

# FRAMEWORK FOR DEVELOPING HEALTH-BASED EMF STANDARDS





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# PREFACE

Understanding the health impact of electromagnetic fields (EMF) falls within the mandate of the World Health Organization (WHO) in the area of environmental health. WHO aims to help Member States achieve safe, sustainable and health-enhancing human environments, protected from biological, chemical and physical hazards. In this context, the International EMF Project was established at WHO in 1996 in response to general concern over health effects of EMF exposure.

WHO's International EMF Project has provided a unique opportunity to bring together over sixty countries to identify criteria for EMF standards setting and to develop the *Framework for Developing Health-based EMF Standards*. The aim of the EMF Project is to encourage the establishment of exposure limits and other control measures that provide the same or similar level of health protection for all people. Meetings on standards development were held in all six WHO regions to obtain input from scientists and government officials around the globe for inclusion into this Framework.

While WHO strongly promotes the use of international standards, some countries feel the need to develop or refine their own standards. This Framework is intended for national advisory and/or regulatory bodies that are developing new standards for EMF, reviewing the basis of their standards, or reconsidering specific quantitative values such as reference levels and safety factors. The overall purpose of this Framework is to provide advice on how to develop science-based exposure limits that will protect the health of the public and workers from EMF exposure.

Further information about the International EMF project can be obtained from WHO's web site at: <http://www.who.int/peh-emf/en/>.





# WHY A STANDARDS FRAMEWORK?

With the growth of electric power generation and transmission, the development of new telecommunication systems and advances in medical and industrial applications, humans are increasingly exposed to electromagnetic fields (EMF). The need to understand the potentially harmful effects of EMF on human health has been met by several decades of research, but the development of exposure standards is more recent and a variety of national standards now exist.

Globalization of trade and the rapid expansion in the use of technologies emitting EMF have focused attention on the differences that exist in exposure guidelines or standards in various countries. In some cases, these differences are large. Some of the disparities in EMF standards around the world have arisen from the use of only national databases, different criteria for accepting or assessing individual studies, varying interpretations of the scientific data or different philosophies for public health standards development. Such differences in EMF exposure guidelines might reflect, in part, deficiencies in communications among scientists between different regions as well as certain social differences.

Large disparities between national limits and international guidelines can foster confusion for regulators and policy makers, increase public anxiety and provide a challenge to manufacturers and operators of communications systems who need to tailor their products to each market. These factors have motivated the World Health Organization (WHO) to build a Framework for developing health-based EMF exposure standards using a rational scientifically-driven process.

## 1.1 GUIDING PRINCIPLES

WHO encourages the establishment of exposure limits and other control measures that provide the same or similar level of health protection for all people. It endorses the guidelines

of the International Commission on Non-Ionizing Radiation Protection (ICNIRP) and encourages Member States to adopt these international guidelines. However, if a Member State wants to develop its own standards, this Framework can be used as a guide.

## 1.2. PURPOSE

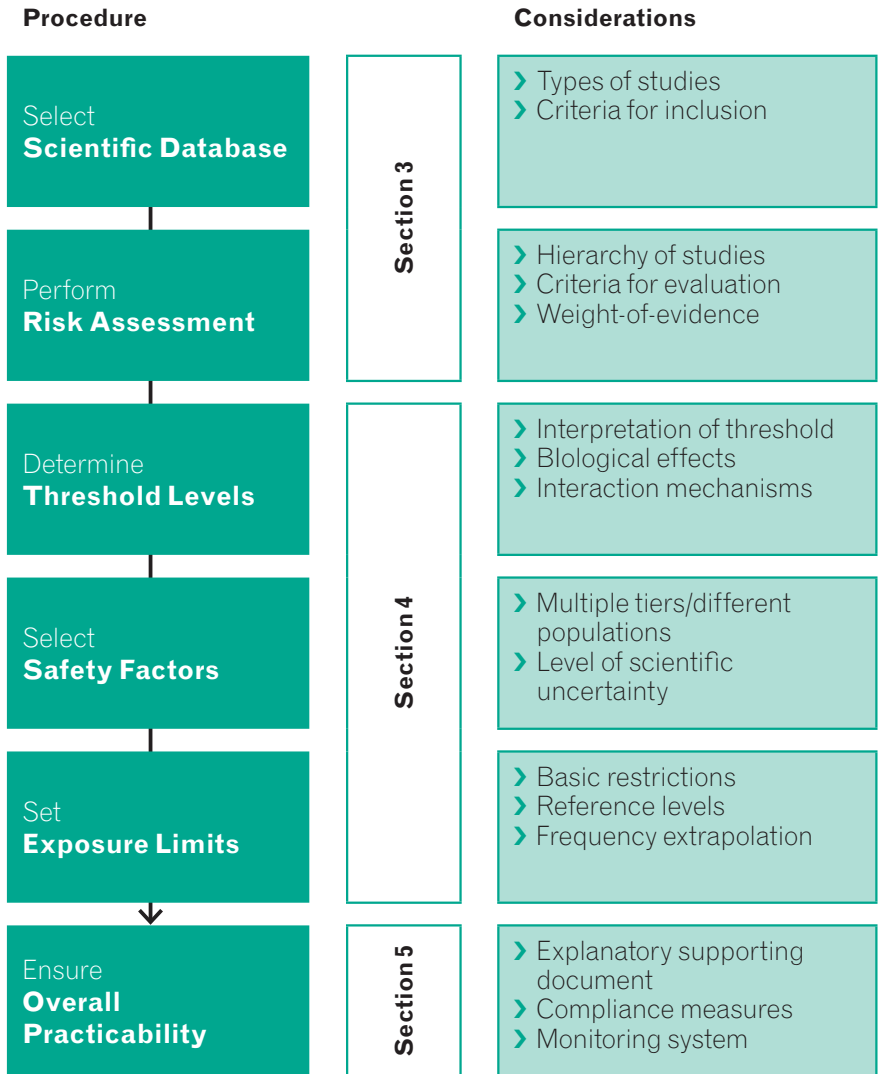
The Framework for Developing Health-based EMF Standards provides advice on how to develop science-based exposure limits that will protect the health of the population from EMF exposure. This Framework is intended for national advisory and/or regulatory bodies that are either developing new standards for EMF or reviewing the basis of their existing standards.

## 1.3. SCOPE

This Framework addresses how quantitative exposure standards can be developed. As shown in Figure 1, the general steps in this process include an evaluation of the scientific literature, determination of threshold levels, choice of safety factors for different populations at risk, and derivation of exposure limits. Other considerations regarding the overall practicability of the standard, compliance procedures and the use of precautionary measures are also addressed.

This document does not include:

- guidance on the principles and practice of measurements
- electromagnetic compatibility (EMC) issues, including equipment design
- exposure of patients under medical care
- development of emission limits for specific types of devices.



**Figure 1 - Procedure for developing EMF exposure standards**



# 2

## EMF STANDARDS

A standard is a general term incorporating both regulations and guidelines and can be defined as a set of specifications or rules to promote the safety of an individual or group of people. The ultimate goal of health-based EMF standards is to protect human health. However, there is often confusion about the various types of standards that exist to limit human exposure to EMF.

### 2.1 EXPOSURE, EMISSION AND MEASUREMENT STANDARDS

EMF standards can specify either limits of *emission* from a device, or limits of human exposure from all devices that emit EMF into a living or working environment.

*Exposure standards* are basic standards of personal protection that generally refer to maximum levels to which whole or partial body exposure is permitted from any number of EMF emitting devices. This type of standard normally incorporates safety factors and provides the basic guide for limiting personal exposure. Such standards have been developed by the International Commission on Non-Ionizing Radiation Protection (ICNIRP, <http://www.icnirp.org>), the Institute of Electrical and Electronic Engineers/International Committee on Electromagnetic Safety (IEEE/ICES, <http://grouper.ieee.org/groups/scc28/>) and many national authorities.

Emission standards set various specifications for electrical devices and are generally based on engineering considerations, e.g. to minimize electromagnetic interference with other equipment and/or to optimize the efficiency of the device. A number of emission standards have been developed by IEEE, the International Electrotechnical Commission (IEC, <http://www.iec.ch/>), the European Committee for Electrotechnical Standardization (CENELEC, <http://www.cenelec.org>) and national standardization authorities.

While emission limits are aimed at ensuring, inter alia, compliance with exposure limits, they are not explicitly based on health considerations. In general, emission standards aim to ensure that aggregate exposure to the emission from a device will be sufficiently low that use, even in proximity to other EMF emitting devices, will not cause exposure limits to be exceeded.

*Measurement standards* describe how compliance with exposure or emission standards may be ensured. They may provide guidance on how to measure the EMF exposure due to an installation or a product, e.g., phantom measurement for SAR values for mobile phones. EMF measurement standards have been developed by the IEC, IEEE, CENELEC, the International Telecommunications Union (ITU) and other standardization bodies.

## 2.2 VOLUNTARY AND MANDATORY STANDARDS

At the country level, regulations for exposure EMF can be broadly categorized as either voluntary or mandatory instruments.

Voluntary instruments include guidelines, instructions and recommendations that are not legally mandated, and generally have no legal force. International guidelines, such as those developed by ICNIRP, IEEE and others, provide guidance to national agencies, and only become legally binding if the country incorporates them into its own legislation.

Mandatory, compulsory or legally binding instruments include laws, acts, regulations, ordinances, decisions, and decrees, and require a legislative framework. Procedures should exist to ensure compliance of mandatory standards. For EMF exposure standards, an agency is normally mandated to check compliance through calculations and measurements made in the workplace and other areas. For emission standards, compliance of devices is usually certified by the manufacturer.

At present, there are no internationally mandated standards for EMF such as the *International Basic Safety Standards* for ionizing radiation (IAEA, 1996). However, for telecommunications services, ITU recommends adoption of the ICNIRP guidelines where no national standard exists (ITU, 2004). Given the large differences between national standards and the varied bases on which these standards have developed exposure limitation, WHO's EMF Project felt it was more helpful to promote existing international standards and, at the same time, to develop model legislation that would enable national authorities to enact

international EMF standards or their own standards. For details on model legislation see: [http://www.who.int/peh-emf/standards/emf\\_model/en/index.html](http://www.who.int/peh-emf/standards/emf_model/en/index.html)

### 2.3 DETERMINING THE NEED FOR STANDARDS

WHO strongly recommends that Member States adopt international standards that limit both EMF exposures to people and EMF emissions from devices. If international emission standards do not exist for certain devices that emit EMF at levels approaching exposure limits, then Member States should strongly encourage the development of standards by the appropriate international organization.

Member States who do not want to adopt international standards should carefully consider the reasons for and the value of developing their own standards before embarking on this long process. Questions to address before developing national standards include:

- Do international standards truly not provide adequate protection?
- In developing national standards, what is the accrued benefit to health?
- Is the development of a separate, more stringent national standard and the additional compliance procedures truly cost-effective from both a public health and an implementation perspective?
- Will more conservative limits be a barrier to the introduction of new technologies, which may have significant benefits to health, and to international trade?
- If the underlying reason comes from public concern, will the existence and implementation of these new regulations or guidelines alleviate the problem?





# 3

## ASSESSMENT OF THE SCIENTIFIC RESEARCH

Before proceeding with the development of standards, one must review thoroughly the available scientific literature on biological effects. This section distinguishes a biological effect from a health effect, identifies what literature should be selected and how it can be evaluated, and highlights possible problems of bias.

### 3.1 BIOLOGICAL EFFECT AND HEALTH HAZARD

According to the WHO Constitution (WHO, 1946), health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

A *biological effect* is any physiological response to EMF exposure. Some effects may be subtle responses within a normal physiological range or may result in pathological conditions, while others may have beneficial consequences for a person.

Annoyance or discomforts caused by EMF exposure may not be pathological per se but, if substantiated, can affect the physical and mental well being of a person and the resultant effect may be considered as a *health hazard*. A health hazard is thus defined as a biological effect that has health consequences outside the compensation mechanisms of the human body and is detrimental to health or well-being.

### 3.2 TYPES AND HIERARCHY OF SCIENTIFIC DATA

Exposure standards that limit human EMF exposure are based on studies from various disciplines of health sciences, including biology, epidemiology and medicine, as well as physics and engineering. All of these play important individual and collective roles in identifying possible adverse effects on health and in providing information on the need for, and appropriate levels of, protection. Relevant to standards are studies that provide information on biological effects from EMF, the physical characteristics and the sources in use, the resulting levels of exposure, and the people at risk.

The relevance of these different studies to health risks in people varies. Epidemiological studies of the distribution of disease in populations and the factors that influence this distribution provide direct information on the health of people exposed to an agent and are given the highest 'weighting'. However, they may be affected by bias and confounding, and their observational nature makes it difficult to infer causal relationships, except when the evidence is strong.

Experimental studies using volunteers can give valuable insight into the transient, physiological effects of acute exposure, although for ethical reasons these studies are normally restricted to healthy people. Studies on animals, tissues and cell cultures are also important but are given less weight. Animal studies can often be expected to provide qualitative information regarding potential health outcomes, but the data may not be extrapolated to provide quantitative estimates of risk, largely because of differences between species. However, it should be noted that the International Agency for Research on Cancer (IARC) (1995) considers that exposure to any biological, chemical or physical agent is likely to cause cancer in humans if such a risk has been identified in at least two different animal species. Studies carried out at the cellular level are normally used to investigate mechanisms of interaction, but are not generally taken alone as evidence of effects *in vivo*. Nevertheless, all types of study have a role to play in determining the scientific plausibility of any notional health risk.

### 3.3 REVIEW OF THE SCIENTIFIC LITERATURE

There needs to be a comprehensive and critical scientific review undertaken by a panel of recognized experts that includes all appropriate scientific disciplines.

For the evaluation of individual studies, criteria have been developed to determine if they are worthy of inclusion in the database for health risk assessments. To ensure a comprehensive assessment, it may be helpful to use standard review forms, such as those used by the IEEA for dosimetry, *in vitro*, *in vivo*, human volunteer and epidemiological studies. Several selection criteria for individual studies are mentioned below and possible biases in the evaluation of research results are highlighted in Table 1:

- **Quality of study design:** When evaluating research results, it is important to verify that the study design and power were sufficient to detect an effect under given exposure conditions. For example, a study not showing an effects may have had flaws in design or insufficient power (e.g. numbers of animals or repeated tests) to show an effect. On the other hand studies showing an effect must also be evaluated

to determine if the effect was truly due to the EMF exposure and not some other factor or bias in the study. A set of criteria for human, animal and cellular studies are presented in the Appendix, and are intended as a guide only. Both positive and negative studies must be evaluated in the same way; using the same criteria.

- **Quality of study conduct:** All studies must be conducted strictly according to the protocol using good laboratory practice (GLP) as appropriate.
- **Quality of reporting:** In general, publications should include a clear statement of objectives and hypotheses, a description of the exposure methods, experimental design and statistical analysis, and a detailed description of the biological systems and the experimental procedures.
- **Peer-reviewed publications:** Peer-reviewed scientific studies should be preferentially included in the review over conference abstracts which generally contain sparse information. As the mechanism by which the quality of research is judged by a researcher's peers, peer review contributes to maintaining standards in published science by improving the quality of accepted articles before publication, even though the rigour of peer review varies widely among scientific journals,
- **Usefulness for standards:** An important task of the review panel is to assess the relevance of the study for standards-setting. Many papers contain excellent research, but may not be relevant for standards setting; e.g. studies of effects at field levels well above the limit values for established adverse health effects.

**Table 1 - Possible biases when evaluating research results**

**Geographical bias:** The review committee should endeavor to be inclusive of scientific literature published worldwide, and include studies from other countries (e.g. Russia and China) where publication is sometimes less accessible to English speakers and therefore tends to be less frequently cited.

**Publication bias:** Journals may be biased towards papers reporting positive data rather than those reporting a lack of response. Publication bias of this type can result in an unbalanced database. If all studies in the database are positive, no negative studies exist, then the threshold for no-effect has not been identified, and so limits cannot be set. Well designed and conducted studies should be published regardless of the outcome, because negative results (no effect observed) are as useful as positive studies (effect observed) when evaluating the scientific evidence.

### 3.4 OVERALL RISK ASSESSMENT

Interpretation of these studies can be controversial, as there exists a spectrum of opinion within the scientific community and elsewhere. In order to achieve as wide a degree of consensus as possible, an overall assessment (also called health risk assessment) often draws on reviews already completed by other national and international expert review bodies.

In spite of ensuring that only sound scientific studies are used in the evaluation process, as described above, uncertainties and inconsistencies can still be encountered in comparative evaluations of the literature. Any evaluation is at least partly based on judgements. Various schemes and “criteria” exist in order to make this judgement process transparent, among these the Bradford Hill criteria (Hill, 1965) and the IARC scheme for assessment of carcinogenicity (IARC, 1987) can be mentioned. When evaluating the database for any health outcome the following questions need to be addressed (Repacholi and Cardis, 1997):

- For epidemiological studies, the strength of association between exposure and risk is important: is there a clearly associated risk with exposure? A strong association is one with a risk ratio (RR) of 5 or more. For tobacco smoking, many of the RRs were in excess of 10. However, the EMF studies of 50/60 Hz exposures, for example, suggest a RR of about 1.5 - 2 for childhood leukaemia. This is more susceptible to bias and confounding than stronger associations, and alone suggests that more evidence is needed to reach any valid conclusions. Supporting evidence of cancer in laboratory animals exposed to EMF fields is important to increase confidence that the epidemiological studies could be indicating a real risk.
- How consistent are the studies of association between exposure to EMF fields and the risk of some health outcome? Do most studies show the same risk for the same disease? Using the example of smoking, essentially all epidemiological studies of smoking demonstrated an increased risk for lung cancer. Studies may show statistically significant associations between some types of cancers and some types of exposures, but others do not. Alternatively, studies reporting an association with cancer may be inconsistent with each other in their types or subtypes. The ability of the study design to identify true risk without bias and confounding should be weighed.
- Is there a dose-response relationship between exposure to EMF fields and the health outcome? Again, the more a person smokes, the higher the risk of lung cancer. Do

the EMF field exposure studies demonstrate a dose-response relationship between EMF field exposure and a health outcome?

- Is there laboratory evidence for an association between exposure to EMF and the health effect being considered? The evidence is considered much stronger if effects can be demonstrated in animals rather than cells or tissues alone, since whole animals are able, through various mechanisms, to amplify, minimize or negate the effects of exposure to physical agents. The weight assigned to studies of whole animals is greater than the weight assigned to studies of isolated tissues and cells because of the absence of systemic regulatory controls and mechanisms in cells and tissues.
- Are there plausible biological mechanisms for a link between EMF field exposure and the health outcome being considered? When it is understood how an agent causes disease, it is easier to interpret ambiguous scientific evidence. The biological significance of responses observed in cellular studies should not be assumed unless it has been demonstrated that similar responses do occur in animal studies and are relevant to human health effects.

**Weight of evidence:** The body of scientific evidence must be considered as a whole to reach an overall evaluation of any adverse health consequences from EMF exposure. A common approach for determining this is by weight of evidence. For an effect to be established, most of the evidence from the epidemiological, human volunteer, animal and cellular studies should indicate that an effect occurs. It should be remembered that there is no way to prove that a health outcome does not occur; rather the weight of evidence should suggest strongly that it does not occur. One should also estimate how much of a given set of evidence changes the probability that exposure causes an effect. If most of the evidence suggests that an effect does not occur, but one set of studies suggests it does, one should be assessing whether the positive results were due to some other factor common to the health outcome and the EMF exposure.

The existence of biological effects and health hazards can only be established when research results are replicated in independent laboratories or supported by related studies. This is further strengthened when:

- there is agreement with accepted scientific principles
- the underlying mechanism is understood
- a dose-response relationship can be determined.

**Risk estimation:** An estimation of the size of the risk within the population is needed to determine its public health impact. For an estimate of risk in the general population or in a specific group the selected studies should provide mostly quantitative data. Such data would include:

- the definition of the biologically effective mechanism or characteristic of the field, which may vary with tissue or organ
- an exposure-effect relationship, and identification of a threshold, if any
- an exposure distribution and identification of sub populations with high exposure
- differences in susceptibilities within a population.

# 4

## KEY ELEMENTS OF EMF STANDARD SETTING

Exposure limits are intended to protect against adverse health effects of EMF exposure across the entire frequency range.

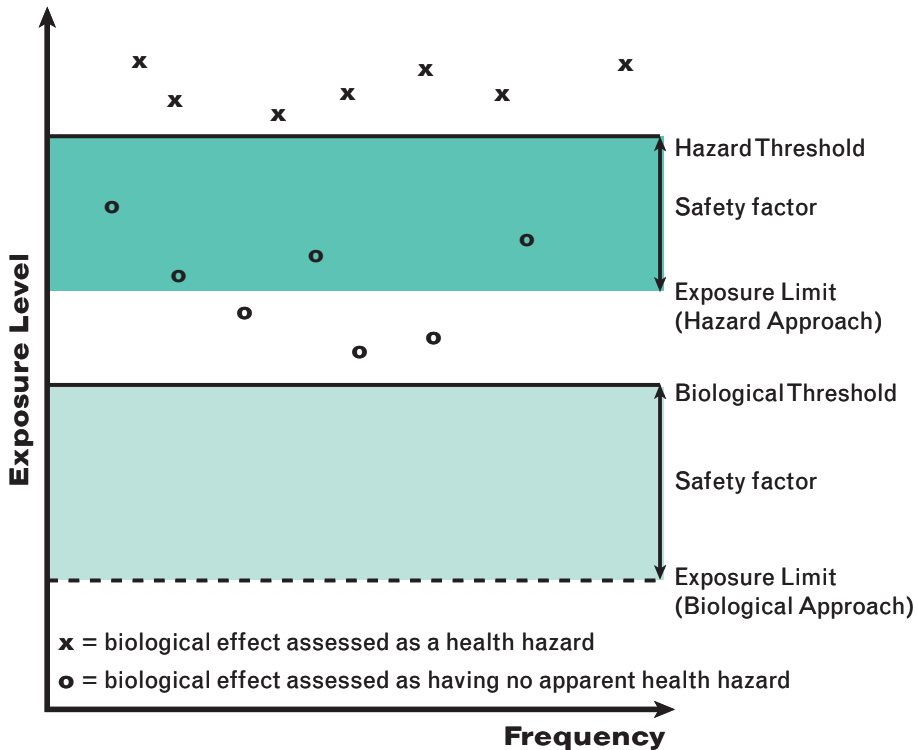
### 4.1 THRESHOLD LEVELS

There are a number of approaches that can be taken to determine threshold levels. First, a threshold exposure level may be derived on the basis of a health risk assessment of the scientific data. The threshold is judged as being the lowest exposure level, below which no health hazards have been found. Since there will be some imprecision in determining this threshold, primarily because of an incomplete knowledge of the biological effects, a range of uncertainty will exist. The degree of uncertainty will then be directly proportional to the value of a safety factor that should then be incorporated to arrive at the final exposure limit (Figure 2). This approach has been the basis of most western standards, and in particular the ICNIRP international guidelines (ICNIRP, 1998) and the IEEE/ICES standards (IEEE, 2004, 2005).

This approach requires a good understanding of the interaction mechanisms involved and supposes that a true threshold exists. It also assumes that cumulative effects do not occur. Evidence for cumulative damage would need to show that small amounts of damage may be occurring from low level (sub-threshold) exposure and that an accumulation of this damage is necessary before it becomes detectable. Further, there is a dependence on information from extensive research, including long-term follow-up studies. Without such studies, it is possible that illnesses or effects which manifest themselves after a long latency period would be excluded from consideration.

Another way of determining exposure limits is to adopt a “biological approach” (Figure 2). From the scientific database, a threshold exposure level is determined below which no biological effect is observed. This method alleviates the necessity of making a

health risk assessment of the biological effects data and assumes an incomplete knowledge of the interaction mechanisms. This approach will result in an unduly conservative standard which could not only restrict technological advances but would be unacceptable in terms of the loss of benefits accruing from technology; all for protection against questionable risks. This approach has been the basis for some Eastern European standards, leading to significantly lower exposure limits (<http://www.who.int/docstore/peh-emf/EMFStandards/>).



**Figure 2 - Determination of exposure limits using the hazard threshold and biological approaches (Repacholi, 1983)**

## 4.2 SAFETY FACTORS

Identification and quantification of various adverse effects of EMF exposure on health are difficult at best, and such judgments require extensive experience and expertise. Once the threshold exposure level that produces an adverse health effect at the lowest exposure level has been identified, exposure limits may be derived by reducing this



threshold level by a safety factor (Figure 2). Safety factors in health protection standards represent an attempt to compensate for unknowns and uncertainties in the science. Examples of sources of uncertainty about threshold levels include the extrapolation of animal data to effects in people, differences in the susceptibility of different groups or individuals, statistical uncertainties in the dose-response function, estimation of dose, and the possibility of combined effects of exposures at different frequencies and other environmental factors.

Generally acute effects can be quantified with reasonable precision and so derivation of limits to prevent these effects will not require a substantial safety factor below the observed threshold levels. When the uncertainty of the relationship between exposure and adverse outcome is greater, a larger safety factor may be warranted. There is no rigorous basis for determining precise safety factors; however, probabilistic approaches have been suggested for some parameters (Bailey, 1997).

### 4.3 BASIC RESTRICTIONS AND REFERENCE LEVELS

Limits on EMF exposure are termed basic restrictions and are based directly on established health effects and biological considerations. The physical quantities used in the international guidelines reflect the different concepts of “dose” relevant to the lowest-threshold for a health effect at different frequencies. In the low frequency range (between 1 Hz and 10 MHz) the current basic restriction is the current density ( $J$ , in  $A\ m^{-2}$ ) for preventing effects in excitable tissues such as nerve and muscle cells; and in the high frequency range (between 100 kHz and 10 GHz), the basic restriction is the specific absorption rate (SAR, in  $W\ kg^{-1}$ ) for prevention of whole-body heat stress and local heating. In the intermediate frequency range (between 100 kHz and 10 MHz) restrictions are on both the current density and SAR, while in the very high frequency range (between 10 and 300 GHz) the basic restriction is the incident power density ( $S$ , in  $W\ m^{-2}$ ) for excessive tissue heating near or at the body surface. Protection against known acute adverse health effects is assured if these basic restrictions are not exceeded.

Because basic restrictions are often specified as quantities that may be impractical to measure, other quantities are introduced for practical exposure assessment purposes to determine whether the basic restrictions are likely to be exceeded. These reference levels (ICNIRP) or maximum permissible exposure levels (IEEE) correspond to basic restrictions under worst case exposure conditions for one or more of the following physical quantities: electric field strength ( $E$ ), magnetic field strength ( $H$ ), magnetic flux density ( $B$ ), power density ( $S$ ), limb current ( $I_L$ ), contact current ( $I_C$ ) and, for pulsed fields,

specific energy absorption (SA). Exceeding the reference levels does not necessarily imply that the basic restrictions are exceeded. However, in this case, it is necessary to test compliance with the relevant basic restrictions and to determine whether additional protective measures are necessary.

#### 4.4 PROTECTING DIFFERENT POPULATIONS

Different groups in a population may have differences in their ability to tolerate a particular EMF exposure. If the scientific database suggests it, consideration should be given to the normal spectrum of sensitivities to stress that would exist in any population, to the possibility that certain drugs may produce adverse reactions in patients exposed to EMF, and to people who are sick to the extent that they may be particularly sensitive to additional stress. Thus it may be useful or necessary to develop separate guideline levels for different population groups. This can be accomplished by the use of larger safety factors for population groups that have an increased sensitivity to EMF when determining guideline limits.

A complementary approach is to distinguish between members of the general public and adult working population exposed under known conditions. Such distinction acknowledges the ability to better control the levels and duration of occupational exposures and to provide instruction and training to workers. In addition workers are usually a healthy adult population with medical monitoring available. By contrast, the general population is composed of people with a wide range of health sensitivities, age and illness. The general public will not necessarily have any knowledge of their EMF exposure or be able to minimize it. Thus, it is reasonable that an additional safety factor be incorporated into the public exposure limits and these should also account for continuous exposure conditions.

Some standards make provisions for occupationally exposed women who are pregnant to be considered as general public for the purpose of exposure limits. An example of how a national authority has managed this issue comes from the Australian RF standard (RPS<sub>3</sub>, [http://www.arpana.gov.au/rps\\_\\_pubs.htm](http://www.arpana.gov.au/rps__pubs.htm)):

“In order to reduce the risk of accidental exposure above occupational limits a pregnant woman should not be exposed to levels of RF fields above the limits of general public exposure. Occupationally exposed women who are pregnant should advise their employers when they become aware of their pregnancy. After such notification, they must not be exposed to RF fields exceeding the general public limits. Pregnancy should

lead to implementation of relevant personnel policies. These include, but are not limited to, reasonable accommodation/adjustment or temporary transfer to non- RF work without loss of employment benefits.”

#### 4.5 EXPOSURE STANDARD REQUIREMENTS

To ensure that an exposure standard has all the elements necessary to be complete, the following points must be addressed:

- **Frequency:** since the absorption of electromagnetic radiation is frequency-dependent, the same limits cannot be applicable over the whole frequency range. Thus, in the development of the standard there is a need to address the issue of frequency extrapolation from regions where there is little information on health effects, and to set limit values that harmonize with other standards; for example at the high frequency end of the standard, the limits should harmonize with the infrared standard.
- **Exposure level:** the level of exposure can be practically expressed in terms of reference levels. Situations where simultaneous exposure can occur to multiple frequency fields must be accounted for in the standard.
- **Exposure duration:** the time of exposure to various power levels should be quite precise. In many standards a certain power level is set for continuous exposure for 8 or 24 h per day, but higher levels of exposure are generally permitted for short periods of time. In this respect, the time over which the exposure level is averaged is important. The exact means of averaging exposures must be clearly indicated so that no confusion arises in the minds of persons responsible for compliance.
- **Whole-body and partial-body exposure:** For cases where only part of the human body is close to the EMF source (near field), supplementary guidelines should be provided for partial body exposure in addition to whole-body exposure. In general, partial body exposures may have higher limits than the whole body, but this depends on the mechanism of interaction (or alternatively on the operating frequency). This will be the case if the mechanism is heating, but would not be the case if the mechanism is induced currents.



# 5

## DISCUSSION

### 5.1 PRACTICABILITY OF STANDARDS

Governments should provide the legal framework that provides their departments with the mandate to develop and implement EMF standards that are mindful of the health implications, including uncertain ones. The standards should be relevant, effective and workable. It should be recognized that the standard does not operate in isolation from the national legal framework, and in particular from other occupational, health, safety and environment laws.

### 5.2 VERIFICATION OF COMPLIANCE

Exposure standards have no value in protecting public health if they are not complied with. National authorities should only establish standards if there is a strategy for cost-effectively determining if the standards are being met and if an appropriately qualified and experienced person or authority has been identified and resourced to conduct compliance monitoring.

A standard should include practical information on measurable levels that correspond to basic restrictions on EMF exposure. Verification of compliance may be based on measurements or evaluations, and must be performed periodically. Several international standards provide technical advice on how to conduct compliance measurements. This includes guidance on the principles and practice of measurements and design of equipment and/or shielding to reduce exposure. Organizations carrying out such tasks are the international, regional and national technical standards bodies, including the International Electrotechnical Commission (IEC), the International Telecommunication Union (ITU), the International Organization for Standardization (ISO), the Institute of Electrical and Electronics Engineers (IEEE) and the European Committee for Electrotechnical Standardization (CENELEC).

Uncertainty in measurements used to evaluate compliance is a practical problem best handled by organizations responsible for the development of compliance methods. However, it is worth noting that better technical measurement techniques and computational dosimetry are available, and when properly incorporated in guidelines, these will reduce uncertainty and thus the magnitude of safety factors.

### 5.3 PRECAUTIONARY ASPECTS

The existence of well-established adverse health effects forms the basis of current EMF exposure guidelines. The increasing awareness of the need to account for uncertainty in the science database has been addressed primarily through research. However, research programmes may take several years to complete, and the long latency associated with diseases such as cancer in people may also preclude a rapid outcome in some studies. The issue of current uncertainty is addressed by some countries that wish to be more protective by requiring that exposures be reduced or avoided where possible. While EMF standards include exposure limits, some authorities now also have additional measures. Examples of such measures for ELF fields from power lines include minimum height of electrical conductors and necessary clearance between a transmission line and buildings (more specifically schools). For RF fields, restrictions on the siting of base stations, mandatory specifications for mobile phones and recommendations for use of hands-free-kits have been provided by different authorities.

In this context, WHO is currently developing a framework to guide public health policy in areas of scientific uncertainty (<http://www.who.int/peh-emf/en/>). In general terms, this aims to develop a set of policy options for protecting public health according to the degree of scientific uncertainty and the anticipated severity of the harm that might ensue, taking into account the size of the affected population and the cost. A principal requirement is that these types of policies be adopted in such a way as not to undermine scientific assessments of risk and science-based exposure limits. Effective risk communication and consultation between stakeholders are also seen as integral parts of this process.

### 5.4 AN ACCOMPANYING GUIDANCE DOCUMENT

The publication of a prescriptive standard should be accompanied by a guidance document which provides information supplementary to the requirements embodied in the standard. It should be written in an explanatory and non-regulatory style, and describe the basic concepts and objectives of the standard. This document should provide

material that will help in the interpretation of the standard, and background information relevant to the development of the standard, e.g. underlying rationale and scientific judgement. More specifically, the explanatory document may provide information on technical matters relating to quantities and units, mechanisms of interaction and field measurements, updated summaries of research, information on measures to be taken for persons occupationally exposed to EMF, and contact details of the relevant radiation protection and regulatory authorities.

For standards developed without reference to other standards it is important to explain the reason for not using international guidelines, and to describe the differences between the international guidelines and the requirements of the new standard.

Standards and guidance documents that are related to each other may be published separately, e.g. the Australian ARPANSA (2002) standard, or as a separate document (ICNIRP, 2002). Several standards have been developed without such a rationale or criteria document, making it difficult to interpret their basis.

## 5.5 PERIODIC EVALUATION

As new scientific information becomes available, standards should be updated. Therefore, a mechanism for periodic scientific evaluation by an appointed council should be set up that would issue, where necessary, amendments to the standard.

Certain studies may be more likely than others to prompt a re-evaluation of the standards because of their strength of evidence or because of the severity of the health outcome under study. Changes to standards or policy should only be made after a proper assessment of the science base as a whole to ensure that the conclusions of the research in a given area are consistent.

## 5.6 STANDARDS TERMINOLOGY

Consistent international guidance requires that all countries have a common understanding of the meaning of terms and concepts used. Many countries having EMF standards use different terminology which can lead to confusion and misunderstanding. Definitions of concepts and terms used in this document are given in <http://www.who.int/emf/glossary>.





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# APPENDIX– CRITERIA FOR RESEARCH STUDIES

This appendix addresses the accepted criteria for each type of scientific study (from Repacholi, 1998).

## HUMAN STUDIES

Investigations of associations between exposure levels and adverse health effects can utilize either human volunteer or epidemiological studies. Such studies require the fulfilment of a number of criteria that effectively take into account and reduce possible impacts of bias, confounding, and chance variation in the interpretation of results. Bias is the operation of factors in the study design or execution that lead erroneously to a consistently weaker or stronger association than actually exists between exposure and the adverse-health end-point under study. Confounding occurs in situations in which a relationship is made to appear stronger or weaker than it actually is as a result of an association between the exposure under study and another factor that is causally associated with the adverse health effect. Lack of appropriate action to reduce the impact of these sources of error can decrease the credibility and the final weight given to the results of the study.

Guidelines on the conduct of high-quality epidemiology are given in Beaglehole et al. (1993) or Ahlbom (1996) and, for human trials, in Pocock (1983). A summary of these criteria is given below.

1. The study design must lead to maximum efficiency, both in reaching study objectives and in utilizing resources. Depending on the nature of suspected relationships between exposure and adverse health effects, as well as the specific study aim, various designs, such as case-control or cohort, may be appropriate.

2. Ascertainment of an adequate population sample size and statistical power should be based on prior statistical evaluations. These are important considerations when small elevations in relative risk are expected.
3. Study populations should be well defined at the outset. Hypotheses to be investigated must be explicitly and clearly stated. The manner by which cases of adverse health are ascertained must also be clearly stated, and case identification must be independent of exposure.
4. In case-control studies, controls should be appropriately chosen, taking into account the specific study aim and design. This enables the study to minimize the impact of factors other than those under study.
5. Regardless of study design, the minimization of non-response or non-participation is important, both to achieve the required study sample size, and to minimize the possibility of bias due to selective non-response (e.g., related to both disease and exposure status). A high participation rate may be encouraged by the careful dissemination of information on the study and the involvement of representatives of study groups in the planning process.
6. Both in study design and analysis, researchers should take into account the possibility of confounding factors. Data on potential confounders should be collected and appropriate statistical analysis used to minimize the effect of confounding on results and conclusions. It is recognized that identification of possible confounders may be difficult given the often-limited knowledge about causal factors that may affect the adverse-health end-point(s).
7. Investigators should characterize the exposure as precisely as possible. Data on different levels of exposure, its duration and temporal location should be collected, and the dosimetric measure utilized should be identified. Such data, and successful ascertainment and utilization of them should be taken into account at both the design and analysis stage of the study. It is important that the exposure is assessed in a way that is not related to the case status. Preferably, exposure assessment should be on an individual basis. It is recognized that, in practice, there may be a need to utilize surrogate measures of exposure. Categorizing exposure into groups can lead to misclassification. Such non-differential exposure misclassification often produces a bias towards the null, i.e. it tends to underestimate real effects.

8. In light of the complexity of the topic, studies should be designed and implemented using expertise from all appropriate scientific disciplines.
9. The method(s) used for statistical analysis should be appropriate for the purpose of the study, and they should be clearly described.
10. When sophisticated or non-standard analytical procedures are used, researchers should also report a descriptive analysis of the data. At a minimum, the number of exposed and unexposed cases and controls in case-control studies, and the number of observed and expected cases in cohort studies, should be provided. The effects of factors investigated (potential confounders) other than the exposure of interest, should also be reported.
11. Well-designed and -conducted studies should be published regardless of the outcome, since negative results are as useful as positive studies in the context of the database.
12. To allow combined analysis of several studies in the future, appropriate means to enable this, such as the use of standardized questionnaires, methods and reporting data should be considered.

In human volunteer studies, such as clinical trials or provocation studies, in addition to the points raised above, good practice should include:

1. a double-blind design, as appropriate to the study aim
2. appropriate and well described criteria for inclusion and exclusion of volunteers
3. adherence to relevant ethical rules and restraints.

### **ANIMAL STUDIES (IN VIVO)**

All known human carcinogens studied adequately in experimental animals have produced positive results in one or more animal species (IARC, 1995). In general, if adequate data are absent from human studies, it is biologically plausible and prudent to regard studies that provide sufficient evidence of disease in animals, as evidence of disease risk in humans (IARC, 1995). However, animal models need to be relevant to diseases reported in humans. The possibility that exposure may cause a certain disease through a species-specific mechanism which does not operate in humans should also be considered. Consistency of positive results using a variety of animal models is important.

1. An assessment of disease from exposure involves several considerations of qualitative importance. These include the experimental conditions under which the study was performed (exposure regimen, animal species, strain, sex, age, and duration of follow-up), the consistency of the results across species and target organs, spectrum of disease outcomes (e.g., for cancer, the spectrum of neoplastic response from preneoplastic lesions and benign tumours to malignant neoplasms), and the possible role of modifying factors.
2. Complete characterization of exposure and related environmental factors is essential for animal studies.
3. The probability that a disease will occur may depend on the species, sex, strain, age of the animal, and the duration of exposure. Evidence of an increase in disease with level of exposure strengthens the inference of a causal association. The form of the dose-response relationship is important and may vary widely. For carcinogenesis, both DNA damage and increased cell division are important aspects.
4. If human studies suggest, for example, a 25% increase in a rare cancer, the animal studies should be sensitive enough to detect this small effect. The animal model should be sufficiently well characterised so that the basic level of cancer incidence is known, and that it is low enough to allow the detection of increases resulting from exposure, if they occur. If studies are negative, they should be able to demonstrate this with some assurance and should indicate the magnitude of risk they had power to detect. Many negative studies do not have enough power to detect effects of interest.
5. When considering statistical analyses of long-term animal experiments, adequate information should be given for each treatment group. These include the numbers of animals studied and the number examined histologically, the distribution of disease types, and survival time. Types of analyses and statistical methods used should be those generally appropriate and refined for this purpose (Gart, 1986).

### CELLULAR STUDIES (IN VITRO)

Detailed guidelines on the conduct of high quality laboratory research can be found in the good laboratory practice guidance of the US Food and Drug Administration (FDA, 1993) and in the specifications of the US National Toxicology Program (NTP, 1992). A summary of the essential points is given below.



Experimental techniques, methods and conditions should be as completely objective as possible and based on biological systems appropriate to the endpoints studied. Safeguards from bias, such as double-blind techniques, blind scoring or codes, should be employed where appropriate. Where separate controls are used, an effort should be made to employ both positive and negative controls. The sensitivity of the experiment should be adequate to ensure a reasonable probability that an effect would be detected, if indeed one exists.

1. All data analyses should be fully and completely objective, with no relevant data deleted from consideration, and with uniform use of analytical methods. Data from experiments within the same protocol should be internally consistent. When results are reported as ratios, the underlying data should also be reported, or be available for in-depth analysis.
2. Published descriptions of methods should be given in sufficient detail that a critical reader would be convinced that all reasonable precautions were taken to meet requirements 1 and 2, and that other researchers can reproduce them.
3. Results should be statistically significant using appropriate tests.
4. Results should be quantifiable and susceptible to confirmation by independent researchers. Preferably, the experiments should be repeated and the data confirmed independently, or the claimed effects should be consistent with results of similar experiments, for which the biological systems involved are comparable. Theories (e.g., for mechanisms of interaction) should make sufficiently concrete predictions that they can be tested experimentally and be capable of being verified, if correct.
5. Results should be viewed with respect to previously accepted scientific principles before ascribing them new ones. Research findings pointing to previously unidentified relationships should be carefully evaluated and appropriate additional studies should be conducted before the findings are accepted.

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