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A Study of Federal Microwave Standards

August 1980

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Prepared for:
U.S. Department of Energy
Office of Energy Research
Satellite Power System Project Division
Under Contract No. AC01-79ER10041

DOE/NASA
Satellite Power System
Concept Development
and
Evaluation program

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ABSTRACT

Present and future federal regulatory processes which may impact the permissible levels of microwave radiation emitted by the SPS Microwave Power Transmission (MPTS) have been studied. An historical development of U.S. occupational and public microwave "standards" includes an overview of Western and East European philosophies of environmental protection and neurophysiology which have led to the current widely differing maximum permissible exposure limits to microwaves. The possible convergence of microwave standards is characterized by a lowering of Western exposure levels while Eastern countries consider standard relaxation. A trend toward stricter controls on activities perceived as harmful to public health is under way as is interest in improving the federal regulatory process. Particularly relevant to SPS is the initiation of long-term, low-level microwave exposure programs. Coupled with new developments in instrumentation and dosimetry, the results from chronic exposure program and population exposure studies could be expected within the next five to ten years. Also discussed is the increasing public concern that rf energy is yet another hazardous environmental agent.

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The organizations and individuals listed are for identification only, and do not represent an endorsement of the findings and conclusions of this report.

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LIST OF EXHIBITS

GLOSSARY

Cardiovascular: Pertaining to the heart (cardio-) and blood vessels.

Cataract: An opacity of the lens of the eye or its capsule. The term is general; there are many types of cataracts, classifed according to appearance, cause, or location (capsular vs. lenticular).

Continuous Wave (CW): Refers to an unmodulated electromagnetic wave. When a wave is abruptly turned "on" and "off," the resulting burst is referred to as a pulsed wave. The Satellite Power System (SPS) Reference Design is configured to operate at continuous-wave, 2,450 MHz frequency.

Diathermy: The therapeutic use of high-frequency electrical current to generate heat in some part of the body.

Dosimeter: A device that measures and indicates the amount of radiation absorbed.

Electromagnetic Energy: A form of energy, both man-made and natural, with electrical and magnetic properties. Electromagnetic energy includes ionizing radiation, x-rays, ultraviolet and visible light, microwaves, radio waves, heat, and electricity.

Electromagnetic Spectrum: The entire range of wavelengths or frequencies of electromagnetic radiation extending from gamma rays to the longest radio waves and including visible light.

Electron: A subatomic particle with a negative electrical charge.

Frequency: As used to describe electromagnetic energy, the frequency of an oscillating wave is the number of cycles that occur in one second, measured in hertz. One hertz equals one cycle per second.

Gigahertz: Or 1,000,000,000 hertz, a measure of radio wave frequency. Conventional electricity in the home has a frequency of 60 hertz. The proposed SPS operating frequency is 2.45 gigahertz, or 2,450,000,000 hertz. Microwave ovens also operate at gigahertz frequencies. Also see "frequency."

Gigawatt: Or 1,000,000,000 watts, a measure of electrical power.

Hematology: A branch of biology dealing with blood and blood-forming tissues.

Hertz (abbrev., Hz): The cyclical rate at which a wave of energy rises from zero to maximum in the positive direction, falls past zero to reach a maximum in the negative direction, and then returns to zero; equivalent to frequency in cycles per second.

Immunology: A branch of biology dealing with immunity to disease and the ability of the body to respond to and destroy or reject foreign substances introduced into it.

Ion: An atom, group of atoms, or molecule that has a net positive of negative electrical charge.

Ionizing radiation: Radiation capable of producing ions by adding electrons to, or removing electrons from, and electrically-neutral atom, group of atoms, or molecule.

Joule: Under the International System, the basic unit of all forms of energy. As a thermal unit, one joule equals 0.239 calories. Since the calorie is defined as the energy required to heat one gram of water from 4 to 5^{o} C, 4.184 joules is the equivalent of one calorie.

Kilo: Prefix denoting thousand(s), i.e., 1000 or 10^3.

Mega: Prefix denoting million(s), i.e., 1,000,000 or 10^6

Microwave: Denotes the range of frequencies (0.3 to 30 gigahertz) used for radar and space communications. The Satellite Power System (SPS) utilizes a microwave power transmission system (MPTS).

Milliwatts per square centimeter: A commonly used measure of electromagnetic energy flow, called power density. It is most often used to measure energy transmitted by microwave systems and to identify microwave exposure levels for biological effects experiments.

Modulation: When a continuous series of waves of electromagnetic energy is modified by pulsing, or by varying its amplitude, frequency, or phase, the waves are said, respectively, to be pulse-, amplitude-, frequency-, or phase-modulated. In order to convey information by radiating electromagnetic energy, it must be modulated. See "Milliwatts per square centimeter."

Neurasthenic Syndrome: A physical and psychological state with symptoms of neurasthenia. Neurasthenia is a vague term, and may refer to one or more of a number of symptoms (fatigue, weakness, headache, sweating, ringing of the ears, dizziness, fear, poor memory, inability to concentrate, insomnia, various aches and pains, etc.) for which no underlying disease process can be identified.

Nonionizing Radiation: Radiation not normally capable of dissociating atoms or molecules into charged particles.

Power Density: The quantity of electromagnetic energy that flows through a given area per unit of time. Formally, power density is specified in watts per square meter (W/m^2), but by tradition it is usually expressed in milliwatts per square centimeter (mW/cm^2). The power density of energy that is radiated by a source is technically termed "radiance," while that of energy incident on a body is termed "irradiance." In common usage, power density if synonymous with "irradiance," i.e., is it taken to mean the time rate at which electromagnetic energy is incident on a body per unit of surface area.

Radio Frequency (rf): Any frequency between normally audible sound waves and the infrared light portion of the spectrum, lying between 10 kilohertz and 1,000,000 megahertz.

Reticulohistiocytic System: A little-used synonym for the reticuloendothelial (RE) system. The RE system refers to cells of several types throughout the body having phagocytic ability. A phagocyte is a cell with the ability to ingest (engulf) and destroy or carry away particulate substances. The system is involved in blood cell formation and destruction,

storage of fatty materials, the metabolism of iron, and also plays a role in inflammatory responses and immunity.

Specific Absorption Rate (SAR): The quantity of electromagnetic energy that is absorbed by a body per unit of mass during each second of time; expressed formally in watts per kilogram (W/kg); often, informally, as milliwatts or watts per gram (mW/g or W/g). "Specific Absorption Rate" is being considered by the National Council on Radiation Protection and Measurements as the official nomenclature for expressing the dose rate of radio-frequency electromagnetic radiations. Synonymous with (energy) dose rate, q.v.

Teratology: A science dealing with the study of abnormalities in the anatomic development of the fetus.

Glossary adapted from Preliminary Environmental Assessment for the Satellite Power System (SPS), Revision 1, DOE/ER-0036/1, January 1980, and Compilation and Assessment of Microwave Bioeffects, PNL-2634 (Rev.), May 1978.

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EXECUTIVE SUMMARY

Standards for permissible exposures to microwaves used throughout the world vary several orders of magnitude. Most of the Western world, with little alteration, has adopted microwave exposure standards originally set by the United States. The U.S. "voluntary" guidelines of 10mW/cm^2 evolved from events as early as the 1920's, stimulating research in the 1930's and 1940's on "thermal" effects of radio frequency (rf) radiation as a therapeutic technique. In the 1950's, prompted by reported ill-effects in radar workers, research was expanded to determine permissible levels of microwave exposure to the human.

Soviet and East European microwave exposure levels are based primarily on reported "non-thermal" effects on the central nervous system (CNS) and behavioral responses. Bolstered by epidemiologic studies, microwave exposure standards for most East European and Soviet bloc nations are founded on established limits set by the U.S.S.R. Soviet occupational and public microwave standards are considerably more stringent than comparable U.S. values.

To a large degree, discrepancies between Eastern and Western microwave standards are due to contrasting philosophies. For the U.S. the concept of risk/benefit criterion has been accepted, involving use of an adequate safety margin below a known threshold of hazard. On the other hand, Soviet and most East European microwave standards are based on a "no effect" philosophy—all deviations from normal are hazardous. Yet to be determined, however, are definitions of what connotes a "hazard" or "adequate" safety margin in terms of microwave exposure.

Historically, for the U.S., development of radar technology used in World War II led to reports of bioeffects among military personnel, with studies ordered to analyze the impact of microwave radiation on the human. A 10mW/cm^2 level, as a microwave protection guide, was initially proposed in 1953 by a biophysicist, Dr. Herman Schwan. This value was established from theoretical calculations on the amount of exogenous thermal loading that can be tolerated and dissipated by the body without a harmful rise in body temperature.

The four-year Air Force Tri-Service program, starting in 1957, verified biological damage from exposure to 100 mW/cm^2 of microwave radiation. A factor of 10 was considered a reasonable margin of safety, giving birth to the concept of 10 mW/cm^2 as a standard.

Upon the recommendation of the American National Standards Institute (ANSI), the 10 mW/cm^2 value was adopted and promulgated as an Occupational Guideline by the Department of Labor's Occupational Safety and Health Administration (OSHA) in 1971.

Presently the lead federal agencies with regulatory responsibilities for microwave radiation are the Department of Health, Education and Welfare (HEW)*, the Department of Labor (DOL), and the Environmental Protection Agency (EPA). Each of these agencies contains specialized subsidiary offices, research, or advisory bureaus to assist in establishing and enforcing microwave regulations.

The Food and Drug Administration (FDA) within HEW is responsible for protecting the public from potential health hazards of electronic products that emit radiation. The FDA's Bureau of Radiological Health (BRH) exercises the regulatory authority given to HEW in the microwave radiation area. Several nonionizing radiation product standards have been established including microwave ovens and lasers. The microwave oven performance standard is perhaps the only example of an unambiguous mandatory national standard regarding microwaves. Presently the FDA is developing performance standards for microwave diathermy units, and dielectric units. HEW's subsidiary, the National Institute for Occupational Safety and Health (NIOSH) is preparing a criteria document on rf and microwave radiation hazards for consideration by OSHA.

The Department of Labor's Occupational Safety and Health Administration (OSHA) regulates radiation levels in the workplace. Mandatory standards, however, do not exist and OSHA's Radiation Protection Guide is considered as only advisory.

Regulating radiation levels in the environment is the role of the Environmental Protection Agency (EPA). At this time, the United States does not have an environmental standard for protecting the general public from nonionizing radiation exposure. EPA's Office of Radiation Programs (ORP) and Office of Research and Development (ORD) assist in developing suitable environmental regulations. EPA is presently developing federal guidance for the protection of the environment from electromagnetic radiation, with final federal guidance anticipated in the fall of 1981. A future trend is the increased involvement of EPA in establishing environmental radiofrequency exposure guidance.

The Federal Communications Commission (FCC) has initiated a Notice of Inquiry attempting to determine its future regulatory responsibilities relating to the biological effects of radiofrequency radiation. The Inquiry is designed to determine whether it is appropriate for the FCC to take any action under existing standards now applied by the

* In 1980, the Department of Health, Education and Welfare is to be changed to the Department of Health and Human Services.

health and safety agencies. In addition, the FCC would like to ensure that any standards adopted adequately take into account the impact of any proposal on the licensees and equipment it is now regulating.

In administrating microwave rulemaking, each regulatory agency is subject to procedures outlined in the Administrative Procedure Act of 1946. Notice and Comment rulemaking allows for the public, public interest groups, industries, other federal agencies, and state and local governments to participate in the process of creating, modifying, or amending a rule.

The entire federal regulatory process is presently under review, aimed at streamlining and improving the system. Proposed changes include a Committee on Regulatory Evaluation to oversee the regulatory efforts of all agencies. The regulatory changes would also require each new ruling with an economic impact of more than $100 million to consider alternatives to the ruling, including projected costs and benefits of the proposal. For SPS, these regulatory changes would demand an assessment of microwave health effects and a cost and benefit analysis of SPS-derived energy weighed against non-SPS energy sources. In general, there is a continuing and growing trend toward stricter controls on activities perceived to be harmful to public health.

In reforming the regulatory process, increased public participation can be expected, with "intervenor funding" available for public involvement. New channels for public participation in regulating microwaves could have an impact on SPS, depending upon citizen attitudes regarding microwave radiation. Such channels would be open to pro-SPS space advocates as well.

A bill (S. 1938) is now before the Senate calling for effective coordination among the various federal agencies involved in radiation protection. Central to the bill is establishment of a Federal Council on Radiation Protection, with the Administrator of EPA as chairman. Functions of the Council include reviewing the authority of any federal agency in regulating human radiation exposure standards. In addition, a Presidential Executive Order in February 1980 established a Radiation Policy Council to coordinate the formulation and implementation of federal radiation policy. This Council, among other responsibilities, will assist in resolving conflicts in jurisdiction among federal agencies that deal with radiation matters. Although the Council will initially concentrate on ionizing radiation policy, a broadening of its activities is likely to include nonionizing radiation policy.

Several groups coordinate and provide reviews of the multiagency activity in nonionizing radiation research and regulation. In particular, the Interagency Regulatory Liaison

Group (IRLG) provides intragovernmental coordination, attempting to lessen overlapping agency jurisdiction in regulatory matters.

There is a trend toward the convergence of microwave standards worldwide, characterized by a lowering of Western exposure levels while some East European countries consider a relaxation of their standards. It should be noted, however, Canada has recently proposed a reduction in its former 10 mW/cm^2 exposure limit (identical to the U.S. guideline) to 5 mW/cm^2 (1-300 GHz frequency range) and 1 mW/cm^2 in the 10 MH_z-1 GHz frequency range. Cooperative exchange programs and an increasing dialogue between countries and scientists have contributed to a better understanding of methodology, experimental techniques, and basis used to develop standards.

The United States is now reviewing its 10 mW/cm^2 guideline for microwaves and other rf electromagnetic (RFEM) radiations. The trend for recommended occupational and public exposure limit appears to be downward and to be frequency dependant. Recommended exposure limits could be reduced to levels between 1 mW/cm^2* and 5 mW/cm^2, at microwave frequencies, but economic impact upon the workplace should be evaluated. However, there is the option to better monitor exposure to radiation in the workplace and to specify additional controls in that limited environment.

The need for additional research is central to adopting public and workplace standards. Of particular relevance to SPS is the initiation of programs of long-term, low-level microwave exposure. Coupled with new developments in instrumentation and dosimetry, the results from chronic exposure programs and population exposure studies could be expected within the next five to ten years.

Public interest in microwave, and other rf radiations is on the increase. Public concern that rf energy is yet another hazardous environmental agent is sparked by increasing media attention to the topic. In the absence of definitive scientific data on electromagnetic bioeffects, discussions of utilizing microwaves may engender all the rhetoric, pro and con, that surrounds the implementation of nuclear power.

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*This reduction to 1 mW/cm^2 is only likely in the 10 - 400 MH_z frequency range.

1.0 INTRODUCTION

The U.S. Department of Energy and the National Aeronautics and Space Administration are investigating a potential source of energy called the Satellite Power System (SPS).[1] [2] The SPS concept involves placing a satellite equipped with large solar cell arrays in orbit around the earth. The arrays collect solar energy and convert it to electricity, which is then converted to 2,450 MHz continuous wave (cw) microwaves. This unmodulated electromagnetic wave is beamed by a transmitting antenna to a receiving antenna located on the ground. The receiving antenna, or rectenna, changes the microwaves back into electricity. The system is designed so that each rectenna will provide 5,000 megawatts to the utility grid for industrial and domestic use.

An SPS rectenna site measures 17 km x 13 km, which includes a 2-km "buffer zone." Approximately 23 milliwatts per square centimeter of microwave energy would be received at the center of the rectenna, diminishing to 1 milliwatt per square centimeter or less at the edge of the rectenna[3]. Use of the buffer zone lowers the microwave power density to 0.1 mW/cm^2 at the edge of the buffer.

Microwave radiation is a form of radio frequency electromagnetic energy (RFEM), generally defined as bands of frequencies in the RFEM spectrum that extend from 300 to 300,000 megahertz (MHz). A hertz (Hz) is a unit of frequency equal to one cycle per second. A MHz is one million cycles per second. Microwave radiation in these bands have wavelengths that range from one meter (100 centimeters (cm)) to 1 millimeter (mm), which is 0.1 cm.

All life is constantly exposed to various kinds of electromagnetic radiation. These include visible light, infrared, ultraviolet, radiowaves, lasers, ultrasound, x-rays, gamma rays, and cosmic particulate radiation. The general types and sources of major electromagnetic radiations are summarized as follows[4]:

Wave Type	Common Source
Radio (including microwaves)	Radar, radio, and TV transmitters
Infrared	Hot objects
Visible	Hot objects; excited molecules
Ultraviolet	Sun; hot objects; excited gasses
X-rays	Atoms struck by high energy particles; cosmic sources

Electromagnetic radiation affects living organisms essentially in two ways:

(1) Radiowaves (including microwaves), infrared, visible, laser, and ultraviolet radiations cause molecular oscillations and excitations which result mainly in heating. These sources of radiation normally do not dissociate atoms or molecules into charged particles or ions, however. Damage, if it occurs, is usually a result of increased temperature. For this reason, these types of radiation are commonly referred to as "non-ionizing radiation." It should be noted, however, that higher wavelengths of ultraviolet radiation can ionize tissues.

(2) X-rays, gamma rays, and cosmic particulate radiation penetrate biological tissues with greater energies than the non-ionizing radiation; in so doing, they may cause breaks in the genetic material, inducing a positive or negative charge in a formerly neutral atom or molecule. The principal means by which x-rays and gamma rays transfer energy in matter is by absorption of this energy by orbital electrons from atoms. The removal of one or more of these orbital electrons is called "ionization." For this reason, these types of radiation are commonly referred to as "ionizing radiation."

Not every interaction between ionizing radiation and matter may result in ionization. Excitation, a less drastic process than ionization, may also occur. Here, an electron in an atom is raised to a higher energy state in that it is shifted to a more distant orbit from the nucleus of the atom but not ejected from the atom. Excitation is probably responsible for a significant percentage of the energy absorbed from ionizing radiation. Both ionization and excitation are responsible for the biological damage produced by ionizing radiation.

There are basic dissimilarities between the biological effects of ionizing and non-ionizing radiation. At present, non-ionizing radiation effects are believed to be, for the most part, short-term, acute, and somewhat reversible in nature. For example, radiowaves and microwaves from radar, TV, microwave ovens, and radio sources can cause tissue heating at sufficiently high power intensities. Tissue heating may result in temporary or permanent destruction or injury of the tissue or organ affected. A common type of microwave injury is cataract formation in the eye due to thermal injury to the lens.

At present, there is dispute regarding the possibility that radiowave and microwave radiation may have subtle but deleterious effects at power levels below that which cause gross heating of biological tissues. The controversy is fueled by experimental and clinical findings in the Soviet Union, Eastern European countries, and, most recently, the United States, which indicate that various organisms, including the human, are possibly sensitive to low-level (presumably non-thermal) radiation. Thus far, it has been difficult to find

agreement among investigators on the chronic effects of exposure to low-level microwave radiation below which no damage will occur.

The biological effects of ionizing radiation are somewhat better understood than those of non-ionizing radiation. In the field of radiological health, four categories of effects of ionizing radiation on human beings are generally described. Changes caused by this type of radiation are usually discussed in terms of: (1) acute effects caused by relatively large doses; (2) chronic effects caused by repeated, intermediate level doses; (3) large population effects resulting from exposure to repeated or sustained small doses and examined in terms of population statistics; (4) genetic effects of small doses on large populations which are manifested in future generations, again discussed in terms of changes as measured by population statistics. Of these four methods of examining effects, the first three involve direct injury to body cells (somatic effects). The consequences of such injury may be immediate (nearly instantaneous death of cells) or delayed for months or even years. Delayed effects from small or intermediate doses of radiation are commonly expressed as cancer. Leukemia is a frequent consequence of a delayed low-level ionizing radiation effect. Genetic effects are produced when the reproductive cells are damaged, causing mutations which are passed on to progeny.

Despite the fact that many aspects of the biological effects of ionizing radiation remain unclear, experimental observations have resulted in certain widely accepted concepts, including the following:

1. All living cells are subjected to change (usually undesirable) by being exposed to ionizing radiation.

2. The amount of change is related to the amount of radiation exposure and is usually proportional, although it is not known to what degree this relationship extends in very low doses approaching background levels. For genetic materials, there is a general and growing belief that there is no threshold of doses below which genetic damage will not result.

3. Living cells have a relatively higher biological response to highly ionizing particles (neutrons, alpha particles, protons, etc.) having higher rates of linear energy transfer (LET) than the more common x-rays, gamma radiation, and beta particles.

4. Some biological effects of radiation are subject to recovery, others are not. Recovery is probably attained by the elimination of damaged cells or products of radiation at a higher rate than the damage is sustained or increased by the reproduction of damaged cells.

The electromagnetic spectrum, its wavelengths and frequency ranges, are depicted in exhibit 1. The RFEM spectrum and typical uses are depicted in exhibit 2.

In determining effects of microwave exposure, power density is the parameter most commonly used to index the relative capacity of RFEM radiation to produce an observable effect on biological materials.

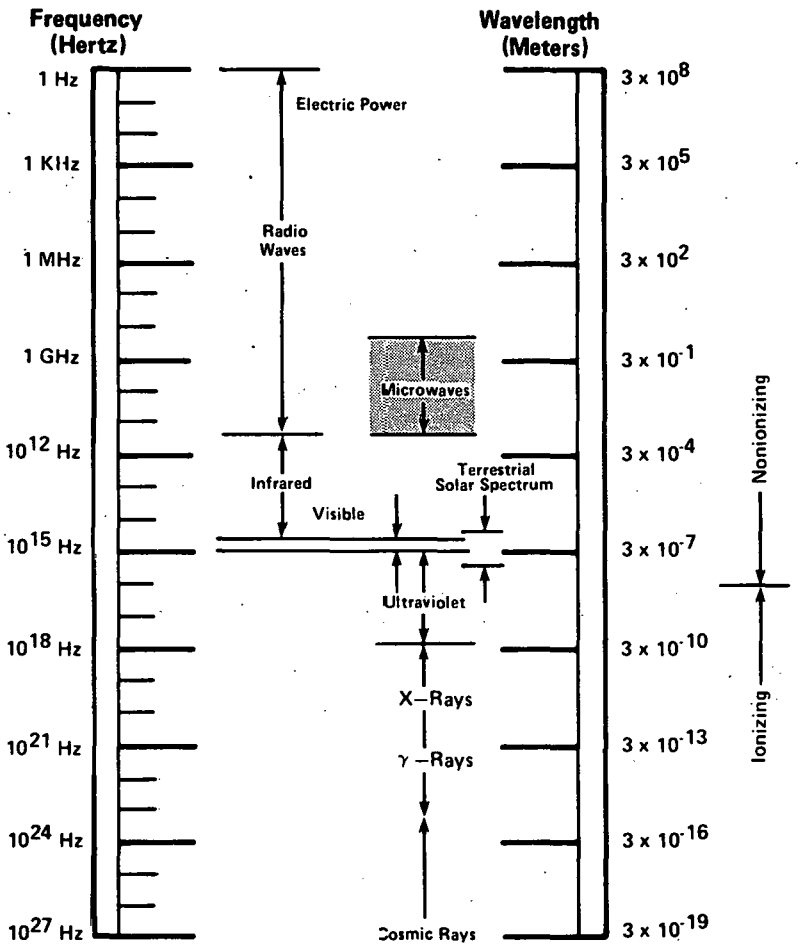
Power density of RFEM is given in units of watts per square meter (W/m^2) or (milli) watts per square centimeter (mW/cm^2). Radiofrequencies with power densities of 100 mW/cm^2 or greater are generally conceded capable of causing thermal damage to biological tissue, although such damage may not always occur, and any changes may be reversible. Experiments with animals have shown that prolonged whole-body irradiation at microwaves frequencies leads to hyperthermia (overloading of the temperature of the regulatory system of a mammal) and possible death.[5]

The U.S. guideline for human exposure to microwave energy is 10 mW/cm^2 based, in part, on the potential of RFEM energy at a power density of 100 mW/cm^2 to produce tissue heating. A safety factor of 10 yields the current U.S. guideline for human microwave exposure. At present, the United States does not have a microwave exposure standard for the general public. In other countries, such as the Soviet Union, microwave exposure standards appear to be somewhat more restrictive, basing their standards upon reported central nervous system and behavioral effects.

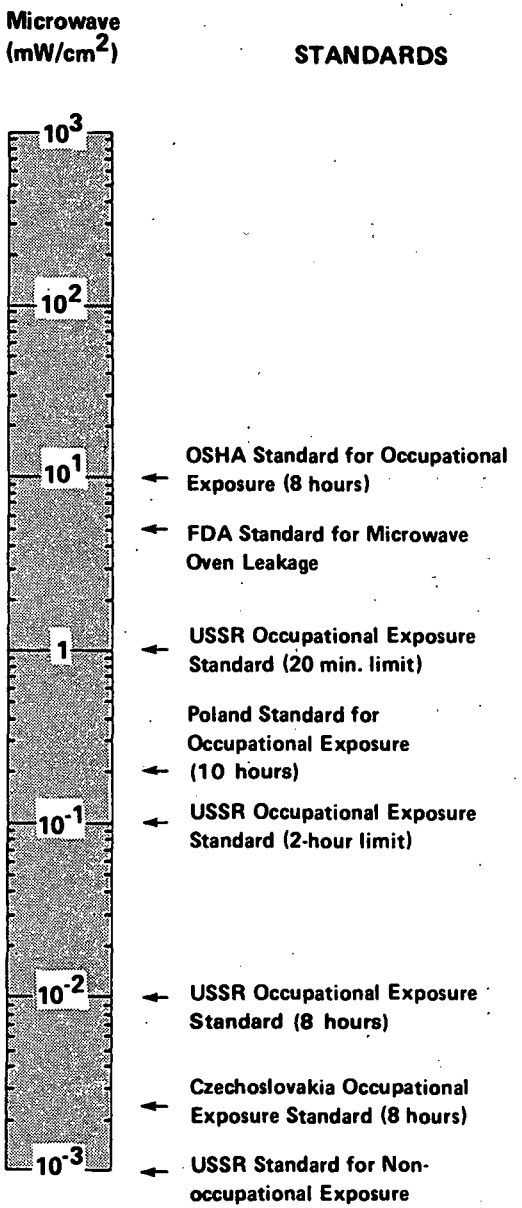
Data on human microwave effects are derived primarily from acute accidental exposures to microwave generating equipment, and from retrospective studies of occupationally exposed personnel. Although the REFM radiation responses of several types of mammals are similar to those of human beings, the validity of extrapolation of experimental animal data to humans is problematic, especially with respect to the quantity of radiation necessary to produce a given effect.[6]

In summary, the capacity of microwave radiation to elevate temperature in biological tissues and to cause heat-related effects during exposure at high levels, such as cataractogenic effects in the eye, has been known for some time. However, effects at low level exposure, such as the reported potential to cause subtle changes in behavior or physiological functions, are less definite, due to the many parameters associated with RFEM exposure conditions. These include, for example, frequency, orientation of the body in the field, duration of exposure, power density, and the quantity of absorbed radiation.

Studies indicate that brief exposure to continuous-wave 2,450-MHz radiations at power densities below 1 mW/cm^2, which would occur beyond a rectenna's buffer zone, do not result



3×10^{8} m/sec = Speed of Light
= Frequency (Hz) x Wavelength (m)



Adapted from: Human Health and the Environment—Some Research Needs, Report of the Second Task Force for Research Planning in Environmental Health Sciences, DHEW Publication No. NIH 77-1277, 1977.

Exhibit 1. Electromagnetic Spectrum

Frequency	Wave Lengths	Band Designation	Typical Uses
300 GHz	1 mm	Extremely high frequency (EHF)	Satellite communications, radar, microwave relay, radionavigation, amateur radio, industrial, scientific, medical (ISM)
30 GHz	1 cm	Super high frequency (SHF)	Satellite communications, radar, amateur, microwave relay, airborne weather radar
3 GHz	10 cm	Ultra high frequency (UHF)	Short range communications, amateur, taxi, police, fire, radar, citizens band, radio navigation, UHF - TV, microwave ovens, medical diathermy, ISM
300 MHz	1 m	Very high frequency (VHF)	Police, fire, amateur FM, VHF-TV, industrial RF equipment, diathermy, emergency medical radio
30 MHz	10 m	High frequency (HF)	Citizens band, amateur, medical diathermy, Voice of America, broadcast, international communications, industrial RF equipment
3 MHz	100 m	Medium frequency (MF)	Communications, radionavigation, marine radiophone, amateur, industrial RF equipment, AM broadcast
300 KHz	1 km	Low frequency (LF)	Radionavigation, marine communications, long range
30 KHz	10 km	Very low frequency (VLF)	Very long range communications, audiofrequencies
3 KHz	100 km	Voice frequency (VF)	Voice, audiofrequencies
300 Hz	1000 km	Extremely low frequency (ELF)	Powerlines, audiofrequencies, submarine communications
0 Hz			

Source: A Technical Review of the Biological Effects of Non-Ionizing Radiation, a report prepared for the Office of Science and Technology Policy, May 15, 1978.

Exhibit 2. Radio Frequency Bands

in morbid biological effects.[7] However, these data have been produced from studies involving acute exposures. In addition, both airborne, and terrestrial species near the rectenna could incur RFEM radiation at power densities exceeding 20 mW/cm^2, by flying through the center of the beam or residing on the rectenna. Microwave effects upon these species, as well as ground biota (including soil organisms) must be evaluated. Only intensive experimental and theoretical study can reveal whether the SPS concept safely can be implemented.

Biological data and resulting requirements for exposure standards will play an important role in evaluating the SPS as a potential energy-producing technology for the future.

Within this context, this study intends to outline the historical and philosophical background that led to creation of the present permissible levels for microwave exposure; the regulatory process in establishing and promulgating exposure guidelines; future trends in microwave standards (both public and occupational); and the regulatory processes that could impact design, development, and deployment of the Satellite Power System.

2.0 PHILOSOPHICAL APPROACHES TO MICROWAVE STANDARDS

Divergent findings of Western and Eastern scientists regarding bioeffects of microwave irradiation have resulted in dissimilar standards, guidelines and recommendations for limiting human exposures. These standards differ markedly, as evidenced by the maximum RFEM radiation intensity of 10 mW/cm^2 in effect in the United States, compared with 0.01 mW/cm^2 for the same exposure duration in the U.S.S.R.--a level 1000 times lower. Standards or guides for permissible exposures to microwaves throughout the world vary over 4 orders of magnitude.[8]* A comparative chart of major worldwide microwave standards is listed in exhibit 3.

Most countries of the Western world, with little alteration, have adopted microwave exposure standards that follow the guidelines originally set by the United States. The present 10 mW/cm^2 level, which was initially proposed as a protection guide by biophysicist Dr. Herman Schwan in 1953, was established from theoretical calculations on the amount of exogenous thermal loading that could be tolerated and dissipated by the body without a harmful rise in body temperature. The capacity of microwaves to produce a measurable elevation of temperature in tissues, and the susceptibility of certain tissues (skin, testes, lens of the eye) to thermal injury, notably the cataractogenic effect, have been the basis for protective guides or standards in the U.S.[9]

Maximum East European exposure levels for microwaves, on the other hand, have been based primarily on reported central nervous system (CNS) and behavioral responses. Bolstered by epidemiologic studies, microwave exposure standards for most Soviet Bloc and East European nations are founded, with minor variations, on limits established by the U.S.S.R.

This East/West dichotomy has fueled public apprehension and debate as to uses of microwaves and the resulting potential hazard to human beings. What are the causes for this disparity?

To a large degree, the differences in standards are based on contrasting philosophies. Koslov indicates several factors that contribute to the differing U.S. and Soviet definitions of permissible microwave exposure, and asserts that the U.S. and the Soviets have fundamental differences in their philosophies of environmental control.[10] In the U.S., the

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*Range is from 10 mW/cm^2 U.S. occupational exposure guide to Soviet environmental standard of 0.001 mW/cm^2.

Exhibit 3. Comparison of Major Microwave Exposure Standards

	Occupational	Frequency	Exposure Duration	Public
Canada[1] (Proposed)	5 mW/cm^2	(1 - 300 GHz)	No limit	1 mW/cm^2
Czechoslovakia	0.01 mW/cm^2	(0.3 - 300 GHz)	8 hours	0.001 mW/cm^2
Poland	0.2 mW/cm^2	(0.3 - 300 GHz)	10 hours	0.01 mW/cm^2
Sweden	1 mW/cm^2	(0.3 - 300 GHz)	8 hours	None
U.S.[2]	10 mW/cm^2	(0.01 - 100 GHz)	No limit	None
U.S.S.R.	0.01 mW/cm^2	(0.3 - 300 GHz)	Entire workshift	0.001 mW/cm^2

1. Canada is also proposing a 1 mW/cm^2 exposure limit at 10 MHz - 1 GHz Frequency.

2. Also with slight modification is the United Kingdom, German Federal Republic, Netherlands, and France. A new RFEM exposure guideline is being proposed by the American National Standards Institute (ANSI) that would cover the general population in the United States.

concept of risk/benefit criterion has been accepted, involving the use of an adequate safety margin below a known threshold of hazard. On the other hand, the Soviets consider a pollutant as any perceptible change in the environment. "Thus," observes Koslov, "an 'effect' can be considered justification for defining excessive environmental perturbation."

A similar interpretation of the philosophical gap in the U.S./Soviet microwave standards has been expressed by the Committee on Man and Radiation (COMAR) of the Institute for Electrical and Electronics Engineers (IEEE).[11] COMAR states, "the Soviet approach is to observe for a threshold of rf radiation below which no biological effect occurs and then to incorporate an additional safety factor of one or more orders of magnitude. The approach in the United States has been to observe for a threshold of damaging radiation and then incorporate a safety factor of an order of magnitude." The COMAR adds that both methods have their limitations.

> "The American approach encounters a conceptual snag in that no consensual basis has been reached for differentiating benign effects from hazardous effects. The more conservative Soviet approach suffers from a failure to entertain a trade-off between risks and benefits."

In the United States, the recommended level for microwaves was calculated to be 10 mW/cm^2 for an 8-hour day, supported by the belief that 100 mW/cm^2 was the lowest level at which significant biological damage could occur. Above 100 mW/cm^2, irradiation of test animals, such as dogs, sheep, rodents, or cats, produce hyperpyrexia, skin burns, organ congestion and degeneration effects, unquestionably of a thermal nature. From this finding, a factor of 10 has been used as a reasonable margin of safety, leading to the 10 mW/cm^2 recommended standard. A detailed history of the creation and promulgation of the thermally-based U.S. 10 mW/cm^2 value is found in Section 3.

Soviet and East European standards are supported by experimental animal data showing microwave induced changes affecting various organs. Also, reports by researchers of changes in Pavlovian conditional responses of workers, have been utilized to set standards.[12] Results of Soviet and East European surveys continue to report various reversible functional changes in the nervous, cardiovascular, and blood forming systems of workers exposed at microwave power densities that are generally well below 10 mW/cm^2. "Microwave or radiowave sickness" is referred to as a distinct clinical entity in the Soviet Union.[13]

These worker responses, termed the "neuraesthenic syndrome," are usually reported after chronic (approximately 3 to 6 years) exposure to microwaves at power densities

ranging from several hundredths of a mW/cm^2 to "a few" mW/cm^2. It has been observed, as a rule, that cessation of work involving exposure to microwave/rf radiation results in symptomatic stabilization, or recovery, if such cessation takes place in the initial stages of symptoms. It is implied, however, in some studies that symptoms may stabilize or grow worse if exposure continues.[14]

Soviet clinical studies have catalogued complaints by workers of insomnia, headache, impotence, fatigue, irritability and other symptoms. These subjective complaints are referred to as evidence of the direct or indirect effect of low-level microwaves on the Central Nervous System (CNS).[15]

Soviet scientists claim the CNS is the most sensitive of all body systems to microwaves at intensities below those associated with measurable elevations of temperature.[16] In addition, other "non-thermal" effects reported by the Soviets include decreased arterial pressure and heart rate. Due to such observed reactions, which may be reversible or may lead to pathologic processes or signs of organic disease, the Soviets have set a level for safe microwave exposure 1000 times lower than that of the United States.

Cited by Baranski and Czerski[17] are the systematic studies on health status of personnel exposed to microwaves in 1948, and clinical investigations from 1953 to 1966 by the Moscow Institute of Industrial Hygiene and Occupational Diseases. The studies were primarily based on periodic examinations of over 1,000 individuals observed for more than 10 years. Three worker exposure levels were examined: periodic exposure to high energy density levels, periodic exposure to low energy density levels, and systematic exposure to low energy density levels.

Examinations were given to 100 of these Soviet workers, along with a control group of 100 persons. Personnel examined worked with microwave equipment for more than 5 years. Conclusions reached from that study indicated, among other symptoms, functional disturbances in the central nervous and vegetative systems, as well as cardiovascular disturbances.[18]

Using both occupational microwave exposure studies and animal experimentation, the minimal exposure causing functional changes corresponded to 1 mW/cm^2 during 1-hour durations at 10-centimeter wavelength. This threshold value was used and extrapolated for a 10-hour work day, yielding 0.1 mW/cm^2. A tenfold safety margin, due to individual variation in susceptibility, health status, and similar variables, resulted in the current Soviet occupational microwave health standard. The population exposure standard was set at 0.001 mW/cm^2.[19]

Commenting on basic principles which may be used to establish safe exposure limits, Baranski and Czerski contend that the determination of safe exposure limits for any artificial factor introduced into the environment rests on three tenets. Taken into consideration is the relationship between exposure level and the observed or rather demonstrable bioeffects. These three basic principles are:[20]

1. The principle of "zero" interaction: this level is safe; no effects are demonstrable.

2. The principle of maximal comfort: certain signs are observable but no differences between the functional efficiency of the organism in optimal conditions and on exposure are demonstrable.

3. The principle of the limit of physiological compensation: the exposure causes various disturbances and imposes a stress on the compensatory mechanisms. Nevertheless, no irreversible functional impairment and certainly no irreversible structural changes occur, i.e., exposure does not lead to deviations from the statistical norm.

Further, they add:[21]

> "It must be said that the decisions as to what constitutes 'maximal comfort' or 'limit of physiological compensation' levels are in the present state of biomedical knowledge somewhat arbitrary. It is the present authors' feeling that in the U.S.S.R. the principle of 'zero' interaction was adapted, which is certainly the most cautious and biologically reasonable standpoint in respect to a factor causing so many questions and uncertainties. The same principle was adopted for the general population both in Poland and Czechoslovakia, the main reason being that knowledge of the mechanism of the interaction of microwaves with living systems is insufficient. As concerns occupational exposure, i.e., exposure of healthy adults under medical supervision, a principle of 'in between' the 'maximal comfort' and 'physiological compensation' was aimed at."

Again, the philosophical differences between East and West in establishing microwave exposure limits become apparent.

This is supported by the statement attributed to Dr. Karel Marha, Director of the Department of High Frequency of the Institute of Industrial Hygiene and Occupational Diseases in Prague, Czechoslovakia. In finding a wide variety of neurological problems among individuals working in factories where microwave devices were manufactured, radio and television stations, and radar centers, Czechoslovakia set standards for microwave exposure at similar levels in force in the Soviet Union. These neurological problems, some purportedly induced at power densities as low as 0.1 mW/cm^2--a hundred times less than the

American standard--were thought to be cumulative with repeated irradiation, and because large variations had been found in the sensitivities of different people, the Czechoslovak standard incorporated a safety factor of 10. Epitomizing the difference in thinking and approach between U.S. and Eastern European scientists, Marha states "our standard (Czechoslovakia's) is not only to prevent damage but to avoid discomfort in people."[22]

Eastern and Western approaches to establishing microwave standards may thus be reduced to two basic concepts: a threshold of harmful effects (U.S.) versus a threshold of no effects (Soviet/E. European).[23]

Comparing U.S. and Soviet microwave standards, Milroy and Michaelson[24] see the differences as being based "not on actual factual information but on differences in basic philosophy." In addition to the reporting of scientific data, basic scientific research, and industrial hygiene, are suggested as primary areas for philosophic variance. Also identified as an area in which large differences exist is that of commercial applications of technology. "The Soviets are not faced with the same degree of consumer technology as the U.S. They need not concern themselves with the microwave oven, rapidly expanding commercial radio and television transmission, or radar for commercial uses since these are not as readily available."

It should be noted, however, Koslov[25] indicates this situation may be changing. Industrial and consumer-products organizations within the Soviet Union are interested in expanding use of RFEM energy for industrial processes and microwave ovens for the public. These organizations are requesting that the Soviet Academy of Sciences to reexamine the scientific basis for the Soviet standards, with an eye toward lessening their rigidity.

In addition, believes Koslov, distinct traditions underlie U.S. and Soviet physiological research. In the Soviet Union, total animal behavior subjectively observed can be considered adequate criteria, derived from the work of Sechenov and Pavlov.[26] For the United States, measurable physiological change has to be demonstrated, drawn from the 19th century Western European schools of Bernard and Muller.[27]

An interpretation of industrial hygienic standards in the U.S.S.R. has been suggested to explain philosophical differences between Soviet and U.S. microwave standards.[28] In 1964, the United States Industrial Toxicology Delegation to the U.S.S.R. offered this elucidation of Soviet practices:[29]

a) Maximum permissible level is defined as that level of a substance at which a worker could be exposed daily without undergoing any deviation in normal state or incurring disease;

b) The setting of such levels should be based entirely on the presence or absence o. biologic effects, regardless of whether it is feasible to reach such levels in practice;

c) The standards established should represent maximum permitted levels rather than time-weighted average (TWA) considerations; and

d) Regardless of the value set, the optimum level and goal should be zero.

The delegation further concluded that Soviet values are not rigid ceilings and, in fact, excursions above these values "within reasonable limits" are permitted. The observation that Soviet microwave standards appear to be ultimate goals for which to strive, rather than absolute values to be used in practice, has also been noted.[30] A comparison of U.S. and U.S.S.R. microwave exposure standard philosophies is listed in exhibit 4.

Until recently, Soviet and East European reports of low-level microwave effects were met with skepticism in the United States. A growing U.S. acceptance of some physiological and behavioral alterations reported in Soviet and East European research is now apparent. Yet to be determined, however, is the long term significance to human health of observed transient non-thermal effects. There continues to be no unanimous agreement as to mechanisms of central nervous system responses to low-level microwave fields.

Attempts to reproduce some Soviet experiments in the U.S. have led to differing results. Explanations have been offered:

> First the cause and effect implications in the Soviet and East European research might be invalid due to experimental design, measurement inaccuracy, lack of control of experimental variables, or other factors. Second, our (U.S.) inability to reproduce these results might stem from our lack of knowledge of how their experiments were conducted. Many Soviet and East European reports do not provide sufficient detail on experimental design and research methodology to permit accurate replication. Information is usually given on frequencies of exposure, incident power densities, duration of exposure and the observed biological changes. However, information is often lacking on how the animals are exposed, on field characteristics, on energy absorption, on maintenance of control animals, or other important experimental design parameters.[31]

In addition, Koslov indicates, "Soviet scientific publication in the past, and to some extent at the present time, has suffered from inadequate peer review. Thus a number of articles may have been published without adequate refereeing. More careful review of some papers should have resulted in withdrawal due to observational or statistical misinterpretations or inadequate presentation of data."[32]

Exhibit 4. Comparison of U.S. and U.S.S.R. Microwave Exposure Standards (Philosophical approaches)

	U.S.	U.S.S.R
Standard	Maximum permissible exposure: 10 mW/cm^2 averaged over 0.1 h	0.01 mW/cm^2 for work day*
"Critical organ"	Lens of the eye (cataraciogenic threshold apparently in 100 mW/cm^2 range)	Central nervous system causing neurasthenic syndrome (threshold apparently in 10 mW/cm^2 range)
Industrial hygiene philosophy	• Threshold concept • "Effects" become "hazards" only if injurious or irreversible • TLV concept (A) • Feasibility considered • Excursions permitted by TLV concept • Standards are fairly uniformly applied and enforced	• Optimum value=zero • All deviations from normal are hazards • MAC concept (B) • MAC's based solely on bio-effects, not feasibility • Excursions above MAC permitted "within reasonable limits" • Standards appear to be desirable levels toward which to strive
Scientific	• Objective scientific data • Statistical analysis • Quantitative reporting • Pathophysiological effects	• Subjective observations • Few statistics • Qualitative reporting • Neuropsychological effects and Pavlovian conditional responses
Shortcomings	• No consensual basis for differentiating benign from hazardous effects • Preconception that non-thermal effects can't exist?, and few clinical studies	• Poor research documentation and absence of dosimetry • Decision not to entertain a trade-off between risks and benefits?

Notes
A. Threshold Limit Value (TLV)
B. Maximum Allowable Concentration (MAC)

Adapted from Milroy and Michaelson - 1973

*Greater exposures allowed for shorter periods of time.

These criticisms might be balanced, however, by the comment that the past U.S. publishing record is certainly not much better. Seventy-five percent of the papers constituting the proceedings of the Tri-Service effort (described in 3.1) failed to list all of the basic parameters that should be included in any research paper, such as the frequency used or type of experimental animal exposed.[33] In either case, such conditions could be expected in an immature science. Initially, the importance of certain parameters may not be appreciated.

While apprehension continues in the East as to the potential hazards resulting from occupational exposure to low-level microwaves, there exists no compelling clinical information from the West to support that apprehension. From the West it is held that Soviet studies of non thermal effects are poorly documented, are incomplete in the presentation of experimental methodology and data, use inadequate and unreliable dosimetry, and contain problems in the selection of adequate control groups for use in clinical surveys.[34] It should be noted that this last situation is common to most epidemiological studies. Also, epidemiological studies performed in the U.S. have generally included limited numbers of clinical or physiological end points. These U.S. studies were hampered by difficulty in ascertaining exposure history, exposure levels and duration, or even whether individuals classified as "exposed" were, in fact, exposed to RFEM radiation.[35]

Epidemiologic criteria used in Russian occupational survey work has been criticized in the past. Dodge states that "not enough was known about irradiation protocol, and environmental and other exposure conditions upon which to base meaningful judgements of symptomatic findings."[36] Justesen has questioned East European surveys, "Whether the higher incidence (of reported microwave effects on workers) is a reflection of failures to adhere to exposure standards, of greater susceptibility to radiation by inhabitants of Eastern Europe, of more sensitive medical measures or of more candid medical reporting, or of a geopolitically inspired mass hysteria, is impossible of reckoning at the present time."[37]

East European regulations allegedly require candidates for work which involves exposure to microwaves to undergo medical examinations and obtain a medical certificate of fitness. Identical requirements are made with respect to candidates for schooling in professions necessitating future exposures to microwaves. Medical examinations of microwave workers are compulsory on an annual basis. Microwave workers in Soviet and East European countries are encouraged to report perceived effects from microwave exposure to a factory physician. Similar practices are not observed to such a degree in the United States, a situation that is criticized by some Soviet and East European scientists.

However, it has been viewed that the "maternalistic" climate surrounding the reporting of microwave-related illnesses, could involve a "tremendous amount of hypochondria." This possibly, it is suggested, could be the reason for the plethora of supposed microwave-created symptoms recorded in East European and Soviet literature.[38]

Baranski and Czerski provide counter arguments to Western misgivings of Soviet and East European findings. A view particularly held by Czerski is that inadequate translations of scientific papers have contributed much to the misunderstanding and improper interpretation of research results. Regarding the value of epidemiological studies used by some Eastern Bloc nations, Baranski and Czerski state that difficulties do arise in assessing "the relationship between exposure levels and observed effects. As often happens in clinical work, it is difficult to demonstrate a causal relationship between a disease and the influence of environmental factors, at least in individual cases. Large groups must be observed, to obtain statistically significant epidemiological data. The problem of adequate control groups is controversial and hinges mostly on what one considers 'adequate'." Baranski adds "it is far better to present approximative evaluations that to create an impression of accuracy where none can be had."[39]

Programs of cooperative exchange between Soviet and American engineering and biological scientists have aided the mutual edification of the respective country's bioeffects research. COMAR observes:[40]

> The American delegations have learned that Soviet biological studies often possess an important feature lacking in Western studies: ecological validity--or what might be called experimental modeling that more nearly resembles the way that RF radiation is encountered by people in the real world. Soviet biologists have conducted many long-term experimental studies; only a handful has been reported by western investigators. Soviet physicians have conducted numerous epidemiological surveys; few have been attempted in the West. And finally, the long-term Soviet studies, experimental and epidemiological are closely matched; i.e., animals are exposed in settings that closely resemble those that characterize workers who are exposed to RF fields. The Western scientist can make a good case for the tightly controlled environmental conditions that have characterized his researches, but he is beginning to realize that a pooling of methodologies that incorporate the environmental and dosimetric rigor of the West with the long-term exposures and ecologically valid designs of the East will be necessary if the potential hazards of low-level fields are to receive credible scientific evaluation. In short, the Soviet scientist has profited from U.S. engineering, and the U.S. scientist, from Soviet methodology.

In summary, today there is no worldwide consensus on what levels of non-ionizing radio-frequency radiation constitute a hazard to the human. Soviet and some East European standards are based on the possibility of any noticeable biological effect in contrast to thermal injury. Most western countries view minor reversible effects as not necessarily hazardous to humans. Yet to be determined, however, are definitions of "adequate" safety margins, or what constitutes a "hazard" in terms of microwave exposure. In addition, there are those who question risk-benefit criteria in the context that societal benefits should not be ascribed to societal risk-taking. Still others question if a no-effect, no risk acceptance is a philosophy by which a modern society can maintain its technological progress. Comments one researcher, "We are in a Renaissance in electromagnetic biology. Groping around in 19th Century terms, gifted with 20th Century technology."[41]

Views Dr. Moris Shore of the Food and Drug Administration's Bureau of Radiological Health:[42]

> "The scope and applicability of general radiation protection standards are broad. So is, unfortunately, the present range of numerical values of safe limits. The standards are designed to provide protection based on considerations of health. Knowledge of health effects appears severly inadequate, so that the larger margin of safety may be needed to provide health insurance against a public health error resulting from lack of information.
>
> The intent of standards is not to stifle technological development. We should not accept without careful study, the notion that conservative standards and technological development are mutually exclusive. Our goal should be that expansion of knowledge and elimination of scientific uncertainty that will ultimately lead to more uniform standards for health protection. Standards which will be based on sound science, on sound radiation protection philosophy. Standards which will be dynamic and responsive to changes. Standards that will be credible and enjoy acceptance."

3.0 HISTORY OF THE U.S. MICROWAVE "STANDARD"

The advent of radar and particularly its use by the military early in World War II raised concerns of possible deleterious effects of microwave radiation upon operating personnel. Prior to the invention of radar, interest by medical researchers centered upon the controlled effect of rf energy on living things and its ability to heat body tissue.

It is important to note the use of highly thermalizing RFEM energy in the 1920's as a primary application to medicine. Medical utilization of electromagnetic waves formed a technique called "diathermy," a treatment in which heat is produced in tissues beneath the skin by high frequency RFEM waves on current. This medical application was greatly spurred by the invention of the magnetron tube in 1920. Developed at the General Electric Company laboratories in Schenectady, New York, the magnetron became a recognized piece of convenient medical apparatus, generating ultra-shortwaves at high energy levels. In the application of the magnetron to medical treatment, controversy ensued as to whether heating was the only effect in using the device. Debate centered on possible "nonthermal" or field "specific" effects. Discussion of such nonthermal effects became less an issue with the start of World War II, as medical researchers postponed experimental test programs until the end of the war.

The development of other shortwave machines, including shortwaves, led to shorter wavelengths and higher powers, with creation of the triode by Lee de Forest and an improved magnetron tube by Bell Telephone Laboratories. In 1939, research engineers at Stanford made a breakthrough in generating wavelengths as short as 10 to 40 centimeters, with several hundred watts of output, giving birth to the invention of the klystron tube. The use of the multicavity magnetron tube in 1940 made possible the generation of very high power microwave radiation and led to the development of radar. With the same priority given to the atomic bomb, radar technology research advanced at a fast pace. Attached to this research came reports of biological effects by personnel exposed to radar. Symptoms of warming, sterility, and baldness were reported, and medical investigations were ordered. As early as mid-1942, in response to concerns of radar bioeffects and decreased morale of personnel, the Navy's Bureau of Ships directed the Naval Research Laboratory (NRL) to supply data on potentially harmful microwave radiation effects. Similar studies by the Army Air Corps also were performed. Those investigating radar bioeffects reported no harm would come to individuals involved in operating such equipment. The results of these studies did lead to recommended caution of prolonged overexposure to radar, although no general guidelines were established.

With the close of the war effort, interest in selective heating of the body by RFEM radiation as a therapeutic technique was renewed. Microwave equipment built during the war, such as the Raytheon microtherm, became available to medical researchers for studying diathermy effects. In 1948, researchers at the Mayo Clinic, according to Steneck, et al., reported the first confirmed hazards resulting exclusively from microwave exposure--cataract formation in dogs. Similar studies by the military verified the Mayo data; additional findings, also using dogs as test animals, suggested that microwave energy could produce testicular degeneration.

In 1953, stimulated by concerns of reported ill-effects in radar workers, the Air Research and Development Command (ARDC) directed its microwave research scientists to expand their activities to include determination of permissible exposures of microwave radiation, including single and repeated dosages. The Navy, also in 1953, convened a conference attempting to determine human tolerances based on the effects of microwaves on living organisms.

Concurrent with the creation of initial guidelines by the military, Bell Telephone Laboratories and General Electric, two of the larger military contractors, organized meetings to set guidelines governing microwave exposure for their personnel. These industry-sponsored meetings paid particular attention to a 1952 Sandia Corporation report that a lab technician, regularly exposed to microwaves at power levels estimated at 100 mW/cm^2 had developed lenticular opacities (cataracts) in the eyes.

Partly based on the Sandia information, GE researchers decided in June 1954 that if damage at 100 mW/cm^2 can occur, a factor of 100 should be built in as a safety margin, with exposure guidelines set at 1 mW/cm^2. An earlier Bell Labs Central Safety Committee in November 1953 adopted a 0.1 mW/cm^2 standard, which represented a safety factor of 1,000 on a known point at which eye injury occurred. By late 1954, industry and the military generally agreed that 100 mW/cm^2 was a value leading to possible injury. The margin of safety that should be adopted, however, was an area of differing opinion. Continuing evaluation of possible microwave hazards to animals was carried out by the Air Force during the mid-1950's. These studies evolved into a four-year research effort, beginning in 1957, known as the Tri-Service Program.

3.1 Tri-Service Program

The objectives of the Tri-Service effort were the study of microwave effects on living tissue, the determination of the extent of observed bioeffects, and the accumulation of empirical data on safe and hazardous exposure levels.

Experimental programs exposing given species of animals were instituted, a majority of which were conducted at levels above 100 mW/cm^2. Most testing was characterized by short-duration, high-powered rf radiation exposures. The Tri-Service Program assigned to university research scientists a number of specific frequencies and test animals to be studied. According to Steneck, et al.:

> There were numerous studies conducted through the Tri-Service Program that exposed animals to amounts of (rf) radiation in excess of 10 mW/cm^2 and found no evidence of irreversible injury. A selection of papers presented at the Third Tri-Service conference reported the following: The Buffalo group working with 200-millicycle microwaves found no ocular changes in guinea pigs, dogs, sheep and mice at 100 mW/cm^2 and were able to breed four generations of mice in a chamber continuously irradiated with 50-200 mW/cm^2. Researchers at Berkeley working with 3 centimeter microwaves found that below 60 mW/cm^2 temperature rise in rats stabilized and that the animals recovered without any noticeable ill-effects. Studies on rats conducted at the University of Miami using 24,000-millicycle microwaves reported no blood abnormalities at 6-10 mW/cm^2 and moderate but apparently reversible changes in male hormone circulation at 300 mW/cm^2. These and other experiments supported the position that animals, and therefore humans, could tolerate exposures well in excess of the 10 mW/cm^2 guideline without suffering any serious or permanent damage. Some studies even went on to suggest that animals could adapt making them better able to cope with repeated exposures.[43]

With termination of the Tri-Service Program, an earlier conclusion was confirmed; perceptible pathological lesions, i.e., burns, were produced by moderately extended exposure to 100 mW/cm^2 of microwave radiation. The program also concluded that a safety factor of ten should be a reasonable margin of safety. The basis for the "10 mW/cm^2 standard" was thereby born.[44]

In accumulating data, the Tri-Service Program did not formally address the role of standard settings. This process steadily grew within the Navy, as well as some industrial organizations.

In August 1957, the Department of Defense ordered the Chief of Naval Operations to conduct hazards tests for microwave exposure, a duty then assigned to the Bureau of Ships. During the testing, the DOD broadened that assignment to include the responsibilities for setting a standard. To carry out the assignment of standard setting, the Navy interfaced with the work carried out by the Tri-Service Program.

3.2 American Standards Association (ASA)

In May 1959, the Bureau of Ships requested the American Standards Association (ASA), assuring industry participation, to aid in the establishment of guidelines. In July 1959, ASA formally agreed to assist, establishing a National Committee, jointly sponsored by the Bureau of Ships and the American Institute of Electrical Engineers (AIEE). This committee was designated C95, with Dr. Herman Schwan as its chairman. Among the subcommittees established, Subcommittee IV, created in 1960, became the most important body in recommending microwave guidelines. In 1966, after extensive review of data, Subcommittee IV of the USA Standards Institute (formally ASA and now the American National Standards Institute, ANSI) and under Committee C95.1, recommended the 10 mW/cm^2 standard. This standard permits a maximum exposure of 10 mW/cm^2, as averaged over any six-minute period, for frequencies from 10 MHz to 100 GHz, using the safety factor of ten, suggested by the Tri-Service Program.

Approved as USAS C95.1-1966, the recommended standard was titled "Safety Level of Electromagnetic Radiation with Respect to Personnel." This guideline, reaffirmed in 1974 as ANSI C95.1-1974, and carrying the same 1966 title, was based on the following conditions:[45]

1. frequency range of 10 MHz to 100 GHz,
2. all possible sources of electromagnetic radiation in the above range,
3. continuous and/or intermittent radiation,
4. normal or moderate environmental conditions,
5. whole body and partial body exposure, and
6. not applicable to the deliberate exposure of patients.

ANSI coordinates America's federated national standards system. Some 900 companies and 200 organizations that develop standards--professional, scientific and technical societies, trade associations, and consumer and labor organizations--are ANSI members. The federation is dedicated to meeting standards needs through the cooperative efforts of commerce, industry, standards developing organizations, and public and consumer interests.[46]

In 1979, the C95.4 Committee of ANSI began reviewing the existing ANSI recommended microwave exposure standard. ANSI rules require that its standards be reviewed every five years for reaffirmation or revision. The ANSI review will be discussed in section 5.0 of this report.

3.3 Application of ANSI Recommended Standard

In May 1971, under the Department of Labor, the Occupational Safety and Health Administration (OSHA) established an occupational guideline for microwave exposure, based upon the ANSI recommendation of 1966. OSHA was authorized to adopt, without notice or hearing, nonmandatory standards published by nationally recognized private standard setting organizations. In accordance with an OSHA directive, the Director of OSHA determined that the 1966 ANSI nonionizing radiation standard had been adopted and can be promulgated as a "radiation protection guide," labeling it as a "national consensus" standard.[47] A chronological summary of events leading to the U.S. microwave "standard" appears as exhibit 5.

1920 - Magnetron tube created. Use of diathermy devices for medical applications becomes widespread.

1940 - Multi-cavity magnetron tube makes possible concept of radar.

1942 - Naval Research Lab requested to supply data on radar bioeffects.

1948 - Mayo Clinic reports first confirmation of hazards resulting from microwave exposure - cataract formation in dogs.

1952 - Sandia Corporation reports eye damage of technician regularly exposed to 100mW cm^2 microwave power levels.

1953 - Air Research Development Command directs its microwave specialists to determine permissible exposures to human of microwave radiation including single and repeated dosages.
Navy Conference convened to determine body tolerances to microwave radiation.
Bell Telephone Labs and General Electric Company organize meetings to set microwave guidelines for company personnel.

1954 - Industry and military generally agree that 100mW/cm^2 is a value where injury might occur. The safety margin remains area of differing opinion.

1957 - Start of four-year Tri-Service program; Navy's Bureau of Ships investigates microwave exposure hazards, including setting of standard.

1959 - Bureau of Ships requests American Standards Association (ASA) to aid in setting microwave guidelines. Committee C95 established, chaired by Herman Schwan.

1960 - ASA's C95, Subcommittee IV created with duty to set microwave guidelines.

1961 - Tri-Service program ends, concluding a safety factor of 10 should be margin of safety, with a 10 mW/cm^2 as recommended guideline.

1966 - Subcommittee IV of USA Standards Institute (formally American Standards Association (ASA) and now American National Standards Institute (ANSI) recommends 10 mW/cm^2 as microwave guideline.

1968 - Radiation Control for Health and Safety Act passed.

1971 - OSHA establishes voluntary occupational guidelines for microwave exposure, based on 1966 ANSI recommendations.

Exhibit 5. Chronology of Events Leading to U.S. Microwave "Standard"

4.0 LEAD FEDERAL AGENCIES AND ADMINISTRATIVE PROCEDURES

Currently, the lead federal agencies with regulatory responsibilities for microwave radiation are the Department of Health, Education and Welfare (HEW)*, the Department of Labor (DOL), and the Environmental Protection Agency (EPA). Within each agency a specialized subsidiary office, research or advisory bureau, assists in carrying out an agency's microwave regulatory responsibilities. An overview chart of agency responsibility is provided in exhibit 6.

Agency scope of authority, jurisdiction, and key responsibilities concerning microwave radiation and regulation of current voluntary guidelines are outlined in the following subsections.

4.1 FDA/DHEW*

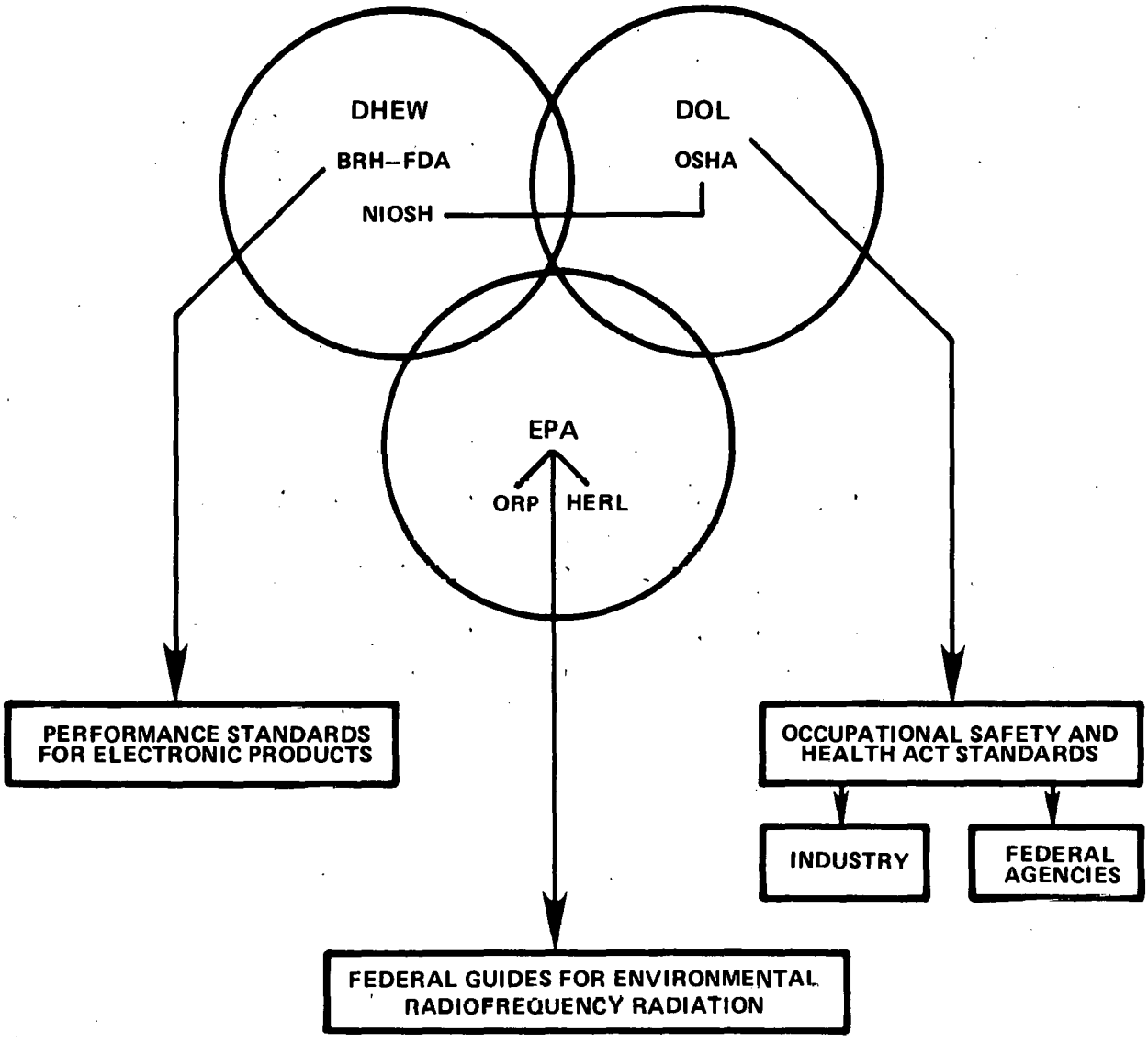
The Food and Drug Administration, within the Department of Health, Education and Welfare, has responsibility for protecting the public from the potential health hazards of impure and unsafe foods, drugs, cosmetics, medical devices, and electronic products that emit radiation.

Specific legislation which authorizes the FDA to set performance standards for products that emit radiation (microwave ovens, TV sets, X-ray machines, etc.) is contained in the Radiation Control for Health and Safety (RCH&S) Act signed by the President on October 18, 1968.[48] The Act calls for "the establishment . . . of an electronic product radiation control program which shall include the development and administration of performance standards to control the emission of electronic product radiation from electronic products." In the microwave area, the FDA identified two products for which it believes performance standards are needed--microwave ovens and medical diathermy equipment. An FDA standard for diathermy machines is expected to be proposed shortly. A chart detailing FDA microwave regulation development processes appears in exhibit 7.

The key responsibilities of the FDA involving microwave radiation are:

- developing regulations on the safety, labeling, and efficacy of medical devices that involve use of rf power;
- conducting research on the effects of radiation exposure;

*In 1980, the Department of Health, Education and Welfare is to be changed to the Department of Health and Human Services.

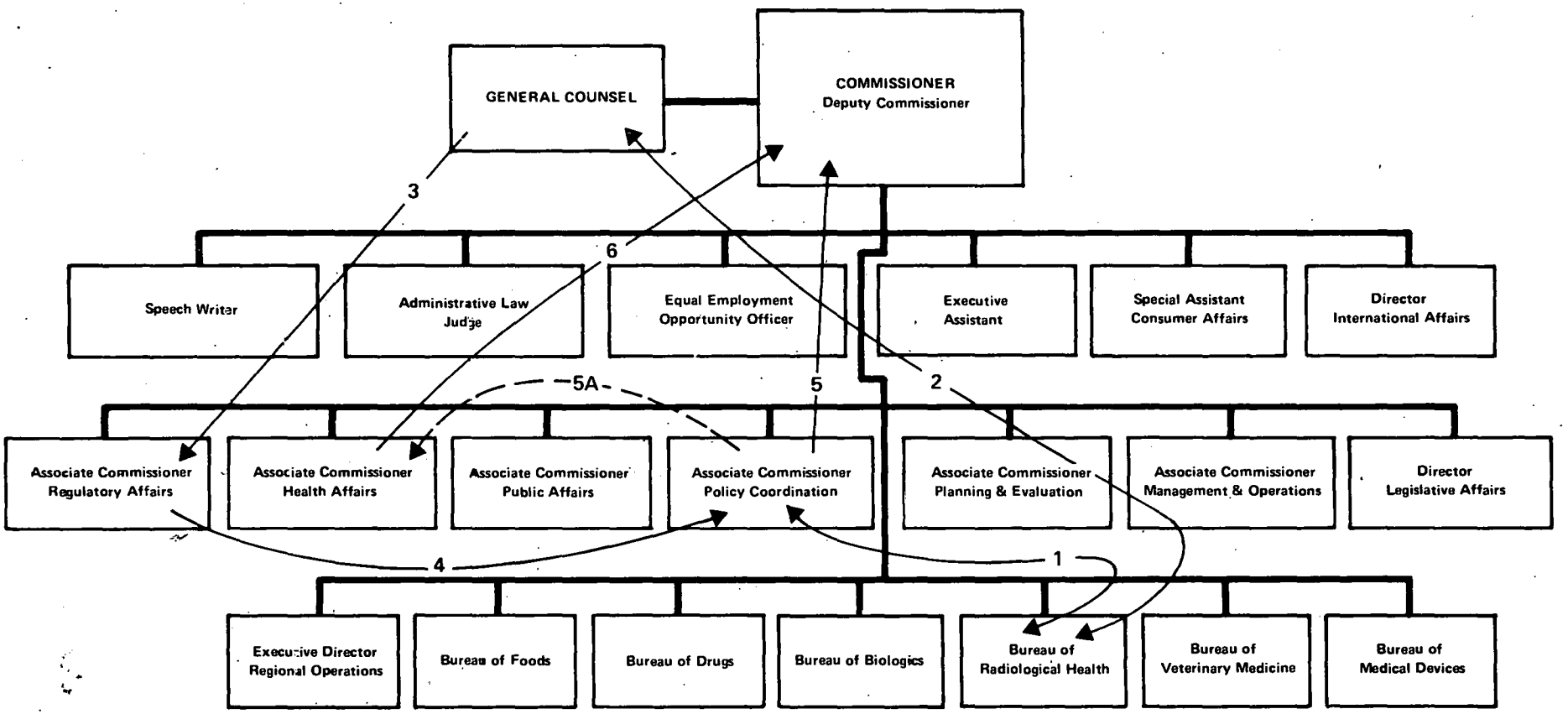


BRH	-	Bureau of Radiological Health
DHEW	-	Department of Health, Education and Welfare*
DOL	-	Department of Labor
EPA	-	Environmental Protection Agency
FDA	-	Food and Drug Administration
HERL	-	Health Effects Research Laboratory
NIOSH	-	National Institute for Occupational Safety and Health
ORP	-	Office of Radiation Programs
OSHA	-	Occupational Safety and Health Administration

Source: David Janes, Jr., The EPA Environmental Radiofrequency Program: Present Status and Environmental Findings, October 14, 1978.

Exhibit 6. Federal Agencies With Microwave Regulatory Responsibilities

*In 1980, the DHEW is to be changed to the Department of Health & Human Services.



FDA regulations are usually initiated within the regulations office of a bureau [1].

With the Commissioner wanting to be made aware of regulatory incentives before extensive Agency resources have been committed, bureau directors now make it a policy to send the Associate Commissioner for Policy Coordination a strategy document for each regulation [1].

The bureau directors then (or simultaneously) send the draft regulation to the Compliance Regulations Policy Staff, and to the Associate Chief Counsel for the bureau. These people refine the draft regulation; when the draft is satisfactory, it is sent to the General Counsel's office [2].

If the General Counsel approves the draft, it is sent to the Associate Commissioner for Regulatory Affairs [3].

The draft is reviewed and sent to the Associate Commissioner for Policy Coordination [4].

A draft may then be sent directly to the Deputy Commissioner [5], but if necessary the draft can first be sent to the Associate Commissioner for Health Affairs [5A] before going to the Deputy Commissioner [6].

Unlike other HEW Agencies, FDA does not usually send its regulations to the Secretary for signature. The Associate Commissioner for Regulatory Affairs, the Deputy Commissioner and the Commissioner all have the authority to sign regulations. Generally, the more important the regulation, the farther up the chain it moves to be signed.

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Exhibit 7. Food and Drug Administration Regulation Development Process

- testing products that are voluntarily submitted by manufacturers; and,
- inspecting manufacturers' facilities for standards compliance.

The FDA's powers and authority include the establishment of safety standards for products that emit radiation such as microwave ovens. The Commissioner of FDA has authority to issue regulations and standards for industries under its jurisdiction. Manufacturers of products that emit radiation must register and list their products with the FDA.

Enforcement activities available to the FDA if violators of the law are found are recall of a product, voluntarily by the manufacturer or at the request of the FDA; injunction if voluntary recall is not effective; seizure of a product by filing a complaint with U.S. District Court; and, prosecution by filing a criminal action against a company or individual in violation of laws administered by the FDA.

In the case of microwave radiation guidelines, the FDA relies upon the expertise of its Bureau of Radiological Health (BRH).

BRH

The BRH exercises the regulatory authority given to HEW under the Radiation Control for Health and Safety Act of 1968 and Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act. Among its duties the BRH is responsible for:

- developing radiation criteria and standards for the resulting exposure;
- developing programs designed to reduce exposure to nonionizing radiation;
- carrying out the research on radiation exposure and its impact on health;
- promoting safe and effective methodologies, procedures, and techniques for using radiation; and,
- operating surveillance and compliance programs.

The BRH also assists in the writing of model codes and recommendations for the guidance of state and local radiation control agencies. Through grants, private research on the health effects of radiation exposure is supported by the BRH.

Five nonionizing radiation product standards have been set by the BRH: lasers, microwave ovens, sunlamps, mercury vapor lamps, and ultrasound therapy.

NIOSH

The National Institute for Occupational Safety and Health (NIOSH) is a part of HEW and is a component of the HEW's Center for Disease Control.

NIOSH conducts research and investigates various toxic substances, pollutants, and other physical agents, including electromagnetic radiation which may pose dangers in the workplace. Among its duties, NIOSH is responsible for:

- preparing criteria documents on occupational electromagnetic radiation hazards, and
- responding to requests from workers or management for inspection of workplaces where environments hazardous to workers are suspected.

NIOSH also serves as a research and advisory arm for the Occupational Safety and Health Administration (OSHA) of the Department of Labor (DOL). After preparation of a criteria document, NIOSH can recommend occupational exposure standards and work practices for consideration and adoption by OSHA.

Standard for Microwave Ovens

An October 1970 FDA regulation was published setting forth a performance standard for microwave ovens.[49] The standard provides that no oven manufactured after October 6, 1971, shall emit a level of rf radiation in excess of 1 mW/cm^2 prior to purchase, or 5 mW/cm^2 after purchase, measured at 5 centimeters distance or more from the external surface of the oven. This standard applies to microwave ovens operating in the frequency range of 890 to 6,000 MHz.

According to FDA's "Documentation Report"[50] of December 1970, which summarizes the basis for establishing the standards, their determination provides a safety factor of 2 to 10 against the U.S. exposure guideline of 10 mW/cm^2.

During development of the microwave oven standard, the FDA sought consultation and comments from the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC). This committee consists of five representatives of government (state and federal), five representatives of the affected industry, and five representatives drawn from the public sector (of which one must be a representative of organized labor). The RCH&S Act requires the Secretary of HEW to consult the committee before prescribing any standard. TEPRSSC is chartered to advise the Secretary of HEW on electronic product radiation safety standards. The Secretary of HEW has delegated this responsibility to the Commissioner of FDA.

In establishing the FDA microwave oven emissions standard, various biological effects were noted from studies with animals following microwave exposure. Effects listed included cataract induction, altered testicular pathology, and central nervous system disorders.

According to the 1970 Documentation Report, the lowest level of microwave exposure to cause cataracts in animals from a single treatment was 120 mW/cm^2 for 35 minutes. With multiple exposures, the lowest microwave dose shown to produce cataracts in animals was 80 mW/cm^2. Regarding cataracts in humans the report states:

> There have been reports of cataracts and lenticular opacities in microwave workers. The lowest exposure in man, in which a cataract was observed was estimated to be 100 mW/cm^2, intermittent, over a period of one year."[51]

With regard to the effects of microwave radiation on animal testes, the report states "it was observed that the lowest exposure capable of producing minimal changes was 5 mW/cm^2 for 60 minutes."

The report cites effects to the central nervous system based primarily on behavior studies in humans and pathological observations in animals conducted in Russia. The report states that exposures "which produce biological effects range to levels below 1 mW/cm^2 with repeated exposures."

4.2 OSHA/DOL

The Occupational Safety and Health Administration (OSHA) was established as an agency within the Department of Labor, by the Occupational Safety and Health Act of 1970. The Act authorizes OSHA to establish "mandatory occupational safety and health standards applicable to businesses affecting interstate commerce." Inspections and proceedings to enforce OSHA standards are also provided by the 1970 Act.

The key responsibilities of OSHA involving microwave radiation are:

- to develop, promulgate, and enforce mandatory occupational safety and health standards;
- to develop and issue regulations;
- to conduct investigations and inspections to determine status of compliance with safety and health standards and regulations;
- to propose penalties and issue citations for noncompliance with health standards and regulations; and,
- to grant variances in regulations for special circumstances.

OSHA regulations and standards, in general, extend to employers and employees in the 50 states, the District of Columbia, Puerto Rico, and all other territories under federal jurisdiction.

Federal agencies are not directly subject to OSHA regulation and enforcement provisions. Each agency, however, is required to establish and maintain on their own an effective and comprehensive job safety and health program. Such programs must be partially based upon consultations with representatives of the agency's employees and consistent with OSHA standards for private employers.

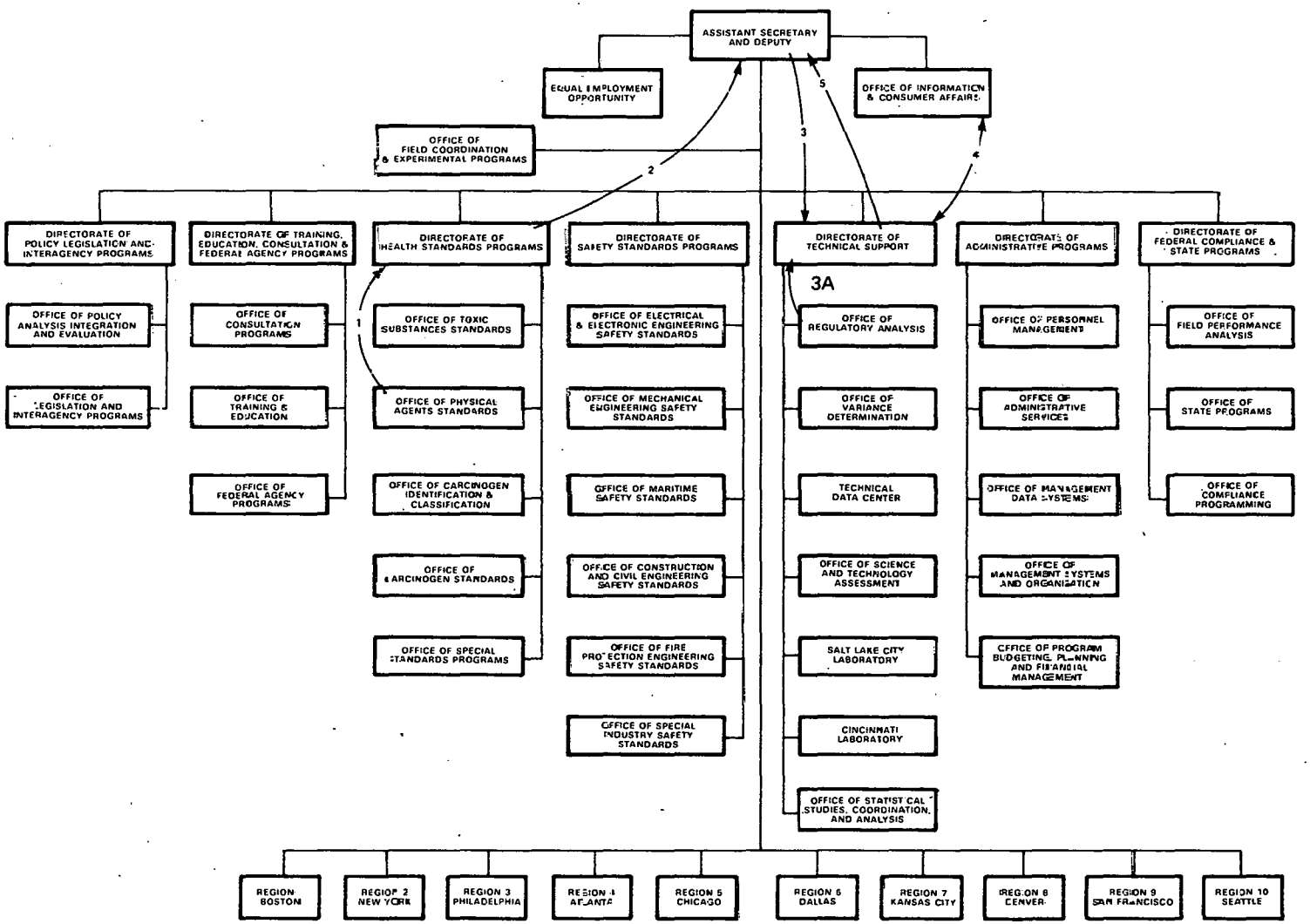
OSHA monitors these federal agency programs, requiring each agency to submit an annual report to OSHA on job safety and health efforts. OSHA is authorized to conduct workplace inspections, thereby enforcing its standards and regulations. In many instances, advisory committees are established to make recommendations to OSHA. In the case of microwave radiation standards, NIOSH also serves as a research and advisory body to OSHA, developing criteria documents to assist OSHA in development of microwave standards.

OSHA legislation stresses that standards developed should be feasible, established from experimental programs, research and demonstration, and past or present available scientific data.

In settings that are dangerous, but where no standards exist, emergency temporary standards can be imposed by OSHA without delay to avoid serious injury or loss of life. If such emergency standards are imposed, regular standard setting procedures must be initiated within a six-month period. For standard variance, proof of equally effective alternative methods to protect workers is required. If a specific standard has not been developed for worker protection, OSHA legislation can provide at least minimum protection by making it the duty of employers to provide a safe and healthy workplace. An OSHA microwave regulation development chart appears in exhibit 8.

As described earlier, OSHA adopted the ANSI C95-1966 guide as an OSHA microwave exposure standard in 1971. This guide, generally regarded as only advisory, limits the maximal permissible continuous exposure of workers to irradiation at 10 mW/cm^2; higher intensities are permissible if averaged over any 6-minute period, (for the frequency range of 10 MHz to 100 GHz.). These guidelines apply to employees in the private sector and to federal employees, including the military.

A bill is before the Congress which calls for the establishment of OSHA standards to protect employees from nonionizing electromagnetic radiation. This bill would include the



OSHA microwave regulations can be initiated by the Office of Physical Agents Standards [1]. This office is under the Directorate of Health Standards Programs which studies and evaluates the need for new health standards and, if new standards are required, works toward their development. New standards or modifications to existing standards are submitted to the Assistant Secretary [2] for evaluation and decision to proceed or stop standard development. Given a proceed order [3], the Directorate of Technical Support, and Office of Regulatory Analysis [3A], further define the needed technical support data for the regulation, creating a timetable for regulation rulemaking, plans for public comment, and conduct cost-benefit analyses. This Directorate works with the Labor Department's Office of the Solicitor (not shown), which provides general counsel to OSHA, acting as a legal representative in the rulemaking process. The Office of Information and Consumer Affairs supplies administrative assistance in facilitating public participation in OSHA regulatory activities [4]. After management review, the regulation is given final approval by the Assistant Secretary [5], and is published in the Federal Register.

Exhibit 8. Occupational Safety and Health Administration Regulation Development Process

establishment of emergency temporary standards for radiation from radiofrequency industrial heating devices until permanent standards are established. The bill will be discussed further in section 5.0 of this paper.

Lastly, at the request of Congress, of organized labor, and of OSHA, the NIOSH is developing a criteria document with recommended standards for occupational microwave and other RFEM sources. This criteria document, presently scheduled to be completed in 1980, will also be discussed in section 5.0 of this paper.

4.3 EPA

The Environmental Protection Agency (EPA) was created as an independent agency within the Executive branch of government, pursuant to Reorganization Plan No. 3 of 1970.[52] EPA was established to permit coordinated and effective governmental action on behalf of the environment, serving as the public's advocate for a livable environment.

Under EPA authority, its Administrator is to "advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States."

EPA authority in the radiation area was transferred from the former Federal Radiation Council (FRC) which was comprised of various department and agency representatives. The FRC was created by President Eisenhower in July of 1959, and abolished as a result of the 1970 Reorganization Act. FRC's functions were originally set forth within the Atomic Energy Act of 1954.[53]

The key responsibilities of the EPA involving microwave radiation are:

- to provide overall guidance to other federal agencies and states on matters of radiation protection affecting public health;
- to develop a national program and needed instrumentation to measure environmental radiation; and,
- to establish environmental radiofrequency exposure guidance.

A large percentage of the EPA-developed standards are the result of research performed by agency technical personnel. Environmental surveillance by EPA is carried out in the Office of Radiation Programs (ORP), a part of the Office of Air, Noise, and Radiation. Nonionizing radiation research is conducted in the Health Effects Research Laboratory, Research Triangle Park, NC, under the auspices of EPA's Office of Research and Development (ORD).

Responsibilities of EPA's Office of Radiation Programs include:

- developing radiation protection criteria, standards, and policies;
- studying measurements and controls of radiation, providing technical assistance to states;
- directing a national surveillance program which measures environmental radiation levels; and,
- evaluating new and emerging radiation technologies.

Activities of EPA's Health Effects Research Laboratory include:

- conducting biological effects experimentation;
- providing biological effects information useful in development of exposure criteria, guidelines, or standards; and,
- development of exposure facilities and dosimetric instrumentation systems.

EPA has extensive monitoring programs to determine standards compliance, developed by its Office of Monitoring and Technical Support. Voluntary compliance to EPA's standards and programs is encouraged, but enforcement can be mandated by the agency. The assistant administrator in the Office of General Enforcement creates procedures, guidelines, regulations, and policy statements to enforce standards in the area of radiation.

Initially, EPA will issue a stop order to a violator of EPA standards. Informal negotiation, if such a violation is not corrected, may be used to resolve differences. Failure of informal negotiations can lead to argument of a charge in an open hearing. Barring agreement at the hearing, EPA has authority to initiate civil proceedings in U.S. District Court, forcing a violator to comply with EPA standards. EPA may also revoke or suspend licenses and permits for activities regulated by the agency, without going into federal court. At this time, however, EPA's authority in the microwave area is more restricted compared to its other activities.

EPA received three contracts in FY78 from the U.S. Department of Energy (DOE) to study SPS microwave impacts on public health. EPA's research in this area will be aided by modification and expansion of its 2,450 MHz exposure facilities to accommodate Satellite Power System related work.[54]

Presently, no enforceable federal standards exist to limit public exposure to microwaves. EPA is, however, considering the need for such guidance. Decision by EPA to formulate microwave environmental guidance may result in microwave exposure standards

for the general population, and will be discussed in section 5.0. EPA guidance procedures regarding microwaves appears in exhibit 9.

4.4 Administrative Procedures

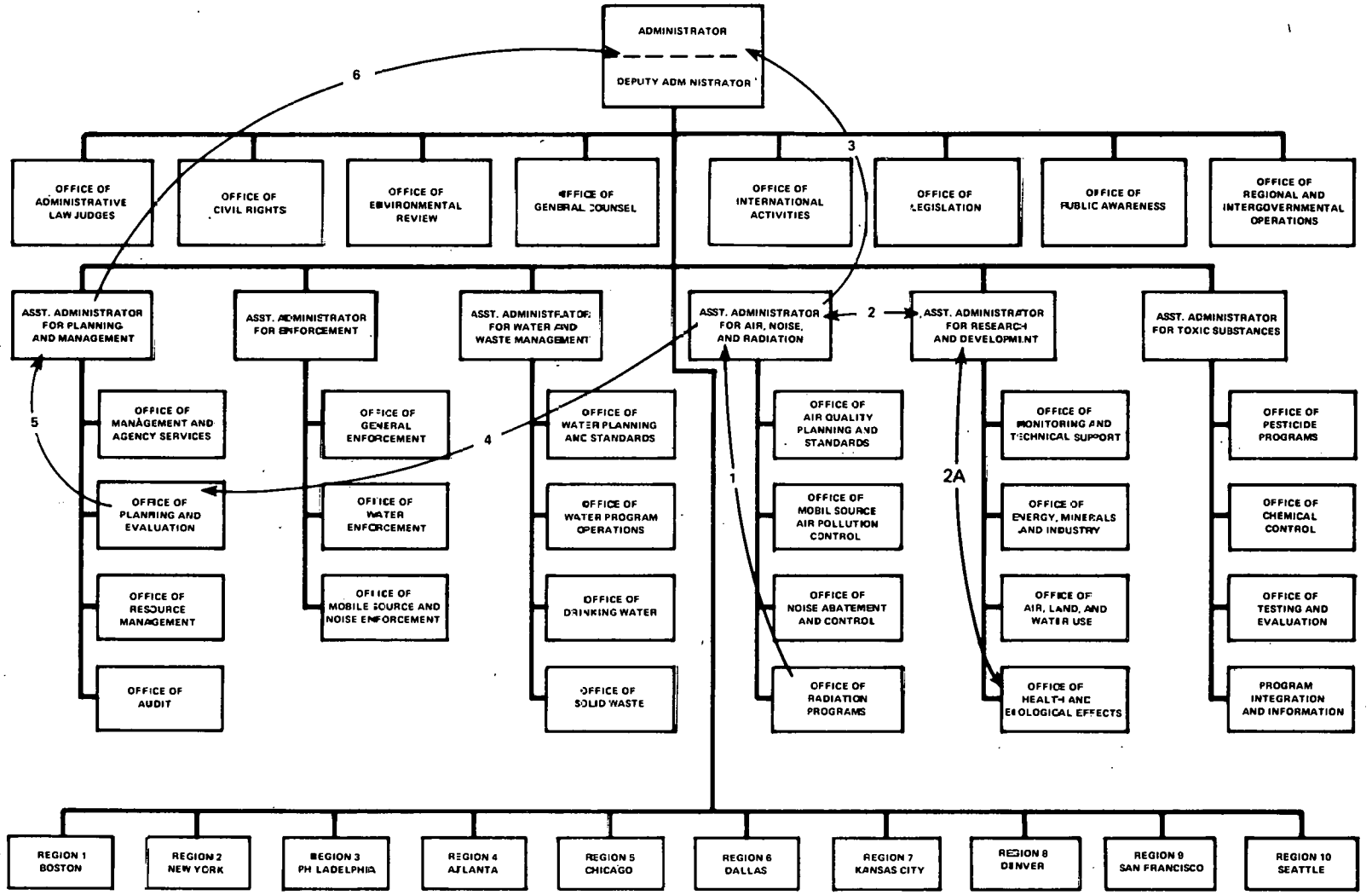
The previously discussed agencies are subject to the Administrative Procedures Act (APA) of 1946 when establishing federal microwave exposure standards. The APA requires that agencies carry out certain stages in rulemaking and adjudicatory proceedings. At the adjudicative stage, APA outlines a format of notice, hearings, procedures, evidence, oral argument, and formal judicial decision. In contrast, APA also prescribes procedures for "notice and comment" rulemaking, detailing the substance of the proposed rule or a description of the subject and issues that are involved. Public hearings on a proposed rule are at the discretion of the particular agency. Final rulings are published in the Federal Register, as are summaries of comments received and responses offered. A summary look at this procedure follows, and is supplemented with a chart on microwave rulemaking, exhibit 10.

Microwave Rulemaking

The process for establishing microwave regulations, as for any new ruling, is complicated and involves a series of steps, with administrative procedures varying from agency to agency. However, it is possible to define a path of generalized rulemaking that would apply to the setting of microwave radiation standards and their subsequent adoption.

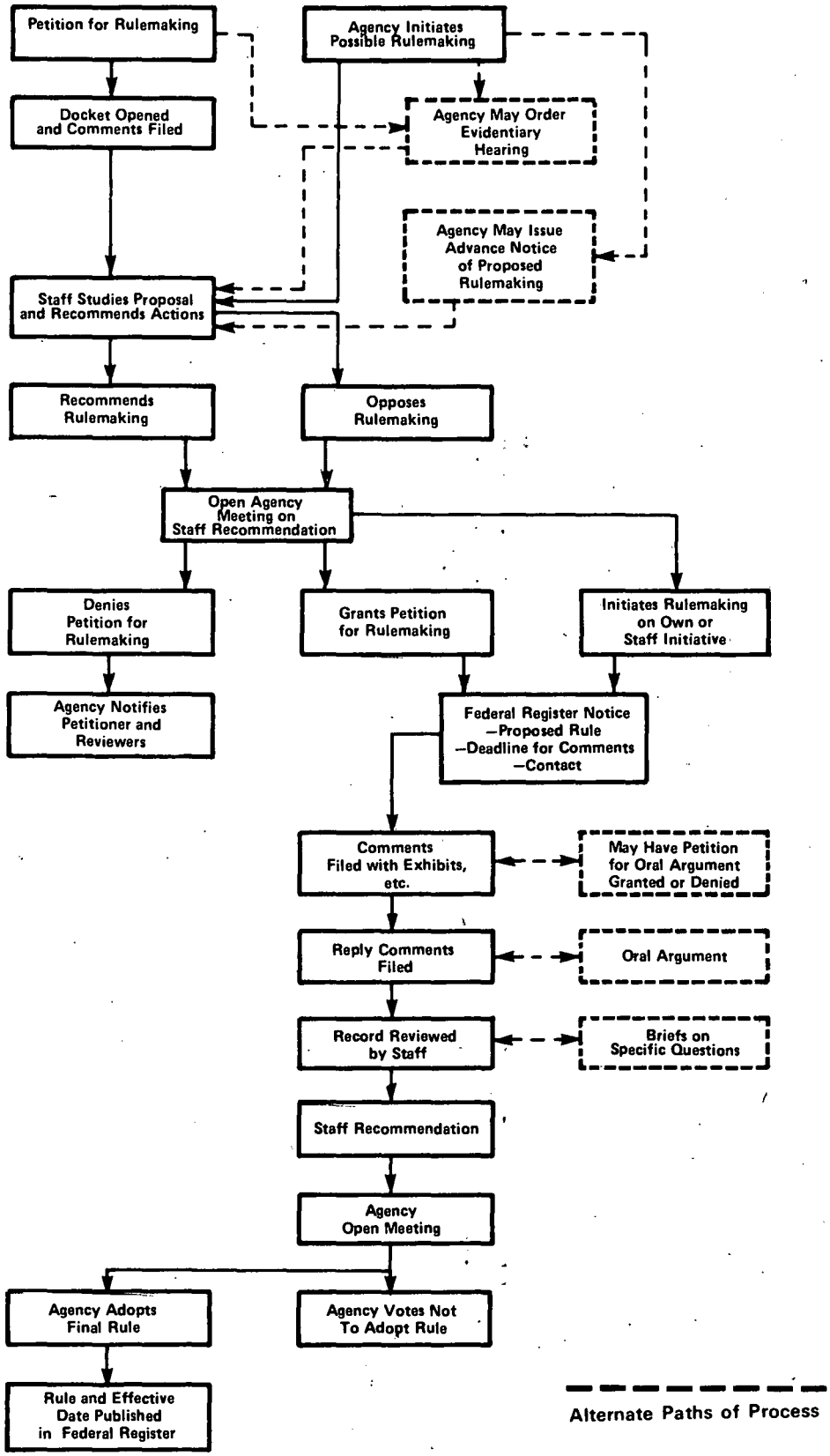
This process begins with a petition to one of the previously outlined agencies with microwave regulatory responsibilities. This petition, originated by any interested party or individual, may request the appropriate agency to amend, modify, or repeal a specific agency regulation. Alternately, the agency itself can initiate possible rulemaking. For the EPA, an internal development plan is established, followed by an announcement of Advanced Notice of Proposed Rulemaking in the Federal Register.

The petition identifies the concerned individual(s), and provides a concise statement of facts upon which the request is based. This petition is then placed in a docket (file) and assigned a number. It is reviewed within the agency who direct the petition to appropriate agency offices or bureaus for comment. In the case of microwaves, and dependent upon which of the agencies circulates the petition, expertise would be drawn from offices such as the Bureau of Radiological Health, NIOSH, ORP.



EPA microwave guidance initiated by the Office of Radiation Programs [1] would be sent to the Assistant Administrator for Air, Noise, and Radiation. Providing science advice in developing the guideline is the Assistant Administrator for Research and Development [2] through its Office of Health and Ecological Effects [2A]. Simultaneously the draft guidance is forwarded to the Administrator [3] and the Office of Planning and Evaluation [4]. This office's Standards and Regulations Division works with the Assistant Administrator for Planning and Management [5] coordinating the agency's development of the guideline. The Planning and Management Office also conducts long range planning, studying economic and industrial impact of guidelines is forwarded to the Administrator [6] for signature and publication in the Federal Register.

Exhibit 9. EPA Guidance Development Process



Adapted from: Understanding the Federal Regulatory Process, The Washington Monitor, Inc., Washington, D.C. 1978

Exhibit 10. Rulemaking Process for Microwave Radiation Standards

At this point, agency staff members provide recommendations to approve, partially approve, deny, or modify the original petition, offering their comments at a specially convened meeting, generally open to the public. At this meeting, decisions are also made on whether or not to institute a rulemaking proceeding without public hearings or oral arguments. If a petition is approved, the agency will prepare a notice of proposed rulemaking, to be carried out in the Federal Register. This document is the only daily publication that prints all rules proposed and adopted by federal agencies.

The published Federal Register notice will list the substance and/or text of the proposed rule, the docket number, legal authority for rule proposal, appropriate agency member to contact for information, and a deadline for public comment. The notice contains suggestions for commenters to address specific points or questions.

Upon publication of a proposed rule, comments from members of the public, public interest groups, industries, other governmental agencies, or state and local governments can be filed. These comments can oppose, support in whole or in part, the proposed rule. Such comments can include exhibits, or can suggest modifications. Oral argument may be granted or denied at this stage by the agency. If a hearing is granted, it would be held before an agency office, or an administrative law judge. Those commenting can file "reply comments" to respond to or rebut other comments submitted. Deadline for comments is flexible and is determined by the agency. The typical comment period is from 30 to 60 days, with agency right to extend the deadline.

With the deadline for comments passed, agency staff members review all comments that are on file in the docket and prepare final recommendations. If the rule is adopted, it will be published in the Federal Register, along with the rationale for rule adoption and its effective date. Before it becomes effective, agencies are required to provide 30-days notice in the Federal Register that a rule has been adopted. A final rule in the Federal Register must include summaries of comments received during the process, and state any changes that resulted from such comments in the final ruling.

SPS and Microwave Regulatory Process

SPS design, research and development, and operation schedules must reflect an awareness of current U.S. and international microwave regulations and standards. SPS implementation must be in concert with federal agencies responsible for utilization and subsequent impact of microwaves on the public, environment, and in the occupational setting, e.g., rectenna maintenance.

At this time, no single interface is available for SPS development, implementation and commercialization regarding production of rf energy by the SPS microwave power transmission system (MPTS). As discussed in section 5.0, however, the recently formed Federal Council on Radiation Policy, chaired by the Administrator of EPA, could ostensibly untangle agency jurisdictional overlap and the various regulations that would affect the SPS MPTS. The Council will involve 12 federal agencies, providing a forum for creating radiation policy (both ionizing and non-ionizing), and will include review of radiation monitoring and protection responsibilities of government agencies. The SPS Program Office (SPSPO) should make its interests known to the Council at an early date.

Previously outlined agencies that currently have microwave regulatory responsibilities are: the FDA for protecting the public from potential health hazards of electronic products that emit radiation; the OSHA for regulating radiation levels in the workplace; and the EPA which develops federal guidance concerning radiation levels in the environment, including public exposure. The intrinsic nature of SPS and its MPTS cuts across numerous agency jurisdictions and regulatory authorities. Yet to be ascertained is the possible distinction of SPS as an "electronic product," hence falling under greater FDA regulation. Also, no microwave exposure criteria apparently exists for SPS astronaut construction workers, or for non-SPS astronauts passing through an SPS-generated microwave beam. Conceivably such standards could evolve from an expansion of OSHA responsibilities.

To determine federal agency involvement with SPS decisionmaking concerning the MPTS, SPS developmental phases are identified as:

Basic Research. Systematic, fundamental study directed toward fuller scientific knowledge of understanding of subjects bearing on national energy needs.

Efforts to increase knowledge and quantitative understanding of natural phenomena and environment.

Applied Research. Systematic study directed toward fuller scientific knowledge for direct use in fulfilling specific energy requirements.

These efforts are directed toward the solution of problems in the physical, biological, behavioral, social, and engineering sciences which have no clear-cut applicability to specific projects. This includes the technical means of obtaining the knowledge, understanding, and solution.

Exploratory Development. Efforts guided by the principle that the work should lead ultimately to a particular application of product. Even so, the techniques and intrinsic intellectual value of the work may compare favorably with that of basic research activity. Exploratory development can cut across several scientific disciplines and is intended to explore possible innovation in a particular area of one or more energy technologies.

Technology Development. Systematic use of the knowledge and understanding gained from research to achieve technical feasibility and to gauge economic and environmental potential of energy concepts, processes, materials, devices, methods, and subsystems.

Comprises development of engineering technologies, subsystems, planning and analysis studies, energy system concept formulation, comparison of alternative concepts, and development and test of laboratory-scale engineering feasibility models. This includes demonstration by experiment of alternative system concepts as well as preliminary studies encompassing system analysis, trade-offs, preliminary cost benefit studies, planning, programming environmental studies.

Engineering Development. Systematic use of the knowledge and understanding gained from research and technology development to achieve the detailed design, construction, and test for performance, producibility, reliability of energy system prototypes and pilot plants.

Detailed design, development and test of energy system prototypes and pilot plants judged to be technically and economically desirable as a means of achieving the principal energy goals. Engineering development may concern itself with processes, preproduction components, equipment, subsystems or systems. This capacity also includes major system test facilities directed toward specific project development and the preparation of appropriate environmental impact statements.

Demonstration for commercial application, through design, construction, test and evaluation, of large-scale energy systems in operational circumstances.

Final engineering design, assembly, test and evaluation of full-scale energy systems aimed at providing directly applicable experience in an operational environment so as to demonstrate economic viability for commercial application. Demonstration projects are intended to: a) overcome "scale-up" problems; b) contribute to the understanding of the economics of fabrication and operation; and c) resolve other questions such as public assistance, institutional and environmental issues. Preparation of suitable environmental impact statements is included in this category.

Commercialization, Production, Operation

a. Commercialization. When the predominant problems become those of bringing the system or project to commercial reality rather than demonstrating technical feasibility such as:

   (1) "scale-up" problems are overcome;
   (2) economics of fabrication and operation are understood;
   (3) public acceptance, institutional and environmental issues resolved;
   (4) commercial interest in project.

b. Production. When the predominant problems become those of producing the item in quantity, bulk or other parameters which meet specifically stated requirements.

c. Operations. When the predominant problems become those of bringing the system or project from prototype or pilot plant operational testing status, to full-scale operational condition to meet stated objectives.

The potential involvement of federal agencies charged with microwave regulation and monitoring, and agency interaction with SPS development phases, is shown in exhibits 11, and 12, respectively.

Federal Agency	Role	SPS Element Affected
Council on Environmental Quality (CEQ)	Regulation/Monitoring—regulates environmental impact statement process to assure compliance with NEPA * requirements; ensures that questionable projects receive adequate public and legal consideration, including Presidential review if necessary.	Microwave health & safety; atmospheric impacts; environmental impacts
Department of Energy (DOE) (Office of Environment—EV)	Standards compliance with NEPA—develops environmental, health & safety standards	All environmental aspects
**Department of Health, Education & Welfare (HEW) (Food & Drug Administration—FDA) Bureau of Radiological Health (BRH)	Standards—sets public standards for radiation exposure from electronic products	Design aspects of microwave beam and rectenna area, electrical connections with utilities
Department of Labor (DOL)—(Occupational Safety & Health Administration—OSHA)	Standards—development of health & safety guidelines for occupations involving microwave exposure	Space & ground rectenna workers, their environments, & measures to ensure health & safety
Environmental Protection Agency (EPA)	Guidance/Enforcement and research—sets standards which meets requirements of NEPA & which environmental impact statements must address.	All microwave & atmospheric health & safety issues
EPA (Office of Public Awareness)	Education & information dissemination	Public involvement on environmental microwave issues
National Aeronautics & Space Administration (NASA)	Standards—performs research and development & sets standards for development of space-related programs	All elements of MPTS hardware design & construction & the software systems serving them; system definition

*National Environmental Policy Act

**In 1980, the DHEW is to be changed to the Department of Health and Human Services.

Exhibit 11. Potential Involvement of Federal Agencies and SPS Element Affected

Adapted from M. Marrs, 1980.

SPS Development Phase		Microwave Aspect	Agency Involvement
1	Basic Research	Environmental and Public Health Effects Evaluation MPTS Technology	DOE, EPA, HEW/FDA, NASA
2	Applied Research	Conduct Experiments and Further Define Health and Safety Risks of MPTS to Public, the Environment and SPS Workers	DOE, NASA, HEW/FDA, DOL/OSHA EPA
3	Exploratory Development	Preliminary Standards Development Radiation Exposure Standards Occupational Health & Safety Standards Development	HEW/FDA, DOE/EV, EPA, HEW/FDA, BRH DOL/OSHA
4	Technology Development	Final Standards for MPTS Chosen Occupational Health & Safety Standards Finalization	HEW/FDA, DOE/EV, EPA DOL/OSHA
5	Engineering Development	Preparation of Environmental Impact Statements, all facets of MPTS	CEQ
6	Demonstration	Guidelines for Health & Safety (Worker) Enforcement Guidelines for Public Health & Safety Environmental Impact Statements	DOL/OSHA HEW/FDA–BRH, EPA CEQ
7a	Commercialization	Review Guidelines for Worker Health and Safety Review Guidelines for Public Health and Safety	DOL/OSHA HEW/FDA, EPA
7b	Production	Enforcement of Guidelines for Worker Health and Safety Enforcement of Regulations for Public Health and Safety	DOL/OSHA EPA
7c	Operations	Enforcement of Guidelines for Worker Health and Safety Enforcement of Guidelines for Public Health and Safety	DOL/OSHA EPA

Adapted from M. Marrs, 1980.

Exhibit 12. MPTS/Federal Agency Involvement

5.0 FUTURE TRENDS

5.1 Regulatory Reform

In 1980, comprehensive regulation aimed at improving and streamlining the entire federal regulatory process is under review.[55] [56] [57] This overhaul has generated White House support and is looked upon favorably by consumer groups. The major thrust of the legislative proposal calls for detailed analysis of all major regulations proposed or issued by federal agencies. Major rules are those with economic impacts of more than $100 million. The analysis would examine other alternatives, projected costs, and benefits of the proposal. In addition, the introduced legislation sets up a Committee on Regulatory Evaluation, which would include functions of the recently formed Regulatory Council to oversee agency regulatory efforts. Currently the Regulatory Council is designed to promote coordination among the government's regulatory agencies. In 1979, the Council implemented a program for commonality of federal agency methodology in assessing cancer risk and regulatory costs.[58]

The general trend of regulatory activities has been, and will probably continue to be, to call for tighter controls on activities perceived as potentially harmful to public health. A proposed regulation that would preclude use of a microwave power transmission system by SPS could be challenged and an analysis of microwave effects would be weighted against not having SPS energy. This pending regulatory legislation would demand evaluation of all effects of a given SPS policy action, not merely the study of microwave exposure impact. Cost and benefit analysis would be ordered to determine whether the direct and hidden costs of imposing a regulation outweigh the tangible and intangible benefits from the regulation.[59]

Public Participation

A future trend in the regulatory process involves increased public participation in rulemaking proceedings. Proposed legislation seeks to increase the level of funding for agency public participation programs. "Intervenor funding" is also proposed which would pay for public participation. The payment of witnesses to represent the public interest is in response to some concerns that only corporations or public interest groups can afford lobbying efforts.

As stated in the 1979-1980 Congressional Quarterly's Federal Regulatory Directory,

> A basic question that has been raised in recent years has been whether there is in fact a need to facilitate representation by

> consumer and citizen groups in the regulatory process. It has been argued that greater public interest representation would provide the agencies with new or different information to enable them to make more informed judgements. And, since regulation exists to protect consumers and workers as well as industry interests, there should be broader representation throughout the process.[60]

This increase in public participation could have negative and positive effects on SPS planning. Public awareness and concern over microwave radiation is steadily increasing, as noted by a study on SPS public acceptance.[61] Environmental groups and public coalitions have already taken issue with the development of projects involving nonionizing radiation, e.g., Sanguine/Seafarer, Pave Paws, and microwave communication relay towers. The lack of conclusive data regarding low-level, long-term effects of microwaves on the population could emulate public concerns and response to nuclear power.

The very terminology, "microwave radiation", may confuse the public; the difference between nonionizing and ionizing may be misunderstood, leading to general citizen apprehension of the term radiation. This apprehension could be vented through public participation in the federal regulatory process. Conversely, pro-SPS space advocates, of course, would utilize these participatory channels as well.

The National Council for Radiation Protection and Measurement (NCRP), a nonprofit corporation chartered by the Congress, is attempting to develop nomenclature that will differentiate between nonionizing and ionizing radiation.[62]

Coordination of Regulatory Agencies

Increasing activity by federal agencies in nonionizing radiation research and standard setting creates, in many cases, overlapping jurisdiction, as well as gaps. The need for federal agency coordination in radiation protection and research has been advocated by several studies.[63,64] Future coordination efforts may involve an executive level position within the Executive Office of the President with the sole responsibility of providing sustained coordination of multiagency radiation research and regulatory efforts. A Radiation Policy Council, formed in October 1979, is currently involved with ionizing radition, but is likely to be broadened to nonionizing radiation in the future.[65]

A bill (S. 1938) is now before Congress which would coordinate agency action in the radiation area. Known as the "Federal Radiation Protection Management Act of 1979,"[66] the bill is designed to "ensure adequate protection of workers, the general public, and the environment from harmful radiation exposure, to establish mechanisms for effective

coordination among the various federal agencies involved in radiation protection activities, to develop a coordinated radiation research program, and for other purposes."

Central to the bill is establishment of a Federal Council on Radiation Protection, composed of agencies with radiation protection responsibilities. The bill calls for the Administrator of the EPA to act as Chairman of the Council. A function of the Council is the review of the authority of any federal agency in regulating human radiation exposure standards.

To foster agency coordination in the nonionizing radiations area, mechanisms have already been established to alleviate jurisdictional and regulatory overlaps. In the absence of a major coordination effort, these groups will play an increasingly important role in the future development of SPS.

ERMAC. Begun in 1967, the Electromagnetic Radiation Management Advisory Council (ERMAC)[67] serves as a central focus in coordinating and overviewing scientific knowledge, requirements, the status of programs, and funding levels in nonionizing radiation research.

ERMAC is a multiagency activity. Until March 1978, it was coordinated and promulgated by the Office of Telecommunications Policy (OTP), Executive Branch of the President. ERMAC has since moved, with OTP, to the National Telecommunications and Information Agency (NTIA) within the Department of Commerce. The fundamental purpose of ERMAC is to develop reliable scientific information on effects and interactions of RFEM energy with living systems and to ensure safe and appropriate use of the rf spectrum. Among its objectives is the establishment of a sound scientific basis for the timely development of appropriate guidelines for exposures or use of RFEM energy.

BENER. At the request of the Science and Technology Adviser to the President, NTIA was requested to prepare a detailed plan for a federal program on understanding the biological effects of nonionizing electromagnetic radiation (BENER).[68] A draft report was published in October 1979.

To reach the BENER goal of providing a sound basis for protection of public health and the environment, program objectives include: assessing population exposure, determining the biological consequences of exposure, developing instrumentation and exposure systems, conducting risk and impact assessments, and recommending control measures.

IRLG. In 1977, the FDA, the Consumer Product Safety Commission, the EPA, and OSHA agreed to form an Interagency Regulatory Liaison Group (IRLG) to "improve the public health by sharing information, avoiding duplication of effort and developing consistent regulatory policies."[69] In 1978, the IRLG formed the Radio Frequency and Microwave Commmittee, comprised of EPA, FDA, and OSHA. NIOSH and FCC have subsequently been requested to participate in the Committee.

The objectives of the Committee are to:

- develop a consistent radiation protection philosophy for radio frequencies and microwaves;
- coordinate the development of a comprehensive biological effects survey report on published experimental and epidemiological studies, considering the efforts of all agencies;
- identify common research needs and coordinate biological and physical research program;
- identify radiofrequency and microwave emitters and the population exposed, identify significant sources and categorize them; and,
- develop a coordinated control and corrective action plan for rf/microwave sources.

5.2 Agency Future Trends

FDA

The FDA will continue to set standards for electronic products, but at a limited pace. The only standard planned currently is for microwave diathermy units. An upgrading of compliance testing equipment will complement the introduction of these new performance standards.[70]

RFEM sealers have been identified as a "high priority for regulatory action."[71] The sealers are used in the manufacturing industry for joining plastics and wood and many other applications. Concern has been expressed that workers who operate the approximately 15,000 rf sealers in use are being exposed to high levels of rf radiation, in some instances, 180 times the present voluntary standards. [2]*

The FDA/BRH is attempting to collect information on the biological effects of RFEM radiation emitted by the sealers, to identify and categorize sources of such exposures, and to develop consistent policies and plans for minimizing operator exposure to such radiation.

*Partial body exposures for many devices, with even lower output than rf sealers, the local fields incident to human tissue can exceed the standards by many orders of magnitude.

The IRLG rf/microwave Committee has developed a plan of cooperative action, lessening the areas of overlapping jurisdiction between such agencies as the OSHA and the FDA.

OSHA

In a December 1975 decision, an administrative law judge for the Occupational Health and Safety Review Commission held that OSHA's standard for RFEM fields is "advisory" rather than mandatory.[73] An effort to establish a mandatory standard for RFEM radiation is currently being developed by OSHA. This standard will be defined from, in part, the NIOSH criteria document recommendations, which were completed for review purposes in 1980. The NIOSH document suggests guidelines essentially the same as those expressed by the 1979 ANSI document.[74] A draft ANSI document appears as appendix D.

Pressure has been placed on OSHA for a permanent, enforceable standard. A bill was introduced in March of 1979 entitled, "Protection from Non-Ionizing Radiation in the Workplace Act of 1979."[75] The Act requires the Secretary of Labor to provide for the establishment of occupational safety and health standards to protect employees from nonionizing radiation (including the establishment of emergency temporary standards for radiation from rf industrial heating devices until permanent standards are established). If passed, the bill would require promulgation of occupational safety and health standards within 60 days to protect workers from nonionizing radiation.

In September of 1979, OSHA released a notice[76] from its Office of Federal Compliance and State Programs, establishing a uniform citation control procedure for rf and microwave radiation in general industry. Citations are to be issued when employees are found to be exposed to electromagnetic radiation in the 10 MHz to 100 GHz frequency range which exceed recommended energy density levels averaged over any 6-minute period of time. OSHA and NIOSH are expanding educational programs for employees and employers by developing material specifically directed at the hazards of nonionizing radiation.

EPA

In 1979, EPA issued a "notice of interest on microwave regulations." A final Federal Guidance for the protection of the environment from electromagnetic radiation is expected in the Fall of 1981.[77] The Federal Radiation Protection Guides will be developed to protect the public from excessive exposures to RFEM radiation through specification of maximal allowable environmental intensities of RFEM radiation intensities as a function of radiation frequency at locations accessible to the public. Instrumentation and measurement techniques appropriate to compliance will be recommended.

Earlier EPA studies concluded that "most people, perhaps greater than 98 percent, are exposed to levels that are less than 0.001 mW/cm^2, most of the time."[78] However, further EPA studies will be directed to specific source categories and the resulting impact on nearby environments.

In gathering data useful in drafting final recommendations for nonionizing radiation guidelines, EPA research efforts include:[79]

- whether prolonged, low level exposures to environmental nonionizing radiation at and below 0.05 mW/cm^2 is correlated with human cancer incidence rates,
- whether prolonged higher level exposure around 0.1 mW/cm^2 correlates with any effect on human life span or cause of death,
- whether pre- and post-natal exposure to nonionizing radiation has any bearing on infant mortality in monkeys,
- whether extended exposures to 0.5-5 mW/cm^2 under a variety of environmental conditions will affect the behavior of primates, and
- whether prolonged, continuous exposures of rodents to 0.5-5 mW/cm^2 affects any of a number of physiologic parameters.

Regarding EPA's future in microwave regulatory authority, the possibility has been raised that the agency be given powers in radiation safety similar to those it already possesses in toxic substances. Such authority would allow EPA to request action from another agency, set deadlines for the other agency's action, and intervene to establish enforceable standards if its deadlines were not met.

EPA authority to issue "guidance" aimed at controlling ambient levels of radiation and exposures thereto of the general public is currently derived from the former Federal Radiation Council (FRC). A possible expansion of authority is, however, questioned on jurisdictional grounds. Resolving such questions and increasing the authority of EPA in the nonionizing regulatory area could close a major gap in regulatory functions, in that no other body possesses general environmental authority over this type of radiation.[80]

FCC

In June of 1979, the FCC initiated a Notice of Inquiry[81] to gather information and views to assist the agency in "establishing the course it should pursue in fulfilling its regulatory responsibilities to promote communications by radio in light of the increased concern about the biological effects of radiofrequency radiation."

Other federal agencies with responsibility in the area of public health may act in response to this increased public concern by initiating or accelerating rulemaking that may result in stricter federal safety standards to reduce or limit the level of RFEM radiation. The FCC feels it is important to have at its disposal sufficient information to interpret the impact of any such proposed standards and to comment on each proposal.

The FCC inquiry is, therefore, designed to serve two purposes: 1) to assist in determining whether it is appropriate to take any action under existing standards now applied by the health and safety agencies, and 2) to provide documentation to allow the FCC to adequately participate in any rulemaking proceedings of these other agencies.

The Commission's interest in the biological effects of nonionizing radiation flows from two basic areas of statutory responsibility. The Commission has licensed the millions of nongovernment transmitters now in use throughout the nation and is granting additional licenses at an accelerating rate. In addition, the FCC authorizes use of microwave ovens, industrial heaters, and many other types of unintentional radiating equipment.

Because of an increasing number of public inquiries about the health effects of FCC authorized facilities and equipment, the FCC could play an important role in future microwave regulatory activities.

It must be noted that the Communications Division of the Electronics Industry Association (EIA) has responded in the negative to the FCC Notice of Inquiry.[82] The Division cites "a significant lack of data" from 30 years of bioeffect research, and believes that the FCC "should not take any regulatory action in the matter of effects of nonionizing electromagnetic radiation at this time."

5.3 International Trends and Cooperative Programs

In a recent survey of selected Soviet and East European literature, a trend toward convergence of Eastern and Western findings with regard to low-level microwave and other RFEM fields has been noted.[83] A similar convergence with regard to East-West occupational standards has been observed. Speculation centers on a lowering of the U.S. occupational level to 5 mW/cm^2 while the current Soviet standard of 0.01 mW/cm^2 might be raised by as much as an order of magnitude. A developing trend is the recognition by both Soviet and American scientists that frequency dependence, in regards to effects, should be used to establish standards.

NIEHS

On a global basis, the exchange of information regarding microwave research is on the increase. Cooperative programs between the U.S. and the U.S.S.R. are expected to augment the dialogue between Eastern and Western scientists. Under an Environmental Health Agreement, coordinated by the National Institute of Environmental Health Sciences (NIEHS), a better understanding of Soviet research methodology and experimental techniques has, and is, being achieved.[84] The U.S.-U.S.S.R. agreements on bioeffects research of NIEHS have received high marks by microwave experts, characterized by an expression that "the age of cooperation has arrived."[85]

The widespread and increasing use of microwave energy greatly increases the possibility of exposure of both occupational and general population groups. It is a worldwide phenomenon. To promote a common understanding of the scientific basis for protective measures, an international symposium in 1973 recommended:[86]

- To promote international coordination of research on the biologic effects of microwave radiation, there should be a continuing exchange of information, improved efficiency of translation services, exchange visits, and closer collaboration in research projects and publications.

- A program concerned with nonionizing radiation should be developed by an international health agency that could exert leadership in this field and facilitate communication among scientists. It was hoped that the World Health Organization would assume this responsibility.

- Every effort should be made to establish internationally acceptable nomenclature and definitions of physical quantities and units and to standardize measurement techniques and dosimetry. An international group should be established to work out procedures for achieving these objectives.

Meetings, symposia, and conferences presently aid in the dissemination of new bioeffects research and standards development. The newly formed Bioelectromagnetics Society (BEMS)[87] offers a newsletter containing updated bibliographies of world literature on bioeffects research. The International Microwave Power Institute (IMPI) produces a journal and sponsors short courses on microwave bioeffects and radiation safety. This activity could have wide influence in making standards uniform on an international basis. Additional organizations which spur cooperative understanding in the bioeffects area include the following:

IRPA - The International Radiation Protection Association (IRPA) charter wa broadened in 1977 to include nonionizing radiation. IRPA is seeking funds to devote to this topic and plans to join forces with the World Health Organization (WHO) in producing a criteria document on rf/microwaves.

WHO - The World Health Organization (WHO) is a United Nations technical agency with headquarters in Geneva. WHO has a program for development of criteria documents that cover a variety of health-related topics. WHO currently plans to develop a criteria document on rf/microwaves, with a final draft scheduled for early 1980.

ERO - The European Regional Office (ERO) of the World Health Organization is currently writing a manual on health aspects of exposure to nonionizing radiation. The document is intended to provide guidance on nonionizing radiation protection and to summarize international experience in the field.

NAS - The National Academy of Science is in the process of undertaking an objective, comprehensive, critical appraisal of the world literature on the biological effects of radio frequency waves. The research would culminate in a document similar to an NAS report on the Biological Effects of Ionizing Radiation (BEIR) which has been used by agencies to develop standards for ionizing radiation.

URSI - The International Union of Radio Science has played an important role since 1976 in consolidating many small workshops and symposium sessions into annual full scale symposia. URSI has gained international prestige by attracting both Soviet and Eastern European researchers. A URSI International Working Group on bioeffects provides communications between Eastern and Western researchers for organizing future symposia and workshops.

6.0 TRENDS IN MICROWAVE STANDARDS AND BIOEFFECTS RESEARCH

6.1 Occupational and Public Standards

The trend for U.S. microwave standards, both occupational and public, is downward to more stringent levels. The ANSI evaluation, now in draft form, lists as a recommendation in the 1,500 to 300,000 MHz frequency range, a power density of 5 mW/cm^2*. The ANSI recommendations, in draft form, appear as appendix B. The NIOSH criteria document, also under preparation, lists similar values as the ANSI document,[88] and will be considered by OSHA in occupational standard setting.

In establishing the revised ANSI recommendations, a C95.4 Subcommittee Working Group concluded, "... 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 condition."[89]

It is possible that future standards for both workers and the general public will be the same.[90] According to extended EPA exposure studies, research results call into question the adequacy of the 10 mW/cm^2 guideline as a point of departure for the development of general population exposure guidelines.[91] The possibility of a limit at or below 1 mW/cm^2 for the public, based on EPA research, is conceivable, although such a standard for the workplace might have an adverse economic impact-a view held by industrial concerns.[93] However, workplace monitoring programs could be intensified, offsetting such an impact.

6.2 Bioeffects Research

Standard setting cannot be isolated from future trends in bioeffects research. New studies are being implemented to evaluate the interaction of microwaves at the cellular and subcellular level.[93] Of particular relevance to SPS are new long-term, low-level microwave exposure programs. Several such studies have recently been funded. One such program, an Air Force-sponsored project, is designing a model experiment for ultra-long-term chronic exposure, with great care being taken to control environmental conditions and dosing of animals with RFEM energy. The project involves lifetime exposure for one generation of rats (at 2450 MHz), with longevity as one of the end points. Exposures should be completed

*For the 30 to 300 MHz frequency range, a power density of 1 mW/cm^2 is recommeded.

in late 1982 with results available in mid-1983. Data produced from this study and other could have implications for the next ANSI standard review at the end of 1984.[94]

Controversy surrounds the application of biological effects data from animal exposure to the development of human exposure limits. Questions have been raised as to whether the average amount of energy per unit time delivered to the entire animal or whether the maximum amount of energy per unit time delivered to a selected organ or tissue area of the animal is the important consideration. The term, specific absorption rate (SAR), is a recently introduced, spatially dependent quantity that specifies the rate of RFEM energy absorption by a specific mass of tissue of the exposed subject. The question remaining 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 peak SAR. Answers to this question could result in a difference by a factor of 10 in regulatory standards.[95]

To resolve such questions, a host of future biological research has been advocated. A report prepared for the Office of Science and Technology Policy (OSTP)[96] lists research areas which are believed to warrant future priority attention. These are:

Instrumentation and Dosimetry - Further development and refinement of instrumentation and techniques are needed for determining dose, relating incident to internal fields, measuring internal fields and energy distribution, and extrapolating laboratory results from experimental animals to man. Development of nonperturbing implantable temperature, physiologic, and field probes should be encouraged.

Mechanisms of Interaction - Theoretical and experimental research is needed to determine the basic mechanisms of interaction with molecules and cellular components and the loci of interaction as a function of power density, frequency and waveform. Particular emphasis should be placed at the membrane level.

Long-term, Low-level, Exposure Studies - Long-term, low-level studies should be performed on animals with exposure durations of at least a year, and preferably over the life of the animal. These experiments should be conducted so that as many physiological and psychological tests as feasible can be performed in the same experiment. Morbidity (overall status of health) and mortality should be an integral part of long-term animal experiments.

Human Studies - Epidemiological and clinical investigations should be undertaken in groups of workers and others exposed to radiofrequency radiation and high voltage transmission line fields at various intensity levels with carefully determined exposures.

Combination of Radiofrequency Radiation or High Voltage Transmission Line Fields With Other Agents - Interaction of radiofrequency radiation and high voltage transmission

line fields in combination with other agents should be investigated. Drugs, pathogenic organisms, and other physical (including ambient conditions) and chemical stressors which could have an additive or synergistic effect should be studied.

Important Biological Effects Studies - High priority should be given to research to determine the effects of radiofrequency and high voltage transmission line fields on the nervous system, reticuloendothelial system, teratogenic and developmental processes, and interaction with membrane structure and function. Research is also needed on other biological systems, but based on present information is not considered to be of the highest priority. Genetic effects are included in this priority grouping, because, despite the far reaching importance of such effects, previous studies do not indicate this occurrence in mammalian systems at moderate exposure levels. Behavioral effects, cardiovascular effects, ocular effects, effects on fertility and reproduction, and effects on the ecosystem should be further investigated. Although the Working Group considered that these studies were not of the highest priority, they are considered important and necessary.

Beneficial Applications - Research to study and develop safe, beneficial uses of radio frequency radiation, particularly in the biomedical field, should be continued and encouraged by appropriate emphasis and support.

Presumably, the results of this research will have significant implications for future microwave standards. However, what role public pressure will play in standard setting before data are available is difficult to determine. As suggested by one researcher,[97]

> The establishment of a clearly defined and legally enforceable standard on a "temporary" basis does not require the final completion of the scientific research that should be done in this field. Careful adjudication of the presently available data viewed against reasonable risk/benefit criteria coupled with the lack of clinically perceptible injury in most of the occupational groups now at risk should permit the establishment of a liveable standard, providing reasonable assurance of safety and avoiding unreasonable constraints on our use of the precious rf spectrum.

7.0 MICROWAVES AND SOCIAL TRENDS

The widespread use microwave and radiofrequency devices has grown enormously in the last 50 years, becoming an integral part of modern society. Radar, industrial processes, communications systems, navigation, consumer products, and medical applications have wrapped populations in a virtual cocoon of electromagnetic radiation.

This growth in the number of RFEM sources represents a significant economic investment, with an estimated U.S. Government depreciated capital investment in electronics expected to grow to $99 billion by 1986. For the consumer, purchase of microwave ovens and citizen band (CB) radios continue on an explosive growth pattern. NIOSH estimated that 20 percent of the U.S. work force will be exposed during the present year to RFEM radiations in the workplace.[98]

This expansion of uses and sources of RFEM energy has led to the question: Is RFEM energy yet another environmental agent that may be hazardous to human and other life forms? Public interest in the answer has been sparked by media attention to controversies surrounding the Seafarer program, the high voltage power line,[99] discovery of microwave signals beamed at the U.S. Embassy in Moscow, recall of microwave ovens,[100] increasing microwave tower and radar antenna installation,[101] as well as the proposed Satellite Power System.[102] Public, and hence, political pressures for adequate microwave safety standards are a major ingredient in future regulatory processes.

The possibility of enforceable new standards, perhaps at more stringent levels, must be balanced, however, within the context of risk and benefit. Is a risk-free society impractical? The recent proposal by the City of New York to establish a strict standard that would limit exposure at 0.05 mW/cm^2 is a case in point. The proposal was considered untenable due to the proposed standard's impact on the services needed to operate and safely maintain a city the size of New York.[103]

The dichotomy of the situation has been explained by one attorney,

> The very fact that society places a high value on defense and communications makes them likely to develop more rapidly than other technologies and to become instantly "essential." Since traditional market mechanisms have failed to account for health costs, health protection requires special governmental attention. Other efforts may be made within the process of cost-benefit analysis to deal with this problem, but the health-based pollution standard serves as a necessary safeguard in a preventive program.

> In determining what the ceiling should be, one should be aware of the important technologies and national functions potentially affected; but one must reject the misguided suggestion that there must be "conclusive scientific evidence" of the threat before critical communications will be restricted. First, this suggestion ignores the realities of regulating on "the frontiers of scientific knowledge" where conclusive proof is probably impossible absent human experimentation or the occurrence of the very accidents a preventive policy seeks to avoid. Second, this position adopts the traditional bias in favor of existing technology rather than human health. As Congress has recognized in recent years in its formulations of environmental legislation, our society needs a corrective bias in favor of health protection; those who support continued use of technologies harmful to health should have the burden of proof. Furthermore, certain absolute standards must be set, because merely imposing the burden of proof on industry has been shown insufficient. It has been necessary to resort to "technology-forcing" provisions to induce industry to do what it can (but claims it cannot) do to reduce pollution. If, indeed, nonionizing radiation poses the case of a pollutant for which ambient levels are still safe, then this standard will help keep them so. It will be "technology controlling," channeling research and development efforts in communications and other affected industries into the creation of nonradiative alternative technologies.[104]

Observes a report by an ad hoc Working Group of the Office of Science and Technology Policy,[105] "the possibility of unjustifiable yet serious restrictions on necessary and beneficial uses of rf radiation and high voltage lines exists as long as definitive information on which to base rational decisions is not available." In the absence of this information, public pressure will be a growing trend in setting microwave regulations. And, as one industry spokesman notes, "how do you explain to the public that a power density of 10 mW/cm^2 could be considered safe one day and hazardous the next day?"[106] Meanwhile, suggests one writer, "inexorably, invisibly, the electronic smog grows thicker."[107]

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APPENDIX A
NON-U.S. MICROWAVE STANDARDS

Canada

Until 1977, the Canadian Department of Health and Welfare standards for microwave exposure were identical to U.S. standards. A reduction in exposure limit from the 10 mW/cm^2 to 1 mW/cm^2 value is now under discussion. The maximum permissible levels (MPL's), when first proposed in 1976 contained two parts: a) 1 $mW\text{-}hr/cm^2$ average energy flux for whole body exposure as averaged over an hour with a maximum exposure during any one minute of 25 mW/cm^2 for occupational settings and (b) one tenth of the occupational MPL's for the general population. The MPL's would apply for the frequency range of 10 MHz to 300 GHz. No distinction is made between continuous or pulsed waveforms. The proposal was subsequently modified to eliminate the tenfold difference for the general population. . . "since it is felt that present data on biological effects does not justify a lower MPL." [108]

Czechoslovakia

Using separate exposure levels for continuous and pulsed radiation emissions, Czechoslovakia is the only country having separate microwave standards for an occupationally exposed group and the general population. (Russia has also adopted a 24-hour exposure standard for the general public of 0.001 mW/cm^2.)

A complex set of microwave radiation guidelines were passed in 1968. Translated roughly into Western terms, the established standards are a multiple of radiation energy flow per unit area and time: [109]

- Maximum daily dose is eight hours at 0.01 mW/cm^2 for workers with microwave units in industry (pulsed radiation).
- Maximum daily dose is 24 hours at 0.001 mW/cm^2 for the general population and all other workers (pulsed radiation).

With the highest standards governing exposure of the general population to microwave radiation of any nation, the Czechoslovakia standard for continuous radiation is two and one-half times that of pulsed radiation. Thus, the maximum permissible levels at 300 MHz-300 GHz is 0.025mW/cm^2 with an exposure limit for continuous wave radiation of 8 hours duration. Pulsed radiation, at the same frequency, has an exposure limit of 0.01 mW/cm^2 at 8 hours exposure duration.

England

In the United Kingdom, recommendations on microwave radiation cover 30 to 30,000 MHz. Continuous daily exposure is limited to 10 mW/cm^2 with no reference to a time-weighted average. If it can be proven that no radiation intensity of greater than 1 mW/cm^2 can be reached anywhere where anyone would normally and reasonably have access, then measurements do not have to be made.[110]

France

French military guidelines have been set at 10 mW/cm^2 for exposures of one hour or longer. A de facto 55 mW/cm^2 limit is recognized for periods of less than one hour. For public areas, a limit of 1 mW/cm^2 is considered "desirable."[111]

Poland

Poland has adopted, essentially, the Soviet standards in 1961. However, a revision in 1972 now sets Poland's occupational level at 0.2 mW/cm^2 and the environmental limit at 0.01 mW/cm^2.[112]

Based on the 1961 Council of Ministers rules, the following maximum allowable mean values of power intensity for microwaves where people are present are:[113]

- o intensity 0.01 mW/cm^2 - no limit,
- o intensity 0.01 - 0.1 mW/cm^2 - cumulative exposure time not to exceed two hours out of 24, and
- o intensity 0.1 - 1 mW/cm^2 - cumulative exposure time not to exceed 20 minutes in 24 hours.

Poland has introduced the concept of "zones" of exposure, defined on the basis of the intensity of microwave fields. "Safe," "intermediate," "hazardous," and "dangerous" zones have been established. Polish standards were compiled by a group of engineers, physicists, physicians, and biologists. Their recommendations were based on statistical and epidemiologic data from Soviet and Polish studies indicating the occurrence of temporary disturbances of function that could not be interpreted as thermal effects.[114]

Soviet Union

There is a large difference in occupational exposure standards of the Soviet Union and the United States. The established Soviet exposure level is:

- o exposure levels during the entire working day cannot exceed 0.01 mW/cm^2,
- o exposure for a maximum two-hour working day must be limited to 0.1 mW/cm^2, and
- o exposure for not more than a 15 to 20 minute working period at 1 mW/cm^2 is permissible if protective goggles are used. [115]

The Soviet adoption of these standards for exposure to microwave radiation is 1,000 times lower than equivalent U.S. standards. Thus, a difference by two to three orders of magnitude exists between U.S. and the Soviet standard. The Soviets have adopted a 24-hour exposure standard for the general public of 0.001 mW/cm^2.*

Sweden

On June 22, 1976, the Swedish National Board of Industrial Safety issued a nonionizing radiofrequency standard. The regulation applies to all work which may involve exposure to radiofrequencies between 10 MHz and 300 GHz. The instruction specifically excludes applications involving the treatment of patients. Maximum permissible exposures (as averaged over a six-minute period) are: 5 mW/cm^2 - 10 MHz to 300 MHz and 1 mW/cm^2 - 300 MHz to 300 GHz.[116]

The maximum permissible momentary exposure in the range 10 MHz - 300 GHz is 25 mW/cm^2.

West Germany

The West Germany Association for Radar and Navigation has published a guide that is considered authoritative in the Federal Republic. It sets the critical limit of microwave radiation intensity at 10 mW/cm^2 for human exposure. No allowance is made for time of exposure.[117]

*At publication time, Donald McRee of the NIEHS reports the Soviet Union has instituted a legally-binding microwave population standard of 0.005 mW/cm^2.

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APPENDIX B

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.

---

*Given in testimony of Dr. Arthur Guy, Chairman ANSI C95.4 Subcommittee on RF Radiation Hazards, Hearing on Non-Ionizing Radiation of the Subcommittee on Natural Resources, Committee on Science and Technology, U.S. House of Representatives, July 12, 1979.

Table I. Whole Body Radiofrequency Protection Guides

(1) Frequency Range	(2) Power Density	(3) E^2	(4) H^2
MHz	mW/cm^2	V^2/m^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 I, columns (3) and (4).

For partial body human exposure at frequencies between 300 KHz and 5 GHz the protection guides in table I 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 I.

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 I, 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 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 handheld, 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.

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