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Exposure Criteria for Non-Ionizing Radiant Energy in the Healing Arts*

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Over the past twenty-five years, there has been a marked increase in the development and utilization of equipment for general and medical applications that emit non-ionizing electromagnetic energies. These include wavelengths in the ultraviolet, visible, infrared, microwave, and radio-frequency regions. To these electromagnetic waves we can add the many uses of ultrasound as a source of radiant energy that is finding many applications in diagnosis and therapeutic management of ill persons (Tables I and II).

All of these radiant energies at certain frequencies, power levels, and durations of exposure can produce biological effects which may be beneficial. An example of this is the generation of therapeutic heat by modalities utilizing these energies. By the same token, the effects produced can be reversibly or irreversibly deleterious if precautions are not taken to protect patients and operators from over-exposure, improper utilization, or inappropriate application of these medical tools.

For the general population and those persons exposed or with potential for exposure to these radiations in the course of their occupations, personnel exposure guidelines and some product emission standards have been promulgated. These, for the most part, are based on the philosophy of maximum permissible exposure and threshold for reversible or irreversible damage to "critical" biological structures. Personnel protection guides or exposure standards are usually those established by the American National Standards Institute (ANSI), American Conference of Governmental Industrial Hygienists (ACGIH) or Department of Defense. Some industrial organizations have standards of their own which may be modifications of the national standards.

The Radiation Control for Health and Safety Act (PL 90-602) requires the Secretary of Health, Education and Welfare to prescribe performance standards to control man-made radiation from U.S. produced and imported electronic products, if he determines that such standards are necessary for the protection of public health and safety. An electronic product, under the Radiation Control Act, is any product that uses an electronic circuit and that may generate ionizing or nonionizing radiation, or sound waves. Once a standard is established for a class of products, the manufacturer must meet the standard or he cannot market the product. If he does market a product which seems to meet the standard, and if it is later determined to violate the standard, or if it is defective in terms of his own standard, then he may be required to replace, repair, or refund the purchase price of the product.

Any manufactured or assembled product is covered by the Act if it emits radiation and contains an electronic circuit or functions as part of an electronic circuit. The Secretary has delegated to the Bureau of Radiological Health (BRH) responsibility for day-to-day administration of the Act.

Since the BRH was assigned to the Food and Drug Administration (FDA) by directive of the Secretary of Health, Education, and Welfare, FDA thus has become responsible for reducing unnecessary human exposure to man-made radiation in the use of electronic products and in the application of radiation in the healing arts.

A summary of the various guidelines and standards are shown in Table III(1-5). In spite of the fact that this compilation is simplified and many details are omitted, it does indicate the complexity and variety of protection guides for these non-ionizing radiant energies and suggests the need for some unifying concepts for standardizing of exposure criteria.

It is necessary to keep in mind the essential differences between a "human exposure" standard and a "performance" standard for a piece of equipment such as

a microwave oven where the level is measured at 5 cm from the external surface and should be considered in relation to a restricted field with only a small area of the body potentially exposed.

It must also be appreciated that, in considering standards for different population groupings, we cannot use the same concepts and criteria that are used in other environmental considerations. One has to use a certain amount of inference calculation and judgment,

Conceptually, as well as practically, these guidelines in essence bear no relationship to the use of these energies in the context of diagnosis and treatment and should not be applied for such purposes. These standards for product emission and occupational personnel exposure are designed to protect the general public and the worker, and are based on entirely different criteria than one would apply for diagnostic and therapeutic purposes. In point of fact, in the medical context, on the basis of occupational and general personnel protection standards, individuals are grossly "over-exposed" to radiant energies to achieve a specific diagnostic or therapeutic result. Diathermy at 2450 MHz creates incident energy exposures on a watt level to achieve desired tissue heating (6, 7); ultraviolet erythemal doses are pushed to the limit to control serious cases of acne vulgaris and psoriasis (6); Q-switched lasers are used by ophthalmologists to literally cook the back of the eye to restore a detached retina to a semblance of its normal anatomic position (8); the Soviets recently have reported "welding" of bone fragments with ultrasound in order to speed callus formation of comminuted fractures, ensure structural stability and accelerate healing (9).

To draw a rather precise parallel with ionizing radiation, used therapeutically, the localized exposures of cancer patients to incident ^{60}Co gamma radiation grossly exceed current quidelines for general population and occupational exposures. This is brought out simply to emphasize that current standards are in no way applicable to medical uses of any of the non-ionizing radiant energies, nor should they be.

The one single factor that has been a source of continuing concern has been the problem of measurement of energy absorbed by biological tissue. Knowledge of the incident energy is inadequate to explain what is happening within biological structures, and these occurrances must be correlated with absorbed energy before any rational basis for therapeutic use and criteria for such can be evolved. In some cases of non-ionizing radiation we are incapable of describing the incident energy, not to speak of its absorption, as is the case with what is happening in the near field of a microwave source.

The phenomena of reflection, transmission, and energy absorption occur in biological tissues that are exposed to non-ionizing radiant energies. These occur not only at the initial entry point or exposed area, but also at deeper structure tissue interfaces such as the fat-facia-muscle layers, and within tissues themselves. When microwaves are used,frequency specificity of interactions create complex problems. When ultrasound is the energy source, electrical and acoustic impedance are the determinants of difficulties encountered within tissues. Considerable effort will have to be expended in this area of dosimetry before problems, controversies, and existing confusion can be resolved.

With all of this in mind, one has to develop perspective as well as realistic approaches in considering medical aspects of non-ionizing radiant energies. Certainly, the axiom of "do no harm" is foremost in medical minds which approach

problems using the many modalities that are sources of these energies. Medical personnel, however, must not be hampered by undue restrictions on the use, research, or development of these modalities in their search for better healing techniques. They do require assistance, however, in evolving rationale for diagnostic and therapeutic uses of these energies. We must supply them with theoretical bases and investigational data upon which they can build their criteria for safe limits within which they may work; or at least to evaluate a "hazard-risk-benefit" problem rationally and in perspective as the particular case may require.

TABLE I

SOME MEDICAL USES OF NON-IONIZING RADIANT ENERGIES - ELECTROMAGNETIC RADIATION

I. Non-Coherent Sources

Ultraviolet
- Germicidal uses
- Virus reactivation
- Dermatologic therapy
- Diagnostic techniques

Visible
- Transillumination
- Treatment of hyperbilirubinemia

Infrared
- Superficial heating
- Thermography
- Photoplethysmography
- Oximetry

Microwave/Radio-Frequency
- Diathermy
- Radiotelemetry
- Blood warming
- Tumor therapy*
- Rewarming from hypothermia
- Electroplethysmography*

II. Coherent Sources

Laser (Maser)
- Surgery
- Tumor therapy

*Investigational

TABLE II

SOME MEDICAL USES OF NON-IONIZING RADIANT ENERGIES -

NON-ELECTROMAGNETIC RADIATION

Mechanical Sources

Ultrasound (Diagnostic and Therapeutic)

- Obstetrics
- Circulation measurements
- Ventriculography of the heart
- Echoencephalography
- Deep tissue therapeutic heating techniques
- Differential heating techniques in tumor chemotherapy*
- Surgical "cutting" and "welding" techniques (orthopedic)*
- Diagnostic ophthalmology

*Investigational.

TABLE III

Protection Guides and Standards for Non-Ionizing Radiant Energies

Energy	Wavelength	Guide Number	Duration of Exposure	Comments
Ultraviolet	200-315 nm	0.1 $\mu W/cm^2$ 0.4 $\mu W/cm^2$ 3.3 $\mu W/cm^2$	8 hr 2 hr 15 min	radiation incident on skin or eye
		(3 mJ/cm^2-1 J/cm^2)*	10^{-3}-$3x10^4$sec	direct ocular or skin exposure
Visible	400-700 nm	($5x10^{-7}$ J/cm^2)	10^{-9}-$1.8x10^{-5}$sec	direct ocular exposure
		($2x10^{-2}$ J/cm^2)	10^{-9}-10^{-7}sec	skin exposure
Infrared	800-10^5 nm	7.6 J/cm^2 10.8 J/cm^2 1.0 J/cm^2	--- --- ---	corneal damage corneal dose causing iris damage corneal dose causing retinal damage
		(10^{-4} W/cm^2-$5x10^{-4}$ W/cm^2) (0.5 W/cm^2)	10^2-$3x10^4$sec 10-$3x10^4$sec	direct ocular exposure skin exposure
Microwave	3 mm-100 cm	10 mW/cm^2 25 mW/cm^2	continuous 10 min during any 60 min period	whole body (higher power permitted for localized exposure)
		1-5 mW/cm^2 at 5 cm from external surface	continuous	microwave oven product emission standard
Radiofrequency	1 m-1000 m	0.3 mA/cm^2-1mA/cm^2 1000 V/m	continuous	whole body

* ( )for coherent sources - laser

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