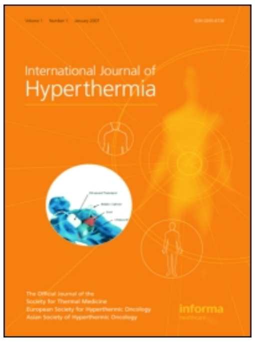

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Letter to the Editor

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Letter to the Editor

ARPANSA, standards development, and the need for thermal effects research

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is a scientific and regulatory agency of the Australian Government, the national (Commonwealth) government. ARPANSA has a responsibility under its act, the Australian Radiation Protection and Nuclear Safety Act 1998 (ARPANS Act), to protect the Australian people and the environment from the harmful effects of radiation, including non-ionising radiation such as radiofrequency (RF) electromagnetic radiation (EMR). Departments within the State and Territory governments are independently responsible for radiation protection within their jurisdictions, and ARPANSA has a national role to promote uniformity in radiation protection regulation across all jurisdictions. In this context, ARPANSA prepares radiation protection standards, codes of practice, and other guidance documents to assist in the implementation of uniform radiation protection requirements within the Commonwealth, State and Territory jurisdictions.

In developing health-related exposure standards for radiation, ARPANSA, like other health agencies around the world [1], uses a process involving evaluation of the scientific evidence by experts from the relevant disciplines, determination of critical effects and, where the evidence indicates a threshold for harm, formulation of basic restrictions based on this threshold. In the absence of an identified threshold for harm, as in the case of ionising radiation, a standard-setting body may need to consider the community's views on acceptable risk in determining limits. To permit practical assessment of compliance and effective risk management, the standard will typically include readily measurable reference levels, and may include requirements for exposure controls and other risk management strategies.

Like many other standard-setting bodies, ARPANSA considers it important to undertake effective consultation with a range of stakeholders, including industry and community representatives. This generally includes the invitation to make submissions on a consultation draft and the provision of responses to the matters raised, as well as more focused consultation on specific issues as they arise. Such consultation can improve the quality and practicality of a standard and make the process more transparent. The Australian Government also has a requirement to assess, and undertake consultation on, the costs and benefits of any regulation or standard in the form of a Regulatory Impact Statement [2].

ARPANSA developed an exposure standard for RF EMR published in 2002 [3]. It was developed following the process described above and contains limits closely aligned with the International Commission on Non-Ionizing Radiation Protection (ICNIRP) *Guidelines* for time-varying fields [4]. While based on the same science as the ICNIRP *Guidelines*, and building upon existing practices for RF EMR protection, the ARPANSA Standard also includes sections which explain the rationale behind the basic restrictions and which give an overview of the scientific knowledge regarding possible effects of low-level long-term exposures. Many of the studies that provoked particular concerns during the consultation process were specifically examined and discussed within an informative annex.

It is clear that in this process a good understanding of the thermal effects of RF EMR absorption, of the threshold for harm to humans, and of any side-effects of the absorption process is essential. A good understanding of the basic threshold for harm, be it expressed in terms of a temperature rise, or of a specific absorption rate (SAR), is fundamental. It is also important to understand what variability in this threshold might be encountered within a diverse population, not only of healthy adult workers, but also within the young, the sick, the pregnant and the unborn. This variability becomes one factor in setting a conservative safety factor between the empirically determined threshold and the eventual basic restriction of the standard.

In a practical RF EMR exposure standard it is important to understand the consequences of exceeding exposure limits by various degrees. This may be necessary, or highly desirable, for medical

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patients undergoing imaging, for emergency workers, or for volunteers in research, for example.

To provide a high level of protection it is useful to understand what limitation may apply to the threshold determined from experiment and whether other environmental factors need to be considered if present simultaneously. For example, in human volunteer studies, exposure times will typically be restricted to short times, perhaps only as long as a single working day or even very much less. Does the same threshold for harm apply if the exposure continues during sleep, for extended periods, or during crucial stages of development?

In current standards the whole-body SAR limit takes into account the body's ability to thermoregulate. The localised restriction on SAR allows for the ability of blood to transfer heat away from the site of absorption. There are cellular mechanisms to reduce the harm caused by the remaining temperature rise. If exposure continues indefinitely it may be necessary to consider whether long-term dependence on these mechanisms may exact any penalty on the body. As discussed by Foster and Glaser [5], the understanding of thermal transfer mechanisms is important to the secondary aspects of exposure standards, those that specify spatial and temporal averaging.

Apart from the determination of protective exposure limits, there is another very good reason to have an understanding of thermal effects. There is considerable concern in the community, including the general public, politicians and some scientists in most countries around the world that there may be harmful effects of EMR exposure that do not stem from the relatively well understood deposition of energy as heat within tissue. Much of the research effort goes into attempting to establish whether or not such effects occur and to determine possible mechanisms. The existence of adverse effects due to heating places an upper limit on the exposures that can be used in these experiments. The possibility of subtle effects due to even small temperature rises can make interpretation of other effects very difficult. An example, discussed by Foster and Glaser [5], is the work of de Pomerai and associates on gene expression and development in the nematode *Caenorhabditis elegans* and the evolving understanding of the role of heating in explaining experimental observations. While early work showed an apparently non-thermal heat-shock response [6] and changes in growth and maturation [7–8], subsequent refinement of technique and equipment identified the presence of unexpected heating and of a biological response to a very small temperature change [9]. Later work produced negative results at higher SAR [10] and for a wider range of candidate genes [11].

Agencies such as ARPANSA with responsibilities for protecting people from the effects of EMR need to have a good understanding of thermal effects. They require this to help in setting exposure limits, to understand when limits may be exceeded without unacceptable risk, and to interpret the scientific research that is looking for any non-thermal effects.

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