

From MAYS to

IRLG Radio Frequency/Microwave Committee:

Interim Statement on RF Sealers

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Introduction

The Interagency Regulatory Liaison Group (IRLG) was formed in 1977 by the U.S. Consumer Product Safety Commission, the U.S. Environmental Protection Agency, the Food and Drug Administration, and the Occupational Safety and Health Administration. Its expressed goals included the initiation of a process by which interagency co-operative efforts can be improved, augmented or modified as needed. Since its inception, the IRLG has sought to enhance the efficiency of the regulatory process by developing co-ordinated approaches to problems involving its member agencies. One such problem is the potential exposure of humans to unnecessarily hazardous levels of radiofrequency (RF) and microwave energy. The Radio Frequency/Microwave Committee was created to address this problem in October 1978.

One significant issue which has come to the attention of this committee is the potential exposure of workers to fields emanating from RF sealers. These devices nominally operate primarily in the 27.12 MHz ISM band, although operating frequencies from at least 10 to 60 MHz have been observed. RF sealers have been produced for more than 30 years, and there are an estimated 5000 in use today. They generate an RF field which emanates from special electrodes, and serves to heat, melt, and seal materials such as plastic and rubber. RF sealers are used in the manufacture of many commercial products such as handbags, golf bags, shoes, etc., as well as in embossing and drying operations. Several investigators from a number of different laboratories have performed measurements of the fields generated by these devices. Levels in excess of 2000 V/m and 10 A/m have frequently been observed. ~~These levels would correspond to far field equivalent power densities of about 1000 mW/cm² and 4000 mW/cm², respectively.*~~

Reviews of the available scientific literature have revealed a relative paucity of information on the biological effects at the frequencies used by most RF sealers (i.e., 13 to 40 MHz). Nevertheless, such exposure levels are substantially in excess of existing standards (or guidelines) for human exposure, and similar levels of exposure at other frequencies have been conclusively demonstrated to be hazardous to experimental animals. Moreover, the incompleteness of the present bioeffects data base does not obviate the responsibility of the IRLG member agencies to provide the best

~~*It should be noted that the operators' proximity to the RF sealers results in a near-field exposure situation. Equivalent far-field power densities are quoted throughout this statement for ease of comparison.~~

possible assurance that workers and others are not exposed to unnecessarily hazardous levels of RF energy. As explained in the committee's previous statement,* the nature of regulatory responsibility imposes an inescapable obligation to conservatism where public health is involved.

Statement

In the view of the IRLG Radio Frequency/Microwave Committee, workers exposed to RF fields equivalent to plane-wave, far field exposures of 30 mW/cm² (or higher) at 27 MHz have an increased risk to their health and safety.

Explanation

Two significant caveats exist regarding interpretation of this statement. The first is that the cited level describes exposures believed to be clearly undesirable for humans. However, no attempt has been made to identify an exposure level at which hazards are believed to be insignificant. In particular, it is not intended to suggest that all exposures to levels below the cited level are acceptable or safe.

The second caveat is that the statement is intended to be provisional in nature, not final. Substantial biological research is ongoing. Furthermore, several scientific organizations (and/or professional associations) are presently engaged in a comprehensive review of the available scientific literature relevant to human exposure standards. It is therefore anticipated that the present recommendations may be modified at some future date to reflect newly available information.

Background

Several topics were deemed relevant to the cited level in the statement. A review of the biological effects literature by John C. Monahan of FDA's Bureau of Radiological Health yielded approximately 40 reports of experiments conducted in the frequency band from 3 to 70 MHz. These reports were roughly divided into two groups. Both groups of studies showed a broad spectrum of biological end points in a variety of laboratory animals. One group contained five Russian studies reporting effects at electric field strengths between 50 and 200 V/m. The second group of about 35 studies reported numerous effects at field strengths of 2000 V/m and up. Using absorption curves from the literature,** it was determined that the comparable energy absorption of a grounded man is about 20 dB greater than in a laboratory rat (taken as an "average" experimental animal) for the 27 MHz ISM band where RF sealers

*"Radio Frequency and Microwave Radiation Protection: Elements of a Consistent IRLG Philosophy and Approach," by W. Herman. *→ IT IS EITHER A HEDONIC STATEMENT OR*

**Tell, R. A., An Analysis of Radiofrequency and Microwave Absorption Data with Consideration of Thermal Safety Standards, 2/78; and Durney, C. H., et al., Radiofrequency Radiation Dosimetry Handbook, 5/78.

A COMMITTEE STATEMENT NOT BOTH
*** NOTE. IF THESE FIELD STRENGTHS WERE EXPERIENCED IN THE FAT FIBER THEY WOULD REPRESENT A PHASE WITH POWER DENSITY OF 50 mW/cm²

ALSO NOTE THAT IF MY ACUAT JANE HAD BALLS SHE WOULD BE MY UNCLE HEATH.

→ OF 340 V/m OR 0.9 A/m ***

operate. This may suggest that the energy absorption associated with the 2000 V/m level for a rat is roughly associated with an exposure level of 200 V/m for a grounded man. ~~This is equivalent to a far-field power density of about 10 mW/cm².~~

*of 46 Hz
and 600 V/m*

The present ANSI C95.1 personnel exposure standard* promulgated by the American National Standards Institute (ANSI), cites the fields equivalent to an average plane wave exposure of 100 mW/cm² as "certainly dangerous" throughout the frequency band of 10 MHz to 100 GHz. Much of the information available when this standard was promulgated was derived from frequencies of 1000 MHz and higher. Moreover, the ANSI committee explicitly noted in 1974 that "sufficient information concerning . . . frequency dependencies and limits is not currently available to substantiate adjustment of the radiation protection guide to account for these effects." Using the more recent references cited above, it was determined that the comparable energy absorption of a grounded man is about 8 dB greater at 27 MHz than it is at 1000 MHz (and above). This may suggest that for a grounded man, the thermal absorption associated with (1) the fields equivalent to a far-field power density of 100 mW/cm² at 1000 MHz and up, may also be roughly associated with (2) the fields equivalent to a far-field power density of about 15 mW/cm² at 27 MHz. *C95.1 is presently considering a frequency dependent standard which would be more stringent at 27 MHz.*

Much more information exists about the biological effects of electromagnetic fields in the 2450 MHz ISM band than in the 27 MHz band. Using the previously referenced curves, it was determined that the comparable energy absorption of a grounded man at 27 MHz and a laboratory rat at 2450 MHz were roughly equal. This suggests that the thermal absorption of these two cases may be compared directly. Clearly, much of the 2450 MHz literature may have relevance to the RF sealer question. Particular attention was paid to a recent study by Lovely, et al. showing a number of effects in the offspring of pregnant rats exposed to 0.5 mW/cm² at 2450 MHz.**

Numerous world standards delineate "acceptable" limits of human exposure at the RF sealer operating frequencies. It was noted that all of these lie below the level cited in this statement. Among the world standards applicable at 27 MHz are: the ANSI standard (10 mW/cm²), the Swedish Occupational Standard (5 mW/cm²), and the Soviet Occupational Standard (20 V/m, equivalent to 0.1 mW/cm²).

(200 V/m, 0.5 W/m)

*ANSI C95.1-1974 Safety Level of Electromagnetic Radiation with Respect to Personnel, 11/74.

**Mizumori, S. J. Y., R. H. Lovely, R. B. Johnson, & A. W. Guy, "Early Developmental Deficits in Rats Following In-utero Exposure to 500 μW/cm², 2450-MHz Microwaves," Abstract and Summary for presentation at the Bioelectromagnetics Symposium, Seattle, Wash., June '79.

Summary and Conclusion

Because of the disparity between the measured values of electromagnetic fields around RF sealers and existing world exposure standards, and because of the clear obligation of regulatory agencies to address such a disparity, the IRLG Radio Frequency/Microwave Committee has undertaken to identify provisionally a level of human exposure which constitutes clear cause for concern. This level was derived from a number of considerations including (1) available scientific literature, (2) reference curves relating RF energy absorption of man and animals at various frequencies, and (3) existing world exposure standards. It is recognized that the existing bioeffects data base is incomplete, and that revisions to the recommended level may be necessary at a later date. It is the belief of the committee, however, that in questions involving the safeguarding of public health, it is the duty of regulatory agencies to act with responsible conservatism.