SCIENTIFIC BACKGROUND OF THE ICNIRP GUIDELINES

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Abstract
ICNIRP is an independent organisation responsible for providing advice to international and national authorities, and to the public, on exposure to non ionising radiation and related biological and health effects. In particular, ICNIRP develops guidelines for the safe exposure of workers and the general public to different kinds of non ionising radiation, including electromagnetic fields. These guidelines are based on established scientific literature, and are developed following well defined steps and criteria. The basic approach and the fundamental concepts adopted in such process are presented in this paper.

Introduction
The International Commission on Non Ionizing Radiation Protection (ICNIRP) was established in 1992 as an independent scientific organisation whose aim is to provide guidance and advice on the health hazards of non-ionizing radiation exposure. Guidance and recommendations provided by ICNIRP are based on scientific data and on established principles and criteria.

Depending on the nature of the biological effects, and the weight of evidence, different systems of protection may be implemented, to which ICNIRP and other similar organisations may contribute to various extent (Berqvist 1996).

Health threshold based systems are adequate when biological effects that might lead to health detriment have been established and corresponding thresholds have been identified. Guidelines on limits of exposure are adequate to prevent such effects.
Optimisation systems may be appropriate in face of a known and accepted hazard, where a threshold cannot be established. Finally, precautionary measures may be adopted in case of uncertainty, to protect against hazards that have been suggested, but not established by the scientific research.

While the last two systems require economical, social and political considerations to be taken into account, guidelines developed by ICNIRP to protect against established, acute effects of electromagnetic fields are based solely on scientific data and criteria. The basic concepts of these guidelines are shortly discussed in the following. For a more comprehensive discussion, the reader is referred to the text of the guidelines (ICNIRP 1998), and to a specific document on the general approach of ICNIRP towards the protection against non-ionising radiation (ICNIRP 2002).

Review of the literature
ICNIRP continuously carries out critical reviews of the scientific literature concerned with the physical characteristics of sources of electromagnetic fields (EMF) and their possible biological and health effects. In doing so, ICNIRP monitors the accumulation of new evidence, updating health risk assessments as appropriate. Such assessments are based on the totality of the science, and not just on the added information. The process is therefore dynamic: all assessments are based on current knowledge, and are subject to revision in the light of new substantiated evidence.

While any single scientific study may indicate the possibility of a health effect related to a specific exposure, ICNIRP bases its evaluations on the weight of evidence coming from several studies. The scientific quality of the studies is critical; therefore, only peer-reviewed literature is selected in principle, although technical reports of adequate quality may provide further, useful information.

The established effects
In the evaluation of health effects carried out by ICNIRP, three steps can schematically be identified.

Initially, each study is evaluated in terms of its relevance for the health effect being considered and quality of methods used. Different weights may be assigned to the studies, depending on the extent to which they meet quality criteria regarding e.g. the experimental techniques used, the assessment of exposure, the control of environmental conditions, possible biases and confounders, the replicability of the experiments and the reproducibility of results.

As a second step, all information relevant for each health effect is evaluated. This review is normally done separately for epidemiological investigation, human laboratory tests, animal studies and in vitro research.

Finally, the outcomes of the above steps are combined in an overall evaluation, taking the consistency of data in proper consideration. ICNIRP recognises that this process involves some judgements; to minimise bias due to personal attitudes, the steps described above are performed collectively by the whole Commission, with the support of its standing Committees.

When the overall evaluation allows the identification of an effect that is causally related to the exposure, the effect becomes *established*. Leading criteria in the identification of effects are the reproducibility of findings, and the consistency across studies of different nature (e.g. data from research in vitro that may give biological plausibility to a causal interpretation of statistical correlations indicated by epidemiology.

Dosimetric quantities

The entity of a given biological effect of EMF exposure is related not only to the level of the external fields, but also to the coupling of the fields with the exposed body. The quantitative relationship by which the external exposure effects a biologically effective parameter of the target tissues is unique to a single exposure condition. Therefore, effects are better described by quantities that reflect the efficacy by which the external exposure causes a certain biological effect. These quantities are termed *biologically effective quantities*, or *dosimetric quantities*.

Although several dosimetric quantities have been introduced for different regions of the EMF spectrum, the most relevant are the induced current density, that is appropriate for low frequency electric and magnetic fields (up to 10 MHz), and the Specific Absorption Rate (SAR) that is related to thermal effects resulting from exposures to electromagnetic fields of frequency above 10 MHz.

The critical effect

Once the adverse effects have been catablished, and related to the exposure through the appropriate biologically effective (dosimetric) quantity, it is generally possible to rank them according to the exposure level at which each becomes relevant. The *critical effect* is the established adverse effect that is relevant at the lowest level of exposure.

The adoption of limits below the threshold for the critical effect provides in fact protection against any other adverse effect hat has been identified.

Basic restrictions and reference levels

The biological and health effects depend on several parameters characterising the exposure. These include, but are not limited to, the strength of the electromagnetic fields. The strategy of ICNIRP is therefore to define *basic restrictions* in terms of the appropriate dosimetric quantities rather than the intensity of the fields themselves. For each frequency range, the basic restriction is set below the threshold for the appropriate critical effects. For some regions of the EMF spectrum, where available data are insufficient to establish a critical effect with adequate confidence, the basic restriction is obtained by extrapolation from lower and higher frequencies.

Due to practical difficulties in measuring or calculating some dosimetric quantities, these are - in a further step of development of the guidelines - related to *reference levels* that are expressed in terms of a directly measurable parameter of the external exposure (power density, electric field strength or magnetic field strength).

This strategy is conservative. The use of reference levels ensures in fact compliance with the basic restrictions, since the relationships between them have been developed for maximum coupling conditions

between the external fields and the exposed person. On the other hand, exceeding the reference levels does not necessarily imply that the basic restriction is exceeded; whether this occurs or not should be ascertained through a more detailed investigation.

Reduction factors

The identification and quantification of the adverse effects of EMF is difficult, due to uncertainties in the scientific data. Sources of uncertainty include e.g. the intrinsic variability of biological data, experimental errors, extrapolation of animal data to humans, biases and confounders. The derivation of reference levels from basic restrictions is also affected by uncertainties in dosimetry, and in the characterization of the exposure.

To compensate for these uncertainties, *reduction factors* are introduced. Their magnitude varies depending on the degree of uncertainty. Some effects can in fact be quantified with reasonable precision and little reduction, if any, is required below threshold levels; when the precision is lower, a larger reduction may be warranted.

While the use of reduction factors in basic restrictions is a cautionary measure, it should be noted that further precaution is provided by the conservative approach adopted in the derivation of reference levels. These are in fact set in such a way as to assure compliance with basic restrictions in the most unfavourable combination of the many parameters characterising exposure. This means that additional reduction factors are implicitly introduced under realistic conditions. Such factors may be substantially higher than those explicit in basic restrictions.

Conclusions

Over the years, ICNIRP has developed a comprehensive system of protection against the established effects of exposure to electromagnetic fields.

The exposure guidelines are developed through a clear and transparent process, following steps and criteria defined *a priori.* These criteria include rigorous selection and careful evaluation of the scientific data.

The two-level structure, with basic restrictions and reference levels, makes the guidelines flexible and virtually of use for any exposure condition and any category of exposed population. At the same time, margins of precaution are included with the use of explicit and implicit reduction factors, assuring that in realistic conditions exposures are kept well below the threshold for established effects.

Effects that have been established so far are almost completely of acute nature. ICNIRP is aware that long-term effects have been suggested by some epidemiological studies, but not adequately supported by experimental research, or studies on possible interaction mechanisms. In the view of ICNIRP, the overall results of research on EMF exposure and cancer – or other degenerative pathologies – are not strong enough to form a scientific basis for setting exposure guidelines.

More in general, it should be noted that for long-term effects, that are stochastic in nature, protection strategies different from exposure guidelines should be employed. Such strategies should be based on the acceptability of a given risk - taking into account its nature and dimension - but also on social and economic considerations that fall outside the responsibility of ICNIRP.

References

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