ICNIRP-Standards: Rational bases and future developments

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The International Commission on Non Ionizing Radiation Protection (ICNIRP) was created in 1992 as an independent expert group responsible for providing advice to national governments and international organizations on possible health effects of non ionizing radiation (NIR) – including electromagnetic fields – and the ways to protect against such effects. ICNIRP took over activities and responsibilities of an International Non Ionizing Radiation Committee (INIRC) that operated from 1977 to 1992 inside the International Radiation Protection Association (IRPA).

During thirty years, guidance provided first by IRPA/INIRC and later by ICNIRP has evolved from simple recommendations for limiting exposure to specific sources and in restricted frequency ranges to a complex and comprehensive protection system. The general approach to NIR protection and the basic criteria for the development of ICNIRP recommendations are detailed in an *ad hoc* scientific paper [1].

ICNIRP issued in 1998 a guideline document on the exposure of workers and the general public to electromagnetic fields in the frequency range from 0 Hz to 300 GHz [2]. Such document superseded previous guidelines that had been published by IRPA/INIRC, separately for radiofrequency electromagnetic fields (100 kHz – 300 GHz) [3] and for power frequency (50/60 Hz) electric and magnetic fields [4]. Although the new standards were based on a much wider scientific database, the very rationale and the exposure restrictions did not change substantially, indicating

that the research in the area had already reached a high level of maturity, both in the identification of biological and health effects, and in the understanding of underlying interaction mechanisms.

The long time elapsed since the issue of last guidelines, and the accumulation of new data, require however that the existing recommendations be reviewed and updated, and ICNIRP has already started the revision process. Considering the different advancement of scientific research and risk assessment, the Commission has decided to split the new guidelines in two documents, covering low frequency (0 Hz – 100 kHz) and high frequency (100 kHz – 300 GHz) fields, respectively. The basic criteria and the steps of the process will be the same in the two cases, and are briefly discussed in the following sections.

Steps in the development of ICNIRP standards

A basic feature of ICNIRP guidelines – and of similar standards developed by a number of international organizations and national governments – is that they are firmly based on established science, and aim at protecting against all, and only, adverse effects that have been clearly indicated by high-quality research.

The starting point for the development of guidelines is therefore an in-depth analysis of the literature, and a scientific assessment of health risks. ICNIRP performs this task in cooperation with other international bodies, namely the World Health Organization (WHO) and the International Agency for Research on Cancer (IARC).

As a first step, ICNIRP carries out a comprehensive review of the scientific literature concerning exposure assessment and dosimetry, biological effects, epidemiology, and interaction mechanisms. On its side, IARC evaluates those studies that specifically address a possible role of EMF in the development of cancer and, when appropriate, classifies the different types of EMF according to their carcinogenic power. Finally, WHO uses input from ICNIRP and IARC to perform a global evaluation of all possible health risks of EMF exposure.

The deliverables of such risk assessment procedure are in the form of ICNIRP reports (so-called "blue books"), IARC monographs, and WHO's Environmental Health Criteria (EHC). They constitute the scientific basis for ICNIRP to revise and update its guidelines.

The process described above has been completed for low frequency fields, and the corresponding monographs have been published [5,6,7]. Based on these documents, ICNIRP has recently started the revision of its guidelines for the frequency range between 0 Hz and 100 kHz.

The corresponding process for radiofrequency (RF) electromagnetic fields has been intentionally delayed, due to the present, rapid evolution of scientific knowledge. A very intensive research effort has in fact been produced in the last years, focusing in particular on RF fields generated by mobile telecommunication systems. Within the 5th Framework Program of Research funded by the European Union, several large projects have been launched involving international collaboration between different research units; while most of the experimental work has been completed, some data are still being analysed or waiting for publication. Of special interest in this context is Interphone, an epidemiological case-control study on tumours in the head and neck in relation to the use of mobile phones. With research units from 13 different countries and several thousands of cases collected, Interphone represents the largest study of this kind ever performed.

Scientific bases of guidelines for radiofrequency fields

As already mentioned, ICNIRP guidelines are only based on science, and on effects that have been scientifically *established*. An effect is considered established when it is indicated by high-quality studies, the findings are independently reproduced in replication studies, and the evidence is consistent across different research areas (e.g. epidemiological findings on humans are coherent with laboratory studies on animals, results of *in vivo* studies are supported by those *in vitro*, etc.).

At the time the first RF guidelines were issued by IRPA/INIRC, the only established health effects of RF fields were acute in nature, and were associated to the absorption of electromagnetic energy by body tissues, with an associated increase of body temperature. These "thermal" effects were clearly established, physically and biologically understood, and well characterized in terms of exposure-effect relationships. There was in fact clear evidence that such effects only occur above a threshold depending on a number of exposure characteristics that had also been identified.

Though a number of biological responses to low-level exposures have been indicated by laboratory studies, no biological effect potentially relevant for human health was identified below thermal thresholds. Based on the general approach of IRPA/INIRC, the scientific rationale of the guidelines was therefore based on thermal effects only.

The basic restrictions and reference levels recommended in 1988 were essentially confirmed in 1998. The large number of studies carried out in the time period elapsed between the two standards had in fact provided further support to the original conclusions and the scientific rationale remained unchanged, though based on more data and refined analyses.

While confirming that only acute effects were scientifically established, in the rationale of the revised guidelines some discussion is devoted to the issue of possible long-term risks of exposure, that has raised big controversies and public debates in recent years.

Consideration of long-term effects

A variety of studies, both biological and epidemiological, have been carried out in recent years to test the hypothesis of long-term effects – including cancer – of chronic exposures to field levels below the ICNIRP guidelines.

The issue was already considered by IRPA/INIRC in its 1988 guidelines, with a short mention in the last paragraph of the rationale for exposure limits: *"The Committee considered the recent data linking electric and magnetic field exposure to increased cancer risk or congenital anomalies [...]. Available data are inconclusive and cannot be used for establishing exposure limits".*

In the two last decades, however, the possibility of long-term effects has become a central issue both from the scientific point of view and for the development of health policies. ICNIRP has paid continuous attention to the advancement of research, through its Standing Committees on Epidemiology (SC I) and on Biology (SC II). In the 1998 guidelines a full section of the chapter on the biological basis for limiting RF exposure is dedicated to a critical review of cancer studies (epidemiological), and a relevant part of

the discussion on cellular and animal studies deals with biological endpoints that may be relevant for the promotion of tumours or other degenerative diseases. The conclusion essentially confirms the position of IRPA/INIRC, but on the basis of a much more consistent literature: *"Although there are deficiencies in the epidemiological work, such as poor exposure assessment, the studies have yielded no convincing evidence that typical exposure levels lead to adverse reproductive outcomes or an increased cancer risk in exposed individuals. This is consistent with the results of laboratory research on cellular and animal models, which have demonstrated neither teratogenic nor carcinogenic effects of high-frequency EMF".*

ICNIRP continuously monitors the advancement of research and checks the adequateness of its recommendations to most recent findings. In 2004, a review paper was published by ICNIRP's Standing Committee on Epidemiology [8]. The main conclusion was that *"Results of epidemiologic studies to date give no consistent or convincing evidence of a causal relation between RF exposure and any adverse health effect. On the other hand, these studies have too many deficiencies to rule out an association".* At the same time, biological studies on animal and cellular models have provided no support to the hypothesis of a role of RF electromagnetic fields in the development of cancer and other long-term pathologies.

The most recent results, both epidemiological and biological, did not modify the above evaluations, and there is therefore no reason for ICNIRP to change its judgement on the impossibility to define any sound exposure limit to prevent long-term effects.

Science-based standards and precautionary policies

While only acute effects have been scientifically established, the possibility of long-term adverse consequences of chronic exposure below the thresholds for acute effects cannot be dismissed in principle, since science cannot prove the negative.

In order to prevent or reduce these risks, though hypothetical, some national governments or local authorities have adopted measures that replace or complement science-based exposure limits. In general, the *precautionary principle* is invoked to this purpose. In spite of its popularity, the principle is not well defined, and is variously interpreted. In addition, a possible conflict between science and the principle has been outlined [9]. An important clarification was provided by the European Commission (EC) [10]; it stressed that a basic condition for the principle to be invoked is that a potentially serious health hazard had been identified and scientifically evaluated. Therefore, science should be the fundamental basis – though not the unique one – for the adoption of precautionary policies.

Other criteria are indicated by EC for the correct application of the principle. The selected measures should be *inter alia*: tailored to the chosen level of protection, non-discriminatory, comparable to measures taken in equivalent areas, based on a cost/benefit analysis, and provisional.

Examining in this respect the case of EMF, WHO considers that *"[...] a cautionary policy for EMF should be adopted only with great care and deliberation. The requirements for such a policy as outlined by the European Commission do not appear to be met in the case of either power or radio frequency EMF"* [11].

The inapplicability of the precautionary principle does not necessarily mean disregarding any precaution. On the contrary, WHO recommends that in the presence of scientific incertitude (that is unavoidable in principle) any political decision be taken in the context of a *precautionary framework*, where besides scientific evidence of risk also social and economic factors are taken into account, including public sensitivities.

As already noted, socioeconomic considerations fall outside the remit of ICNIRP, whose role in the implementation of precautionary measures is limited to a scientific assessment of the plausibility of a health effects ant to an esteem of the potential health impact, where possible.

Anyway, both WHO and ICNIRP stress the importance that precautionary measures, and the way by which they are implemented, be such as not to undermine science-based exposure limits.

Future developments of the ICNIRP guidelines

The development of safety guidelines is a dynamic process that evolves with the progress of knowledge. ICNIRP continuously checks the validity of its recommendations by monitoring both the advancement of research on biological and health effects of electromagnetic fields, and the development of emerging technologies that may involve the introduction of new sources and new modalities of exposure. While there seems not to be an urgent need to change basic restrictions and reference levels, an update of the scientific rationale that includes the most recent research findings could be appropriate.

A comprehensive review of RF guidelines would be illogical and unwise at this moment. What national health authorities and the public expect is in fact not the confirmation of restrictions based on acute effects (that appear quite consolidated), but rather a position of ICNIRP on long-term risks. Whichever position is premature, however, before the publication of final results of the Interphone study and of some important biological research that is being finalized right now. Only after completion of these studies, IARC will convene an expert group for the classification of radiofrequency fields with respect to human carcinogenicity. Further steps of risk assessment by WHO and revision of guidelines by ICNIRP will follow in sequence, and the whole process will necessarily take some years.

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