ICNIRP Statement

USE OF THE ICNIRP EMF GUIDELINES

(March 31, 1999)

Introduction and purpose

Since the publication of the ICNIRP guidelines for limiting EMF exposure up to 300 GHz[1)] several institutions have criticized the guidelines as lacking clear interpretation on exposure safety or direct application to equipment in existence. Concerns have also been expressed about the use of safety factors, precautionary aspects and long term exposure as well as points not included in the ICNIRP guidelines. This STATEMENT from the International Commission on Non-Ionizing Radiation Protection (ICNIRP) addresses these concerns and clarifies points such as the criteria used for evaluating scientific studies, the development and practical application of the guidelines, the need for special technical advice, how to consider social and economic aspects and how to handle current research. This statement clarifies the way in which the guidelines should be used in a regulatory and legislative context. Some questions have already been addressed by publications in Health Physics.[2)]

Quality criteria for evaluating scientific studies

Development of guidelines on exposure limits requires a critical, in-depth evaluation of the established scientific literature using internationally accepted quality criteria. Experimental results can only be accepted for health risk assessment if a complete description of the experimental technique and dosimetry are provided, all data are fully analyzed and completely objective, results show a high level of statistical significance, are quantifiable and susceptible to independent confirmation, and the same effects can be reproduced by independent laboratories.[3)] When evaluating epidemiological studies, quality criteria are based on the need to evaluate, reduce or adjust for the influence of chance, bias and confounding. Cases of disease should be identified independent of exposure, and exposure should be assessed in a way not related to disease status. The influence of other variables should be handled in the design or in the analysis of the study. Any data on which the conclusions are based should be reported.[4)] The final overall evaluation of the evidence should include the assessment of the strength and consistency of the association between EMF exposure and biological effects from both epidemiological and experimental studies, as well as the plausibility that biological systems exposed to EMF fields could likely manifest biological effects. It is also necessary to identify which EMF-induced biological effects are to be considered a hazard to the human health.

The role of ICNIRP

International recommendations of health-based guidance to limit exposure require an assessment of possible adverse health effects using established scientific and medical knowledge. This must be based mainly on the science and should be free of vested interest. ICNIRP, as an independent scientific body comprising all essential scientific disciplines, is qualified to carry out the task of assessing possible adverse health effects, together with WHO. ICNIRP is the formally recognized non-governmental organization in NIR protection for the WHO, the International Labour Organization (ILO), and the European Union (EU) and maintains a close liaison and working relationship with these international bodies as well as IEC and CIE for the optical region and with other bodies engaged in NIR protection. ICNIRP's review process includes Standing Committees and additional experts. The consultation process is extensive and includes IRPA national bodies and other independent scientists and organizations worldwide. ICNIRP works in conjunction with the WHO to assess health effects of exposure to NIR, which are published in the WHO Environmental Health Criteria monographs, and uses the results of this assessment to draft health-based exposure guidelines.

Developing of exposure guidelines

Recently the ICNIRP adopted guidelines on limits of EMF exposure for frequencies up to 300 GHz.[1)] While all the scientific literature was reviewed, the only adverse effects on humans that were fully verified by a stringent evaluation were short term, immediate health consequences such as stimulation of peripheral nerves and muscles, functional changes in the nervous system and other tissues, shocks and burns caused by touching conducting objects, and changes in behavior caused by elevated tissue temperatures. There are also data for chronic low level exposure that indicate that there may also be other health effects. It is, however, ICNIRP's view that in the absence of support from laboratory studies the epidemiological data are insufficient to allow an exposure guideline to be established.

Limiting values are given as basic restrictions and reference levels. Basic restrictions directly relate to established health effects. Appropriate safety factors are included. Reference levels are derived from the basic restrictions for worst-case exposure situations and are in quantities that can be easily measured. They provide levels that can be used to determine compliance with the basic restrictions. By using the system of basic restrictions and derived reference levels, the new ICNIRP guidelines offer flexibility for many exposure situations.

The use of safety factors

It is ICNIRP's view that safety factors in the ICNIRP EMF guidelines should relate to the precision of science, reflecting the amount of established information on biological and health effects of EMF exposure. Numerically uncertain relationships between established effects and exposure levels result in higher safety factors and vice versa. As with the assessment of adverse health effects, setting safety factors should be free from vested interests. There is no rigorous basis for determining precise safety factors. Safety factors are based on a conservative value judgment by experts. In the new ICNIRP guidelines the safety factors vary from approximately 2 to > 10 (see next section) depending upon the extent of uncertainty in knowledge of thresholds for health effects for direct and indirect field interaction at various frequencies. For the purpose of defining guidelines for protection, a simplified and conservative approximation of the frequency dependence of biological effects was chosen. In general, threshold field levels for indirect effects (e.g., response to contact currents) are better defined than for direct effects, and hence, less conservative safety factors are required. Public guidelines include additional safety factors of 2 to 5 relative to occupational guidelines (depending upon the frequency and the relevant dosimetric parameters). Occupational health standards are aimed at protecting healthy adults exposed as a necessary part of their work, who are aware of the occupational risk and who are likely to be subject to medical surveillance. General population guidelines must be based on broader considerations, including health status, special sensitivities, possible effects on the course of various diseases, as well as limitations in adaptation to environmental conditions and responses to any kind of stress in old age. In most cases these considerations will have been insufficiently explored, so guidelines for the general population must involve adequate safety factors.

Special concern about safety factors for the ELF basic restrictions

Basic restrictions for the ELF range roughly follow the frequency dependence of thresholds of peripheral nerve and muscle tissue stimulation. These are well known between several Hz and about 100 kHz. Field-induced current densities that are unable to stimulate excitable tissues directly may nevertheless affect tissue electrical activity and influence neuronal communication. It has been suggested that time-varying peri-cellular electric fields of 10-100 mV m^{-1} (about 2-20 mA m^{-2}, which can be induced by power frequency optimally oriented magnetic fields above 100-1000 µT at a few locations in the body) can affect biological signals. Furthermore, the electrical inhomogeneity of living tissue can enhance electric field intensities, and hence induce higher currents at some points in the body. However, there is a lack of microscopic dosimetric data.

Within a limited frequency range, between about 15 and 60 Hz, the safety factor between the basic restriction of 10 mA m^{-2} and the threshold of some nervous system effects (i.e., magnetophosphenes or visual evoked potentials) are even lower (safety factors between 2 and 5). While there are some biological effects that have been reported from cellular and animal studies (see p. 501 of the ICNIRP

guidelines), there is no clear evidence that these biological interactions from exposure to low-frequency fields lead to adverse health effects. However, the severity and the probability of irreversibility of tissue effects becomes greater with chronic exposure to induced current densities above 10 to 100 mA m^{-2}. Thus, summarizing the evidence for health effects for current densities greater than 10 mA m^{-2}, ICNIRP decided to limit human exposure to fields that induce current densities not greater than 10 mA m^{-2} in the head, neck, and trunk at frequencies of a few hertz up to 1 kHz. As a consequence, the safety factor around 1 kHz may be unnecessarily conservative, but this is the result of insufficient knowledge, and ICNIRP will reconsider this as soon as more scientific data are available.
With regard to severe and potentially life-threatening effects such as cardiac extrasystoles, ventricular fibrillation, muscular tetanus, and respiratory failure, the safety factor between these effects and the basic restriction is about 100 or greater. This is the same order of magnitude as safety margins limiting exposure to dangerous toxicologic substances.

Practical application of the guidelines
Reference levels are provided for practical exposure assessment purposes, to determine whether the basic restrictions are likely to be exceeded. The reference levels are derived from the basic restrictions by mathematical modeling and extrapolation from the results of laboratory investigations at specific frequencies. They apply for maximum coupling conditions of the field to the exposed person, thereby providing maximum protection. Restrictions are different for workers and the general public. The frequency dependence of the reference field levels is consistent with data on both biological effects and coupling of the fields. ICNIRP recommends the use of the reference levels as general guidance for EMF limits for workers and the general public.

Safety factors and reference levels for ELF fields
There is special concern about the ICNIRP reference levels for magnetic fields below several MHz which are low, relative to some other guidelines or standards. Since one of the objectives of the new ICNIRP guidelines is to avoid stimulation of peripheral nerves and muscles, it is reasonable to use models describing worst-case coupling. An ellipsoidal model for magnetic fields, to represent the trunk for estimating induced current densities will produce approximate results. There is evidence, however, that a small fraction of such conductive loop currents run through areas of the central nervous system.

There exist several investigations, resulting in current densities of 10 mA m^{-2} in peripheral areas of the body for a 500-µT field at power frequencies (see p. 510). These come from microdosimetric predictions, including conductivities of sub-cellular organelles, the presence of biological cells and inter-cellular junctional arrangements. These may result in significant differences in the patterns of flow of induced currents compared to those predicted by simplified analysis. In summarizing the available dosimetric data it is ICNIRP's view that the dosimetric models used for magnetic field coupling are defensible.

Need for technical standards
ICNIRP recognizes that the reference levels are given for the condition of maximum coupling of the field to the exposed individual, thereby providing maximum protection. However, when reference levels are exceeded this does not necessarily mean that the basic restrictions will be exceeded. These need to be determined by further investigations which may cause difficulties in some special exposure situations.
Near-field exposure situations, localized and non-uniform field exposure are of special interest. Examples of typical EM sources with near-field exposure are hand-held mobile telephones, inductive or capacitive heating equipment, antitheft devices or electric appliances in homes and workplaces. Such devices can emit localized fields in excess of the reference levels. In such situations, while the reference levels may be exceeded, there may be compliance with the basic restrictions due to the weak coupling of the field with the human body.
ICNIRP recognizes the need for technical advice on the translation of biologically justified restrictions on human exposure into practical exposure limitations for such special exposure

situations. This requires physics and engineering expertise to develop practical measures that lead to compliance with these guidelines. This includes guidance on the principles and practice of measurements, design of equipment and/or shielding to reduce exposure. For these reasons the ICNIRP EMF guidelines do not address product performance standards or guidance concerning computational methods or measuring techniques.
The organizations best qualified to carry out such tasks are the international, national and regional technical standardization organizations. These include the International Electrotechnical Commission (IEC), the International Standards Organization (ISO), the International Commission on Illumination (CIE), the Institute of Electric and Electronics Engineers Standards Committee (IEEE), and the European Committee on Electrotechnical Standardisation (CENELEC).
ICNIRP considers that international bodies for technical standardization (e.g., IEC, CENELEC) should develop product standards for special types of devices to determine compliance with the basic restrictions.

Assessment of social and economic impact of compliance
Assessment of adverse health effects of EMF exposure and ICNIRP's health-based guidance limiting EMF exposure are based on established scientific data and are free of vested interest. They do not take into account political, social and economic considerations. It is ICNIRP's view that political, social and economic considerations of higher or lower margins of safety in the exposure limits is the responsibility of national authorities.

How to handle current research?
Development of EMF standards is an ongoing process. WHO's International EMF Project includes encouragement of focused, high-quality research and incorporation of research results into WHO's Environmental Health Criteria monographs where formal health risk assessments will be made of EMF exposure. ICNIRP as the scientific arm of WHO's NIR activities will use the results of these assessments together with assessments carried out by its own Scientific Committees to revise the present health-based exposure guidelines.

References
1. International Commission on Non-Ionizing Radiation Protection (1998). Guidelines for limiting exposure in time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz). *Health Phys.* **74**, 494-522.
2. International Commission on Non-Ionizing Protection (1998). Response to questions and comments on ICNIRP Guidelines. *Health Phys.* **75**, 438-439.
3. Repacholi, M.H. and Cardis, E. (1997). Criteria for EMF health risk assessment. *Radiat. Prot. Dosim*. **72**, 302-312.
4. IARC (1995). Monographs on the evaluation of carcinogenic risks of humans: Preamble. Lyon: International Agency of Research of Cancer.