulatory plan that I mentioned earlier directs research toward regulatory needs, and thus serves the public interest by demanding that research programs be directed towards pressing public health problems.

Due to time constraints, the fourth objective of the IRLG Committee—to identify radiofrequency and microwave emitters and populations exposed—has not yet received our full attention.

The committee has, however, identified the industrial radiofrequency heatsealer as a high priority for regulatory action, and we have developed a plan of action as directed by our fifth objective.

The fifth objective of the IRLG Committee is to develop a coordinated control and corrective action plan in areas of overlapping jurisdiction.

Mr. Chairman, more than one regulatory authority can sometimes be applied to a particular radiation exposure situation, such as the case of a radiation-emitting product which is used for industrial purposes. The manufacture of that product can be controlled under the Radiation Control for Health and Safety Act administered by FDA, and the use of the product in the workplace can be controlled under the Occupational Safety and Health Act, administered by OSHA.

Due to the potential hazard of exposure to workers by radiation from radiofrequency sealers, the IRLG committee has selected this product as the first concern under this objective.

Radiofrequency—RF—sealers operate primarily in the 27.12 megahertz industrial scientific medical ISM band, although operating frequencies from at least 10 to 60 MHz have been observed. RF sealers have been produced for more than 30 years, and an estimated 5,000 are in use today. They generate an RF field originating from special electrodes which serve to heat, melt, and seal materials such as plastic and rubber. RF sealers are used in the manufac-

ture of many commercial products such as handbags, golf bags, shoes, et cetera, as well as in embossing and drying operations.

Several investigators from a number of different laboratories have performed measurements of the fields generated by these devices. Levels in excess of 2,000 volts per meter and 10 amperes per meter have been observed.

Although these levels are in excess of present guidelines issued by the American National Standards Institution, the paucity of biological effects information in this particular frequency range makes it difficult to take immediate regulatory action.

The problem is complicated because even if bioeffects experiments had been done at 27 MHz, the results might not really be useful. The degree of energy absorption by an animal in an RF field depends on the ratio of the size of the animal to the wavelength of the radiation. Humans absorb much more at 27 MHz than do small laboratory animals. We are trying to develop practical ways to correlate effects information between different frequencies and animal sizes, but the work is incomplete and presently relies on some unproven assumptions.

Although a comprehensive data base is not yet available, the IRLG committee feels that some workers are presently being exposed to excessive levels of radiation.

As a result, we have developed a plan of action entitled, "An IRLG Plan to Reduce Excessive Exposure of Operators to Radiation from RF Sealers," which calls for specific actions by FDA, OSHA and NIOSH. Upon completion of this plan, the product manufacturers and user manufacturers will have been made thoroughly aware of the problem and the technical methods for correcting it.

In addition, the agencies will have complete their required preliminary deliberations and investigations for any further regulatory actions deemed appropriate.

Mr. Chairman, this concludes my testimony. I would be pleased to respond to any questions you or members of the subcommittee may have.

Mr. AMBRO. Thank you, Mr. Swicord. Is it true that your research planning effort proceeds rather independently of the NTIA sponsored BENER task force?

Mr. SWICORD. Not independent totally. We are cooperating with that group. We, as a committee, are making the plans as we see those needs develop for the regulatory agencies. We are submitting our plans and our recommendations to the NTIA group.

In a sense, we are independent, yes, but we are cooperating.

Mr. AMBRO. Well, would you say then that you are cooperating with all other agencies who were, or are, involved in this kind of research?

Mr. SWICORD. In what sense do you mean the cooperation?

Mr. AMBRO. For example, are you cooperating with all other agencies by virtue of your cooperation with the BENER task force?

Mr. SWICORD. We are cooperating with them.

Mr. AMBRO. Maybe I should ask you how. You described it a bit, but in what specific form does that cooperation take?

How do you get with them?

What do you provide to them?

How do you coordinate what you are doing?

What are the mechanisms?

Are you fairly apprised?

Mr. SWICORD. All right, we are taking our plans and we are submitting them to the BENER task force. The BENER task force has met as a total working group I believe two times. The last time we took the plans from the IRLG to this BENER task force meeting and worked with the other agencies that were there, for example the research groups, in editing those plans.

The plans are different in some respects. The BENER task force plan originally followed the seven point outline of the previous OSTP recommendation of the research needs. This was a list of items which was very effective in listing research needs. However, from the IRLG committee's viewpoint we felt this list did not provide us the structure to coordinate the research programs to a specific regulatory need, so we restructured our list in terms of regulatory research needs and developed independent plans under that document. That document has also been submitted to the BENER task force committee. I am not sure what the procedures are for incorporating those comments exactly.

We have had informal feedback from the chairman of that committee.

Mr. AMBRO. Suppose you were interested, for example, in developing a standard. Who would you look to?

Mr. SWICORD. We have traditionally done that ourselves.

Mr. AMBRO. Could not the National Bureau of Standards help you in that regard?

Mr. SWICORD. We have, in the past, contracted with the National Bureau of Standards when we felt it was appropriate to develop a specific instrument as part of our program need.

Mr. AMBRO. You see, I ask these questions. I do not, however, ask the questions for the enjoyment of the audience or myself, and I am really interested in how fragmented these efforts are, if they are; and how insulated from each other they might be and whether or not they are coordinated and other concerns of that nature. I think that is the essence of these hearings and of the criticisms as well, and I do not know, but maybe you can comment on the general question of whether or not you think we could do a better job in the area of bringing these things together and minimizing the kinds of independence you talk about.

I think sometimes we cooperate more with the Soviet Union than we do with other agencies of the Government.

Mr. SWICORD. There is a degree of truth in that, Mr. Chairman. I feel that the whole area has been lacking in coordination. I think that there remains the question of how to cooperate and not compromise the regulatory functions and that is a difficult question for us.

In terms of the research needs, I think the regulatory agencies have to determine what their own research needs are in order to and respond to regulatory demands.

Mr. AMBRO. I think there is no question with respect to that, but as I said earlier, if you were here, we may be headed in the direction of developing a centralized reservoir for research efforts in some organization.

Mr. SWICORD. Right.

Mr. AMBRO. Which will, as the result of the identification of needs by the regulatory arms conduct research and bring together all of the agencies of Government that can do research in order to centrally coordinate all of this, so that the different needs of the different regulatory arms can be satisfied.

For example, there is no question that the needs of the FDA are different, in part, from the needs of OSHA or EPA, or other groups.

What do you think of that kind of a plan? That is what these hearings are all about.

Mr. SWICORD. Let me make myself clear. I think agency and interagency cooperation and coordination is needed and I think that an overall plan of attack of that type of coordination is definitely needed.

I am, at the same time, saying that the regulatory agencies have their particular needs and those particular needs are being coordinated and directed through the IRLG committee that has been formed and we will be glad to cooperate with any committee that has been established to do overall coordination. At the same time, I can not compromise the regulatory agencies' independent stance.

Mr. AMBRO. I do not think any research effort would be geared to compromising any regulatory arm. Research is there, in fact, to help them be more effective. That is my view of it, but here we are with efforts by EPA, NIOSH, NIEHS, BRH, the Air Force, the Army, NSF, CIA, DOE and if I missed perhaps four, so be it; and then we have a lot of pavlovia about the Interagency Regulatory Liaison Group, the BENER task force and things of that nature, but it seems to me if we really get into intensive questioning here, the left hand would not know what the right is doing. Trying to pull together all of these elements together—if we determine that the subject is significant enough to warrant that kind of an effort—is what this is all about.

I should not, of course, Mr. Swicord, use you as the sounding board for all of this, but let me be specific with one last question and I will turn to Mr. Walker.

You said in your statement, and maybe I missed the follow on, that it is the intent of IRLG member agencies to proceed with regulatory action on those problems already identified but how do you intend to do that?

You know, that is a large leap from the numerous concessions here that we know something, or a little more than something, but we have to know a lot more to get to the point where you are ready to proceed with regulatory action on problems already identified.

Are you suggesting by that statement that you have enough information and research and data to proceed with regulations?

Mr. SWICORD. Absolutely not. The statement, I hope, was preceded by a statement that said there was a strong lack of information.

Mr. AMBRO. It was preceded by, "Although the NAS study will take approximately 2 years to complete * * *." That is why I asked the question.

Mr. SWICORD. OK, an example is given in the written testimony, as to how we are trying to proceed to address one problem. The net problem was raised by Congresswoman Holtzman this morning in

here testimony, her concern for exposure of workers to radiofrequency.

We have developed a plan of action, which I have also introduced into the record, for us to proceed with the regulatory function of collecting the data to establish what means and manner in which we can control these devices with the possibility of establishing some sort of standard as the individual agencies see fit, and from that particular information.

If I might refer back to some ancient history and that is the microwave oven standard which has been referred to several times today. The microwave oven is a product that is being effectively regulated even though there is a great lack of information concerning the relative safety of microwaves. This is a product that is on the market which is being controlled and being used in the home. So effective measures can be and have been used, with judgmental factors, by the regulatory agencies in the control of radiating devices.

Mr. AMBRO. Suppose—and this is the last question—but I would like your opinion of the Congress legislating a standard.

Mr. SWICORD. The proposed 10 mW/cm^2?

Mr. AMBRO. Yes.

Mr. SWICORD. I think as regulatory agencies we would like to work with Congress on any type of deliberation that they wished to make in that regard.

I think that through IRLG deliberations we can respond to that question and go ahead and act in a responsible manner.

Mr. AMBRO. You see, and I will just make this as a comment, and you can say whatever you want in conclusion, but there are a number of us who are a bit sensitive about the ability of the FDA to act. Now, I am not one that attacks regulatory agencies. Without independent regulatory agencies the United States would have been raped a long time ago by those groups that the agencies were set up to control.

There is no question that in looking at some of the recent foot dragging by the FDA that one is less than sanguine about your ability to act in less than 5 to 8 years on anything, from a determination of whether something is carcinogenic to how much salt should be allowed in childrens' food, and as a result of all of that, I think legislating in this area would be a method of beating you over the head and saying, "Hey, if you won't do it, we will," and that will act as a kind of slap that is necessary to get things moving in this area. That is where I am headed at the moment.

Do you want to comment on that? If so, go ahead.

Mr. SWICORD. Well, I just want to say I am thankful that I am here today as a representative of the IRLG and not the FDA.

Mr. AMBRO. Mr. Walker?

Mr. WALKER. Mr. Chairman, I apologize for not being here earlier.

Mr. Swicord, my prime concern in this is the average consumer who is out there, many of whom are fearful of what they hear about the radiation hazard and the dangers of microwave and other radiation. It appears to me that this is an area where there is real concern on the part of the public.

I am wondering. How long do you think it is going to take to gather sufficient data to regulate? You talk about all of this, but what kind of timeframe are we talking about?

Mr. SWICORD. That is an excellent question. If research proceeds at the present rate, I think that we will be talking about another 10 years or so before we really are coming up with the type of answers that you are really addressing.

Mr. WALKER. Is there no way to speed up that process? I mean we are talking about the likelihood of ever more products coming into the marketplace and expansion of those which are presently in the marketplace.

We are really talking about a decade of that kind of marketplace impact without adequate research to regulate. Does that seem to you to be a reasonable type of thing?

Mr. SWICORD. No; it does not.

Mr. WALKER. Well, is there any way of speeding that up, of getting more research data on which to base some regulations?

Mr. SWICORD. You are asking this of me as an individual, not as a representative of the agency?

Mr. WALKER. Yes.

Mr. SWICORD. Yes. Increased funding in this area will increase the rate of return of information.

Mr. WALKER. Do you think increased funding is the answer?

Mr. SWICORD. Well, that is part of the problem, certainly, yes; that the rate at which research data is coming in now is slow and a part of that slowness is due to the level and effort of work that is currently going on and if we want answers at a faster rate, we are going to have to speed up the amount of research which means more funding.

Mr. WALKER. Let me make another suggestion. I assume you would agree with me that the various agencies involved in the research work have as their prime concern, the health and safety of everyone involved. Is that not a goal of sufficient importance that maybe we ought to end a lot of competition going on in the research and substitute for that, some cooperative research.

Mr. SWICORD. Absolutely.

Mr. WALKER. And thereby maybe get a little bit more for the dollars we are spending.

Mr. SWICORD. Absolutely.

Mr. WALKER. Does that not sound reasonable to you?

Mr. SWICORD. Yes.

Mr. WALKER. I guess my problem is, as I look at it, I am wondering how long in an area like this, where there is public impact and where it does appear there is going to be more public consumption of products, how long can we wait for rational regulation, because Congress in the meantime will do irrational regulation if there is enough public pressure out there. We have done that before, we get the public pressure and Congress simply regulates. It appears to me that this is an area having the potential for that if we look only a couple of years ahead.

I find it very disturbing when we talk about a decade.

Thank you, Mr. Chairman.

Mr. AMBRO. Mr. Swicord, we will hold the record open for written questions if you will be kind enough to respond to them.

I want to thank you for appearing.

[Additional questions, and their answers submitted for the record, follow:]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
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AUG 31 1979

Honorable Jerome A. Ambro
Chairman, Subcommittee on Natural
Resources and Environment
Committee on Science and Technology
House of Representatives
Washington, D. C. 20515

Dear Mr. Ambro:

This is in reply to your July 31, 1979 letter to Mr. Mays Swicord regarding your additional questions for the record of the July 12, 1979 hearing before your Subcommittee.

First, I should like to express my appreciation for Mr. Swicord's opportunity to testify on July 12, 1979 on behalf of the Interagency Regulatory Liaison Group (IRLG) Radiofrequency and Microwave Committee, and to summarize the relevant Food and Drug Administration (FDA) scientific activities. We are extremely gratified by your interest, and by that of Representative Holtzman. Your Subcommittee's hearings and Representative Holtzman's continuing efforts have helped to focus attention on the difficulties of dealing effectively with this topic of growing concern. Let me turn now to your questions.

Question 1: What are the immediate and long-range public health and safety problems associated with radiofrequency and microwave radiation and how can they be best addressed by the Federal Government?

Answer: The major practical public health and safety problems associated with radiofrequency and microwave radiation involve the workplace, consumer products, electric power generation and distribution systems and communications systems. Radiation problems in these areas are the responsibilities of the Occupational Safety and Health Administration (OSHA), the FDA's Bureau of Radiological Health (BRH), the Environmental Protection Agency (EPA) and the Federal Communications Commission (FCC), respectively, under existing legislative mandates.

As the specific characteristics of the actual problems in each of the areas cited above vary considerably, it will be most effective to proceed against individual problems under these existing mandates. There does not seem to be any important gap in the coverage of the problem areas by existing legislative mandates. There are

two remaining issues. The first is to make certain that the various problem-solving activities of these agencies stem from a common understanding of the health-risks of this form of radiation. The second is the coordination of the various programs to assure consistency of action, completeness of coverage of problem areas, reasonable ordering of priorities for action, etc.

Question 2: What is the charter and makeup of the IRLG Radiofrequency and Microwave Committee and how can its deliberations affect and coordinate agency programs to address these problems?

Answer: The IRLG Radiofrequency and Microwave Committee was formed in 1978. Former FDA Commissioner Kennedy's letter formally initiating that effort and stating the overall objective is enclosed. The agencies participating on this committee are:

The Food and Drug Administration
The Environmental Protection Agency
The Occupational Safety and Health Administration
The National Institute for Occupational Safety and Health
The Federal Communications Commission

In general, these agencies are represented on the Committee by working level or first level management individuals who are directly involved in the radiofrequency and microwave regulatory and research programs. The activities and recommendations of this Committee are brought to the immediate attention of upper level management, through the IRLG structure, and to intermediate management through the normal agency chain-of-command. This dual reporting process results in rapid management response on needed action items even though several agencies are involved.

Since its inception in September 1978, the IRLG Radiofrequency and Microwave Committee has sought to move quickly and decisively on those issues most in need of coordinated effort. We have formulated five specific objectives, and a comprehensive detailed set of specific guiding principles. These are contained in the document entitled "Radiofrequency and Microwave Radiation Protection: Elements of a Consistent IRLG Philosophy and Approach" previously submitted to the Subcommittee.

As an example of the effectiveness of the Committee, we have developed and implemented a plan for interagency action on the problem of excessive radiation exposure to operators of radiofrequency (rf) sealing and welding devices. A copy of that plan is enclosed. The public meeting to announce the interagency program and to discuss the problem with industry and labor will be held on September 12 and 13, 1979. A copy of the Federal Register notice of the meeting published in August 1979 is enclosed.

Question 3: What is the most effective way for the Federal Government to manage research on the biological effects of non-ionizing radiation to support action programs to solve the public health and safety problems?

Answer: The accelerating growth of the number of human exposure problems requiring investigation and, possibly, solution, coupled with the very large gaps in our understanding of the interaction of electromagnetic radiation in this frequency range with biological systems, require that the highest priorities be assigned to research programs that are application-and-goal-oriented. The first priorities are to evaluate needs to do something about specific problems and to provide criteria for acceptable solutions.

The IRLG Committee serves as a model for interagency cooperation and coordination on such applied research problems. The signed agreement of cooperation by the agency heads requires a coordinated effort by program administration and workers. It is our firm expectation that the Committee will provide an effective forum for addressing the numerous knotty research problems arising from specific regulatory needs. Through a regular series of meetings at different geographical locations, it has provided a forum for exchange of current research data and coordination of working-level research efforts. Such continuing research efforts relate to the safety or hazard associated with exposure. They arise from actions required by specific legal responsibilities, as distinct from more variable research programs, by user-and other nonregulatory agencies lacking specific legal responsibilities, as distinct from more variable research programs, by user-and other nonregulatory agencies lacking specific legal authorties or responsibilities.

Such applied research programs will identify those specific areas of biology and biophysics where basic research is most urgent. Basic research problems so identified can be addressed both by the research arms of the regulatory agencies and by research agencies, such as the National Institutes of Health, having expertise in areas of particular interest. The IRLG Committee provides an excellent vehicle for coordination of these efforts. We are developing a plan which will coordinate the research activities of all participating agencies in the direction of the regulatory concerns which have been defined by the Committee. By mutual agreement of the agencies, the final products of those activities will direct coordinated research and regulatory programs.

Finally, we are optimistic about speeding research answers by efficient coordination; but we recognize that the present resources of all involved agencies, with or without coordination, will not sustain any major increase in rate of progress.

Question 4: Are the quality and scope of the existing scientific literature on the biological effects of non-ionizing radiation adequate to permit derivation of estimates of human risk?

Answer: While there has been a slow accumulation of research data over the years, there are substantial variations in the quality of the work and very large gaps in coverage of the areas of interactions with biological systems and effects at the organ and organism levels. Consequently, it is not possible to derive estimates of human risk from existing literature.

There exist several surveys of this literature sponsored by various institutions. After careful consideration of these, the IRLG Radio-frequency and Microwave Committee was in overwhelming agreement that there remained an urgent need for analysis of the literature. It called for a comprehensive study which was not just an uncritical compendium summarizing reams of data of uneven (and sometimes doubtful) quality and reliability. Rather, we have sought a thoroughly critical review of world literature to clarify the true state of knowledge by separating the scientific wheat from the (considerable) chaff. Therefore, we have provided a detailed plan to the National Academy of Science (NAS) for a comprehensive, critical evaluation of the existing biological research literature.

Question 5: What role should the nonregulatory agencies play in addressing the health and safety problems?

Answer: There are roles for both regulatory and nonregulatory agencies. Research must have utility, and the practical and immediate problems are invariably the lot of the regulatory agencies. For this reason, the regulatory community should play a central role in developing comprehensive research plans. However, an efficient use must be made of the separate areas of specialized expertise of the user and research agencies and industry.

For example, while the National Bureau of Standards (NBS) provides no routine calibration service for instruments used to evaluate microwave radiation hazards, it does have considerable experience in microwave power measurements in waveguide and coaxial systems and proves excellent standards and measurement assistance for conducted and guided power. Using such NBS assistance, BRH scientists and engineers have developed an excellent standard microwave-radiation facility and, using it, have disseminated power density calibrations to state and local agencies and the appliance and instrument industry to facilitate accurate leakage measurements on microwave ovens.

NBS scientists have, in the past, laid down some of the basic principles of measurement of electromagnetic fields in the near fields of radiators, (the usual case in hazard evaluation) and have built some prototype instruments for such use. The state-of-the-art of implementation of these principles today, however, has progressed to the application of high technologies possessed only by industry and those Federal agencies (primarily the Department of Defense (DOD)) with specific responsibilities for device and technology development. For example, the BRH has contracted with the Collins Radio Division of Rockwell International Corporation for development of miniature probes employing thin-film thermocouples, and is presently involved with the Naval Research Laboratory in the development of a miniature probe employing optical microcircuit techniques. In each of these development efforts there has been input as to performance requirements, cooperation, and in some instances co-funding, from other regulatory agencies.

In summary, the problems facing all agencies dealing with the safety of applications of radiofrequency and microwave technology are so enormous that the assistance of every able agency will be required. The participation of the nonregulatory agencies will need to be coordinated to assure that prioritizations of effort are commensurate with public needs. As these needs are (or should be) most immediately perceived by the regulatory agencies, and are the responsibility of those agencies for resolution, the input of other agencies must be responsive to the requirements of the regulators. I believe that the IRLG Committee is the vehicle of choice to provide such identification of need and coordination of effort for the Federal Government.

I hope I have been able to shed additional light on some of the issues broached in the hearing. Please let me know, if you have additional questions.

Sincerely yours,

Robert C Wetherell Jr.

Robert C. Wetherell, Jr.
Associate Commissioner
for Legislative Affairs

4 Enclodures
Cy ltr Kennedy/Costle 8/1/78
Cy FR 8/17/79
Cy Memo Swicord/Heim 5/29/79
Proceedings of Conference 2/16-18/77

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

August 1, 1978

Mr. Douglas M. Costle
Administrator
Environmental Protection Agency
401 M Street, S.W.
Washington, D. C. 20460

Dear Doug:

We have all, I think, become aware that there is increasing public concern about the risks of exposure to nonionizing radiation in the RF/microwave part of the spectrum. This concern will likely be enhanced by a final GAO report on programs to safeguard the public from microwave-emitting products. A draft of this report includes the recommendation that OMB direct all of us to review the adequacy of existing exposure guidelines.

I realize that this is an area beyond our present agreement, but I don't see why we need to wait to be directed to work together in this area since we are already working effectively in another! There is clear need for a review of the adequacy of the 10mW/cm2 (ten milowatt per centimeters squared) exposure guideline. I would suggest that we might take the lead by coordinating, through IRLG, a review and analysis of the available data on RF/microwave exposure hazards. Having established such a position, we could then move toward specific and correlated actions in each of our areas of responsibility.

I invite your comments on this; my own suggestion would be that, if you agree, we invite the surrogates to synthesize an appropriate working group from among the four agencies to tackle this problem in the same fashion we have applied successfully to others.

Sincerely yours,

Donald Kennedy
Commissioner of Food and Drugs

cc:
Dr. James O. Pierce, II
✓Dr. Allen H. Heim
Dr. Marilyn Bracken
Mr. Don Clay
Mr. Colin Church
Dr. Edwin H. Clark, II
Ms. Carol Sanford

This letter has also been sent to: Dr. Eula Bingham and Ms. Susan B. King.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

48355

[Docket No. 79N-0314]

Radiofrequency Sealers, Heaters, and Gluers; Open Workshop

AGENCIES: Food and Drug Administration; Occupational Safety and Health Administration.

ACTION: Notice.

SUMMARY: The Bureau of Radiological Health (BRH) of the Food and Drug Administration (FDA) and the Occupational Safety and Health Administration (OSHA) announce an open workshop to discuss potential hazards to persons involved in the use of radiofrequency (RF) sealers, heaters, and gluers. Techniques for the control or elimination of hazards from such RF-emitting devices are also being sought.

DATES: The workshop will be held September 12 and 13, 1979, and will convene at 9 a.m. each day.

ADDRESSES: The workshop will be held at the Department of Labor auditorium, New Department of Labor Building, Second and Constitution Ave. NW., Washington, DC 20210.

Written supplemental comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Zory Glaser, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426; or

Frank Tipton, OSHA—OHP, Rm. N-3718, Department of Labor, Second and Constitution Ave., NW., Washington, DC 20210, 202-523-7174.

SUPPLEMENTARY INFORMATION: BRH and OSHA are concerned about potential adverse health effects on personnel exposed to RF energy emitted from RF sealers, heaters, and gluers. these RF-emitting devices are also known as: heat sealers, fusers, molders, fasteners or embossers; high frequency (HF) sealers or dryers; electronic or electromagnetic sealers or welders; and dielectric heaters. They are generally designed to operate at a frequency between 5 and 100 megahertz (MHz). Another class of electromagnetic radiation-emitting devices which operate at or near these frequencies include induction heating equipment.

NOTICE

Radiofrequency sealers, heaters, and gluers hazards; workshop

48355 48385

The open workshop is being scheduled to bring together users, manufacturers, Federal agency staff, employee representatives, trade associations, and others concerned with RF sealers, so that BRH and OSHA may benefit from their expertise, as well as to ensure that the present knowledge of the possible hazards of these devices is appreciated in the affected industries. Field measurements have confirmed that a significant number of personnel are exposed to high levels of RF radiation from these devices. Because the RF energy at these frequencies can penetrate deeply into the body without activating the heat sensors located in the skin, operators of such RF equipment may be unaware of exposures to the RF energy.

The workshop will cover topics important to the assessment and control of the possible hazards of RF energy from RF sealers, heaters, and gluers. The topics to be discussed are expected to include:

a. Measurement of electric and magnetic field intensities generated by these devices;

b. A brief review of biological effects at frequencies between 3 MHz and 100 MHz;

c. Explanation of the near-field conditions that are a part of these exposures, and the difficulty posed under these conditions in exposure measurement and in predicting possible adverse effects to persons so exposed;

d. A discussion of RF radiation measurement equipment and techniques;

e. Procedures or techniques available for control of RF emissions;

f. Possible initiatives of Federal agencies on the control of RF-emitting devices;

g. Technical aspects related to the use or application of RF heater-type equipment, and the possible resultant effects upon intended functions and unnecessary radiation emission; and

h. Other topics pertinent to the discussion of possible health hazards from RF equipment, particularly RF heaters, sealers, and gluers.

BRH and OSHA are anxious to gain information especially from users and manufacturers of RF sealers, heaters, and gluers, on the techniques for

DEPARTMENT OF LABOR

48335

Occupational Safety and Health Administration

Radiofrequency Sealers, Heaters, and Gluers; Open Workshop

Cross Reference: For a notice of open workshop issued by the Food and Drug Administration and the Occupational Safety and Health Administration to discuss potential hazards of using radiofrequency sealers, heaters, and gluers, see FR Doc. 79-25278 appearing in the Notices section of this issue.

BILLING CODE 4110-03-M

48336

measurement of emissions of such RF energy assessment of operator exposure to the RF energy, and the techniques and procedures for the control or elimination of stray RF emission from sealers, heaters, and gluers. Other relevant information is also solicited.

Several speakers from the involved agencies are expected to make short presentations on the above topics. Opportunity will be provided for comments and questions by any interested person. Persons wishing to present brief prepared statements should contact Zory Glaser or Frank Tipton by September 5, 1979.

As time permits, other persons present will be given the opportunity to make brief statements. This will be an informal open workshop, but a transcript will be made so that the maximum benefit may be derived from the workshop. Anyone wishing to submit written statements or other information relevant to the subject of this workshop for inclusion in the permanent record may do so at the workshop, or by sending it to the FDA Hearing Clerk (address above) by October 12, 1979. Written submissions should be clearly identified with the words "BRH-OSHA open workshop on RF sealers."

Although this workshop is not a hearing, and is not a part of any formal rulemaking, all the information and opinion submitted in preparation for, during or in response to this workshop will become a part of a permanent file for any new or modified rules that may be issued by either agency concerning RF heaters, sealers, and gluers.

Dated: August 10, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-25278 Filed 8-16-79; 8:45 am]

BILLING CODE 4110-03-M

U.S. CONSUMER PRODUCT SAFETY COMMISSION
U.S. ENVIRONMENTAL PROTECTION AGENCY
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION
DEPARTMENT OF LABOR

MEMORANDUM

SUBJECT: Interagency Cooperation

TO: Our Employees

After serious discussion, we have concluded that within our collective legislative mandates there are significant and exciting opportunities--acting as a team--to effectively control hazardous materials for the protection of public health. We have agreed to examine, assess, and redesign, if necessary, the processes by which we collectively regulate the chemicals which impact upon people and the environment. This will necessitate a serious look at the common requirements and functions of our agencies as they relate to the regulation of such hazardous materials and the initiation of a process by which our present interagency cooperative efforts can be improved, augmented, or modified as needed. We want to do everything possible to make the regulatory process more efficient for our agencies, for industry, and for the public.

We have directed the establishment of work groups to examine common:

- o standards and guidelines for testing and epidemiology
- o risk and safety assessment
- o information sharing
- o regulation development
- o compliance/enforcement
- o research planning
- o communication with the public.

Each of these work groups, which has our fullest support, is charged with building a strategy to implement one of these initiatives.

In spite of the fact that we are all overburdened, we want to urge you to lend your fullest support to this effort. We expect each of you to contact and work with your colleagues in the other agencies. We should

look upon it as pursuing the President's desire for more effective and more responsive government as well as meeting the mission of all four agencies."

S. John Byington, Chairman
U.S. Consumer Product Safety Commission

Douglas M. Costle, Administrator
U.S. Environmental Protection Agency

Donald Kennedy, Commissioner
Food and Drug Administration

Eula Bingham, Assistant Secretary
of Labor, Occupational Safety and Health Administration

I think this one is
extremely important!
Don

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Allen Heim, Ph.D.

DATE: May 29, 1979

FROM : Mays Swicord, Chairman
IRLG Radiofrequency and
Microwave Committee

SUBJECT: Plan to Reduce Excessive Radiation Exposure to RF Sealer Operators

The purpose of this memorandum is to request approval for a coordinated action plan to reduce RF sealer radiation.

Background:

One of the stated objectives of the radiofrequency and microwave committee, formed in October, 1978, is to develop a coordinated control and corrective action plan in areas of overlapping jurisdiction.

One significant issue which has come to the attention of this committee and requires coordinated action is the exposure of workers to fields emanating from RF sealer products. These devices nominally operate primarily in the 27.12 MHz ISM band, although operating frequencies from at least 10 to 60 MHz have been observed. RF sealers have been produced for more than 30 years, and there are an estimated 5000 in use today. They generate an RF field which emanates from special electrodes, and serves to heat, melt, and seal materials such as plastic and rubber RF sealers are used in the manufacture of many commercial products such as handbags, golf bags, shoes, etc., as well as in embossing and drying operations. Several investigators from a number of different laboratories have performed measurements of the fields generated by these devices. Levels in excess of 2000 V/m and 10 A/m have been observed.

Reviews of the available scientific literature have revealed a relative paucity of information regarding biological effects at the frequencies used by most RF sealers (i.e., 13 to 40 MHz). Nevertheless, such occupational exposure levels are substantially in excess of existing standards (or guidelines) for human exposure, and similar levels of exposure at other frequencies have been conclusively demonstrated to be hazardous to experimental animals. Moreover, the incompleteness of the present bioeffects data base does not obviate the responsibility

of the IRLG member agencies to provide the best possible assurance that workers and others are not exposed to unnecessarily hazardous levels of RF energy.

Recommendation:

The attached plan to reduce excessive exposure of operators to radiation from RF sealers has been developed by the committee (committee membership also attached). The intent of the committee is that the items listed on the plan be the primary responsibility of the designated agency. The designated agency will request help and advice from from others when needed or when appropriate.

We request that the surrogates consider this plan of action and forward to the principals for their approval.

Mays I. Swicord

Enclosures

IRLG MICROWAVE COMMITTEE

EPA	Phone #	Address
Dave Janes	427-7604	EPA - 9100 Brookville Rd. Silver Spring, Md. 20910
Joe Elder	8-629-2541	Experimental Biology Div. (MD-71) Health Effects Res. Lab USEPA Triangle Park, NC 27711
Fred Hodge	557-9380	Criteria & Standards Div., ANR-46 Crystal Mall #2, Rm. 1015 USEPA 401 M. Street SW Washington, D.C. 20460
OSHA		
Frank Tipton	523-7151	USDOL-OSHA-OHP Rm. N-3718 Washington, D.C. 20210
Bob Curtis	8-588-5896	OSHA Health Response Team 390 Wakara Salt Lake City, Utah 84108
FDA		
Alan Andersen	443-4006	HFX-140 12709 Twinbrook Pkwy, rm. 32 Rockville, Md. 20857
Morris Shore	443-2356	HFX-100 12709 Twinbrook Pkwy., rm. 2C Rockville, Md. 20857
Mays Swicord	443-3840	HFX-240 12721 Twinbrook Pkwy., rm. 703 Rockville, Md. 20857
NIOSH		
Dick Boggs	443-3680	Parklawn Bldg., rm. 8A-55 5600 Fishers Lane Rockville, Md. 20857
Zory Glaser	443-2100	Parklawn Bldg. Rm. 8A-30 5600 Fishers Lane Rockville, Md. 20857
FCC		
Will McGibbon	632-7060	Federal Communications Commission Rm. 7002 2025 M Street, N.W. Washington, D.C. 20554

AN IRLG PLAN TO REDUCE EXCESSIVE EXPOSURE OF OPERATORS TO RADIATION FROM RF SEALERS

Date	
Continuing	The IRLG Committee on Radiofrequency and Microwave Radiation works to develop recommendation for controling radiation exposure from RF sealers. Final recommendation due March 15, 1980.
Continuing	BRH (DEP) to continue development of RF radiation survey techniques for RF sealers, to come up with as simple, inexpensive, and useful an instrument package and procedure as possible. The techniques would be intended for use both by inspectors, and by sealer manufacturers and users. Survey procedures ready for field test due Sept. 15, 1979.
Continuing	BRH (DEP) to continue contacts with RF sealer manufacturers and users, to document the exact types of equipment already in use and now being manufactured, to document existing provisions made to shield against emission of unwanted RF radiation, and to document the difficulties encountered in applying and maintaining various types of protective shielding. Report on suppression techniques due December 15, 1979.
Continuing	OSHA to continue to respond to inquiries from employees and employers who are concerned about RF radiation. RF inspectors, surveys, and medical evaluations of exposed workers will be conducted as appropriate.
Continuing	In lieu of any court action to the contrary, OSHA to continue to enforce compliance with its present "should" standard of 10 mW/cm^2 (CFR 29.1910.97) and the far-field equivalents (200 V/m, 0.5 A/m) as an "interpretation" of 1910.97. If the far-field equivalents or the 10 mW/cm^2 standard are not upheld in court, OSHA will enforce compliance to levels of exposure recognized as definitely dangerous (e.g., 30 mW/cm^2 and the far-field equivalents) under the OSHA General Duty Clause (5(a)(1)).
Continuing	OSHA will increase its efforts in writing and promulgating new radiofrequency and microwave standards upon receiving the completed criteria document from NIOSH.

Date	
Continuing	The IRLG Radiofrequency and Microwave Committee will include in its coordinated research plan, projects that address dose rate and dose rate distribution resulting from exposure to non-uniform electromagnetic fields.
July 30, 1979	BRH (DOC) and OSHA collaborating through IRLG co-sponsor public meeting (a) to explore the need for corrective actions, (b) to examine the need for further performance (BRH) and exposure control (OSHA and State) standards, (c) to examine the state-of-the-art in survey techniques, (d) to examine the state-of-the-art in RF shielding techniques, (e) to discuss exposure control methods, (f) to describe the legal precedents for Federal and State actions, and (g) to determine training and information needs for all concerned Invited to the meeting would be the RF sealer manufacturers, users, representatives of State and Federal regulatory agencies, IRLG representatives, with participation by the Conference of Radiation Control Program Directors, labor unions, ANSI, etc. The proceedings of the meeting would be transcribed.
August 15, 1979	BRH (DOC) publish regulation naming RF sealers as listed products under 1002.61.
September 1, 1979	OSHA briefs its field staff on the hazards of industrial RF sealers and instructs its field offices to identify these sources within their jurisdiction.
September 15, 1979	BRH (DEP) drafts RFP for contract for survey instrument development.
November 1, 1979	BRH (DEP) forwards RFP for contract for instrument development.
December 1, 1979	NIOSH completes the development of good work practice document.
December 1, 1979	BHR (DEP) completes prototype survey procedure, ready for field test.

Date	
February 1, 1980	OSHA completes evaluation of BRH survey procedures and adopts a procedure for compliance purposes.
February 15, 1980	BRH (OEP) completes report on radiation suppression techniques.
March 1, 1980	OSHA will produce a training film to instruct compliance officers in conducting RF inspections.
March 1, 1980	OSHA orders survey instrumentation for each Regional Office (approximately 10 sets) and identifies facilities for maintaining and calibrating the equipment.
March 15, 1980	Complete IRLG recommendations for controlling radiation exposure from r.f. sealers and forward to member agencies.

Now I want to call up Dr. Stephen Gage, Assistant Administrator for Research and Development, Environmental Protection Agency.

STATEMENT OF DR. STEPHEN GAGE, ASSISTANT ADMINISTRATOR FOR RESEARCH AND DEVELOPMENT, ENVIRONMENTAL PROTECTION AGENCY; ACCOMPANIED BY DR. D. F. CAHILL, DIRECTOR, EXPERIMENTAL BIOLOGY DIVISION; AND FLOYD GALPIN, OFFICE OF RADIATION PROGRAMS

Dr. GAGE. Thank you, Mr. Chairman.

Once again, I am pleased for the opportunity to meet with you and your subcommittee members. With me is Dr. Daniel Cahill, Director of our Division of Experimental Biology and in charge of our nonionizing radiation research program located at the Health Effects Research Laboratory, Research Triangle Park, North Carolina and Mr. Floyd Galpin, Director of the Environmental Analysis Division, representing the Office of Radiation Programs.

Before Dr. Cahill addresses your specific questions, I want to share with you a brief progress report on our plans for the fiscal year 1980 public health initiative of which nonionizing radiation research is a part, since presenting it to you in my testimony on February 13.

You will remember that the Interagency Regulatory Liaison Group—EPA, FDA, CPSC, and NIOSH—determined that there were several common gaps in their research programs that were to be addressed through:

One. Development of tests that would allow us to rapidly and economically identify toxic pollutants.

Two. Refinement of techniques for conducting human population studies to confirm results of laboratory tests.

Three. The development of data on the movement of toxic pollutants through the environment which will allow us to better predict amounts reaching man.

In response, EPA proposed a cross-media initiative in health effects work that spans air, drinking water, nonionizing radiation and toxic substances.

The latter includes ecological effects work as it relates to pathways to humans. We anticipate the funding of this initiative and

are proceeding to plan the specific research that will be undertaken. These plans are currently being reviewed by our internal research committees to assure their applicability to agency requirements and are already being integrated into the laboratories' work plans for fiscal year 1980.

The nonionizing radiation research portion of the public health initiative for fiscal year 1980 is funded at $2 million and three positions. In addition, the base program for this next fiscal year is $930,000 and 26 positions. This base is $1 million less than fiscal year 1979 because a congressional add-on was not carried forward. However, the net result is that the program will have a $1 million increase in fiscal year 1980 with $2 million of the total resources being dedicated to the initiative.

Dr. Cahill will provide you with a brief overview of our nonionizing radiation research program. He will address your specific questions with responses which have been coordinated with the Agency's Office of Radiation Programs.

Dr. CAHILL. Thank you, Dr. Gage, and Mr. Chairman. EPA's nonionizing radiation—NIR—health effects research program is an activity of the Office of Research and Development. It is currently a $1.93 million, 26 man-year effort. In fiscal 1980, the President's budget requests an increase to $2.93 million and 29 man-years.

This program is, I believe, the largest intramural effort in nonionizing radiation health effects research in the country, and accounts for approximately 25 percent of the total Federal funding in this area.

The ORD program has developed an interdisciplinary team representing electrical engineering, physics, biophysics, behavior, immunology, teratology, and biochemistry. The individuals in the group conduct research within their respective areas of expertise as well as participating as a team in multidisciplinary studies of the health effects of prolonged exposure to NIR, particularly broadcast frequencies.

To complement this program in the development of a basis for Federal guidance, and provide the Agency with a broad view of the public health implications of NIR, the Office of Radiation Programs, or ORP, conducts environmental assessments. This activity involves a further investment of $350,000 and 9 work years.

The "health effects of nonionizing radiation" is an enormously broad category whether one considers what might be entailed in the words "health effects" or that "nonionizing radiation" covers frequencies from $1\text{-}10^{15}$ Hertz. No one document could hope to adequately address this broad an area in specific terms.

The research needs in this area were well defined in general terms by the Electromagnetic Radiation Management Advisory Council—ERMAC—in 1971. These needs have remained relatively unchanged throughout reassessments by Johnson in 1973, Guy in 1975, Elder in 1977, and the Office of Science and Technology Policy in 1978.

Thus, the OSTP report provides as valid a general statement of the research needs as any of its predecessors. It divides these needs into seven research categories:

One, instrumentation and dosimetry;

Two, mechanisms of interaction;

Three, long-term, low-level exposure studies;
Four, human studies;
Five, combination studies with other agents;
Six, biological effects studies; and,
Seven, beneficial applications.

These seven OSTP research categories provide a framework within which agency-specific research can be developed which would eventually lead to a sounder basis for regulatory decisions. In EPA's case, our specific research must primarily be relatable to the health effects of continuous, low-level exposure to broadcast and radar frequencies on human subpopulations of all ages under a variety of ambient conditions. This will require concomitant research on mechanisms and the instrumentation and dosimetry to support experimental and monitoring responsibilities.

It should be noted that although the documents I have referred to give general outlines for research, two efforts are currently underway to develop more specific plans. These are being conducted by the Interagency Regulatory Liaison Group—Radiofrequency and Microwave Committee, and a National Telecommunications and Information Administration—NTIA—task force.

From EPA's point of view, our unique problems associated with conduct of health effects research within the various OSTP categories would be:

One. The need to design and construct most of our animal exposure facilities because of lack of commercially available systems for use at frequencies of environmental significance.

Two. The need to relate our experimental research results to ambient conditions which involve exposure levels from nanowatts per square centimeter—$nW/cm^2 = 10^{-6} mW/cm^2$—up to tens of microwatts per square centimeter—$\mu W/cm^2 = 10^{-3} mW/cm^2$.

Three. The need to consider all age groups and particularly susceptible populations.

Four. The interactive efforts of NIR with various environmental factors.

In addition, we have problems in common with everyone else in:

One. Obtaining consistent experimental results at relatively low exposure levels.

Two. Establishing clear dose/response relationships.

Three. Determining correlation between the exposure to NIR and the internal distribution of absorbed energy in both experimental animals and humans.

Four. The differences in thermoregulatory mechanisms of animals and humans.

Five. Ignorance of the mechanism responsbile for effects at low levels.

Six. The identification of appropriate human study populations with reasonable exposure histories.

The mechanism with the highest probability of success for ensuring that a coordinated research plan is carried out is the professional respect and good will among the several Federal program managers.

In this respect, the small size of the Federal research community has been and is an advantage. The NTIA is serving as a focal point for the development of a coordinated strategy and like its predeces-

sor, the White House Office of Telecommunications Policy—OTP—it could provide a forum for the review and discussion of the Agency's programs and a clearinghouse for information.

The current concept of the NTIA role is one of coordination, not drection. The specific research needs of a regulatory agency will have to be fulfilled by that agency's research program with perhaps NTIA acting as a broker to obtain special assistance from other agencies. In fact, regulatory agencies do coordinate their programs through the existing IRLG committee. EPA's fiscal year 1979 effort is $1.93 million which includes a $1 million congressional add-on. In fiscal year 1980, the President's budget proposes $2.93 million. Our fiscal year 1979 budget breakdown in terms of the seven OSTP categories is as follows:

	Percent
Instrumentation/Dosimetry	15
Mechanisms of Interaction	11
Long-term, low-level exposure studies	22
Human Studies	3
Biological Effects Studies	30
Combination Studies	2
Beneficial Applications	0

The remaining 17 percent is in overhead.

We believe that our current efforts will provide the Agency with pertinent information that will be useful in the drafting of final recommendations for environmental NIR guidelines. Among these are indications of whether prolonged, low-level exposures to environmental NIR at and below 0.05mW/cm² is correlated with human cancer incidence rates; whether prolonged higher level exposure around 0.1mW/cm² correlates with any effect on human life span or cause of death; whether pre- and post-natal exposure to NIR has any bearing on infant mortality in monkeys; whether extended exposures to 0.5–5 mW/cm² under a variety of environmental conditions will affect the behavior of primates; whether prolonged, continuous exposures of rodents to 0.5mW/cm² affects any of a number of physiologic parameters.

The proliferation of literature reviews has little impact on current research efforts except that the area could use more researchers and fewer reviewers.

In the opinion of the EPA research group, results from the Soviet and East European literature must be viewed with skepticism, but cannot be rejected as out of hand. This opinion is based on the results of studies in this country that attempted to reproduce Soviet and Eastern European experiments. These U.S. studies have been conducted using more carefully designed protocols than those described by the original investigators. In most cases, they have not confirmed the Soviet and East European studies. One notable exception is the recent—and still unpublished—work by Dr. Lovely and colleagues at the University of Washington. This study examined the behavioral and clinical chemistry changes in rats exposed to 0.5mW/cm², 2450 MHz, 7 hours a day for 3 months. They have reported that their findings agree in part with some of the Soviet findings. It should be noted that Dr. Lovely spent several weeks in a Soviet laboratory observing their methods before beginning his work.

Concerning the range of current public health concerns, the use of NIR sources in industry, the healing arts, the home, and communications creates a variety of exposure scenarios.

Occupational exposures are largely restricted to certain ISM frequency assignments in the HF band. This applicaiton of RF sources involves electric and magnetic field exposures at levels approaching the equivalent of 100 mW/cm^2. The population at risk is, to a large extent, adult females who are on occasion pregnant and often of child-bearing ages, and adult males. These exposures are frequently at levels which are known to impose a thermal load on the body. Certain organs such as the eyes and testes and the developing embryo and fetus are particularly heat sensitive. Research needs for thermal loading are based upon how the body distributes and disposes of this energy. Normally, relatively high-level, short-exposure regimens can be used to obtain this information.

On the other hand, frequencies in the environment cover a wider range and generally provide much lower exposures to people in a continuum of age groups and health conditions. Based on measurements made at 486 different locations in 15 cities with a 1970 population of over 44 million, the median exposure in urban areas of the United States is $5 \times 10^{-6} mW/cm^2$, that is, 50 percent of the population is exposed to higher and 50 percent to lower levels. These exposure estimates do not include refinements which account for population mobility, exposures at heights greater than 6 meters, building attenuation or for periods of time when sources are not transmitting. In this case, the potenital health effects problem and the research needs they generate are associated with the question of the existence of mechanisms other than direct heating. Although the potential health risks of continuous, low-level exposure of the general population are the subject of intense concern by both the public, the Congress, and the scientific community, it should be recognized that there are no mechanisms known which could explain any effects under these conditions.

This situation creates a need for long-term investigations of chronic, low-level effects at frequencies of environmental significance as well as studies to delineate possible mechanisms of interaction.

Mr. Chairman, you have asked us to prepare summary sheets on our research program. These are attached, as are answers to your specific questions on our programs.

Mr. AMBRO. They will appear in our record. [The research summary appears in appendix 1.]

[The questions and answers referred to follow:]

Question 1

1a. How have the regulatory needs of ORP impacted on the research programs of ORD? 1b. and vice versa? Please give examples.

1a. The regulatory responsibilities of ORP include the development of generally applicable environmental guidelines for exposure to non-ionizing radiation (NIR). In order to begin to discharge this responsibility, ORP needs a definition of the ambient radio frequency (RF) environment, a working hypothesis on the mechanisms by which RF interacts with biological systems and an assessment of the health risks associated with continuous, very low level RF exposures.

ORP's monitoring activities over the past several years have provided valuable information on the ambient RF environment. Field studies and source evaluations have provided estimates of population exposure to continuous wave NIR. These studies led to the conclusion that the FM radio and UHF- and VHF-TV broadcast frequencies are the principle sources of population exposure to NIR.

When the information was relayed to ORD's research program, our response was to design, construct and calibrate two unique animal exposure facilities to operate in the FM band and near the UHF-TV band. This gave ORD the capability to provide ORP with biological effects data unavailable from any other program in the U.S. ORD then conducted interdisciplinary studies of the biological effects of prolonged exposures to RF of these frequencies. These studies have involved exposures of rodents daily from shortly after conception through young adulthood to 10 mW/cm^2 or the equivalent energy absorbed by a human exposed to 10 mW/cm^2. The biological end-points assessed included neonatal reflex development, the spontaneous and operant behavior of the young adult, immunologic, hematologic and genetic effects, and the reproductive performance of the adults.

We have also conducted research on the interaction of ambient temperature and microwave exposure levels on the behavior of rodents. This research has shown that these two factors interact to produce behavioral decrements greater than the sum of both factors alone. This has provided an experimental basis indicating that NIR exposure guidelines should consider a provision for establishing maximum exposure levels in concert with the ambient temperature humidity index.

Awareness of ORP's potential regulatory needs provided ORD with the stimulus in 1978 to support an epidemiologic study of the correlation between ambient RF emission density and the incidence of certain types of cancer in a metropolitan area.

(Question 1 continued)

Recent theoretical studies by ORP have suggested that the exposure of humans to the current NIR occupational exposure guideline of 10 mW/cm^2, which was established to protect against thermal overloading of the body, may in fact result in significant temperature rises in localized cirtical areas of the body at certain frequencies. This has implication for the thermal physiology of the body. ORD's response has been to identify one of the three additional FY 80 positions assigned to the non-ionizing radiation program under the Public Health Initiative for a thermal physiologist and to assign approximately 10% of our FY 80 resources to this area of research.

1b. ORD's impact on ORP's regulatory responsibilities cannot be fully assessed at this time. The Notice of Intent to develop NIR guidance has only very recently been issued by ORP and ORD's role in this process has not yet been specifically defined.

However, a long standing objective of the ORD health effects research program has been to try to determine within the constraints of animal research, whether the 10 mW/cm^2 exposure guideline was a good departure point for the development of population exposure guidance. After four years of research at and below 10 mW/cm^2 the results have provided both our researchers and ORP with indications that 10 mW/cm^2 does not provide an adequate safety margin in certain frequency bands.

ORD has provided ORP with experimental data on the biological effects of chronic $\leq$10 mW/cm^2 exposure to frequencies of environmental significance.

Within the context of the FY 80 Public Health Initiative, ORD's health effects research program is committed to provide ORP with $75,000 to enhance the pulsed RF monitoring equipment to more completely define the U.S. ambient RF environment, $25,000 for the refinement of population exposure models and $50,000 to provide the Regional Radiation Representatives with basic NIR monitoring equipment.

Question 2

2a. OMB cut 2.0 million from the EPA budget request for FY80. What impact will this cut have? 2b. What specific projects won't be funded? 2c. What is the highest priority unfunded research project and why?

2a. The initial ORD request for an FY80 Public Health Initiative in Nonionizing Radiation Health Effects was for 4.0 million. The main elements of the initiative were:

a. Increased epidemiologic studies to evaluate the health effects of exposure to environmental levels of NIR.

b. The conduct and support of health effects research directed towards an assessment of the environmental impact of DOE's Satellite Power System (SPS).

c. The conduct and support of animal toxicologic studies of low level exposures.

d. Dosimetry modeling and measurement.

e. Preparation of a document summarizing and analyzing current knowledge of the bioeffects of microwave radiation.

The impact of the 2.0 million cut will be minimized by shifting the burden of the conduct and support of SPS-related health research largely to DOE. We will also proceed more slowly into the area of population studies by building upon information to be derived from ongoing epidemiologic studies and through advanced identification and characterization of potential study populations.

2b. The initiation of pilot epidemiologic studies of appropriate populations identified and characterized in an FY80 study would be delayed until FY81 or later. The specifics of these projects are contingent upon the results of the FY80 studies. We will not be able to conduct interdisciplinary studies of continuous, low level exposures to the SPS-specific frequency of 2450 MHz on animals or support ecological studies of the effects of exposure to NIR.

2c. At the time of submission of the request for 4.0 million, the planning had not advanced to the point of identification of specific projects.