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Microwave radiation emitted by products such as microwave ovens, medical and dental diathermy apparatus, alarm systems, radar, communication relay systems, and power devices poses a potential hazard because of its biological effects. Under the Radiation Control for Health and Safety Act, the Food and Drug Administration (FDA) is required to establish a radiation control program which must include: development of performance standards, research and investigations into effects and control of radiation emissions, compliance activities to make sure that manufacturers meet program requirements, and training activities to minimize unnecessary radiation exposure. Findings/Conclusions: The FDA has identified two microwave products--microwave ovens and medical diathermy equipment--which need performance standards; it has issued a standard for the ovens but not for diathermy equipment. The FDA has not always reviewed manufacturers' reports promptly so that problems could receive early attention. There are no Federal standards to protect the public and workers from potential hazards of microwave exposure, but voluntary guidelines setting 10

milliwatts per square centimeter as a maximum safe level of occupational exposure were published. The adequacy of this level of exposure was questioned because of studies which indicated undesirable biological effects resulting from such exposure. Since this exposure guideline was a consideration in the FDA's microwave oven emission standard, the standard should be reevaluated. The FDA's diathermy equipment surveys identified several operator practices which could result in unnecessary radiation exposure to patients and operators. Recommendations: The Secretary of Health, Education, and Welfare (HEW) should direct the Commissioner, FDA, to: issue and implement a performance standard which provides appropriate safety requirements for microwave medical diathermy equipment; establish procedures to ensure that all manufacturers' initial, supplemental, and annual reports are reviewed promptly; and develop training material for diathermy equipment operators to better ensure that unnecessary exposure of patients and operators to microwave radiation due to operator controllable factors is minimized. The Administration, Environmental Protection Agency, and the Secretary of Labor should establish mandatory standards to protect the public and workers from exposure to microwave radiation. (HTW)

REPORT BY THE

Comptroller General

OF THE UNITED STATES

8470

Released 12-11-78

More Protection From Microwave Radiation Hazards Needed

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

Food and Drug Administration efforts to regulate these products need strengthening. The Administration has not (1) issued a performance standard, which it has determined is needed for diathermy equipment, (2) always reviewed manufacturers' reports promptly so that problems could receive early attention, and (3) developed material for use in training diathermy equipment operators, which would help to minimize patient and operator exposure to unnecessary radiation.

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

HRD-79-7
NOVEMBER 30, 1978

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-164031(2)

The Honorable John E. Moss, Chairman
Subcommittee on Oversight and Investigations
Committee on Interstate and Foreign Commerce
House of Representatives

The Honorable A. Toby Moffett
House of Representatives

The Honorable Elizabeth Holtzman
House of Representatives

This report is in response to your requests for information on the regulation of microwave radiation. The Food and Drug Administration is responsible for regulating the level of radiation emitted by electronic products. The Environmental Protection Agency regulates radiation exposure levels in the environment and the Occupational Safety and Health Administration regulates radiation exposure levels in the workplace.

As requested, we did not obtain formal comments on the report. However, we did discuss it with representatives of the Food and Drug Administration, Environmental Protection Agency, Occupational Safety and Health Administration, and other cognizant agencies and have considered their views in preparing the report.

As arranged with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of the report. At that time we will send copies to interested parties and make copies available to others upon request.

Comptroller General
of the United States

Contents

ABBREVIATIONS

ANSI	American National Standards Institute
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
HEW	Department of Health, Education, and Welfare
Hz	Hertz--cycle per second
MHz	Megahertz--one million cycles per second
mW/cm^2	One thousandth of a watt per square centimeter --a unit of measurement for radiation power density
NTIA	National Telecommunications and Information Administration, Department of Commerce
OSHA	Occupational Safety and Health Administration of the Department of Labor
RCH&S Act	Radiation Control for Health and Safety Act
TEPRSSC	Technical Electronic Product Radiation Safety Standards Committee

COMPTROLLER GENERAL'S REPORT TO THE HONORABLES JOHN E. MOSS, CHAIRMAN, SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS, HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE, A. TOBY MOFFETT, AND ELIZABETH HOLTZMAN

MORE PROTECTION FROM MICROWAVE RADIATION HAZARDS NEEDED

D I G E S T

Concern is increasing over the potential hazards of exposure to microwave radiation emitted by products such as microwave ovens, medical and dental diathermy apparatus, alarm systems, radar, communication relay systems, and power devices. Microwave's capacity to generate heat in body tissue and cause effects has been known for some time.

Under the Radiation Control for Health and Safety Act, the Food and Drug Administration is required to establish an electronic product radiation control program to protect the public health and safety. The program must include (1) development of performance standards to control the emission of radiation from electronic products, (2) research and investigations into the effects and control of such radiation emissions, (3) compliance activities to make sure that manufacturers meet program requirements, and (4) training activities to minimize unnecessary electronic product radiation exposure.

LIMITED DEVELOPMENT OF PERFORMANCE STANDARDS

The Food and Drug Administration has identified two microwave products--microwave ovens and medical diathermy equipment--which need performance standards. A performance standard for microwave ovens has been issued.

Although the Food and Drug Administration in 1974 identified the need for a standard for medical diathermy machines to protect the patient, operator, and the public from microwave radiation, it has not yet established any standard.

GAO also believes a standard for diathermy machines should be established because of potentially adverse biological effects reported in human and animal studies at exposure levels well below those to which machine operators and patients may be exposed. (See pp. 17 and 18.)

COMPLIANCE ACTIVITIES

The Food and Drug Administration reviews manufacturers' reports to verify compliance with requirements related to product labeling, emission levels, safety, and installation and operation instructions.

The reviews have not always been prompt. Some of the reports on microwave ovens had not been reviewed for extended periods and a third of those reviewed either identified a potential radiation hazard or needed clarification. As of February 28, 1978, about 75 percent of the manufacturers' reports for other microwave equipment had not been reviewed; most of the reports were more than 3 years old. (See pp. 22 and 24.)

Because many of the reports are incomplete or contain information which indicates microwave radiation-emitting products could be detrimental to the public health, prompt attention is essential.

MICROWAVE EXPOSURE STANDARDS ARE NEEDED

A number of studies have questioned the safety of exposure to microwave

radiation. No Federal standards exist to protect the general public and workers from potential hazards of such exposure. Voluntary guidelines setting 10 milliwatts per square centimeter (mW/cm^2) as a maximum safe level of occupational exposure have been published.

Over 1,000 U.S. and foreign research reports contain study results or analyses on biological effects caused by exposure to microwave radiation. Of these, 112 reports have been cited as reference material supporting the Food and Drug Administration's microwave oven emission standard, or were identified by Administration officials as particularly important to their continuing evaluation of the standard's adequacy. (Exposure and emission standards approach radiation regulation differently. Exposure standards set limits on the amount of radiation a person can be subjected to in his environment; emission standards set limits on the amount of radiation a product can leak into its surroundings. See p. 15.)

Over half of the 112 reports state that animals and humans exposed to microwave radiation levels of 10 mW/cm^2 or less experienced biological effects, some undesirable.

Because a number of these reports warn of effects in animals and humans at the above-mentioned exposure levels, GAO discussed the adequacy of 10 mW/cm^2 as a safe level of exposure with four cognizant agencies.

Representatives from two of these agencies pointed out that, in addition to the 112 reports GAO reviewed, many other reports show no effects from exposures to microwave radiation at the same exposure levels.

Representatives from all four agencies, however, believe there is a need to evaluate the adequacy of the 10 mW/cm^2 microwave exposure guideline.

The Food and Drug Administration's standard for microwave ovens limits emissions to 1 mW/cm^2 before purchase and to 5 mW/cm^2 after purchase when measured at 5 centimeters (about 2 inches) or more from the oven's surface.

The implications of the findings contained in the 112 reports GAO reviewed on this emission standard are less clear because oven emissions are measured at a fixed distance from the oven and as the distance between a subject and the oven increases, the exposure level decreases.

However, since the 10 mW/cm^2 exposure guideline was a consideration in establishing the microwave oven emission standard, exposure standards providing new levels may require a change in the emission standard. (See ch. 4.)

NEED FOR MEDICAL DIATHERMY OPERATOR TRAINING MATERIAL

The Food and Drug Administration is required by the Radiation Control for Health and Safety Act to conduct, coordinate, and support training activities to minimize unnecessary electronic product radiation exposure.

Food and Drug Administration diathermy equipment surveys have identified several operator practices which could result in unnecessary radiation exposure to both patients and operators. The Administration should develop material for training operators of microwave diathermy equipment to make sure that they are

adequately trained in the latest procedures to minimize exposure due to operator controllable factors. (See pp. 43 to 45.)

The Secretary of Health, Education, and Welfare should direct the Food and Drug Administration to improve its regulation of microwave radiation-emitting products. The Administrator, Environmental Protection Agency, and the Secretary of Labor should establish mandatory standards to protect the public and workers from exposure to microwave radiation. (See pp. 20, 29, 36, and 45.)

CHAPTER 1

INTRODUCTION

By letter dated January 21, 1977, Representative John E. Moss, Chairman, Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce, and Representative A. Toby Moffett requested us to obtain information on the possible biological hazards posed to the public by microwave radiation. Particularly they wanted information on:

--How the Department of Health, Education, and Welfare (HEW) has implemented the Radiation Control for Health and Safety Act (RCH&S Act) (42 U.S.C. 263b).

--Known or suspected threats to human health posed by microwave radiation.

--How HEW standards establishing permissible levels of microwave radiation exposure were established and the criteria and research used to support the standards.

--HEW's enforcement of the standards.

--The interaction, liaison, and coordination between HEW and the Environmental Protection Agency (EPA), the Department of Defense, the Department of Labor's Occupational Safety and Health Administration (OSHA), and the Consumer Product Safety Commission regarding public exposure to microwave radiation.

In addition, by letter dated April 20, 1977, Congresswoman Elizabeth Holtzman expressed concern about the levels at which the American public is being exposed to microwave radiation and requested that we examine the extent to which the requirements of the RCH&S Act have been implemented as they relate to such radiation. In subsequent discussions she also requested that we identify those studies used by the Food and Drug Administration (FDA) as the basis for the microwave oven standard and more recent studies which FDA believes are relevant to determining the continued adequacy of that standard.

WHAT IS MICROWAVE RADIATION?

Microwave radiation is a form of electromagnetic energy which is generated during the operation of certain electronic products such as microwave ovens, medical and dental diathermy apparatus, alarm systems, radar, communication relay systems, power devices, and other commercial and industrial apparatus. This form of radiation falls within the radiowave frequency band of the total electromagnetic spectrum. (See app. I.) While the total spectrum includes all electromagnetic waves from one wave (cycle) per second, called one hertz (Hz), to as much as 10^{25} Hz (10 followed by 25 zeros), microwave radiation is generally defined as the band of frequencies from about 300 megahertz (MHz) to about 300,000 MHz. 1/ By comparison, AM radio broadcasts occur in a band around 1 MHz, while TV broadcasts occur in a band ranging from about 50 MHz to about 1,000 MHz.

Radiation frequencies in the electromagnetic spectrum are classified as either ionizing or nonionizing. Ionizing radiation includes those frequencies of about 3×10^{16} Hz and higher, and is produced by sources such as X-ray equipment and nuclear material. It destroys or damages living cells and can cause illness such as cancer or genetic injuries which, in turn, can cause birth defects and embryonic death.

Nonionizing radiation includes all frequencies below about 3×10^{16} Hz and includes radiation commonly known as ultraviolet light, visible light, infrared light, microwaves, and radiowaves. Nonionizing radiation, of itself, does not destroy or damage cells but can cause damaging heat in body tissue and changes in behavior and physiological and neurophysiological functions. (See ch. 4.)

In the past several years concern has significantly increased over the potential hazards posed by exposure to microwave radiation. Such concern has been generated by the significant increase in the use of microwave-emitting

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1/One MHz is equal to 1 million hertz, or 1 million cycles per second. In scientific notation, 300 MHz equal 300 million cycles per second and 300,000 MHz equal 300 billion cycles per second.

products and by a new awareness of microwave radiation as a potential health hazard. Its capacity to generate heat in body tissue and to cause heat-related effects during exposure at high levels, such as cataractogenic effects in the eye, has been known for some time. Its effects at low levels of exposure, however, such as its reported potential to cause changes in behavior or physiological functions, are less definite.

RADIATION REGULATION

The RCH&S Act, dated October 18, 1968, amended the Public Health Service Act (42 U.S.C. 201) to provide for establishing an electronic product radiation control program to protect the public health and safety. The RCH&S Act states that the program shall include developing and administering performance standards to control radiation emissions from electronic products and undertaking and distributing the results of research and investigations into the effects and control of such radiation emissions. The program must also include (1) liaison and cooperation between the various Federal agencies having related radiation responsibilities, (2) review and evaluation of industry programs to ensure that products meet performance standards, and (3) training activities to minimize unnecessary electronic product radiation exposure.

The act states that in developing performance standards consideration must be given to (1) the latest available scientific and medical data in the field of electronic product radiation, (2) standards currently recommended by other Federal agencies and public or private groups, and (3) the reasonableness and technical feasibility of such standards as applied to a particular electronic product. The act allows different and individual performance standards to be prescribed, to the extent appropriate and feasible, for different electronic products so as to recognize their different operating characteristics and uses. Standards may include provisions for testing electronic products and measuring their radiation emissions and requirements for affixing to the product warning labels and instructions for its installation, operation, and use.

If a product is found likely to create an immediate, significant risk of injury because of radiation emission, the RCH&S Act states that it can be declared to be defective. Manufacturers of products which are identified as defective, like manufacturers of products which fail to meet provisions of performance standards, can be required to eliminate

the risk by repairing or replacing the product or may be required to refund the cost of the product.

The act requires the Secretary of HEW to establish the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) "which he shall consult before prescribing any standard." The committee "may propose electronic product radiation safety standards to the Secretary for his consideration." The committee is to be composed of 15 technically qualified members with 5 members from each of 3 groups--Government, including Federal and State agencies, affected industries, and the general public--one of which must be from organized labor.

The present membership of TEPRSSC consists of three Federal and two State government officials, four product manufacturer officials, one industry research company official, three educators, one hospital official, and one labor official. The committee's present charter states that it is to provide advice and consultation on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control radiation emissions from such products and recommend electronic product radiation safety standards. In addition, the committee may make recommendations on other matters it deems necessary in fulfilling the purposes of the act.

FDA's Bureau of Radiological Health 1/ is responsible for carrying out the provisions of the RCH&S Act by establishing policies, standards, and procedures to protect the public safety and for conducting compliance activities to ensure that manufacturers meet program requirements. In addition to a staff of 379 located in Rockville, Maryland, to carry out the FDA radiation control program, FDA has programed 94 staff-years of effort for regional radiological health representatives

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1/The Bureau of Radiological Health became part of FDA in May 1971. Previously, it was part of HEW's Environmental Health Service. For simplicity of presentation, references in this report to FDA actions prior to May 1971 represent actions taken by the Bureau of Radiological Health. The responsibilities assigned to the Secretary of HEW under the RCH&S Act have been delegated to the FDA Commissioner.

and radiation control officers in the 10 HEW regions. The regional staffs are responsible for field compliance activities and, in some cases, are assisted by State radiation control organizations.

FDA's radiation control program consists of four project areas. These areas and the resources allocated to each in fiscal year 1978 are shown below.

Project area	Staff positions	Funds
		(000 omitted)
Ionizing radiation--products and devices	181	$ 6,972
Ionizing radiation--use control	130	5,359
Light and sonic radiation	106	4,738
Radio frequency/microwave radiation	56	2,434
Total	473	$19,503

Most of the Bureau's staff and funding resources were allocated to the first three project areas because FDA believes their relative potential risk of injury to the public is greater and because of public sensitivity to the problems associated with the risk.

PRODUCTS UNDER FDA'S JURISDICTION

Under the RCH&S Act, electronic product radiation includes any nonionizing electromagnetic or particulate radiation which is emitted from an electronic product as a result of the operation of an electronic circuit in such product. The act defines an electronic product as

> "(A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product * * * which when

in operation emits (or in the absence of effective shielding or other controls would emit) such radiation: * * *"

Senate Report 1432 (90th Cong., 2d sess.) submitted by the Senate Committee on Commerce on the bill (H.R. 10790) which ultimately became the RCH&S Act defined the bill's scope as covering

"* * * all electronic products which purposely or incidentally emit radiation, and which are a source of human exposure at work, in the home, or during medical treatment."

FDA regulations (21 C.F.R. 1000.15(b)) list the following illustrative examples of sources of microwave electronic product radiation: alarm systems, diathermy units, dryers, ovens, heaters, medico-biological heaters, microwave power-generating devices, radar devices, remote control devices, and signal generators.

The responsibilities of FDA and other Federal agencies concerning radiation control differ in that FDA regulates the amount of radiation emitted by products, and other agencies control the amount of radiation to which a person can be exposed.

According to an FDA Associate Chief Counsel, FDA is the only Federal agency authorized to act directly to regulate electronic product radiation emission levels and to require manufacturers to modify products which pose a significant risk of injury because of radiation emissions. If a product is shown to cause potentially dangerous levels of microwave exposure to individuals and the most feasible corrective measure is to require the manufacturer to reduce the product's emission levels, FDA can immediately declare the product to be defective or, as a long-term solution, issue and enforce product performance standards.

By contrast, EPA regulates radiation levels in the environment and OSHA regulates radiation levels in the workplace. In addition EPA, under the President's Reorganization Plan No. 3, effective December 2, 1970, is responsible for recommending to the President, policies concerning radiation problems that directly or indirectly affect health.

Recommendations approved by the President would be published as guidance to Federal agencies that have responsibility for regulation.

The Secretary of Labor, acting through OSHA, is responsible for setting occupational safety and health standards for private businesses engaged in interstate commerce. These standards recommend microwave radiation exposure levels that are intended to create a safe working environment for employees exposed to these radiation sources.

CHAPTER 2

LIMITED DEVELOPMENT OF PERFORMANCE STANDARDS

The RCH&S Act (42 U.S.C. 263f) requires FDA to issue regulations prescribing performance standards to control radiation emissions from electronic products if such standards are necessary for the protection of the public health and safety. FDA has identified two microwave products for which it believes performance standards are necessary. These are microwave ovens for which a performance standard was issued in October 1970 and microwave medical diathermy equipment for which a standard is being developed. Presently FDA is surveying other microwave radiation-emitting products to identify those which it believes may require standards.

CRITERIA FOR SELECTING PRODUCTS NEEDING STANDARDS

An FDA official told us that in selecting those radiation-emitting products for which standards are needed, three factors--risk, public interest, and the practicality of correcting the problem--are considered. Risk considerations include the possibility and extent of consumer injury, illness, or economic loss. Public interest considerations include such factors as the inability of consumers to determine the amount of danger associated with a product and the need to provide special protection for certain consumers such as children and the elderly. An evaluation of the practicality of correcting a problem considers constraints, such as (1) lack of scientific knowledge regarding the cause or solution of the problem, (2) agency authority to take action, and (3) size of the problem as it relates to agency priorities.

Based on these factors and continuing evaluations of the safety of microwave-emitting products, FDA has identified at the present time only two products--microwave ovens and medical diathermy equipment--for which it believes performance standards are needed.

MICROWAVE OVEN STANDARD

In 1969 FDA determined that there was a need for establishing a performance standard on microwave ovens to protect the public health and safety because (1) there

was a potential health hazard associated with microwave radiation, (2) surveys showed that a high proportion of ovens (22 percent of those surveyed) leaked radiation in excess of 10 milliwatts per square centimeter (mW/cm^2), the level considered by the industry to be acceptable, (3) an FDA laboratory investigation of safety interlock switches on certain commercial and home microwave oven models indicated that they could fail or be purposely bypassed, allowing the ovens to operate with the door open, potentially causing emissions up to 700 mW/cm^2, and (4) projections indicated that the number of ovens in use, particularly in homes, was expected to increase significantly during the next few years (annual sales were projected to increase from 40,000 in 1968 to 500,000 in 1975).

During development of the microwave oven standard, FDA sought consultation and comments from TEPRSSC, oven manufacturers, and other Federal agencies and organizations with related responsibilities and interests.

On May 22, 1970, FDA issued a Federal Register notice proposing a performance standard applicable to the emission of radiation from microwave ovens. It proposed that the power density 1/ of the microwave radiation emitted by a new oven should not exceed 1 mW/cm^2 at any point 5 centimeters or more from the external surface of the oven. The notice stated that, in the development of the proposed standard, it became evident that consideration should also be given to the gradual increase in microwave radiation leakage due to normal wear over a long period of oven use. Therefore, FDA's notice proposed that an oven's power density emissions after purchase should not exceed 5 mW/cm^2 at any point 5 centimeters or more from the external surface of the oven.

On October 6, 1970, FDA published in the Federal Register a final regulation (42 C.F.R. 78.212 (1971)) setting forth a performance standard for microwave ovens. The regulation applies to ovens which operate in the frequency range of 890 to 6,000 MHz and which are used in homes, commercial establishments, and interstate carriers. The standard provides that no oven manufactured after October 6, 1971, shall emit a level of radiation in excess of 1 mW/cm^2

1/Power density is the intensity of electromagnetic radiation at a given point and is expressed as the average power per unit area--usually mW/cm^2.

prior to purchase or 5 mW/cm² after purchase measured at 5 centimeters or more from the external surface of the oven.

The regulation also requires that ovens be subject to measurement and tests to determine compliance with radiation-emission limitations, that ovens have two operative safety door locks, one of which must be concealed, and either of which will cause the oven to become inoperative if the door is opened, and that manufacturers provide instructions for operating and maintaining the ovens. The manufacturer must provide to its dealers and distributors at the time of delivery, a certification that each oven conforms to all applicable provisions of the standard.

In the October 6, 1970, Federal Register, FDA noted that several comments responding to the proposed standard concerned the basis for the established power density limits. FDA explained:

> "The limit of 1 mW/cm² established for microwave ovens prior to transfer to a purchaser is an emission limit for one source of microwave radiation. It should not be construed as an exposure limit for the using population. This emission limit embodies a factor of safety which is considered sufficient at this time to protect the public health. The limit of 5 mW/cm² after acquisition by a purchaser was established so that the possible increase of leakage radiation over the lifetime of the oven would not be permitted to exceed this value."

FDA's general regulations (21 C.F.R. 1010.4) covering all radiation-emitting products permit manufacturers of such products, including microwave ovens, to apply for and be granted a variance from performance standards when an alternate means is used to provide radiation safety or protection equal to or greater than the protection required by the standards. None of the oven manufacturers has applied for a variance from the standard.

FDA has published three amendments to this standard. The first, which became effective August 7, 1974, added performance requirements to microwave oven safety interlock systems to improve their reliability.

The second, which became effective October 3, 1975, requires the manufacturer to permanently affix or inscribe labels on the oven warning users and repair men of essential precautions to be taken to avoid unnecessary exposure to microwave radiation. The amendment permits manufacturers to be granted, upon application, an exemption from the user-warning label requirement when the manufacturer can demonstrate to FDA that its oven will continue to comply with the performance standard under adverse operating conditions due to an object caught in the oven door, an improperly closing door, or a damaged door, hinge, latch, or sealing surface. One firm was granted an exemption because of the unique design of its door seal which prevents excess radiation emissions even when there is incomplete physical contact between the door and the body of the oven under the three adverse conditions of operation.

The third amendment, effective November 7, 1976, placed more stringent safety requirements on the oven door's safety interlock mechanisms.

Others that have established similar emission standards include the Army and Japan. During a TEPRSSC meeting at which the FDA microwave oven standard was being discussed, a TEPRSSC member, who was also an official of the Department of Defense, advised the group that the Edgewood Arsenal Army Environmental Health Agency used 1 mW/cm^2 as the acceptable emission level for microwave ovens and ovens which were found to emit radiation of more than 5 mW/cm^2 were returned for correction. Japan, on June 30, 1970, established an emission standard for new and used ovens of 1 mW/cm^2 when the door is fully closed and 5 mW/cm^2 when the oven is operated under certain conditions which prevent the door from sealing completely.

Basis for emission standard

In establishing the microwave oven emission standard of of 1 mW/cm^2, FDA considered several factors, including (1) studies of biological effects caused by exposure to microwave radiation, (2) the need for a desirable margin of safety, and (3) existing microwave exposure guidelines.

Studies of biological effects

FDA's "Documentation Report" dated December 1970, which summarizes the basis for the microwave oven performance standard, lists various biological effects which had

been observed, primarily in studies with animals, following microwave exposure. These effects included cataract induction, testicular pathology, and central nervous system disorders.

According to the report, the lowest microwave dose to cause cataracts in animals from a single exposure 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 * * *."

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 pathologic 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 * * *." Regarding these findings, however, the report states:

> "This work has been questioned, particularly since work from the U.S.S.R. [Union of Soviet Socialist Republics] is not reported in great detail * * *, and there is a lack of direct communication between American and Russian investigators."

Margin of safety

According to FDA's documentation report, the emission standard of 1 mW/cm^2 for new ovens provides a safety factor of 10 against the U.S. exposure guideline of 10mW/cm^2 (see pp. 13 and 14). The report states that a safety factor of 10 was needed because:

--Microwave ovens are a potentially dangerous source of electromagnetic radiation and are used under a variety of uncontrolled conditions.

--Microwave oven operators in restaurants, hospitals, and other establishments that serve food could be exposed to microwave radiation for many hours each day.

--No control would be possible over the health of the users of microwave ovens in the home.

--Research studies have suggested the possibility of cumulative effects and the question of effects of intermittent repeated exposure over the lifetime of an individual, especially the young, could not be ignored.

--The findings of the Russian studies cannot be easily dismissed even though uncertainty exists over the work of the Russian scientists.

--Microwave radiation from ovens is only one of several sources of electromagnetic radiation to which the population is exposed; other sources of electromagnetic radiation exist both in the nonionizing and ionizing frequencies and the possibility of biological interaction of multiple electromagnetic radiation exposures has not been fully investigated, nor have the complicated interactions between substances in the environment, including bacterial, viral, and chemical agents, been adequately evaluated.

Microwave exposure guidelines

Before FDA established its microwave oven emission standard, other Federal agencies and foreign governments, and the American National Standards Institute (ANSI) had established occupational microwave exposure guidelines for the working population. The exposure guidelines set by these agencies, organizations, and countries vary widely.

In 1965 the U.S. Army and Air Force adopted microwave exposure standards which restrict workers' exposure to microwave radiation levels of 10 mW/cm^2 for periods of 1 hour or more. For periods less than 1 hour, radiation exposure may increase to a maximum of 100 mW/cm^2.

In 1966 ANSI (at that time known as the United States of America Standards Institute) adopted a similar guideline which permits a maximum power density of 10 mW/cm^2 for periods of exposure of 6 minutes or more and allows

greater exposure for shorter periods of time. According to FDA's documentation report, exposure standards essentially similar to ANSI's have been adopted by the British Post Office, the German Association for Radar and Navigation (West Germany), and the Canadian Standards Association. 1/

According to the documentation report, Russia limits microwave exposure to .01 mW/cm^2 for a working day, 0.1 mW/cm^2 for 2 hours daily, and 1 mW/cm^2 for 15 minutes daily. Poland adopted essentially the same standards.

The report notes that Czechoslovakia is the only country that has separate microwave standards for an occupationally exposed group and the general population. 2/ The standards set separate exposure levels for continuous and pulsed radiation emissions. 3/ Czechoslovakia's standards for occupational microwave exposure to continuous and pulsed microwave radiation are .025 and .01 mW/cm^2, respectively, for an 8-hour period and for 24 hours of exposure from both types of microwave radiation are .0025 and .001 mW/cm^2, respectively.

1/On May 29, 1971, the Occupational Safety and Health Administration established an occupational guideline for microwave exposures based on the Institute's standard. While it has been interpreted as primarily advisory, the guideline recommends a maximum level of 10 mW/cm^2 for exposures of 6 minutes or more. Presently there is no Federal guidance on public microwave exposure; however, EPA is considering the need for such guidance which is discussed in the GAO report "Efforts by the Environmental Protection Agency to Protect the Public from Environmental Nonionizing Radiation Exposures" (CED-78-79, Mar. 29, 1978).

2/Russia has also adopted a 24-hour exposure standard for the general public of .001 mW/cm^2.

3/Continuous radiation refers to an uninterrupted flow of electromagnetic energy. When such energy is abruptly turned on and off at regular intervals, the resulting bursts are called pulsed radiation and are usually described as an average of the peak on and off power density levels. The peak power density level can be many times higher than the average. Czechoslovakia set a lower exposure standard for pulsed microwave radiation to protect against such peak radiation levels.

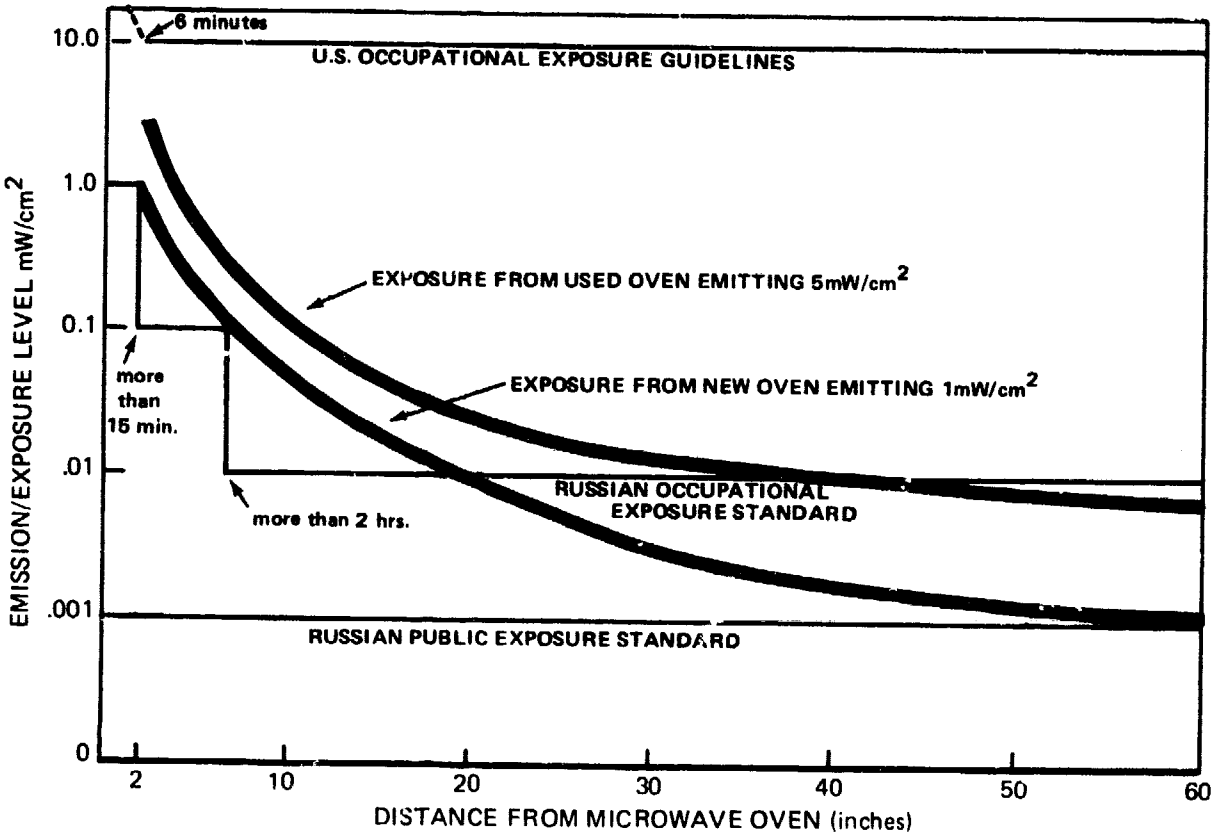
Exposure standard variations exist because research conducted by the United States and Western European countries was directed primarily toward the biological effects caused by high levels of exposure to such radiation. Consequently, their standards were designed to provide protection from high levels of exposure and the resulting heating effects. On the other hand, Russia and other Eastern European countries have conducted considerably more research into the biological effects from low levels of exposure and their standards are intended to protect people from the "non heating effects" of long-term exposure to low microwave radiation power densities. (The wide disparity in the levels of exposure considered safe in various countries would indicate that this matter needs further study. Our recommendation in this regard is contained in chapter 4.)

Exposure versus emission standards

At first glance it may seem that the Russian occupational exposure standard of .01 mW/cm^2 is much more stringent than FDA's oven emission standard of 1 mW/cm^2. However, exposure and emission standards, while related, approach radiation regulation from different viewpoints and a simple comparison of the two is difficult. Emission standards set limits on the amount of radiation a product can leak into its surroundings while exposure standards set limits on the amount of radiation a person can be subjected to in his environment.

While both emission and exposure standards are stated in the same terms of measurement--mW/cm^2 --radiation emissions are measured at a specific distance from a radiation source with no consideration to the length of time a person may be exposed. Radiation exposure, however, is measured in terms of the length of time a person is subject to given levels of radiation with no consideration to the distance from the source or sources.

The following graph depicts the approximate relationship between the exposure a person will receive from a microwave oven emitting 1 or 5 mW/cm^2 (the maximum allowed for new and used ovens) and the distance that person is from the oven. Also shown are the Russian standards for occupational and public exposure and the U.S. occupational exposure guideline. Exposures received from oven emissions will equal Russian exposure standards at the indicated distances where the lines meet.



Any attempt to translate an emission level to an exposure level must consider distance. If, for example, a new microwave oven emits microwave radiation of 1 mW/cm^2 measured at 5 centimeters (about 2 inches) from the external surface of the oven, the exposure to a subject 5 centimeters away would also equal 1 mW/cm^2, the same level of exposure allowed for up to 15 minutes by the Russian occupational standard. If that distance is increased to 16 centimeters (about 6-1/2 inches) the exposure to the subject would decrease to about 0.1 mW/cm^2, the same level of exposure allowed for up to 2 hours under the Russian standard. At 50 centimeters (about 20 inches) from the oven, exposure will equal about .01 mW/cm^2, the level of exposure allowed for a full day by the Russian standard. At 150 centimeters (about 58 inches) exposure will equal about .001 mW/cm^2, the level of exposure allowed by the Russian public exposure standard.

Similarly the exposure caused by a used oven emitting 5 mW/cm^2 would equal 5 mW/cm^2 at about 2 inches, 1 mW/cm^2 at about 4-1/2 inches, 0.1 mW/cm^2 at about 14 inches, 0.01 mW/cm^2 at about 43 inches, and 0.001 mW/cm^2 at about 137 inches.

Another way of stating this comparison would be that in order to receive the same level of exposure from a new oven emitting 1 mW/cm^2 of microwave radiation as a Russian worker may be exposed to in an 8-hour workday, a person would be required to continuously stand about 20 inches from the oven for an 8-hour period. For a 24-hour period a person would be required to stand at about 58 inches from such an oven or about 137 inches from a used oven emitting 5 mW/cm^2 to receive radiation exposure equal to the maximum allowed for the Russian public for the same period of time. Exposure under these occupational and environmental conditions would still be 1,000 and 10,000 times less, respectively, than U.S. guidelines have established as safe.

DIATHERMY STANDARD BEING DEVELOPED

In 1974 FDA identified the need for a performance standard for microwave medical diathermy machines to protect the patient, operator, and the public from microwave radiation. These machines are most commonly used in the treatment of trauma and inflammation of joints, tendons, and muscles. According to FDA an estimated 15,000 machines are currently used in the United States and the frequency of use per machine ranges from 1 time per week to 12 times per day.

FDA found a number of diathermy machine problems which indicated the need for a performance standard. While the useful beam from microwave medical diathermy equipment used in the therapeutic treatment of an injury can reach a level of approximately 370 mW/cm^2, FDA studies indicated that such machines may also produce radiation exposure densities of up to 30 mW/cm^2 to parts of the body not requiring treatment as well as to the machine operator. Such amounts were well above the emission limits established by FDA for microwave ovens and exposure limits established by other domestic organizations. Furthermore, various studies indicate that densities well below 30 mW/cm^2 can injure and dysfunction a variety of biological systems.

Other problems which pointed toward the need for a standard or other form of control activity were (1) entry into areas around microwave diathermy machines is often not controlled, (2) medical operators and staff are frequently of childbearing age and may be more susceptible

to the effects of this radiation, (3) instrumentation to detect excess radiation levels generally does not exist in facilities housing this equipment, (4) operators are often inadequately trained in techniques to prevent excess radiation exposure, and (5) patients may have diseases which make them more susceptible to the hazards of microwave radiation.

FDA published an Advance Notice of Proposed Rulemaking in the Federal Register on June 3, 1975, advising the public of its intent to publish a proposed performance standard for diathermy machines. While FDA has not yet published the proposed standard, it has submitted a draft of the standard to machine manufacturers and TEPRSSC. At TEPRSSC's request FDA held meetings with machine users to determine the clinical impact of the proposed standard. FDA plans to publish the proposed standard in the Federal Register by late 1978 for comment.

PLANS FOR FUTURE MICROWAVE RADIATION STANDARDS

As of February 28, 1978, FDA's planning documents show that FDA's future microwave radiation performance standard work will be limited to developing a medical diathermy equipment performance standard and to preparing amendments to the microwave oven standard. FDA officials explained that, while the agency's planning documents indicate that standards are being developed for only one type of equipment, investigative work is also being performed on other microwave products. They stated that this work is intended not only to identify those products for which standards are needed but also to determine if some less formal methods of public protection, such as operator or consumer education programs or issuance of informal guidelines and recommendations on equipment design and operation, would be more effective.

Since 1968 FDA has conducted surveys on about 40 different products representing 17 kinds of microwave equipment and 21 different producers. (See app. II.) One FDA official said that substantial investigative work in the form of surveys and investigative studies must first be performed before a determination can be made on the most effective method of providing public protection.

Product surveys are generally initiated because of consumer complaints or literature received from manufacturers and involve a relatively informal review of manufacturer product data and limited FDA testing of products. Many of these products were designed for specific industrial, commercial, or laboratory purposes and their production is very limited. The surveys have shown that radiation emissions from these products have not exceeded 10 mW/cm^2 at 5 centimeters and that because of the estimated distance between the operator or the public and the equipment, actual exposure would be much lower than the U.S. exposure guideline of 10 mW/cm^2. FDA has determined that these products do not warrant the development of performance standards at the present.

In 1970 FDA studied selected large industrial microwave ovens. According to the study report, manufacturers designed their equipment so that the maximum radiation emission level was 10 mW/cm^2 measured at 5 centimeters from the oven and test measurements on selected pieces of equipment showed emissions to actually be less than this amount. The study report recommended that manufacturers periodically monitor ovens at user locations for excess radiation emissions and affix labels which caution operators against unsafe operating procedures. The report stated, however, that because it was not feasible at that time to construct industrial ovens to meet the performance standard set for home and commercial ovens, this standard should not be extended to cover industrial ovens. According to FDA officials, future surveys of industrial microwave ovens will be conducted as part of the agency's continuing surveillance of microwave product safety.

In 1975 FDA performed another investigative study of small craft marine radar equipment to determine the range and magnitude of public exposure to microwave radiation from such devices. FDA measurements disclosed that persons using such equipment would normally be exposed to average power densities below 1 mW/cm^2. However, it was noted that operation of the radar with the antenna rotation stopped may increase the level of exposure and the U.S. Coast Guard has agreed to warn boatowners of the potential hazard.

CONCLUSION

FDA has identified two microwave radiation-emitting products for which it believes performance standards are needed. A performance standard providing certain safety

requirements has been issued for microwave ovens. Such a standard has not been issued, however, for medical diathermy equipment even though FDA identified the need for a standard in 1974. Because studies have shown that medical diathermy equipment may cause microwave exposure of as much as 30 mW/cm^2 to machine operators and to parts of the body not requiring treatment, and because potentially adverse biological effects have been reported in human and animal studies at exposures well below that level, we believe FDA should issue a performance standard for such equipment and provide for its timely implementation.

RECOMMENDATION

We recommend that the Secretary, HEW, direct the Commissioner, FDA, to issue and implement a performance standard which provides appropriate safety requirements for microwave medical diathermy equipment.

CHAPTER 3

COMPLIANCE ACTIVITIES FOR MICROWAVE PRODUCTS

The RCH&S Act requires FDA to establish a program to ensure that microwave radiaton products meet applicable performance standards. FDA's program includes (1) reviews of manufacturers' reports, (2) inspections and tests of products and manufacturers' records, facilities and quality controls, and (3) notification to FDA by manufacturers of products that do not comply with standards.

Presently all three elements of FDA's program apply only to microwave ovens as they are the only microwave-emitting products for which a performance standard has been issued. Since no FDA standards exist for other microwave products, FDA's regulation of these products is based primarily on its review of reports for selected products submitted by manufacturers. FDA has not always reviewed these reports in a timely manner.

REVIEW OF MANUFACTURERS' REPORTS

Initial, supplemental, and annual reports for microwave ovens, medical diathermy machines and microwave heating equipment have not, in all cases, been reviewed promptly. Reviewing these reports promptly would help to ensure the correction of potentially serious problems which could pose radiation risks to consumers.

Microwave ovens

The act (42 U.S.C. 263i) requires manufacturers to provide such performance data and other technical data related to product safety as FDA may require. FDA regulations (21 C.F.R. 1002.10) state that oven manufacturers must submit, prior to the introduction of microwave ovens into commerce, an initial report providing general information on the product and specific information on its procedures to ensure compliance with the standard. The regulations (21 C.F.R. 1002.11, .12, and .20) also require the manufacturer to submit (1) supplemental reports whenever changes are made which affect initial reports, (2) annual reports which provide results of safety and endurance tests performed throughout the year, and (3) reports on accidental radiation exposures whenever the manufacturer suspects

that persons have been adversely affected from exposure to radiation during manufacture, test, or use of the prod

Initial, supplemental, and annual reports

FDA officials review initial, supplemental, and annual reports primarily to verify the manufacturers' compliance with requirements related to product labeling, product emission levels, safety design, testing, and measuring methods to ensure quality control, and installation and operation instructions.

As of February 28, 1978, manufacturers had submitted to FDA 1,393 initial, supplemental and annual reports on microwave ovens. Since many duplicates were submitted, FDA determined that only 1,253 reports needed to be reviewed.

At that time FDA had reviewed 1,056 of these reports. Of the 197 it had not reviewed, 83 (42 percent) had been awaiting review for 6 months or less, 43 (22 percent) for 7 to 12 months, 54 (27 percent) for 13 to 24 months and 17 (9 percent) for 25 to 46 months.

FDA does not have written criteria establishing a time limit for completing reviews of manufacturers' reports. The FDA official who is responsible for reviewing these reports, said he would like to have all reports reviewed within 30 days. He added, however, that even though that does not occur in all cases, those oven models for which reports have not been reviewed are included under FDA's oven testing programs or plant inspections.

Of the 1,056 reports reviewed, FDA questioned 315 (about one-third) of them. These questions concerned matters such as the completeness of the data contained in the reports or the ability of the ovens to meet the standard. From its review of four of these reports, FDA determined that ovens produced by two manufacturers posed a risk to individuals and required the manufacturers to make modifications to the ovens. One firm was also required to modify its quality control program.

FDA determined that ovens covered by the other 311 reports did not pose a risk to individuals. We reviewed FDA's disposition of questions raised on 74 of the 311 reports and found that in each case FDA required the manufacturer to submit missing data or to make changes in its manufacturing processes or quality control procedures.

Accidental radiation exposure reports

As of February 28, 1978, manufacturers had submitted five reports to FDA on accidental exposures to microwave radiation. Two reports concerned possible microwave exposures from ovens which had been abused, two others concerned problems caused by improper servicing and one involved the failure of the oven door interlock safety devices.

In one of the five cases, the manufacturer reported that two persons had been exposed to approximately 40 mW/cm^2 of microwave radiation--one for about 5 to 10 seconds and the other for 15 to 20 seconds; however, neither was injured. A potential eye injury was being monitored by a physician in another case, and no microwave related injuries were found in the other three. The faulty ovens were repaired or replaced in each case.

We asked FDA officials what the agency had done to ensure itself that manufacturers were reporting all accidental radiation occurrences of which they were aware. An FDA official said that while guidelines for inspections of manufacturers' records do not specifically identify the the need to review accidental radiation exposure data, inspectors do attempt to review such data, but they have not identified any cases where a manufacturer failed to report an occurrence as required.

In addition to manufacturers' reports, 44 reports of accidental radiation exposures alleged to have been caused by microwave ovens had been reported to FDA by consumers, physicians, and others. FDA completed investigations on 40 of the 44 reports. In 28 of its investigations, FDA concluded that (1) the reported injuries were not attributable to microwave exposure or (2) the ovens were operating as required by the oven performance standard.

FDA determined that in 8 of the 40 cases the ovens were unsafe and needed to be destroyed or repaired. In all but one of these, FDA determined that the unsafe conditions were limited to the specific oven involved in the reported exposure.

In one of the eight cases, FDA suspected that the problem may have involved all ovens of that model because the oven's circuitry had been assembled incorrectly by the manufacturer which had allowed the oven's two safety door

interlocks to be bypassed and the oven to operate when the door was open. As a result, FDA required the manufacturer to test more than 2,500 ovens. The tests found no further indication of interlock failure.

FDA's investigations of 4 of the 40 cases, while completed, were not conclusive because the ovens which caused the alleged injuries were not available for testing.

At the time of our review, FDA's investigation of the remaining 4 of the 44 cases had not been completed.

Other microwave products

FDA regulations (21 C.F.R. 1002.10 and 1002.12) require manufacturers of microwave diathermy machines and microwave heating equipment to submit initial and supplemental reports providing performance and technical data on their products. Medical diathermy manufacturers are also required (21 C.F.R. 1002.11) to submit annual reports on their manufacturing programs.

FDA does not have a plant inspection or product testing program for these products since performance standards do not presently exist. Reviewing manufacturers' reports is the primary method FDA presently has to detect product or quality control defects in microwave diathermy or microwave heating equipment.

As of February 28, 1978, FDA had received from manufacturers 60 reports--40 for heating equipment and 20 for diathermy machines. Most of the 60 reports had been submitted to FDA more than 3 years earlier.

FDA had reviewed 14 of the 60 reports and found that 9 were incomplete. In each case FDA requested the manufacturer to submit the missing data. As of February 28, 1978, none of the products covered by the reports reviewed were declared defective under the act.

According to an FDA official these reports were given only a limited review to determine whether any obvious problems existed which might indicate a failure to comply with the RCH&S Act and which might result in injury to the public. He said that such reviews were limited because there were no performance standards to which FDA could compare the reported data and limited staff resources required that priority be given to microwave oven compliance activities.

FDA INSPECTIONS AND TESTS

FDA has three inspection and testing programs under which it reviews manufacturers' compliance with the microwave oven standard. These are (1) an onsite inspection program of manufacturers' records, facilities, and quality controls carried out by FDA headquarters personnel, (2) a field testing program at dealer, distributor, and purchaser locations carried out by FDA field personnel and other Federal and State agencies, and (3) an oven performance and endurance testing program conducted by an FDA laboratory.

Manufacturers are required to notify purchasers, dealers, and distributors of any deficiencies FDA identifies that pose a significant risk of injury and of the manufacturer's obligation to correct the problem.

Inspections at oven manufacturers' facilities

The RCH&S Act (42 U.S.C. 263i) requires manufacturers to maintain manufacturing records, including test records, and to permit FDA to inspect all appropriate books, papers, records, and documents relevant to determining whether the manufacturer is conforming with established standards. FDA regulations (21 C.F.R. 1002.30, .31) require manufacturers to maintain records of quality control procedures and related tests, correspondence concerning radiation safety, and distribution of such products for a period of 5 years and upon reasonable notice permit FDA to inspect appropriate records.

FDA officials conduct onsite inspections during which they (1) observe in-plant testing used to verify that ovens comply with the standard, (2) review test records and distribution records, (3) inspect instruments used to test ovens, (4) randomly select several ovens from inventory and test them for compliance with the Federal performance standard, and (5) discuss with manufacturers FDA's reporting requirements, any amendments to the performance standard and the relevance of the standard to newly designed ovens that the manufacturer plans to market in the United States in the near future.

FDA inspected at least once 20 of the 22 manufacturers which certified microwave ovens for sale in the United States during fiscal year 1976 and 19 of the 25 manufacturers which certified ovens in fiscal year 1977. FDA inspected

27 plant facilities, 18 in this country and 9 in Japan in fiscal year 1977. The FDA official responsible for scheduling the inspections said that FDA plans to perform about the same number of inspections of manufacturers, domestic and foreign, in fiscal year 1978 as it performed in the previous fiscal year. As of February 28, 1978, FDA had inspected 15 firms during fiscal year 1978.

Based on tests of selected ovens during the onsite inspections, FDA found that ovens in four manufacturers' inventories emitted radiation in excess of the microwave oven standard and that one manufacturer's quality control program was inadequate. Consequently, FDA disapproved the quality control and testing programs which were the basis for the manufacturers' certifications. FDA required four manufacturers to repair ovens held in their inventory, two of which were also required to repair ovens at dealer, distributor, and purchaser locations. While the other manufacturer was not required to repair existing ovens, it was required to improve its quality control and testing program.

Oven tests

Under the provisions of the RCH&S Act, FDA has established a microwave oven testing program which FDA field personnel and other Federal and State officials use to test ovens at distributor and dealer facilities and purchaser locations. This program provides for testing two major safety aspects--radiation emissions and safety interlock operation--of a microwave oven. For ovens manufactured after October 6, 1971, the oven test results are compared with emission standards of 1 mW/cm^2 and 5 mW/cm^2 at 5 centimeters, depending on whether the oven is new or used. For ovens produced before that time, FDA compares radiation emissions with 10 mW/cm^2 at 5 centimeters, the voluntary guidelines generally accepted at that time by the microwave oven industry as a maximum safe emission level.

This program identified six oven models which were found to emit excess microwave radiation or to have defective door interlock systems. Manufacturers corrected the deficiencies in these models.

Under this program 4,634 and 4,110 ovens were selected for testing during fiscal years 1976 (15-month period ended September 30, 1976) and 1977, respectively. Ovens from 16 of the 22 fiscal year 1976 manufacturers and 19 of the 25 fiscal year 1977 manufacturers were included in these inspections. Ovens of manufacturers with the highest production volumes were sampled most frequently.

The 1976 and 1977 tests showed that, 133 and 86 ovens, respectively, emitted excess radiation or had defective door interlock systems that posed a potential radiation hazard. For both years these included certified ovens as well as ovens produced prior to the effective date of the oven standard.

We examined 35 of the 219 test reports to determine what regulatory action FDA imposed in these cases. Three of the 35 reports involved one of the six oven models which were found under this program to emit excess microwave radiation or to have defective door interlock systems. Four test reports were on ovens which were to be repaired by their manufacturers along with all other ovens of these models because of findings of noncompliance with the standard under other portions of FDA's compliance program. FDA's investigation of ovens covered by 11 reports showed that the original test results were incorrect and that the ovens did, in fact, comply with the applicable standard. Seven reports were for ovens produced prior to the effective date of the microwave oven performance standard (October 1971) and were referred to State governments for resolution.

FDA determined that the items of noncompliance in nine of the reports resulted from isolated circumstances not under the manufacturers' control, and did not indicate that all oven units of the model tested were in violation of the standard. The one remaining test report was still under investigation because of the need to conduct additional field tests on the oven model.

Laboratory testing

FDA's Winchester Engineering and Analytical Center Laboratory in Winchester, Massachusetts, performs tests to determine compliance with the performance standard. Selected ovens are also tested to evaluate their performance over a lifetime by cycling the door seals and interlock systems at least 100,000 times for household ovens and 200,000 for commercial ovens. Fifty-nine and 78 ovens were selected for testing during fiscal years 1976 and 1977, respectively. Most ovens tested were models with the most unique designs or the largest production volumes.

This testing program identified three oven models whose emissions exceeded acceptable levels or whose interlock systems did not meet the performance standard. In each of the three cases, the manufacturers were required

to modify the oven models by repairing or replacing interlock systems on all ovens in inventory as well as at dealer, distributor, and purchaser locations.

In addition, in 1972 FDA headquarters identified, through laboratory testing, one oven model whose radiation emissions did not meet the performance standard. The manufacturer in this case, was required to modify all ovens of that model in the manufacturer's inventory as well as at dealer, distributor, and purchaser locations.

NOTIFICATION BY MANUFACTURERS OF OVEN NONCOMPLIANCE

The RCH&S Act (42 U.S.C. 263g) requires that a manufacturer immediately notify FDA if, after an oven is shipped, a defect relating to unsafe radiation emissions or a noncompliance with the standard is discovered. If FDA determines the product will create a significant risk of injury to any person, the manufacturer is required to notify purchasers, dealers, and distributors of the defect or noncompliance and advise them of recourses that are available.

FDA officials stated that as of February 28, 1978, three manufacturers and one manufacturer's distributor had notified FDA that ovens emitted radiation in excess of the performance standard. FDA required three manufacturers to correct oven door interlock assemblies on ovens in inventory and at dealer, distributor, and purchaser locations. FDA was considering similar action on the fourth notification.

Although we were not able to determine whether manufacturers were complying with the notification provisions of the act, an FDA official in charge of manufacturer facilities inspections told us that FDA's inspections have not identified any cases where a manufacturer failed to report as required by the act.

CONCLUSION

FDA's review of manufacturers' initial, supplemental, and annual reports for microwave ovens has shown that about one-third contained information which (1) identified a potential radiation hazard or (2) needed clarification. Some reports had not been reviewed for extended periods of time.

With regard to other microwave equipment, FDA had reviewed only about 25 percent of the initial, supplemental,

and annual reports submitted as of February 28, 1978, and most of these were submitted to FDA more than 3 years ago.

Because FDA's reviews of initial, supplemental, and annual reports showed that many were incomplete or contained information which indicated microwave radiation-emitting products could be detrimental to the public health, these reports should be promptly reviewed so that timely attention can be given to hazardous conditions identified in the reports.

RECOMMENDATION

We recommend that the Secretary of HEW direct the FDA Commissioner to establish procedures to ensure that all manufacturers' initial, supplemental, and annual reports are reviewed promptly.

CHAPTER 4

MICROWAVE EXPOSURE STANDARDS ARE NEEDED

Some studies have questioned the safety of human exposure to microwave radiation. Currently no Federal standards exist to protect the general public and workers from potential hazards of environmental and occupational exposure to microwave radiation. Voluntary guidelines setting 10 mW/cm^2 as the maximum level of occupational microwave exposure have been published, but they are generally regarded as advisory only. (See pp. 13 and 14.) Moreover, the adequacy of 10 mW/cm^2 as a safe level of exposure is questionable.

Over 1,000 reports have been prepared by researchers in the United States and foreign countries which discuss study results or analyses of studies on biological effects caused by exposure to microwave radiation. Of these, 112 reports have been cited as reference material supporting FDA's microwave oven emission standard or were identified for us by FDA officials as particularly important to their continuing evaluation of the standard's adequacy.

Over one-half of the 112 reports state that animals and humans exposed to microwave radiation levels of 10 mW/cm^2 or less experienced biological effects, some undesirable. Ten discuss studies in which effects were reported to occur in animals exposed to microwave radiation levels of 0.1 mW/cm^2 or less. (Appendix III lists (1) the 112 reports, (2) examples of the effects identified in the studies discussed, and (3) the lowest exposure level that was reported to produce the effects. It does not list the other exposure levels which may have been used in the studies or the effects which may have been reported at higher levels of exposure.)

We did not evaluate the quality of the 112 reports or the related studies. However, because a number of these reports warn of effects in animals and humans at microwave exposure levels of 10 mW/cm^2 and below, we discussed with representatives of FDA, EPA, OSHA, and National Telecommunications and Information Administration (NTIA), Department of Commerce, the adequacy of the U.S. exposure guideline which sets 10 mW/cm^2 as a safe level of microwave exposure.

These representatives said that they believe there is a need to reevaluate the adequacy of the 10 mW/cm^2 microwave exposure guideline. EPA and NTIA representatives pointed out, however, that in addition to the studies we reviewed,

there are many other studies which show no effects from exposures to microwave radiation at the same levels of exposure. They also said that the quality of each study should be a determining factor as to the importance each study should be given. EPA representatives agreed, however, that there is a need to reevaluate the adequacy of the existing exposure guideline because (1) a large number of studies have reported biological effects at low exposure levels and (2) its relevance to environmental exposure is particularly questionable since the 10 mW/cm^2 guideline was set primarily to protect workers in occupational situations and other factors must be considered in protecting the public from hazards of 24-hour exposures.

Because the level of exposure decreases as the distance between a subject and an oven increases, the applicability of the studies' results toward determining the adequacy of FDA's microwave oven emission standard is difficult to interpret. (See pp. 15 to 17.)

RESEARCH METHODS

The most commonly used method for evaluating effects from exposure to microwave radiation is to study the effects from such exposure in test animals. Various species of animals, including rats, mice, hamsters, rabbits, dogs, and monkeys, have been used in microwave exposure studies.

During tests the animal's total body or a portion of its body may be subjected to single or multiple doses of radiation for either short or long periods of time. The animal may also be held in a fixed position or allowed free movement within a given area. Effects are usually identified by comparing the physical, functional, or behavioral characteristics of the test animals before and after they are exposed to the radiation or comparing these characteristics of the exposed animals with those of unexposed control animals.

Also, animal tissue and cells may be exposed to various levels of radiation to study the effects of microwave radiation. Such studies have provided information on the effects of radiation to the chromosomal structure and to cell membranes.

While the results of animal and animal tissue studies give indications of effects which might be expected in humans, their direct applicability to humans has not been established.

The most direct method of evaluating the type of biological effects which exposure to microwave radiation causes in humans would be to expose humans in laboratory situations. Since such studies could unnecessarily expose people to hazardous levels of radiation with unknown consequences, such studies are seldom conducted. An alternative, however, is to study individuals or groups of people after inadvertent exposures or after a period of exposure such as those experienced in certain work environments or occupations.

REPORTED BIOLOGICAL EFFECTS

For discussion purposes in this chapter, we have grouped the reported effects into four general categories depending on the body part or function affected--nervous system and behavior, organs and glands, genetic and developmental functions and blood systems. Of the 112 reports we reviewed, 90 concerned studies of biological effects to animals or animal tissues from exposure to microwaves, 11 concerned studies of effects from microwave exposure to humans, and 11 concerned studies of exposure in both animals and humans. 1/

Most U.S. studies conducted in the 1950s and 1960s were directed at evaluating heating effects produced at exposure levels above 20 mW/cm^2. At that time the absence of heat was believed to indicate the absence of an effect from microwave exposure. Many U.S. studies since then and a majority of Eastern European studies have shown that microwave levels below 20 mW/cm^2 cause effects not clearly attributable to heating alone.

Most studies covered by the reports we reviewed showed effects to human or animal organs, cells, systems or functions. The reports show that the type and severity the effects produced--both temporary and permanent--are influenced by a number of variable factors. For example, the rate at which microwave radiation is absorbed and the resulting

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1/Two of the 112 reports discuss studies which evaluate the effects of microwave radiation on bacteria cells commonly found in animal and human intestines, and while they are not studies of strictly animal or human exposures, they are included with the 90 reports evaluating biological effects in animal and animal tissue. They are also included in the discussion of reports on microwave radiation's effect on genetic and developmental functions on page 34.

potential to cause effects varies depending on factors, such as the power density, frequency and length of the radiation exposure; the size, density, and shape of the organ or body part exposed; and the orientation of a test subject to the microwave beam (i.e., parallel vs. perpendicular to the beam).

As the level and duration of microwave exposure increases, the possibility that there will be biological effects also appears to increase. Repeated exposures to microwave radiation at a given level have been reported to cause biological effects when a single exposure at the same level did not. In addition, the same biological effects produced by a single microwave exposure at a given level have been reported from multiple microwave exposures at lower exposure levels. The likelihood of biological effects occurring has also been shown to increase as the length of each exposure increases.

Increases in temperature and humidity of the test subject's environment have been reported to reduce the subject's ability to dissipate heat and, in turn, to increase the potential for microwave radiation to cause effects.

Approximately one-third of the 112 reports we reviewed discuss studies conducted in Eastern European countries. Some U.S. researchers, while recognizing that Eastern European studies must be seriously considered, hesitate to fully accept their findings because, among other reasons, sufficient information is not available concerning study protocols, statistical analysis of study data is limited, and study results have not been quantified, or reproduced elsewhere.

Effects reported in animals

Of the 112 reports, 101 concern studies of microwave exposures to animals or animal tissues. Of these, 56 involve exposures reported to be at levels of 10 mW/cm^2 or less, 41 involve exposures reported to be at levels above 10 mW/cm^2, and 4 reports did not identify exposure levels. The effects reported at the various exposure levels were generally centered in the same body parts, systems, and functions of the animals and as the levels of exposure increased, the effects generally became more severe.

Exposures at 10 mW/cm^2 or less

Fifty-four of the 56 reports in this group discuss animal studies in which effects occurred in the nervous system or behavior, organs or glands, genetic or developmental functions,

and blood systems. Two reported no effects. Twenty-six reported effects from exposure to levels of 1 mW/cm^2 and less and 10 reported effects from exposure to levels of 0.1 mW/cm^2 and less. Some reports discuss effects in more than one category.

Nervous system and behavior--Thirty-four reports noted that exposure to microwave radiation caused various types of physical and functional changes in the nervous system and changes in behavior. All effects were reported at levels above .01 mW/cm^2, except for two reports which discussed effects from exposures as low as .00006 mW/cm^2 and in the range of .005 - .02 mW/cm^2. The effects reported include structural changes to nerve cells and nerve tissues, reduction of electrical activity in the brain which caused increased response times, and evidence of fatigue, sleepiness, excitability, irritability, partial loss of memory and anxiety. Some of these reports noted that the effects were temporary and that the animals reverted to normalcy after they were removed from exposure to the radiation.

Organs and glands--Ten reports discuss effects in certain animal organs and glands. One study reported that exposures at levels as low as .001 mW/cm^2 caused changes in the function of the thyroid gland, which has a regulatory influence on the body. Exposures ranging from 1 through 10 mW/cm^2 of microwave radiation were reported to cause effects in the pituitary and testes glands and one reported an injury to the eye.

Genetic and developmental functions--Eight reports concluded that exposure to microwave radiation could affect genetic characteristics and cell and physical development. In seven of the eight reports, animals exposed to microwave radiation at levels ranging from 1-10 mW/cm^2 were reported to experience malformations to their fetuses and injuries to or disturbances in their bodies' cell division process. Animals in the other study were reported to experience decreased births at an exposure of .25 mW/cm^2.

Blood system--Eleven reports discuss effects in the blood circulatory systems and bone marrow of different animal species from microwave radiation exposure. Exposure levels in these reports were at .01 mW/cm^2 and above, except in one which discussed effects at .005 mW/cm^2. These reports noted that the exposures changed white and red blood cells and cells of bone marrow which, in turn, might lead to diseases or changes in other functions of the body.

Exposures above 10 mW/cm^2

Thirty-eight of the 41 reports in this group discuss animal studies in which effects occurred. Three reported no effects. The type of effects reported are basically the same as those reported in studies of exposures at 10 mW/cm^2 and below; however, they generally occurred more often and were more severe. Heat-related effects are discussed in this group of reports. Heat is less readily dispersed in organs, such as the eye, where blood flow is naturally low. The heat produced in the eyes of animals by repeated exposure to microwave radiation of 80 mW/cm^2 was reported in one study to cause cataracts.

Effects reported in humans

Twenty-two of the 112 reports we reviewed discuss human exposures to microwave radiation. Four reported no effects and 18 reported effects which were observed in the eyes, heart, nervous system or blood systems of individuals who were allegedly exposed. Sixteen of the 18 reports concluded that the effects resulted from exposures to microwave radiation while the other 2 stated that more research needed to be performed before the reported effects could be definitely associated with microwave exposure. Four of the 16 reports did not indicate the power density levels at which the individuals were exposed. The remaining 12 reported that individuals had been exposed to microwave levels from .01 mW/cm^2 to 20 mW/cm^2. (Nine reported exposures of 10 mW/cm^2 or less.) Two of the 12 reports were prepared by U.S. researchers, and 1 of these was a study of cases in which individuals developed cataracts reportedly caused by microwave exposure.

CONCLUSIONS

With the rapidly increasing use of microwave energy, more people are being exposed to microwave radiation. Because there presently is no mandatory environmental microwave exposure standard and the existing voluntary occupational exposure guidelines set at 10 mW/cm^2 are advisory only, enforceable standards are needed to better ensure that the public and workers are protected from the potential hazards of microwave radiation.

Also because a number of reports have indicated that exposure to microwave radiation at levels of 10 mW/cm^2 and below can cause effects in humans and animals,

the safety of exposure at that level seems questionable. In developing mandatory microwave exposure standards, EPA and OSHA should determine whether 10 mW/cm^2 is a safe level of exposure.

The implications of the findings contained in the 112 reports we reviewed on FDA's emission standard for microwave ovens are less clear because oven emissions are measured at a fixed distance of 5 centimeters (about 2 inches) from the oven and as the distance between a subject and the oven increases the exposure level decreases. For example, exposure at about 2 inches from an oven emitting 5 mW/cm^2 will equal 5 mW/cm^2, but exposure at 14 inches from the same oven will be about 0.1 mW/cm^2. (See p. 16.) While studies have reported effects at exposures of 0.1 mW/cm^2 or less, most of these have been conducted by Eastern European researchers and have not been fully accepted by U.S. researchers. (See p. 33.) However, since the 10 mW/cm^2 exposure guideline was a consideration in establishing the microwave oven emission standard, establishing standards providing new levels of exposure may require a change to the emission standard.

RECOMMENDATIONS

We recommend (1) that the Administrator of EPA establish an environmental exposure standard to protect the general public from the hazards of microwave radiation and (2) that the Secretary of Labor direct the Assistant Secretary for Occupational Safety and Health to establish an occupational exposure standard to protect workers from such hazards. Because the safety of the level set by the existing exposure guideline is questionable, the standards set by EPA and OSHA should be based on a current evaluation of scientific data.

If the exposure standards that are established are different from the current occupational guideline, we recommend that the Secretary of HEW direct the Commissioner, FDA, to consider the need to revise the microwave oven emission standard.

CHAPTER 5

IMPLEMENTATION OF OTHER REQUIREMENTS OF THE RCH&S ACT

The RCH&S Act (42 U.S.C. 263d) requires FDA to (1) coordinate its work with other Federal and State agencies, industry and private organizations with related interests, (2) collect and make available to interested parties the results of research and studies, and (3) conduct, coordinate, and support training activities to minimize unnecessary electronic product radiation exposure.

FDA has signed memorandums of understanding and interagency agreements to provide formal coordination of activities concerning microwave radiation with four Federal agencies and has initiated or participated in a number of other less formal microwave related activities with various Federal and non-Federal groups. It has also published microwave research studies in scientific journals or presented them before technical meetings and has published the proceedings of three major symposiums and meetings on microwave radiation. However, FDA's training activities concerning the use of microwave radiation products has been limited.

COORDINATION

According to the RCH&S Act, FDA must consult and maintain liaison with other Federal departments and agencies having electronic product radiation responsibilities regarding techniques, equipment, and programs for testing and evaluating electronic product radiation and developing product performance standards. FDA must also maintain liaison with and receive information from other parties having related interests, such as State governments, industry, and professional and labor organizations, on present and future potential product radiation.

Federal agencies

Consultation and liaison between FDA and other Federal agencies have been either formal, which generally involves signing a document describing the responsibilities of each agency, or informal, which usually involves discussing matters of mutual interest in meetings and symposiums by officials at different organizational levels.

EPA

FDA and EPA have coordinated most microwave radiation regulatory efforts on an informal basis. For example, FDA requested comments from EPA during the development of microwave oven and diathermy product standards. According to FDA officials, personnel at different organizational levels from the two agencies periodically meet and exchange information of mutual interest and visit each other's facilities to review the research activities of each agency. Also the agencies have shared research equipment and facilities to avoid duplicate costs.

HEW, on behalf of FDA, and EPA entered into a memorandum of understanding in January 1977 for the purpose of reducing unnecessary patient exposure to radiation in the healing arts. This memorandum resulted from several years of debate between the two organizations as to which one had responsibility for issuing such radiation protection guidance to Federal agencies. The memorandum formalizes the working relationship between HEW and EPA by stating the responsibilities of each agency and provides that:

--EPA will identify areas of potential reduction in radiation exposure in the healing arts.

--EPA will consult with HEW on the need for Federal guidance for all Federal agencies in formulating radiation standards and in establishing and executing programs.

--FDA may develop and propose such radiation guidance with review from EPA.

--The two agencies will consult on the appropriate division between broad guidance to be developed by EPA and specific implementing guidance to be developed by HEW.

--EPA will coordinate the review by Federal and State agencies, radiation experts, and the public of all proposed Federal radiation guidance.

--HEW will review proposed Federal radiation guidance developed by EPA to determine the anticipated impact on health care while EPA will address in the public record all comments received, including those from HEW.

--EPA will provide followup and coordination with Federal agencies to ensure the implementation of Federal guidance.

As of February 28, 1978, FDA and EPA had not developed guidance for Federal agencies concerning areas of potential reduction in microwave radiation exposure in the healing arts. While the agreement speaks in general terms of "radiation protection," FDA officials stated that it was intended to clarify the two agencies' roles in reducing patient exposure to ionizing radiation only. They expressed some doubt as to its applicability to microwave radiation exposure issues.

EPA officials stated, however, that while the need for this agreement grew from health issues related to ionizing radiation exposures, they believe its provisions establish channels of cooperation which can be used to resolve issues related to nonionizing radiation exposure.

OSHA

In April 1974 FDA and OSHA entered into a memorandum of understanding providing cooperation in establishing uniform Federal standards for electronic product radiation and in determining compliance with the standards. The purpose of the memorandum was to ensure maximum use of resources by eliminating duplicate efforts in standards development. The memorandum states that FDA and OSHA agreed to consult with each other in developing product performance standards and radiation safety and health regulations to ensure that their standards or regulations are compatible. They also agreed to (1) exchange compliance procedures and techniques and cooperate in enforcement efforts to avoid duplication, (2) meet at least quarterly to implement the provisions of the memorandum, and (3) encourage appropriate State officials in States having approved occupational safety and health plans under the Occupational Safety and Health Act of 1970 to cooperate in developing and enforcing electronic product radiation performance standards.

FDA records showed that it has consulted with OSHA when developing performance standards for microwave ovens and diathermy equipment and that FDA has prepared comments on microwave regulations that were proposed by OSHA.

FDA and OSHA officials said that the two agencies do not meet on a routine basis, as stipulated in the memorandum

of understanding, but do meet whenever matters of mutual interest arise. An FDA official said that FDA's enforcement activities include furnishing OSHA with information about recalls of products, including microwave ovens, found to violate provisions of the law or Federal performance standards.

Consumer Product Safety Commission

The Consumer Product Safety Act (15 U.S.C. 2051) states that "The Commission shall have no authority under this act to regulate any risk of injury associated with electronic product radiation emitted from an electronic product" as defined in the Public Health Service Act. The Commission does, however, have authority to regulate non-radiation related aspects of radiation-emitting consumer products. Because of this separation of authority, Commission officials said that no formal agreement exists and only minimal communication takes place between the Commission and FDA regarding microwave radiation. These officials explained that whenever questions are raised regarding radiation problems the Commission refers them to FDA.

Interagency Regulatory Liaison Group

In a meeting on July 22, 1977, the heads of FDA, EPA, OSHA, and the Consumer Product Safety Commission agreed to work together as the Interagency Regulatory Liaison Group to improve the public health through sharing of information, avoiding duplication of effort, and developing consistent regulatory policy. This agreement, announced at a joint press conference on August 2, 1977, grew out of cooperative efforts to resolve jurisdictional problems in regulating hazardous and toxic substances.

While recognizing this agreement was not issued primarily to facilitate coordination of radiation regulatory matters, both FDA and EPA officials have indicated that this liaison group provides appropriate channels through which such matters can be reviewed and mutually resolved.

Department of Defense

In December 1974, FDA and the Department of Navy's Bureau of Medicine and Surgery signed an interagency agreement under which the Bureau was to provide financial and technical support for research programs in the field of nonionizing radiation, including microwaves. The agreement's stated purpose was to support FDA research programs in which both agencies have

a mutual interest. Under the agreement FDA is to negotiate and award all contracts and to monitor their financial arrangements. The Bureau provides management for the technical aspects of the contracts except where the results are of greater benefit to FDA, in which case FDA provides such management. Under the agreement the Bureau provided $500,000 for research for each of 3 fiscal years--1975, 1976, and 1977. FDA, with approval from the Bureau, has used a portion of these funds to perform research on microwave radiation to determine its effect on the crystalline lens of the eye, the nervous system, and behavior.

In May 1977 FDA and the Bureau also entered into a memorandum of understanding to provide for Bureau participation in FDA's microwave oven field compliance testing program. (See p. 26.) Under this agreement, the Bureau is to perform compliance tests of the ovens at Navy installations and submit the results to FDA. In turn, FDA is to prepare quarterly and annual summary reports for the Bureau on the results of ovens tested at Navy installations and calibrate and perform minor repairs on the Bureau's radiation measuring instruments. The Bureau's tests of Navy ovens are intended to provide FDA with a larger sample under its microwave oven testing program.

The Department of the Air Force also performs compliance tests of microwave ovens at its installations. The Air Force has informally agreed to report the results of its tests to FDA.

National Telecommunications and Information Administration, Department of Commerce

In 1972 the Office of Telecommunications Policy, which had responsibility for overall supervision of national communication matters, assumed responsibility for coordinating Federal efforts to control nonionizing radiation pollution in the environment by eliminating unintended duplication and voids in Federal agencies' biological research efforts. The Federal Government did not have a formal program to coordinate these efforts. The Office, with the cooperation of other appropriate Federal agencies, including FDA, publishes an annual summary of the Federal Government's efforts to assess the biological effects of such radiation. The Office's 1975 annual report, its last report, shows that Federal agencies performed most of their nonionizing radiation research during 1975 in the microwave frequency range and that they planned to continue that emphasis in fiscal year 1976.

In addition to assuming overall responsibility for coordinating nonionizing research within the Federal Government, the Office in April 1972 formed an interagency working group called the Side Effects Working Group. The group is composed of officials from about 20 Federal agencies, including FDA, and meets periodically to exchange information on matters relating to nonionizing radiation.

The Office of Telecommunications Policy was abolished on March 26, 1978, and most of its functions, including the coordination of all federally sponsored research activities directed at investigating the biological effects of nonionizing electromagnetic radiation, were transferred to the new National Telecommunications and Information Administration, Department of Commerce.

Non-Federal interests

FDA coordinates its microwave radiation activities with State and local governments, industry, private associations, educational institutions, and foreign governments in such areas as standards development, enforcement, and public safety.

During the development of its microwave oven and diathermy equipment performance standards, FDA solicited comments from State governments, product manufacturers, electronic and health associations, and the Canadian government. Their views were considered in the development of these standards.

FDA also coordinates its compliance testing of microwave ovens with many State and local government radiation control authorities. State and local personnel participate voluntarily with FDA field staff in testing ovens to determine whether they comply with the Federal performance standard and with the RCH&S Act. (See p. 26.) An FDA official said that States are notified when manufacturers are required under the act to repair, replace, or refund the cost of ovens that are found to be noncompliant with the standard so that the States can include samples of the defective ovens in their inspections. For ovens not subject to the standard because of their age, but which pose a radiation hazard, FDA compliance program procedures require that State and local governments be notified so that they can ensure that the hazard is eliminated.

Periodically FDA participates in symposiums and meetings on biological effects and health implications of microwave

radiation with officials from State governments, research associations, educational institutions, and foreign governments. Some of the major symposiums and meetings FDA officials have participated in were (1) 1969--Richmond, Virginia, (2) 1973--Warsaw, Poland, and (3) 1975--Boulder, Colorado. In addition, FDA sponsored its own symposium in February 1977 at Rockville, Maryland. The goals of these meetings were to (1) exchange and evaluate current information from radiation biological effects and measurement studies, (2) identify issues on which additional information is needed, and (3) develop new approaches toward obtaining such information.

DISTRIBUTION OF INFORMATION

The RCH&S Act authorizes the Secretary to collect and make available through publication and by other means the results of research and studies relating to the nature and extent of hazards associated with electronic product radiation and the control of such radiation.

FDA published the proceedings of the 1969, 1975, and 1977 symposiums referred to above.

In addition, FDA has published nine technical reports on its studies of microwave radiation-emitting products. The technical reports are distributed to State and local health personnel, industry, hospitals, laboratories, schools, the press, and other interested individuals through standard HEW mailing lists and Government Printing Office library repositories.

Approximately 65 FDA studies on the biological effects of microwave radiation have been published in scientific journals and presented before technical meetings. FDA has also published approximately 25 reports dealing with microwave issues other than biological effects, such as instruments and techniques used in radiation measurement and microwave product design and performance.

TRAINING

The RCH&S Act requires FDA to plan, conduct, coordinate, and support training activities to minimize the emission of and exposure of people to unnecessary electronic product radiation. FDA's training activities concerning the use of microwave radiation products have been limited. An FDA official said that the agency has not initiated training

programs for operators of home, commercial, or industrial microwave ovens because these products generate a fixed amount of radiation and the amount of radiation emitted is generally not affected by the operator's performance. FDA efforts have been limited to informing the public about microwave ovens by the distribution and publication of a pamphlet and articles in FDA's "Consumer" magazine which explain potential adverse health effects from microwave radiation, the proper use and care of these ovens, and Federal regulatory actions against defective ovens.

Regarding diathermy equipment, the FDA official said that training material on the operation of such equipment may be prepared if comments on the proposed diathermy standard being developed indicate a need for such material.

FDA has performed two "limited surveys" which showed that most diathermy equipment operators are inadequately trained. The report on one survey, which was conducted in a Florida county in 1970, stated that only 8.3 percent of the operators surveyed had received formal training on the application of diathermy treatment and the possible biological hazards from exposure to microwave radiation. The remainder received their training on the job, from equipment salesmen, or from reading trade literature. The report stated that literature provided by manufacturers may be incomplete or not sufficiently definitive with respect to contraindications and precautionary measures, such as protection of the eyes, which some authorities believe can be easily damaged by such radiation.

The report concluded that, because of the potential for harm, the amount of discretion in positioning the device and the operators' freedom in setting equipment output, operator training in treatment techniques is important in controlling patient dose and minimizing hazards. The report recommended that a more intensive investigation be made of this matter.

The report on the second survey, which was conducted primarily in the Washington, D.C., metropolitan area in 1974, stated that all operators surveyed had received formal training, but in varying degrees. According to the report, the survey indicated that the operator's routine in administering the diathermy treatment was standardized. However, the orientation of the equipment to the patient's body and the radiation power settings seemed to be uncertain factors in the treatment process because operators generally

used routines which had, by experience, proven successful. The final comments in the report suggest that, while operators were aware of hazards from high levels of microwave radiation exposure, their limited knowledge of radiation and the diathermy equipment could easily result in exposure to parts of the patient's body not requiring treatment and exposure to the operator as well.

CONCLUSION

FDA's surveys have identified several diathermy equipment operator practices which could result in unnecessary radiation exposure to both patients and operators. Because of the potential harm to patients and operators, FDA should develop training material which provides instruction on the proper use and operation of medical diathermy equipment. FDA or State or local health authorities could use this material to train medical diathermy equipment operators. Various studies performed in the United States and abroad have reported that biological effects occur in different parts of the body, such as eyes, testes, and the nervous system, at much lower power density levels than the density level of approximately 370 mW/cm^2 that can be emitted by diathermy equipment.

Because power density level settings and equipment orientation to the patient's body are important factors in controlling unnecessary exposure to microwave radiation, instructional material developed by FDA would help to better train operators in the latest procedures to minimize exposure due to these or other controllable factors.

RECOMMENDATION

We recommend that the Secretary of HEW direct the FDA Commissioner to develop training material for diathermy equipment operators to better ensure that unnecessary exposure of patients and operators to microwave radiation due to operator controllable factors is minimized.

CHAPTER 6

SCOPE OF REVIEW

We reviewed legislation, regulations, and practices relating to FDA's regulation of microwave radiation products; examined FDA records concerning the development of performance standards for such products; evaluated compliance activities related to microwave products; and reviewed FDA's efforts to coordinate microwave regulatory activities with other interested Federal agencies.

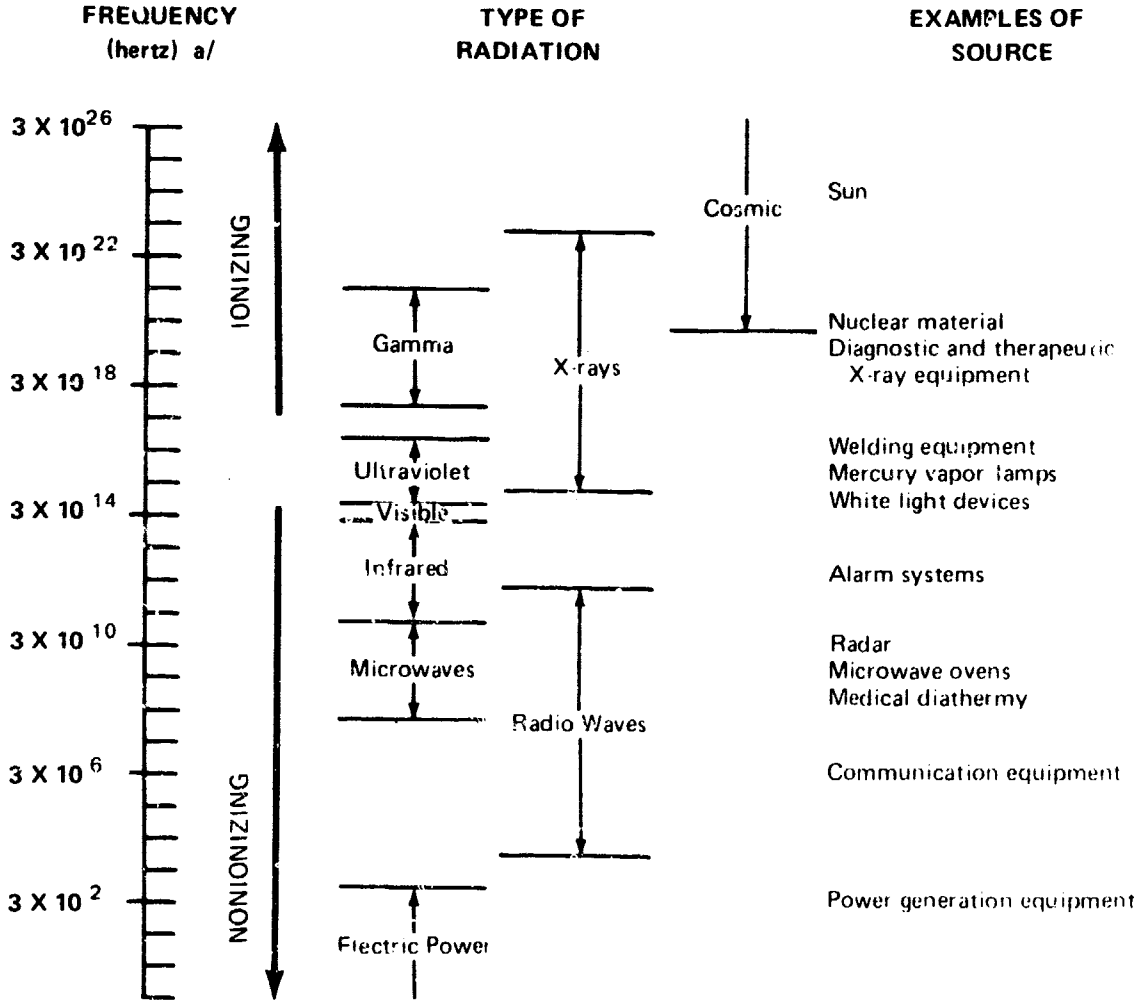
We also reviewed 112 reports of scientific studies and analysis of studies on the biological effects caused by exposure to microwave radiation. These reports were cited as reference material supporting FDA's microwave oven emission standard or identified by FDA officials as particularly important to its continuing evaluation of health effects from exposure to microwave radiation.

Pertinent information was developed through discussions with representatives of FDA, Rockville, Maryland, EPA and OSHA, Washington, D.C., and other cognizant organizations.

Our review of the regulation of microwave products was confined primarily to the period since 1968 when the RCH&S Act was enacted; however, we reviewed scientific studies on microwave exposure reported as early as 1952.

APPENDIX I

SIMPLIFIED ELECTROMAGNETIC SPECTRUM



a/ Frequency is the number of electromagnetic waves (or oscillations) per second. Frequency is measured in hertz, one hertz equals one electromagnetic wave. The frequencies indicated for each type radiation are approximate since the types do not have exact frequency boundaries.

MICROWAVE PRODUCTS FDA HAS STUDIED AND SURVEYED FOR SAFETY 1/

1. Conveyer belt ovens used to heat food.
2. Ovens used to precook or process various products in the food industry.
3. Instruments used to analyze ingredients of raw and manufactured materials.
4. Gauges which measure moisture content of materials during manufacturing processes.
5. Police radar.
6. Marine radar.
7. Motion detection equipment used in security systems.
8. Blood warmers used for medical purposes.
9. Dental and surgical instrument sterilizers.
10. Ovens used to thaw organs for medical transplant research.
11. Research equipment used in food, tobacco, pharmaceutical, and aerospace industries.
12. Equipment to irradiate biological specimens (e.g., bacteria) having bio-medical applications.
13. Clothes dryers.
14. Industrial ovens to dry various kinds of raw and manufactured materials.
15. Equipment to cure, heat and vulcanize rubber.
16. Equipment used in the construction and repair of road and bridge surfaces.
17. Equipment to sterilize soil to prevent weeds and pests.

1/These products include equipment presently for sale and in use and prototype equipment which is being developed.

*U.S. GOVERNMENT PRINTING OFFICE: 1978 620-167/326 1 3

APPENDIX III

SELECTED REPORTS ON THE SAFETY OF EXPOSURE TO MICROWAVE RADIATION

	Title (note a)	Date reported	Author(s), affiliation and reference	Lowest reported (*estimated) exposure causing effect (mW/cm^2 (note b)	Subject irradiated, body part or function affected and effect (note c)
1	Bilateral Lenticular Opacities Occurring in a Technician Operating a Microwave Generator-S	1952	F. Hirsch and J. Parker; Lovelace Clinic, Albuquerque, New Mexico; A.M.A. Arch. Industrial Hyg. and Occup. Med., vol. 6 pp. 512-517, 1952	100	Man--eye--cataract
2	Heating Characteristics of Laboratory Animals Exposed to Ten-Centimeter Microwaves-S	Mar. 1957	T. Ely and D. Goldman; National Naval Medical Center, Bethesda, Maryland; Naval Medical Research Institute Research Report Project NM 001 056.13.02, vol. 15, pp. 77-138, 1957	100	Dogs--testes--reduced sperm production
3	Effects of Radio-Frequency Energy on Primate Cerebral Activity-S	Feb. 1960	M. Baldwin, S. Bach, and S. Lewis; National Institutes of Health, Bethesda, Maryland; Neurology, vol. 10, pp. 178-187, 1960	Above 20, below 40	Monkeys--NS&B--reduced nerve responses and disturbed electrical pattern of the brain
4	The Biological Action of Ultrahigh Frequencies-S	1960	Edited by A. Letavet and Z. Gordon; Academy of Medical Science, Moscow, Russia; Translation--U.S. Joint Publ. Res. Ser. Wash. D.C., JPRS 12471, 1962	0.1* 4* 0.1* 1 1	Man--NS&B--reduced nerve response and changes in behavior Man--eye--reduced translucency of lens Man--blood--change in composition Rabbits--eye--changes in pressure within the eye Rat--heart and blood vessels--altered blood pressure --NS&B--inhibited sensitivity in conditioned reflexes
5	Effects of Chronic Microwave Irradiation on Mice-S	Oct. 1961	S. Prausnitz and C. Susskind; University of California, Berkeley, California; IRE Transactions on Biomedical Electronics, vol. 9, pp. 320-330, 1962	100	Mice--testes--sterility --blood--cancer of white cells
6	An Experimental Study of the Biological Effects of Microwave Radiation in Relation to the Eye-S	Feb. 1962	R. Carpenter; Tufts University, Medford, Massachusetts; Rome Air Development Center, Air Research and Development Command, U.S. Air Force, RADC-TDR-62-131, 1962	80	Rabbits--eye--cataract

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	Title (note a)	Date reported	Author(s), affiliation and reference	Lowest reported (*estimated) exposure causing effect (mW/cm^2 (note b)	Subject irradiated, body part or function affected and effect (note c)
7	Experimental Studies on the Influence of Radar Microwaves on the Human and Animal Organisms-S	1962	L. Gruszecki; Eastern Europe; Biul Wajskowej Akad. Med. (Poland), pp. 61-73, 1962	0.15 0.01	Man--NS&B--changes in behavior Rabbits--blood--changes in composition
8	Changes of Phagocytic Activity and Mobility of Neutrophils under the Influence of Microwave Fields-S	1962	A. Ivanov; Russia; Abstract from Tezisy Nautchn. Konf. Leningrad (USSR). pp. 24-26, 1962, Cited in Influence of Microwave Radiation on the Organism of Man and Animals. I. Petrov--editor, p. 85, Translation - NASA TT F-708, 1970	1	Rabbits--blood--changes in composition of bone marrow cells
9	Effects on Dogs of Chronic Exposure to Microwave Radiation-S	1963	W. Deichman, E. Bernard, F. Stevens, and K. Landeen; University of Miami, Coral Gables, Florida; Journal of Occupational Medicine, vol. 5, pp. 419-425, 1963	20	Dogs--thyroid gland--no effect noted
10	Effect of Microwave Radiation on the Hemopoietic System of the Rat-S	1964	W. Deichman, J. Miale, and K. Landeen; University of Miami, Coral Gables, Florida; Toxicology and Applied Pharmacology, vol. 6, pp. 71-77, 1964.	10	Rats--blood--change in composition
11	Sensitivity of the Central Nervous System of Rabbits to a Continuous UHF Electromagnetic Field-S	1964	Z. Gvozdikova, V. Anan'yev, I. Zenina, and W. Zak; Eastern Europe; Biulleten Bksperimentalnov Biologii Meditsiny, vol. 58, no. 8, pp. 63-68, 1964, Translation - JPRS 26725	0.02	Rabbits--NS&B--changes in brain electrical patterns
12	Radiation Exposure in Parents of Children with Mongolism (Down's Syndrome)-S	1965	A. Sigler, A. Lilienfield, B. Cohen, and J. Westlake; Johns Hopkins University, Baltimore, Maryland; Bulletin of the Johns Hopkins Hospital, vol. 117, pp. 374-400, 1965	Not reported	Man--G&D--suggested mongolism
13	Response to Radio-Frequency Radiation in Environmental Biology-R	1966	R. Carpenter and V. Clark; Tufts University, Medford, Massachusetts; Environmental Biology. FASEB Bethesda, Md., pp. 131-138, 1966	Not reported Not reported	Various animals--NS&B--changes in nerve responses and behavior pattern --eyes--cataracts --testes--reduced sperm production --heart--increased rate --embryo--delayed growth and development --blood--change in composition Man--eyes--cataract --blood--change in composition
14	Soviet Research on the Neural Effects of Microwaves-R	1966	C. Dodge; Library of Congress, Washington, D.C.; Library of Congress, ATD Report 66-133, 1966	7-9.5	Animals (type not specified) --NS&B--changes in brain structure

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	Title (note a)	Date reported	Author(s), affiliation and reference	Lowest reported (*estimated) exposure causing effect (mW/cm^2) (note b)	Subject irradiated, body part or function affected and effect (note c)
15	The Effect of Electromagnetic and Magnetic Fields on the Central Nervous System-S	1966	Y. Kholodov; Academy of Sciences, Russia; Translation - NASA TT F-465, pp. 72-78, 1967	2	Rabbits--NS&B--electrical activity of brain disturbed which in one case caused convulsive reactions
16	No title-S	1966	A. Subbota; Russia; Cited in Influence of Microwave Radiation on the Organism of Man and Animals. I. Petrov - editor, Translation - NASA TT F-708, pp. 69-73, 1970	1	Dogs--NS&B--increase nervous activity, functional disturbances in area around brain, and increase food conditioned reflex
17	No title-S	1966	Z. Svetlova; Russia; Ibid.	1	Dogs--NS&B--increase nervous activity, functional disturbances in area around brain, and increase food conditioned reflex
18	Brain Stem Evoked Responses Associated with Low-Intensity Pulsed UHF Energy-S	1967	A. Frey; Institute for Research, State College, Pennsylvania; Journal of Applied Physiology, vol. 23, pp. 984-988, 1967	0.03	Cats--NS&B--disturbed brain stem nerve responses
19	Biological Aspects of Microwave Radiation, a Review of Hazards-R	1968	W. Moore Jr.; Food and Drug Administration; HEW Report (FDA)72-8030, 1968	10	Animals (type not specified)--testes--reduced sperm production
20	Radiation Biology, Medical Applications, and Radiation Hazards-R	1968	H. Schwan; University of Pennsylvania, Philadelphia, Pennsylvania; Microwave Power Engineering. E. Okress-editor, Academic Press, New York, N.Y., vol. 2, pp. 215-234, 1968	50*	Animals (type not specified)--blood--change in composition--whole body--weight loss
21	Thermal and Nonthermal Cataractogenesis by Microwaves-S	Sept. 1969	H. Baillie; Manchester Royal Infirmary, United Kingdom; Biological Effects and Health Implications of Microwave Radiation. HEW Report BRH/DBE 70-2, pp. 59-65, 1970	5000	Dogs--eye--cataract
22	Experimental Microwave Cataract: A Review-R	Sept. 1969	R. Carpenter; Food and Drug Administration; Ibid., pp. 76-81	80	Rabbits--eye--cataract
23	Biological Effects of Microwave Exposure-S	Sept. 1969	S. Michaelson; University of Rochester, Rochester, New York; Ibid., pp. 35-58	100	Rabbits--whole body--heat exhaustion
				100	Dogs--blood--changes in white blood cells

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	Title (note a)	Date reported	Author(s), affiliation and reference	Lowest reported (*estimated) exposure causing effect (mW/cm^2 (note b)	Subject irradiated, body part or function affected and effect (note c)
24	Effects of 2450 MHz Microwaves on Protein Synthesis and on Chromosomes in Chinese Hamsters-S	Dec. 1969	D. Janes, W. Leach, W. Mills, R. Moore, and M. Shore; Department of HEW, Rockville, Maryland; Non-ionizing Radiation, vol. 1, pp. 125-130, 1969	Not reported	Chinese hamsters--cell--alteration of cell division process
25	Influence of Microwave Radiation on the Organism of Man and Animals-R	1970	Edited by I. Petrov; Leningrad, Russia; Influence of Microwave Radiation on the Organism of Man and Animals. I. Petrov--editor, Translation NASA TT F-708, 1970	0.07 10 3 0.04-1	Rats--NS&B--interference with brain metabolism --blood--change in composition Dog--thyroid gland--functions altered Man--NS&B--sluggishness of muscular reactions and increase in rate of errors
26	Effect of Microwaves on the Responses of White Blood Cell System-S	1971	S. Baranski; Military Institute of Aviation Medicine, Warsaw, Poland; Acta Physiologice Polonia (Poland), vol. 22, p. 898, 1971; also see Aerospace Medicine, vol. 42, p. 1196, 1971	3.5 Not available	Rabbits and guinea pigs--blood--changes in white blood cells and disturbances of blood cell structures Man--blood--changes in white blood cells
27	Microwave Irradiation and Bone Marrow Function-S	1972	P. Czerski, S. Baranski and M. Siekierzynski; Military Institute of Aviation Medicine, Warsaw, Poland; Abstract from Third International Conference on Medical Physics Proceedings (Sweden), 9, 1972	1	Rabbits and guinea pigs--blood--anemia and changes in iron distribution in body
28	The Influence of Microwave Radiation on Iron Metabolism in Rabbits-S	1972	M. Siekierzynski; Warsaw, Poland; Medycyna Lotnicza (Poland), vol. 39, pp. 53-65, 1972	3	Rabbits--blood--decrease flow of oxygen in blood and disturbed iron metabolism in the blood
29	Thyroid Suppression and Adrenomedullary Activation by Low-Intensity Microwave Radiation-S	June 1973	L. Parker; Environmental Protection Agency, Washington, D.C.; American Journal of Physiology, vol. 224, pp. 1388-1390, 1973	15	Rats--thyroid gland--decrease in nutritional and thyroxine secretions from gland
30	Harmful Effects of Microwave Radiation on the Bone Marrow-S	Oct. 1973	K. Yagi, R. Ueyama, S. Kurohane, N. Hiramine, H. Ito, and S. Umehara; Tokyo Medical College, Tokyo, Japan; Biologic Effects and Health Hazards of Microwave Radiation, Proceedings of an International Symposium, Poland, 1973. Polish Medical Publishers, Poland, pp. 75-88, 1974	1300	Rabbits--blood--changes in white blood cells and lack of bone marrow development

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31	The Use of Conditioned Reflexes to Study Microwave Effects on the Central Nervous System-S	Oct. 1973	E. Lobanova; Academy of Medical Sciences of the U.S.S.R., Moscow, Russia; Ibid., pp. 109-118	1	Rats--NS&B--changes in behavior
32	Pharmacologic Analysis of Microwave Effects on the Central Nervous System in Experimental Animals-S	Oct. 1973	S. Baranski and J. Edelwejn; Military Institute of Aviation Medicine, Warsaw, Poland; Ibid., pp. 119-127	7	Rabbits--NS&B--alterations of brain electrical patterns
33	A Quantitative Electro-encephalographic Study of the Acute Effects of X-Band Microwaves in Rabbits-S	Oct. 1973	L. Goldstein and J. Sisko; Rutgers Medical School, Piscataway, New Jersey; Ibid., pp. 128-133	2	Rabbits--NS&B--abnormal behavior
34	Psychogenic Stressors Are Potent Mediators of the Thermal Response to Microwave Irradiation-S	Oct. 1973	D. Justesen, D. Levinson, and L. Justesen; Veterans Administration Hospital, Kansas City, Missouri; Ibid., pp. 134-140	8.7*	Rats--NS&B--intensification of emotional stress
35	Some Effects of Various Pulsed Fields on Animals With Audiogenic Epilepsy-S	Oct. 1973	I. Stverak, K. Marha, and G. Pafkova; Institutes of Aviation Medicine and Hygiene and Epidemiology, Prague, Czechoslovakia; Ibid., pp. 141-144	30	Rats--NS&B--inhibited sensitivity of conditioned reflexes
36	Interaction of Electro-magnetic Fields and Living Systems-R	Oct. 1973	C. Romero-Sierra, J. Tanner, and J. Bigu del Blanco; Queen's University, Kingston and National Research Council, Ottawa, Canada; Ibid., pp. 145-151	0.1	Various types of fowl and rats--NS&B--changes in behavior
37	Microwave Irradiation and Endocrine Functions-R	Oct. 1973	H. Mikolajczyk; Institute of Occupational Medicine, Lodz, Poland; Ibid., pp. 46-51	5	Rats--pituitary and adrenal gland--secretions altered
38	The Biologic Action and Hygienic Significance of Electromagnetic Fields of Superhigh and Ultrahigh Frequencies in Densely Populated Areas-S	Oct. 1973	J. Dumanski and M. Sandala; Kiev Scientific Research Institute of General and Public Hygiene, Russia; Ibid., pp. 289-293	0.005-0.02 0.001 0.005	Rats and rabbits--NS&B--inhibition of conditioned reflexes --thyroid gland--functions altered --blood--change in composition
39	Main Directions and Results of Research Conducted in the U.S.S.R. on the Biologic Effects of Microwaves-R	Oct. 1973	Z. Gordon, A. Roscin, and M. Byckov; Academy of Medical Sciences of the U.S.S.R., Moscow, Russia; Ibid., pp. 22-35	0.03 0.25	Rabbits and cats--NS&B--disruption of brain functions Mice--G&D--decreased number of births

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40	Clinical Manifestations of Reactions to Microwave Irradiation in Various Occupational Groups-S	Oct. 1973	M. Sadcikova; Academy of Medical Sciences of the U.S.S.R., Moscow, Russia; Ibid., pp. 261-267	0.04*	Man--NS&B--changes neurological responses and behavior patterns --heart--reduced heart beat
41	A Study of the Health Status of Microwave Workers-S	Oct. 1973	M. Siekierzynski; Military Medical Academy, Warsaw, Poland; Ibid., pp. 273-280	Above 0.2	Man--eye--change in lens translucency
42	Neurologic Findings in Persons Exposed to Microwaves-S	Oct. 1973	E. Klimkova-Deutschova; Charles University, Prague, Czechoslovakia; Ibid., pp. 268-272	Not reported	Man--NS&B--fatigue and changes in electrical patterns of the brain
43	Thermal Effects of Single and Repeated Exposures to Microwaves-A Review-R	Oct. 1973	S. Michaelson; University of Rochester, Rochester, New York; Ibid., pp. 1-14	10	Rats--whole body--increased body temperature
44	Biologic Effects of Radiation in the 30-300 MHz Range-R	Oct. 1973	T. Kalada, P. Fukalova, and N. Goncarova; Institute of Industrial Hygiene and Occupational Disease, Leningrad, Academy of Medical Sciences of the U.S.S.R., Moscow, and Institute of Industrial Hygiene and Occupational Diseases, Harkov, Russia; Ibid., pp. 52-57	Below 10* Below 10*	Animals (type not specified)--NS&B--disturbed nervous system functions Man--NS&B--distortion and inhibition of reflexes
45	Assessing Microwaves as a Hazard to the Eye-Progress and Problems-R	Oct. 1973	R. Carpenter, E. Ferri, and G. Hagan; Food and Drug Administration; Ibid., pp. 178-185	100 Not reported	Rabbits--eye--reduced lens transparency Man--eye--no effect noted
46	Experimental Microwave Ocular Effects-S	Oct. 1973	B. Appleton; Walter Reed Army Medical Center, Washington, D.C.; Ibid., pp. 186-188	50 300	Rabbits--front of body--death --eye--ocular damage
47	Selected Cases of Microwave Cataract in Man Associated with Concomitant Annotated Pathologies-R	Oct. 1973	M. Zaret; Zaret Foundation, Scarsdale, New York; Ibid., pp. 294-301	1	Man (one case)--eye--cataracts
48	Retinal Changes in Microwave Workers-S	Oct. 1973	B. Tengroth and E. Aurell; University of Sweden, Gothenburg, Sweden; Ibid., pp. 302-305	Below 10	Man--eye--loss of lens translucency and functioning of retina
49	Assessment of Lens Translucency in Juveniles, Microwave Workers and Age-Matched Groups-S	Oct. 1973	S. Zydecki; Military Medical Academy, Warsaw, Poland; Ibid., pp. 306-308	0.01 and below	Man--eye--decrease in lens translucency

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50	Effects of Microwaves on the Cell Metabolism of the Reticulo-Histocytic System-S	Oct. 1973	L. Miro, R. Loubiere, and A. Pfister; Laboratory of Biological Physics, Nimes, France; Ibid., pp. 89-97	2	Mice--spleen, liver and thymus cells--abnormal increase and distribution of cells and disorganization of liver structure
51	Are Microwaves Teratogenic?-S	Oct. 1973	R. Rugh, E. Ginns, E. Ho, and W. Leach; Food and Drug Administration; Ibid., pp. 98-107	123	Mice--G&D--stunted growth and birth defects
52	Effects of Microwave Irradiation in Vitro on Cell Membrane Permeability-S	Oct. 1973	S. Baranski, S. Szmigielski, and J. Moneta; Military Institute of Aviation Medicine, Warsaw, Poland; Ibid., pp. 173-177	1	Rabbits cells--G&D--injury to cell membranes
53	Microwave Thawing of Cells and Organs-S	Oct. 1973	W. Voss, R.Rajotte, and J. Dossetor; The University of Alberta, Edmonton, Alberta, Canada; Ibid., pp. 196-201	Above 1,000*	Dog kidneys--kidney--disruption of function
54	Influence of Microwave Radiation on the Hematopoietic System-S	Oct. 1973	P. Czerski, E. Paprocka-Slonka, M. Siekierzynski, and A. Stolarska; National Institute of Mother and Child, Military Institute of Aviation Medicine, and Military Medical Academy, Warsaw, Poland; Ibid., pp. 67-74	0.5	Mice--blood cells--disturbance of cell division process
55	The Effect of Microwaves on Human Lymphocyte Cultures-S	Oct. 1973	W. Stodolnik-Baranska; Medical Academy, Warsaw, Poland; Ibid., pp. 189-195	20	Human cells--blood cells--disturbances of the cell division process and changes in the number and structure of chromosomes in cells
56	Blood Proteins in Personnel of Television and Radio Transmitting Stations-S	Oct. 1973	J. Pazderova, J. Pickova, and V. Bryndova; Charles University and Research Institute of Telecommunications, Prague, Czechoslovakia; Ibid., pp. 281-288	0.025*	Man--blood cells--no effect noted
57	Electrographic Data on the Effects of Very Weak Microwaves at the Level of the Midbrain Reticular Formation-Hypothalamus-Cerebral Cortex Level-S	1973	M. Bychkov and I. Dronov; Moscow, Russia; Translation - Natl. Tech. Inf. Serv. Report No. JPRS 63321, pp. 75-86, 1974	0.1	Rabbits--NS&B--effect on segment of brain which controls water balance, temperature and sleep
58	Electroencephalographic Changes Under the Influence of Low Intensity Chronic Microwave Irradiations-S	1973	M. Bychkov, V. Markov, and V. Rychkov; Moscow, Russia; Ibid., pp. 87-94	0.153	Rabbits--NS&B--alteration of brain electrical patterns

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59	Pathological Effects of Radio Waves-R	1973	M. Tolgskaya and Z. Gordon; Academy of Medical Sciences of U.S.S.R., Moscow, Russia; Translation by Basil Haigh, Consultants Bureau, London-New York, 1973	4-10	Rats--NS&B--disturbances of conditioned reflexes
60	Experimental Studies on the Biological Effects Evoked by Combined Exposure to Microwaves and High Air Temperature-S	1973	K. Nikonova; Russia; Translation--Natl. Tech. Inf. Serv. Report No. JPRS 63321, pp. 153-157, 1974	10-15	Mice--NS&B--alterations in behavior
61	Experimental Morphologic and Electroencephalographic Studies of Microwave Effects on the Nervous System-S	Feb. 1974	S. Baranski and Z. Edelwejn; Military Institute of Aviation Medicine, Warsaw, Poland; Biologic Effects of Nonionizing Radiation, Annals of the New York Academy of Sciences, vol. 247, pp. 109-116, 1975	5 Not reported	Rabbits--NS&B--changes in brain electrical patterns Man--NS&B--disturbed electrical pattern of the brain; headaches and excessive sweating
62	Microwave Dose-Response Relationships on Two Behavioral Tasks-S	Feb. 1974	W. Galloway; Food and Drug Administration; Ibid, pp. 410-416	Above 20*	Monkeys--NS&B--unable to perform behavior tasks; severe convulsions
63	Do Microwaves Alter Nervous System Structure?-S	Feb. 1974	E. Albert and M. De Santis; George Washington and Georgetown Universities Medical Centers, Washington, D.C.; Ibid., pp. 87-108	25	Chinese hamsters--NS&B--deterioration of nerve cell structure
64	Neural Function and Behavior: Defining The Relationship-S	Feb. 1974	A. Frey, S. Feld, and B. Frey; Randomline, Inc., Huntingdon Valley, Pennsylvania; Ibid., pp. 433-439	0.2	Rats--NS&B--alterations in behavior
65	Behavioral Effects of Pulsed Microwave Radiation-S	Feb. 1974	E. Hunt, N. King, and R. Phillips; Pacific Northwest Laboratories, Richland, Washington; Ibid., pp. 440-453	27*	Rats--NS&B--alterations in behavior
66	Preliminary Investigations of the Effects of Low-Level Microwave Radiation on Spontaneous Motor Activity in Rats-S	Feb. 1974	B. Roberti, G. Heebels, J. Hendricx, A. de Greef, and O. Wolthuis; Medical Biological Laboratory TNO, Rijswijk, and Laboratory for Electronic Developments of the Armed Forces, Oestgeest, The Netherlands; Ibid., pp. 417-424	25	Rats--NS&B-- no effects noted

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67	Synchronization of Cortical Neurons by a Pulsed Microwave Field as Evidenced by Spectral Analysis of Electrocorticograms from the White Rat-S	Feb. 1974	B. Servantie, A. Servantie, and J. Etienne; Hospital d'Instruction des Armees Sainte-Anne, 83800 Toulon-Naval, France; Ibid., pp. 82-86	5	Rats--NS&B--disturbed electrical patterns of the brain
68	Effects of Low-Level Microwave Radiation on Behavioral Baselines-S	Feb. 1974	J. Thomas, E. Finch, D. Fulk, and L. Burch; Naval Medical Research Institute, Bethesda, Maryland; Ibid., pp. 425-432	7	Rats--NS&B--alterations in behavior
69	Biochemical and Neuroendocrine Aspects of Exposure to Microwaves-S	Feb. 1974	S. Michaelson, W. Houk, N. Lebda, S. Lu, and R. Magin; University of Rochester, Rochester, New York; Ibid., pp. 21-43	36	Rats--NS&B--disturbed nervous system and behavior patterns
70	Effects of Low-Intensity Microwaves on Isolated Neurons-S	Feb. 1974	H. Wachtel, R. Seaman, and W. Joines; Duke University, Durham, North Carolina; Ibid., pp. 46-62	1	Ganglion (nerve tissue) of marine life--NS&B--suggested disturbance in brain patterns due to changes in nerve cell responses
71	Some Effects of Electromagnetic Radiation on the Brain and Spinal Cord of Cats-S	Feb. 1974	E. Taylor and B. Ashleman; University of Washington, Seattle, Washington; Ibid., pp. 63-73	Above 20*	Cats--NS&B--reduced functional responses of nerves in spinal cord
72	The Ocular Effects of Microwaves on Hypothermic Rabbits: A Study of Microwave Cataractogenic Mechanisms-S	Feb. 1974	P. Kramar, A. Emery, A. Guy, and J. Lin; University of Washington, Seattle, Washington; Ibid., pp. 155-165	200	Rabbits--eye--cataract
73	Ultrastructural Changes in the Rabbit Lens Induced by Microwave Radiation-S	Feb. 1974	R. Williams, A. McKee, and E. Finch; Duke University, Durham, North Carolina and National Naval Medical Center, Bethesda, Maryland; Ibid., pp. 166-174	165	Rabbits- eye--structural damage to eye including growth of cysts
74	Ascorbic Acid Changes in Cultured Rabbit Lenses after Microwave Irradiation-S	Feb. 1974	J. Weiter, E. Finch, W. Schultz, and V. Frattali; National Naval Medical Center, Bethesda, Maryland; Ibid., pp. 175-181	150	Rabbit lens--eye--reduced transparency of lens
75	Microwave-Induced Acoustic Effects in Mammalian Auditory Systems and Physical Materials-S	Feb. 1974	A. Guy, C. Chou, J. Lin, and D. Christensen; University of Washington, Seattle, Washington; Ibid., pp. 194-218	0.047 0.135	Cats--auditory--no effect noted Man--auditory--no effect noted

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76	Effect of Microwaves on Cell Function and Virus Replication in Cell Cultures Irradiated in Vitro-S	Feb. 1974	S. Szmigielski, M. Luczak, and M. Wiranowska; Institute of Aviation Medicine and University Medical School, Warsaw, Poland; Ibid., pp. 263-274	20	Human cells--G&D--severe cellular damage including damage to cell structure
77	Effect of 10-cm (3GHz) Electromagnetic Radiation (Microwaves) on Granulocytes in Vitro-S	Feb. 1974	S. Szmigielski, Institute of Aviation Medicine, Warsaw, Poland; Ibid., pp. 275-281	5	Rabitt cells--G&D--severe cellular damage causing an increase in cell death rate
78	Genetic Continuity and Metabolic Regulation as Seen by the Effects of Various Microwave and Black Light Frequencies on these Phenomena-S	Feb. 1974	S. Webb; University of Saskatchewan, Saskatoon, Saskatchewan, Canada; Ibid., pp. 327-351	10	Bacteria cells--G&D--interference with cell growth and their production of certain cellular substances
79	Effects of Nonionizing Electromagnetic Radiation on Single-Cell Biologic Systems-S	Feb. 1974	C. Blackman, S. Benane, C. Weil, and J. Ali; Environmental Protection Agency, Research Triangle Park, North Carolina; Ibid., pp. 352-366	5	Bacteria cells--G&D--no effect noted
80	Effects of Electromagnetic Radiation on Implantation and Intrauterine Development of the Rat-S	Feb. 1974	F. Dietzel; University of Giessen, Federal Republic of Germany; Ibid., pp. 367-376	Not reported	Rats--G&D--adverse effect on embryonic development
81	Some Effects of Exposure of the Japanese Quail Embryo to 2.45-GHz Microwave Radiation-S	Feb. 1974	D. McRee, P. Hamrick, J. Zinkl, P. Thaxton, and C. Parkhurst; National Institutes of Health, Research Triangle Park, and North Carolina State University, Raleigh, North Carolina; Ibid., pp. 377-390	30	Quail eggs--G&D--no effect noted
82	Effects of Electromagnetic Fields on Fecundity in the Chicken-S	Feb. 1974	W. Krueger, A. Giarola, J. Bradley, and A. Shrekenhamer; Texas A&M University, College Station, Texas; Ibid., pp. 391-400	1	Chickens--G&D--reduced egg productivity
83	Threshold Effects of Microwave Radiation on Embryo Cell Systems-S	Feb. 1974	S. Pyle, D. Nichols, F. Barnes, and E. Gamow; University of Colorado, Boulder, Colorado; Ibid., pp. 401-407	Over 1,000*	Zebra fish eggs--G&D--abnormalities in embryos
84	The Effect of Electromagnetic Radiation on the Hematopoietic Stem Cells of Mice-S	Feb. 1974	D. Rotkovska and A. Vacek; Czechoslovak Academy of Sciences, 61265 Brno, Czechoslovakia; Ibid., pp. 243-250	100	Mice--blood-cells--change in white blood cells and decrease in the number of cells in bone marrow

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85	Chromosomal Aberrations of Living Cells Induced by Microwave Radiation-S	1974	K. Chen, A. Samuel, and R. Hoopingarner; Michigan State University, East Lansing, Michigan; Environmental Letters, vol. 6, pp. 37-46, 1974	20 20	Hamster cells--G&D--chromosomal damage Human cells (female uterus) --G&D--chromosomal damage
86	Behavior Suppression by 383 MHz Radiation-S	March 1975	R. Cunitz, W. Galloway, C. Berman; National Bureau of Standards, Washington, D.C. and Food and Drug Administration; IEEE Transactions on Microwave Theory and Techniques. MTT-23, pp. 313-316, 1975	Above 20*	Monkeys--NS&B--alterations in behavior
87	Microwave Bioeffects: Current Status and Concepts-R	Sept. 1975	P. Czerski, and S. Szmigielski; Institute of Mother and Child and Institute of Aviation Medicine, Warsaw, Poland; Proceedings of 5th European Microwave Conference, Germany, pp. 348-357, 1975	0.1	Animals (type not reported) --NS&B--disturbed conditioned reflexes and behavior
88	Biomedical Aspects of Radiofrequency and Microwave Radiation: A Review of Selected Soviet, East European, and Western References-R	Oct. 1975	Z. Glaser and C. Dodge; Naval Surface Weapons Center, Dahlgren, Virginia, and Library of Congress, Washington, D.C.; Biological Effects of Electromagnetic Waves. HEW Publication (FDA) 77-8010, pp. 2-34, 1976	0.00006 0.2 5	Animals (type not reported) --NS&B--structural alterations to nerve cells Guinea pigs--blood--injury to white blood cells Cell cultures (type not reported)--G&D--increase in reproduction of viruses in cells
89	Study of the Microwave-Induced Perturbations of the Behavior by the Open-Field Test into the White Rat-S	Oct. 1975	J. Gillard, B. Servantie, G. Bertharion, A. Servantie, J. Obrenovitch, J. Perrin; Hospital d'Instruction des Armees Sainte-Anne, 83800 Toulon-Naval, France; Ibid., pp. 175-186	0.7	Rats--NS&B--alteration of behavior patterns by inhibiting exploratory efficiency
90	Modification of Internal Discriminative Stimulus Control of Behavior by Low Levels of Pulsed Microwave Radiation-S	Oct. 1975	J. Thomas, S. Yeandle, and L. Burch; National Naval Medical Center, Bethesda, Maryland; Ibid., pp. 201-214	5	Rats--NS&B--alterations in behavior
91	Behavioral Effects of Resonant Electromagnetic Power Absorption in Rats-S	Oct. 1975	J. D'Andrea, O. Gandhi, and R. Kesner; University of Utah, Salt Lake City, Utah; Ibid., pp. 257-273	25	Rats--NS&B--alterations in behavior
92	Histological Observations on Central Nervous System-S	Oct. 1975	E. Albert and M. DeSantis; George Washington and Georgetown Universities Medical Centers, Washington, D.C.; Ibid., pp. 299-310	10	Chinese hamsters--NS&B--injury to structure and function of certain cells in brain

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93	Effect of Microwave Radiation on Pentobarbital-Induced Sleeping Time-S	Oct. 1975	S. Cleary and R. Wangemann; Virginia Commonwealth University, Richmond, Virginia; Ibid., pp. 311-322	5	Rabbits--NS&B--heat stress caused alterations to nervous system
94	Microwave-Induced Shifts of Gonadotropic Activity in Anterior Pituitary Gland of Rats-S	Oct. 1975	H. Mikolajczyk; Institute of Occupational Medicine, Lodz, Poland; Ibid., pp. 377-383	10	Rats--pituitary gland--increased production of hormones which effects the reproductive function
95	Evaluation of Dominant Lethal Test and DNA Studies in Measuring Mutagenicity Caused by Non-Ionizing Radiation-S	Oct. 1975	M. Varma and E. Traboulay Jr.; Harvard University, Cambridge, Massachusetts, and Washington Suburban Sanitary Commission, Hyattsville, Maryland; Ibid., pp. 386-396	10	Mice--G&D--increased mutagenicity--fertility--reduced rate of pregnancy
96	Mutagenicity Induced by Non-Ionizing Radiation in Swiss Male Mice-S	Oct. 1975	M. Varma, E. Dage, S. Joshi; Harvard University, Cambridge, Massachusetts, Environmental Protection Agency, Washington, D.C., and National Institutes of Health-HEW, Bethesda, Maryland; Ibid., pp. 397-405	50	Mice--G&D--increased mutagenicity
97	Cytogenetic Consequences of Microwave Incubation of Mammalian Cells in Culture-S	July 1976	K. Yao; Food and Drug Administration; Abstract, Genetics, vol. 83, no. 3 part 1, p. 84, 1976	11-20*	Rat cells--G&D--damage to cell chromosomes which effect heredity
98	Oxygen-consumption Rate of Mice Under Differing Dose Rates of Microwave Radiation-S	Oct. 1976	H. Ho and W. Edwards; Food and Drug Administration; Radio Science, U.S. Natl. Com. Internatl. Union of Radio Science, vol. 12 Supp, pp. 131-138, 1977	14*	Mice--whole body--decrease in rate of metabolism
99	Thermal and Endocrirological Effects of Protracted Irridiation of Rats by 2450-MHz Microwaves-S	Oct. 1976	S. Lu, N. Lebda, S. Michaelson, S Pettit, and D. Rivera; University of Rochester, Rochester, New York; Ibid., pp. 147-156	1	Rats--thyroid gland--excess production of thyroxine
100	Microwave Irradiation of the Isolated Rat Heart after Treatment with ANS Blocking Agents-S	Oct. 1976	J. Reed III, J. Lords, C. Durney; University of Utah, Salt Lake City, Utah; Ibid., pp. 161-165	1-10*	Rat hearts--heart--abnormal slowness of heart beat

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101	The Effect of Microwave Radiation (2450 MHz) on the Morphology and Chromosomes of Lymphocytes-S	Oct. 1976	A. Huang, M. Engle, J. Elder, J. Kinn, and T. Ward; Duke University, Durham, Environmental Protection Agency, Research Triangle Park, North Carolina; Ibid., pp. 173-177	5	Chinese hamsters--G&D--alterations in the production of blood cells
102	Immune Response of Mice to 2450-MHz Microwave Radiation: Overview of Immunology and Empirical Studies of Lymphoid Splenic Cells-S	Oct. 1976	W. Wiktor-Jedrzejczak, A. Ahmed, P. Czerski, W. Leach, and K. Sell; Military School of Medicine and Institute of Mother and Child, Warsaw, Poland, Food and Drug Administration, and National Naval Medical Center, Bethesda, Maryland; Ibid., pp. 209-219	25*	Mice--blood--changes in the immune system
103	The Effect of Ambient Temperature on the Reduction of Microwave Energy Absorption by Mice-S	Oct. 1976	J. Monahan and H. Ho; Food and Drug Administration; Ibid., pp. 257-262	0.8*	Mice--NS&B--alteration of behavior pattern
104	Long-Term Effects of 2.45-GHz Radiation on the Ultrastructure of the Cerebral Cortex and on Hematologic Profiles of Rats-S	Oct. 1976	W. Switzer and D. Mitchell; Trinity University and Southwest Research Institute, San Antonio, Texas; Ibid., pp. 287-293	10*	Rats--NS&B--abnormalities in nerve tissue
105	Are Microwave Cataracts Thermally Caused?-S	Feb. 1977	R. Carpenter, G. Hagan, and G. Donovan; Food and Drug Administration; Symposium on Biological Effects and Measurement of Radio Frequency/Microwaves (HEW Publication (FDA) 77-8026), pp. 352-379, 1977	250	Rabbits--eye--formation of cataracts
106	Free-Operant Avoidance and Escape from Microwave Radiation-S	Feb. 1977	J. Monahan and W. Henton; Food and Drug Administration; Ibid., pp. 23-33	61 *	Mice--NS&B--alterations in behavior
107	Neuroendocrine Responses in the Rat and Dog Exposed to 2450 MHz (CW) Microwaves-S	Feb. 1977	S. Michaelson, R. Guillet, W. Lotz, S. Lu, and R. Magin, University of Rochester, Rochester, New York; Ibid., pp. 263-279	30 60	Rats--thyroid gland--decreased production of growth hormones Dogs--thyroid gland--excess secretion of thyroxine
108	Light and Electron Microscopic Observations on the Blood-Brain Barrier after Microwave Irradiation-S	Feb. 1977	E. Albert; George Washington University, Washington, D.C.; Ibid., pp. 294-304	10	Chinese hamsters--NS&B--damage of nerve cells in and around brain
109	Microwaves Induce an Increase in the Frequency of Complement Receptor-Bearing Lymphoid Spleen Cells in Mice-S	April 1977	W. Wiktor-Jedrzejczak, A. Ahmed, K. Sell, P. Czerski, and W. Leach; Military School of Medicine and Institute of Mother and Child, Warsaw, Poland, National Naval Medical Center, Bethesda, Maryland and Food and Drug Administration; Journal of Immunology. vol. 118, pp. 1499-1502, 1977	28*	Mice--blood--changes in the immune system

APPENDIX III

	Title (note a)	Date reported	Author(s), affiliation and reference	Lowest reported (*estimated) exposure causing effect (mW/cm^2 (note b)	Subject irradiated, body part or function affected and effect (note c)
110	Survey of Microwave and Radiofrequency Biological Effects and Mechanisms-R	June 1977	S. Cleary; Virginia Commonwealth University, Richmond, Virginia; The Physical Basis of Electromagnetic Interactions With Biological Systems, Proceedings of Workshop at Univ. of Maryland June 15-17, 1977. pp 1-33, 1977	0.15 0.5	Rats--NS&B--alterations in behavior Rabbits and mice--blood--changes in white blood cells
111	Observations on Mouse Fetuses Exposed to 2.45 GHz Microwave Radiation-S	Dec. 1977	F. Berman and H. Carter; Environmental Protection Agency, Research Triangle Park, North Carolina; Abstract, Health Physics, vol. 33, p. 661, 1977	28	Mice--G&D--deformed head of fetus
112	Parental Factors in Down's Syndrome-Results of the Second Baltimore Case-Control Study-S (Entry no. 12 is the first Baltimore case-control study.)	1977	B. Cohen, A. Lilienfeld, S. Kramer, L. Hyman; Johns Hopkins University, Baltimore, Maryland; Population Cytogenetics, pp. 301-352, 1977	Not reported	Man--G&D--no effect noted

a/"S" indicates a report on one study.
"R" indicates a report that includes a review of several studies.

b/For those reports showing no effect, the highest level of microwave exposure used in the study is shown. An asterick indicates an estimated exposure level.

c/Abbreviations used: G&D--Genetic and Developmental (includes observations on teratogenic changes, cell and physical development).
NS&B--Nervous System Behavior.

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