



**Conference of Radiation Control
Program Directors, Inc.**

**10th Annual
NATIONAL CONFERENCE
ON
RADIATION CONTROL**

A Decade of Progress

April 30 - May 4, 1978
Harrisburg, Pennsylvania

Published by

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

Food and Drug Administration

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650
8274
1978

FOREWORD

The Bureau of Radiological Health conducts a national program to limit man's exposure to ionizing and nonionizing radiations. To this end, the Bureau (1) develops criteria and recommends standards for safe limits of radiation exposure, (2) develops methods and techniques for controlling radiation exposure, (3) plans and conducts research to determine health effects of radiation exposure, (4) provides technical assistance to agencies responsible for radiological health control programs, and (5) conducts an electronic product and medical device radiation control program to protect the public health and safety.

The Bureau publishes its findings in appropriate scientific journals and technical report and note series prepared by Bureau divisions and offices. Under a memorandum of agreement between the World Health Organization and the Department of Health, Education, and Welfare, three WHO Collaborating Centers have been established within the Bureau of Radiological Health, FDA:

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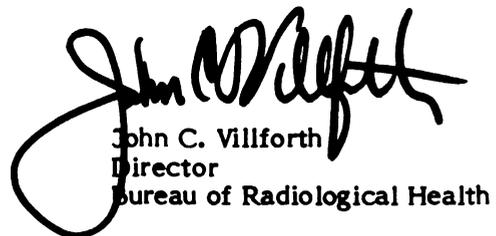
WHO Collaborating Center for Training and General Tasks in Radiation Medicine (Division of Training and Medical Applications)

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Readers are encouraged to report errors or omissions to the Bureau. Your comments or requests for further information are also solicited.


John C. Villforth
Director
Bureau of Radiological Health

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REVIEW of the HISTORY of the TEN-MILLIWATT PER SQUARE CENTIMETER MICROWAVE STANDARD

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INTRODUCTION

During the course of a microwave oven compliance action, which is a matter of public record, the following statement was made on behalf of the oven manufacturer:

"A recent publication of the International Microwave Power Institute. . .describes the safety standards for microwave emissions promulgated by the Occupational Safety and Health Administration (OSHA) and the American National Standards Institute (ANSI). Both standards incorporate the notion of 'Radiation Protection Guide' of 10 mW/cm². By their terms, they allow continuous, whole-body exposure to this level of radiation. . . The OSHA standard (29 CFR 1910.97) is particularly significant because the specified level represents a formal finding by the Secretary of Labor that ' . . .No employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.' " (1)

The implication of safety drawn by the manufacturer should be viewed in the context that OSHA in fact adopted the ANSI standard, and did not independently develop a biological basis for the ANSI formulation which it adopted. Furthermore, to our knowledge neither USASI (United States of America Standards Institute) nor ANSI (American National Standards Institute) provided a biological basis for the 10 mW/cm² standard they promulgated.

CHRONOLOGY and ESSENTIAL PROVISIONS of the ANSI-USASI STANDARD

On November 9, 1966, the United States of America Standards Institute promulgated a standard entitled "USA Standard, Safety Level of Electromagnetic Radiation with Respect to Personnel." This was an occupational exposure guide which specified the following (2):

"For normal environmental conditions and for incident electromagnetic energy of frequencies from 10 MHz to 100 GHz, the radiation protection guide is 10 mW/cm² (milliwatt per square centimeter) as averaged over any possible 0.1-hour period."

The standard cautioned:

"People who suffer from circulatory difficulties and some other ailments are more vulnerable. . . The guide numbers are appropriate for moderate environments. . . Under conditions of moderate to severe heat stress the guide number given should be appropriately reduced. . . These values are based on an evaluation of presently available knowledge and with due consideration of tolerable rise in tissue temperature. . . Radiation characterized by a power level tenfold smaller will not result in any noticeable effect on mankind. . . Radiation levels which are tenfold larger than recommended are certainly dangerous. . . These formulated recommendations pertain to both whole body irradiation and partial body irradiation. Partial body irradiation must be included since it has been shown that some parts of the human body (e.g., eyes, testicles) may be harmed if exposed to incident radiation levels significantly in excess of the recommended levels."

The basic standard was reaffirmed by the American National Standards Institute on November 15, 1974, as its standard entitled "Safety Level of Electromagnetic Radiation with Respect to Personnel." Modifications to account for near field factors were incorporated into this standard (3).

It should be noted that in its publication of this standard the American National Standards Institute listed members who contributed to the effort involved in the development of this standard. The implication was that all members approved the reaffirmation of the 10 mW/cm² exposure standards. This in fact was not the case. Members who represented two U.S. Government agencies with standards setting responsibilities, namely EPA and FDA, voted and counseled against reaffirmation of the standard. The basis for the objections by EPA and FDA was concern over adequacy of the standard to protect public health and safety, particularly with respect to uncontrolled populations.

"BIOLOGICAL BASIS" of the USASI and ANSI STANDARDS

Since the 10 mW/cm² standard promulgated by USASI and ANSI provides the fundamental basis for the safety arguments that have been advanced by many workers in the field, it is appropriate that we examine the scientific basis for the standard.

In 1966, USASI stated (2):

"These values are based on an evaluation of presently available knowledge, and with due consideration of tolerable rise in tissue temperature."

In 1974, ANSI stated (3):

"These guide numbers are based on an evaluation of currently available literature. It is the present consensus that thermal effects are considered to be the most harmful and therefore have been used as the basis for establishing the levels in this standard."

To our knowledge, neither USASI nor ANSI detailed the procedures by which they screened and evaluated "available" knowledge or literature, nor did they present the rationale by which they arrived at the conclusion that 10 mW/cm² was a safe level for indefinite human exposure.

The USASI 10 mW/cm² standard established 10 mW/cm² as a "Safety Level of Electromagnetic Radiation. . ."--a level of whole body microwave radiation to which humans could be exposed continuously and safely. In the absence of studies, either in animals or humans, that systematically evaluated the health implications of indefinite microwave exposure at 10 mW/cm², such a guarantee of safety was unfounded.

In developing the 10 mW/cm² standard on a stated thermal basis in 1966, USASI totally ignored a substantial body of published scientific findings that documented low level biological effects. When ANSI reaffirmed the 10 mW/cm² standard in 1974, it did so on a stated thermal basis and again ignored a large body of scientific literature published up to that time, which documented low level biological effects produced by microwaves. Much of this work was conducted in Eastern European countries including the USSR, Poland, and Czechoslovakia. The significance of this omission becomes apparent when one considers that the work ignored by USASI and by ANSI was the basis for the USSR safety standard for microwave radiation, which for occupational exposure is more conservative than the USASI-ANSI standard by a factor of 1000. Thus the corresponding safety microwave standard in the USSR is 10 μ W/cm² (10 microwatts per square centimeter) as opposed to the USASI-ANSI safety standard of 10 mW/cm² (10 milliwatts per square centimeter) (4).

It is of further significance that, in the USSR, the general population standard is lower than the occupational standard by a factor of 10; i.e., 1 μ W/cm² (1 microwatt per square centimeter) (4). The additional factor of safety for members of the general population recognizes the additional problem associated with uncontrolled exposure, in an uncontrolled

environment, of an uncontrolled population of mixed sensitivity to radiation insult. These were considerations incorporated in the letters of EPA and BRH representatives who counseled against reaffirmation of the 10 mW/cm² "safety level" by ANSI. (Preliminary information suggests that a recommendation of 5 μW/cm² is being considered in the USSR for promulgation as a general population exposure standard in the microwave region.)

USASI and ANSI recognized a number of these factors in the text of their undocumented standards. However, they failed to provide specific guidance to deal with environmental factors or the problem that "people who suffer from circulatory and certain other ailments are more vulnerable." The above statement was made by both USASI and ANSI.

A number of reviews and compilations that include Eastern European literature on microwave biological effects exist (5-14).

ORIGINS of the 10 MILLIWATT PER SQUARE CENTIMETER "SAFE EXPOSURE LEVEL"

In 1959, Frank Leary, Associate Editor of Electronics, stated (15):

"Until five years ago (i.e., 1954), understanding of the effects of R-F energy on living tissue was limited to a handful of experiments performed on rats and dogs, and a small body of experience with microwave diathermy. . . Within the last two years (i.e., 1957), a massive research program has attempted to enlarge our understanding of the biological effects of microwave exposure. The program is sponsored by the Defense Department, and coordinated at . . .Cape Canaveral by Colonel George M. Knauf. . ."

The Defense Department program to which Mr. Leary made reference was the Tri-Service Program with biomedical research responsibility assigned to the Rome Air Development Center, Griffis AFB, New York. Dr. Knauf was designated coordinator for the program. Dr. Sol Michaelson described the program as follows (16):

"The Tri-Service Program included investigation of effects of exposure in the frequency spectrum from 200 through 24,500 MHz. . .

"Annual Tri-Service Conferences were initiated in 1956 by RADC as the means for reporting to the military services.

"In an effort to establish a safe exposure level to microwaves many variables were considered, . . . Sufficient factual data were not available to determine the 'safe' exposure level for each frequency throughout the spectrum; . . . Possibly some cases of reported damage were no doubt caused by power densities of approximately 0.1 W/cm². . . A safety factor of 10 was decided upon, and a safe level of 0.01 W/cm² was established (78)."

Thus, the Tri-Service Program was described as a substantial effort which began in 1957 and culminated in the establishment of a scientifically based "safe level" of 10 mW/cm² in 1966-67. (Michaelson's reference 78 is to the U.S. Air Force, "Electromagnetic radiation hazards, T.O. 31Z-10-4, 1966, rev. 1967).

In 1957, Dr. Knauf stated:

"A maximum allowable ambient level of .01 W/cm² has been arbitrarily established and the field notified. . . No point in time has been considered valid in the absence of data on effects of chronic exposure." (17, page 90).

"Our hand has been to some degree forced in the establishment of this safe exposure level of .01 Watt/cm²." (18, page 44).

The following two Air Force notifications established a "hazardous level of microwave radiation of 10 milliwatts/cm² or greater over the entire microwave spectrum" (19):

1. Microwave Radiation Hazards
Urgent Action Tech. Order 31-1-511
Rome Air Force Depot, Griffis AFB, N.Y.
17 June 1957.
2. Industrial Hazards
RADC Regulation N.R. 160-1, 31 May 1957
Headquarters, Rome Air Development Center
Griffis AFB, N.Y.

Thus it would appear that 10 mW/cm² was established as a "safe exposure level" by the Air Force in 1957--"arbitrarily" in the words of Dr. Knauf.

It is significant to note that this action was taken in 1957, the year in which the Tri-Service Program was initiated.

DID other than BIOLOGICAL RISK BASES "FORCE" the "ARBITRARY ESTABLISHMENT" of the 10 MILLIWATT PER SQUARE CENTIMETER "SAFE" EXPOSURE LEVEL?

If the 10 mW/cm² "safe" exposure level was not scientifically based but rather arbitrarily established, can we obtain any insight into the factors that forced its selection? Let us examine again statements made by Dr. Knauf.

In 1957 Dr. Knauf stated (18):

"Gentlemen, there is nothing about the establishment of a research program or the publication of precautionary instructions which in themselves legislate against the application of a little common sense. Our hand has been to some degree forced in the establishment of this safe exposure level of .01 watt/cm². Some months after we arrived at a decision to establish .01 watt/cm² as the Air Force safe exposure level, we received a report from a leading industrial laboratory in which it was proposed to establish the safe exposure at 1 milliwatt/cm². We did not agree with this level nor did we feel that we had sufficient data to contest this report. In the meantime, the same contractor in connection with another Air Force contract has written to say that in their opinion, .01 watt/cm² constitutes a completely safe exposure level for personnel. I do not know that the 1 milliwatt proposal has been rescinded but do believe the parent company has had a change of heart. More recently, another leader in the field of microwave research has sponsored a level of .1 of a milliwatt/cm² as being the safe exposure level for personnel. They further complicate the picture by saying that when the level exceeds .1 of a milliwatt and lies between .1 of a milliwatt and 1 milliwatt, personnel should be restricted from working in the area in excess of 1/2 hour in any 24 hour period. We can not find justification for this stand anywhere in the literature. In a recent conference with the engineer who wrote the report and the medical director of the company concerned, we got the impression that this level was sponsored in keeping with a company policy to take no chances. We are of the opinion that when they establish such a level they are indeed taking no chances." (page 44).

Thus, while Dr. Knauf agreed to the need for an "arbitrary safe exposure of 10 mW/cm²," he resisted vigorously any suggestion that a limit of less than 10 mW/cm² be considered.

Frank Leary shed additional light on divergent views on safe limits in 1959 when he stated (15):

"Army training areas have certain characteristics in common with industry testing grounds. The army has established these criteria for its training areas: . . . Sets are separated by distances that reduce searchlighting exposures to less than 0.01 w/cm². . .

Rest areas are provided where power densities are 0.001 w/cm^2 or less. . . General Electric has been observing these safety standards since June 1, 1954. . . Prevent exposure to direct beams, especially of the eyes. . . Limit direct or reflected intensity in all areas to which people require access to 0.001 W/cm^2 ." (page 52).

Thus, according to Leary, the army and the General Electric Company had some reservations about 10 mW/cm^2 as an arbitrary safe limit. Apparently, the Bell Telephone Laboratories also dissented.

Dr. Mumford provided the following table as a summary of Bell Telephone Laboratories recommendations in 1961 (20):

Table II

Summary of Bell System Recommendations

L. For the time being, microwave exposure limits may be classified as follows:

<u>Average Power Density mW/cm²</u>	<u>Classification</u>
Above 10	Potentially hazardous
Between 1 and 10	Safe for incidental or occasional exposure
Below 1	Safe for indefinitely prolonged exposure or permanent assignment."

Dr. Knauf also noted (21):

"Because of the peculiar configuration of this equipment, it will be necessary for certain technical personnel to spend varying periods of time in areas where the ambient power level will exceed $.01 \text{ W/cm}^2$. . . It is sufficient to say that the power of this proposed equipment, is much greater than anything we have dealt with before." (page 7)

Thus we see in the overall pattern the following: A safe exposure level of microwave exposure was arbitrarily established--no dissent from the arbitrary safe standard was tolerated--in a largely thermal (i.e., high exposure level) microwave research program sponsors preferred to speak about "effects" rather than "hazards"--a requirement for exposure to levels in excess of 10 mW/cm^2 was specified--the arbitrarily established safe level of 10 mW/cm^2 in 1957 was followed by the promulgation in 1966 and reaffirmation in 1974 (by USASI and ANSI respectively) of a 10 mW/cm^2 safety level standard, which now incorporated a provision for permissible exposure to levels in excess of 10 mW/cm^2 .

The record provides a basis for concern that the "safety level" of 10 mW/cm^2 , and the averaging provisions that permit exposure to levels in excess of 10 mW/cm^2 may represent a directed verdict rather than the culmination of objective and unbiased scientific judgment.

There is a need to comprehensively evaluate existing knowledge of microwave health effects. Such an overview can serve as the basis for the development of consistent national recommendations for permissible general population and occupational human exposure, as well as permissible microwave leakage from electronic products. It should be noted that such overviews are currently being planned or developed by a number of national and international agencies including Food and Drug Administration, Environmental Protection Agency, Occupational Safety and Health Administration, National Institute for Occupational Safety and Health, and the World Health Organization. Significant gaps in information may be identified that will require further attention.

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