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STATEMENT OF
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PUBLIC HEALTH SERVICE

BEFORE THE
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HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY

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Mr. Chairman, the National Institute for Occupational Safety and Health (NIOSH) is pleased to testify on our activities pertaining to the hazards of radiofrequency (RF) radiation from industrial sealers and heaters. I am Dr. Joseph Lary, Research Biologist in the NIOSH Division of Biomedical and Behavioral Science. Accompanying me is Dr. Barry Johnson, Director of the Division, and Mr. Richard Lemen, Acting Director of NIOSH's Division of Criteria Documentation and Standards Development. Dr. David Conover, my colleague at NIOSH, will testify later in this hearing.

At the Subcommittee's request, NIOSH has prepared answers to specific questions on the physical properties and biological effects of RF radiation from heaters and sealers. Let me first present a brief overview of NIOSH activities in this area.

As you know, NIOSH is the single national research agency mandated to conduct research on occupational safety and health. Established by the Occupational Safety and Health Act of 1970, NIOSH is part of the Centers for Disease Control of the Public Health Service, within the Department of Health and Human Services. Its mandate is to conduct research; to develop recommendations to the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA) for occupational safety and health standards; to provide technical assistance to employees and employers in the form of Health Hazard Evaluations and Technical Assistance; and to conduct training and education programs.

Major Activities

RF sealers and heaters have been used for more than 30 years in a wide variety of industrial applications. They are used to heat, melt, or cure materials such as plastic, rubber, or glue. Specific uses include: the manufacture of many plastic products; wood lamination and veneer processes, including glue setting; embossing and drying operations in the textile, paper, plastic, and leather industries; and curing of various materials including plasticized polyvinyl chloride, wood resins, polyurethane foam, concrete binder materials, rubber tires, and epoxy resins.

The Institute first began to actively investigate potential health hazards associated with exposure to RF heaters and sealers in 1973. NIOSH concluded after conducting three preliminary industrial surveys that (1) the operators of this type of equipment were predominantly young women; (2) there appeared to be little if any awareness by the workers of the possible radiation hazard attendant to operation of the sealers/heaters; and (3) commercial equipment had not been developed to permit employers or government agencies to measure the radiation exposures of the employees.

Five Health Hazard Evaluations and five surveys were conducted in 1974-75, and in 1975 we reported that the majority of workers were exposed to RF radiation at levels up to 10 times the 1974 ^{American National Standards Institute} (ANSI) standard of 10 mW/cm². In 1976 we began to actively interact with instrument manufacturers who could commercially produce equipment that could be used in workplace surveys for RF radiation. In 1977 a commercial monitoring instrument was developed that

seemed to fit the needs of government agencies and could be used by industry. During this same period, our HHE activities were continuing.

In 1978 NIOSH began laboratory studies of the possible teratogenic effects of RF radiation, because of new reports in the literature and because of our observation of the high percentage of women operators of RF heaters and sealers. Our laboratory studies clearly reveal that high intensity RF radiation will produce fetal malformations when there are significant elevations in body temperatures.

In 1979 at a joint Bureau of Radiological Health-OSHA Public Workshop, NIOSH reported the results from their field surveys which indicated that RF radiation levels were often in the range considered hazardous to workers. The Institute also commenced developing a criteria document on RF/microwave radiation which is now nearing the final stages. The Institute plans to have this criteria document available for external review by December 1981.

A Current Intelligence Bulletin (CIB) was issued jointly by NIOSH and OSHA in late 1979 and was widely distributed to industrial and labor groups. This CIB expressed the two agencies' concerns about the potential biological effects of RF radiation from RF heaters and sealers and offered general recommendations on hazard control procedures.

Various control technology procedures were also examined in a joint workshop in 1980 with the Bureau of Radiological Health and OSHA and data were acquired as to the effectiveness of various engineering controls methods that

would reduce radiation exposure levels from RF sealers and heaters. NIOSH is developing a publication on this issue which will form the basis of recommended engineering controls for RF sealers and heaters. This will be completed by September 1981.

Finally, NIOSH continues to conduct Health Hazard Evaluations on RF heaters and sealers. To date, we have conducted 32 surveys, including 6 in 1980 and one in 1981. The Institute's results continue to show that RF radiation levels exceed the OSHA standard.

I will now turn to the Committee's specific questions.

Biological Effects of RF Radiation with Emphasis on Operators

Over 6000 articles have appeared in the world literature relating to RF/microwave biological effects. NIOSH has made an extensive search and review of this literature in preparing its criteria document on RF/microwave radiation. It is beyond the scope of this testimony to present a comprehensive review of the available literature. However, some discussion of the types of effects that have been reported, both for human exposure and animal exposure, is needed to assess the possibility of RF effects on operators of RF heaters and sealers.

There have been a few epidemiological studies on populations exposed to RF/microwave radiation. These are considered to be of limited value because of failure or inability to quantify exposure doses, or to compare exposed

groups with properly matched control (unexposed) populations. Some of the studies found no significant differences between exposed and unexposed populations. In several studies, however, some biological parameters in the exposed population differed significantly from those in the control populations. Reported differences included a decrease in cataracts and increases in other lens opacities; fatigue, irritability, cardiac and circulatory disorders; muscular weakness, electrocardiogram changes, headaches, insomnia, hypertension, changes in blood chemistry, nervousness, endocrine changes, changes in counts of red blood cells, white blood cells, and platelets; electroencephalogram disturbances, decreased spermatogenesis, and a greater percentage of mongoloid children of exposed fathers.

Several case reports have been published describing alleged injury to persons exposed to RF/microwave radiation. It should be cautioned that anecdotes or single-person case reports are recognized to be insufficient of themselves to establish a relationship between RF/microwave exposure and illness.

However the following effects have been reported: abnormal bleeding and clotting, various skin problems, weight loss, genital problems, rapid heart rate, hormonal disturbances, fingernail deformities, auditory sensations, cataract formation, blindness, development of ocular opacities, loss of visual acuity, miscarriages, birth defects, retarded fetal development, and even death from accidental overexposure.

Another source of information is clinical and experimental studies of human subjects. During treatment the following effects have been observed.

Diathermy devices, operating primarily at 27 MHz or 2450 MHz, are often used

to induce localized deep body heating. In one study, volunteers subjected to high intensity RF radiation at 55 MHz reported a sensation of warmth, cramps, sweating, fatigue, drowsiness, and headaches. In another study patients clinically treated with 10 MHz radiation had increases of approximately 3.6°C in body temperature and an initial depression of white ~~these~~ ^{blood cell} levels followed by an elevation of these levels. Whole body RF exposure of male volunteers to short-wave radiation has been reported to inhibit spermatogenesis, presumably due to heating of the testes. In a clinical study of microwave heating of human tissues, temperature increases of up to 10.7°C (19.3°F) were reported to occur in some tissues without an increase in rectal temperature. In spite of this high localized temperature increase, volunteers reported only a pleasant sensation of warmth in the skin.

Controlled experiments involving laboratory animals provide the best evidence of RF/microwave-induced biological effects. The effects described below are all from laboratory studies.

Excessive levels of RF/microwave radiation can be lethal in animals. Death is apparently caused by hyperthermia induced by the absorption of RF/microwave energy. The exposure time necessary to cause lethality is inversely related to the power density of the incident radiation.

RF/microwave radiation affects the reproductive systems of animals. Decreased spermatogenesis, testicular degeneration, decreased fertility, and changes in the estrous cycle have been reported. In some cases, incident exposure levels were at or below 10 mW/cm², the present OSHA standard.

Teratogenic effects in animals have been observed after RF/microwave exposure. Most RF induced birth defects occur only after significant elevation of maternal body temperature. However, there have been reports of minor developmental deviations, increased embryonic death, delayed development, and decreased fetal weight in animals exposed during pregnancy to levels at or below 10 mW/cm^2 .

Numerous disturbances attributed to RF/microwave exposure have been reported in endocrine, nervous, auditory, ocular, cardiovascular, hematologic, and immunological systems in animals. Many of the changes noted were reported at levels at or below the current 10 mW/cm^2 standard.

RF/microwave radiation also has been reported to cause changes in animal behavior including changes in learning ability, spontaneous activity, and aggressiveness; disturbance of conditioned reflexes, disturbance of motor coordination and balance, decreased visual discrimination, and decreased exploratory activity. Many of the changes occurred at levels at or below 10 mW/cm^2 .

A wide variety of general physiological changes have been reported to occur after exposure of animals to RF/microwave radiation. These include changes in the digestive system, kidneys, skeletal system, muscular system, and skin in addition to the areas previously mentioned. Biochemical changes in the body have also been reported. Most of the above changes can be duplicated by heating the body by conventional means but some occurred at power levels not expected to cause measurable body heating.

Some of the effects outlined above were definitely harmful. However, the majority were minor or of unknown physiological significance. In most cases the effects were transient.

A few investigators have reported mutations or chromosomal aberrations in plant and animal cells and tissue cultures. Most of these effects are believed to have been caused by thermal stress. It is well known that mutations and chromosomal aberrations increase with increasing temperature. At present, there is no satisfactory evidence that RF/microwave radiation can cause genetic or chromosomal alterations at levels below 10 mW/cm^2 .

It is difficult to predict what effects might occur in human beings exposed to radiation from RF heaters and sealers, despite the rather voluminous literature on RF/microwave biological effects. There are very few reports in the literature of either human or animal exposure to RF radiation in the frequency range of most RF heaters and sealers (10-100 MHz). In most studies, exposure was in the microwave frequency range most often at or close to 2450 MHz. Most of the reports in the literature have inadequate dosimetric or biological information to evaluate the reported effects. The literature is often contradictory. In a great many studies, RF/microwave exposure caused no effect, even at relatively high exposure levels.

Differences in anatomical and physiological makeup, differences in whole or partial body power absorption characteristics at given frequencies, and differences in radiation source characteristics do not permit a simple extrapolation from animal studies to the experience of RF heater/sealer

operators. Additionally, most experimental animal exposures are to continuous, uniform, far-field sources while RF sealer/heater operators experience intermittent, non-uniform, near-field irradiation.

Most of the biological effects reported in the literature, harmful or otherwise, can be attributed to the thermal nature of the absorbed radiation. However, some effects have been reported after exposure to radiation levels which did not result in a measurable increase in body temperature. Some researchers feel that the biological effects from low-intensity radiation are due to intrinsic electrical and magnetic properties of the radiation unrelated to heating, while others attribute them to unmeasurable localized heating.

The current OSHA standard of 10 mW/cm^2 in the frequency range of 10 MHz to 10 GHz is based on a consideration of whole body heating under the assumption that RF/microwave radiation sufficiently intense to cause a measurable elevation in body temperature is potentially hazardous. Calculations were based on exposure to microwave radiation at or close to 2450 MHz. It is now known that maximum absorption of RF/microwave energy by the human body can occur in the frequency range of many RF heater/sealers. Whole body and partial body power absorption in the frequency range of 30-300 MHz is maximum rather than negligible, as previously assumed by some researchers.

In an average-sized man standing in a 10 mW/cm^2 field at 79 MHz, temperature elevations as high as 44°C (111°F) are predicted to occur in some parts of the body within 180 minutes. At 30 mW/cm^2 the human

thermoregulatory system is potentially overloaded and uncontrolled elevation of rectal temperature may occur during sustained RF exposures. Partial body temperature increases of up to 1°C are expected to occur at power density levels as low as 1.5 mW/cm². If elevation of body temperature by RF/microwave radiation is potentially hazardous, the present 10 mW/cm² standard needs to be reexamined in the frequency range of maximum human absorption.

From an analysis of the literature, it seems clear that the current OSHA standard, especially in the frequency range of RF heater/sealers, must be reexamined to assure that sufficient protection is afforded the worker. Since NIOSH and OSHA measurements indicate that unshielded RF heaters and sealers commonly emit radiation in the vicinity of the operator which far exceeds the current OSHA standard, it is apparent that many sealer/heater operators are being exposed to hazardous levels of RF energy. Efforts should be made to ensure that these operators are not exposed to radiation in excess of the current OSHA standard.

Biological Basis for an RF/Microwave Radiation Standard

As previously noted, NIOSH is currently developing and plans to have ready for external review by December 1981 a criteria document on RF/microwave radiation which will recommend maximum permissible occupational exposure limits, based on an analysis of the RF/microwave biological effects reported in the world's literature. Only those papers which contain adequate

information from both a dosimetric and biologic standpoint are being selected to form the basis for the proposed standard.

To compare RF/microwave biological effects among different studies, NIOSH is using an estimate of the rate of power actually absorbed by the body (the specific absorption rate or SAR) rather than reported power density or field strength levels. This SAR is thought by most researchers to be a better measure of the amount of radiation required to produce a given biological effect than is power density or electric and magnetic field strength. Thus, the SAR provides a common basis for comparing the amount of radiation required to cause a biological effect.

All of the critically selected biological effects reported in the literature will be ranked according to the SAR required to produce the effect. NIOSH scientists will determine the lowest SAR values associated with effects that are clearly hazardous and will select a maximum permissible SAR exposure level. The external field strength and power density levels required to produce this maximum permissible SAR in human beings for any given frequency will also be calculated. This approach will result in a frequency dependent exposure standard for RF/microwave radiation. A similar approach has been taken by the American National Standards Institute (ANSI) Committee on Radiofrequency Radiation in the process of developing a proposed RF/microwave exposure standard for occupational exposure.

The proposed ANSI standard recommends a maximum power density exposure level of 1 mW/cm^2 in the frequency range of maximum human absorption (30-300

MHz). Until the NIOSH review process is completed, we cannot predict what maximum permissible exposure levels NIOSH will recommend. We recognize that there is considerable debate about the mechanisms of interaction of RF radiation with human tissue and that not everyone agrees with the use of SAR calculations to determine permissible exposure limits. Therefore, it should be pointed out that the NIOSH recommended standard will be based on a state-of-the-art assessment of the RF/microwave biological effects and dosimetry literature. The NIOSH proposed standard is intended as an interim recommendation which may have to be modified when additional research information becomes available.

Ongoing and Planned NIOSH Research on Biological Effects of RF Radiation

Since 1977 NIOSH's Division of Biomedical and Behavioral Sciences (DBBS) has conducted research to determine the teratogenic effects of radiofrequency (RF) radiation at 27.12 MHz, the operating frequency of most industrial RF heaters and sealers. DBBS has found that high intensity RF radiation at this frequency is definitely teratogenic in laboratory animals. Pregnant rats receiving a single 20-40 minute RF exposure at levels sufficient to cause appreciable whole body heating had a high incidence of malformed offspring. ✓

The entire period of embryonic development appeared to be susceptible to RF radiation, but a much greater incidence of effects occurred after exposure on gestation days 9, 11, or 13. This corresponds to the third through the fifth week of human development. RF also caused a significant incidence of embryonic death during this same period. More than 200 different types of

abnormalities were observed including virtual absence of the head or the brain, exposed brains protruding from the skull, missing or malformed eyes, ears, jaws, and tails; cleft lip and cleft palate; severe limb and digit malformations; exposed spinal cords; missing or fused ribs and vertebrae; and numerous heart defects.

NIOSH has determined that the incidence of birth defects in rats is clearly related to maternal body temperature during RF exposure. Elevation of body temperature by only 2.5° C for a few minutes caused a significant increase in fetal malformations. This is equivalent to a human oral temperature elevation to 103° F. At higher temperature elevations the effects occurred more often and were more severe. The incidence of malformations was also found to increase with exposure duration. If the maternal body temperature remained elevated for longer periods of time, the incidence and severity of fetal malformations increased.

We are currently conducting research to determine if protracted exposure of pregnant rats to lower intensity RF radiation at a level which causes no measurable rise in body temperature is teratogenic or embryotoxic. In addition, cooperative research with teratologists at the University of Cincinnati Medical School is being conducted to determine the mechanisms of RF-induced fetal malformations and death.

Final decisions on future research have not been made. However, NIOSH is planning to begin a study in Fiscal Year 1982 of low frequency RF radiation effects on male reproduction in animals to determine if RF radiation emitted

from such devices is potentially hazardous to male workers. A 1975 study reported decreased spermatogenesis and sexual disturbances in male microwave workers compared to a control population. In addition, a few studies have reported decreased spermatogenesis, testicular degeneration, and decreased fertility in animals exposed to microwave radiation. No male reproductive studies have been conducted in the radiofrequency range typical of RF heat sealers, induction heaters, and similar devices.

As previously noted, RF exposure has been associated in case reports with miscarriages and birth defects. However, there is no definitive epidemiologic study on this subject conducted in the U.S. NIOSH is attempting to define a population of occupationally-exposed female workers suitable for evaluation of pregnancy outcome, suitability being defined as a population in a single plant large enough and with sufficiently detailed work and exposure records to meet statistical needs. NIOSH has contacted 135 companies and has made walk-through surveys and record assessments at 25. No cohort which satisfies the need for approximately 250 pregnancies for the epidemiologic study has been located. NIOSH is continuing its search, and will contact 30 more companies in the next few months.

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This concludes my testimony. I will be happy to answer your questions.

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