ICNIRP 6th International NIR Workshop

Rio de Janeiro, October 2008

Scientific Uncertainty in Developing EMF Exposure Guidelines

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- the science base
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Scientific Uncertainty

Exposure guidelines provide a framework for protection

ICNIRP and IEEE - principal international bodies

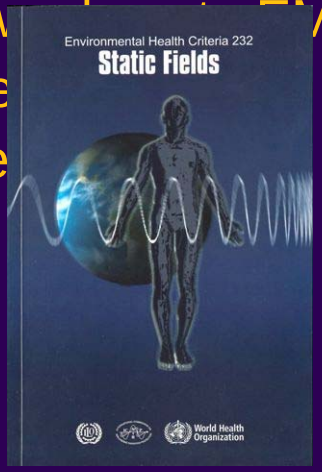
At this ICNIRP Workshop, the focus is on ICNIRP 1998 Guidelines – these form the basis of official European recommendations on limiting public exposure to EMFs and regulations on limiting exposure of v[illegible]MF

These recommendations and regulations affect 27 EU membe[illegible]

Exposure guidelines are underpinned by comprehensive revie[illegible] scientific evidence for harm

ICNIRP

- carries out its own reviews
- looks also to national expert reviews
- and those from WHO independent health risk assessment panels - as set out in EHC publications



Fundamental to the process is the recognition of scientific uncertainty and how to address it.

Cautious Interpretation

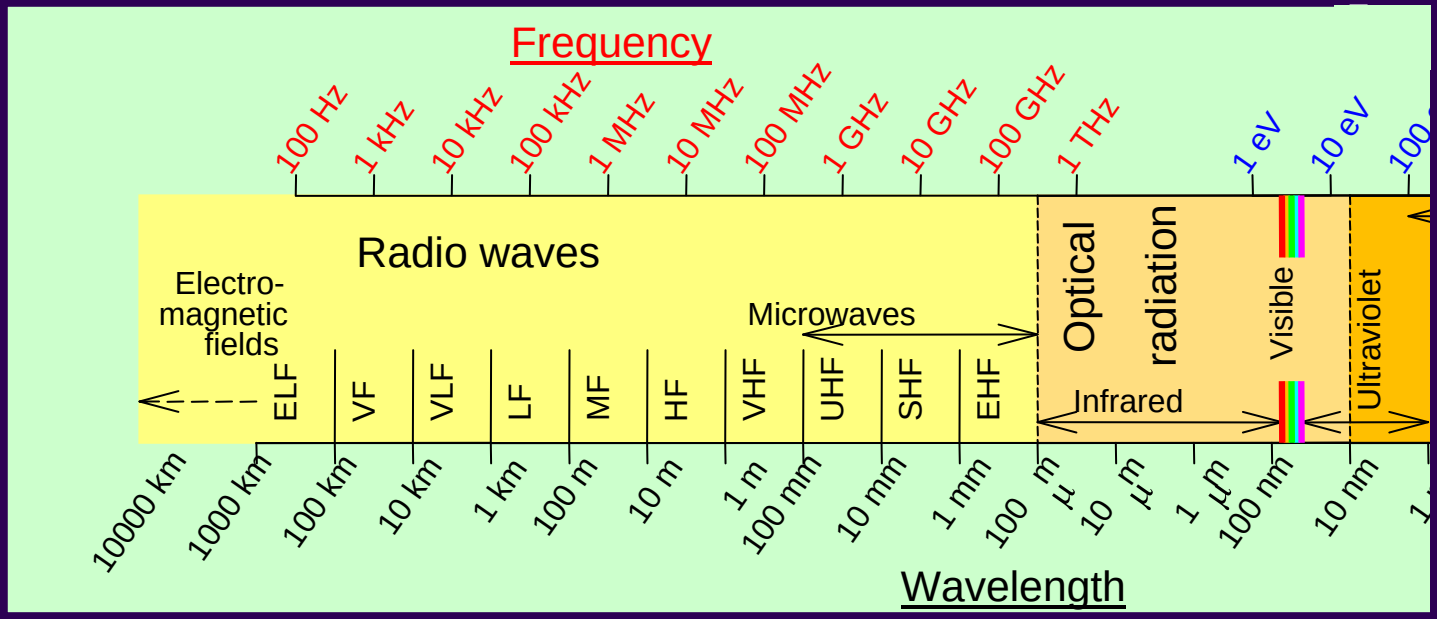
Although in reviewing the science, objective criteria are applied in an impartial manner - the process is inevitably to some degree subjective.

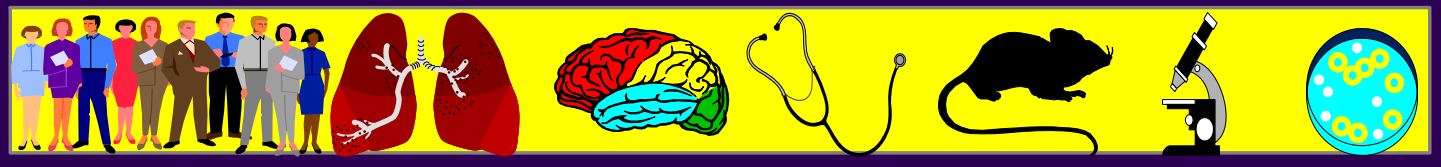
Dealing with public health - the process demands a cautious balanced approach to interpreting the scientific evidence

- caution leans both ways!
  - judge the quality and value of the science against established quality criteria - e.g. Bradford Hill and GLP.
  - if in doubt lean towards public safety

Degree to which caution is applied is a matter of judgement - “judges” must have the relevant scientific expertise and experience of disciplines involved and must be consistent

The Judges Spectrum and Disciplines



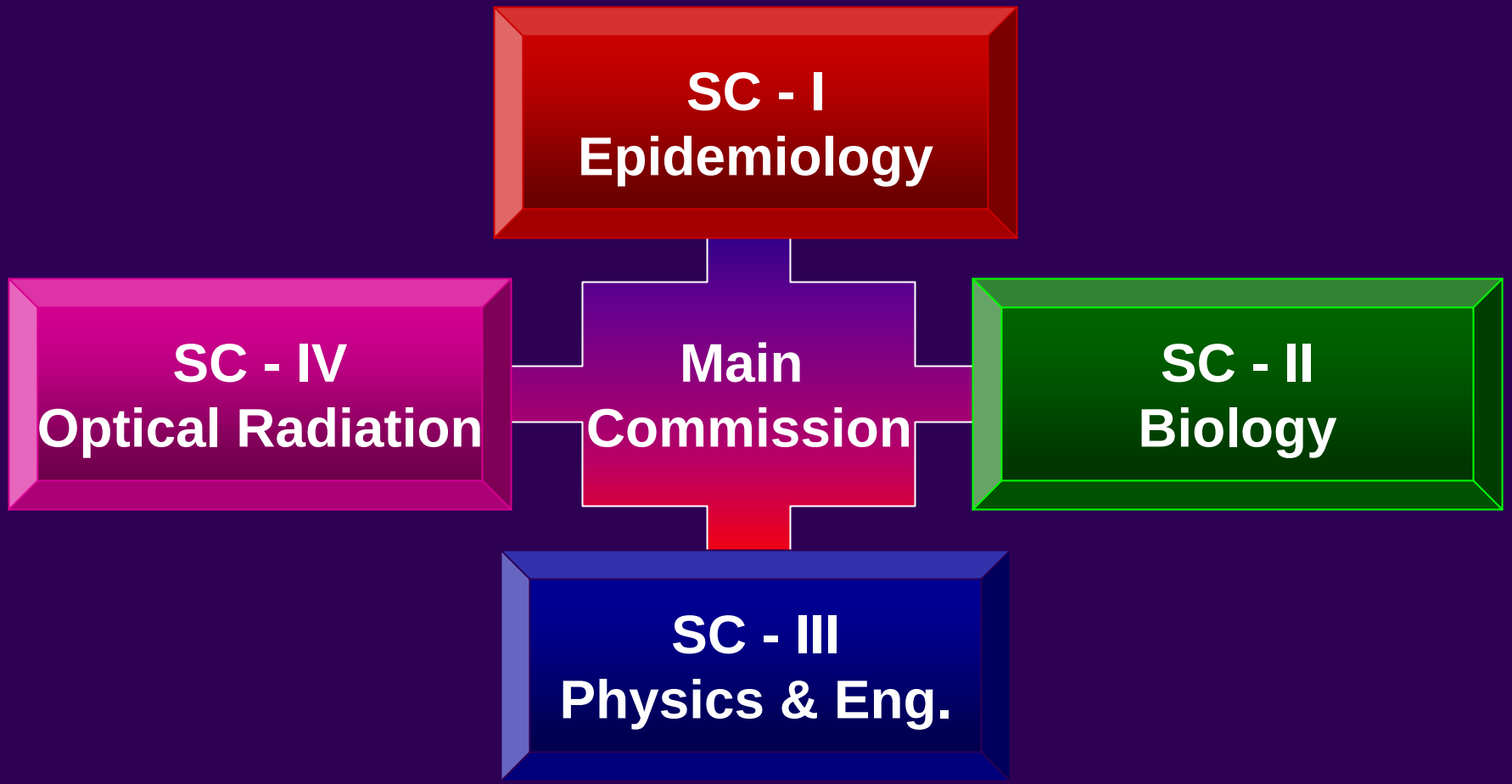


Epidemiology

Medicine and Biology

Physics and Engineering

ICNIRP
Scientific Review



Exposure Guidelines
The Science Base

Big difficulty is that the scientific evidence (particularly from the life sciences) is controversial

There is a spectrum of opinion within the scientific community - this affects

- decision on what adverse health effects should form the basis for setting quantitative limits on exposure
- threshold and/or stochastic effects?
- is the evidence for an effect based on human data - epidemiology - volunteer laboratory studies or biological experimental data - animal - cellular studies?

Fundamental to these and other decisions is the degree of uncertainty in the scientific data

Protection against .....?

Bodies such as ICNIRP have sought to clarify effects as to:

- those effects that in terms of the assessment criteria used, are concluded as being caused by exposure to EMF. Supporting scientific data are sufficient to provide insight into mechanisms underlying the effect
- those effects where, in terms of the assessment criteria used, there is evidence of association with EMF exposure but where the scientific data are judged as insufficient either to conclude causality or to quantify appropriate restrictions on exposure

The first class of effects points to setting quantitative limits on exposure - the second aids decisions on the need to adopt further precautionary measures

General Assessment Criteria

General criteria for assessing the strength of evidence from a number of studies for a particular experimental outcome may include;

- strength of evidence from an individual experiment - adequacy of the experimental design - avoidance of potential confounding and the use of appropriate statistical analysis
- consistency - experimental replication - similarity of outcome in different experiments
- dose-response relationship - agent in question is interacting in a systematic way
- plausibility and coherence - causation is biologically plausible - does not seriously conflict with scientific understanding

What the Science Provides

Epidemiological studies provide evidence most closely related to the exposure of people to EMF - but are observational.

- difficult to decide on causality based on epidemiological studies alone, but possible when the evidence is strong. With information from other sources (e.g. on biological plausibility), epidemiological studies assist in testing for causality

Human laboratory studies provide

- useful information when well controlled, but are restricted in terms of the endpoints that can be examined and the exposures that can be used

Experimental studies on animals are important

- with reservations as to the conclusions that might be drawn with respect to possible effects on human health

Cellular studies can provide an understanding of possible mechanisms of biological interaction

Basis for Quantitative Limits

It has been concluded that quantitative limits on EMF exposure can be set based on:

- preventing adverse effects on the central nervous system (and shock) at ‘low frequencies’ (< 10 MHz)
  - by limiting induced current density (internal electric field strength) and contact currents
- preventing adverse effects on the body from heating (and shock and burn) at ‘high frequencies’ (>100 kHz)
  - by limiting power absorbed per unit mass (SAR) and contact and limb currents

From Thresholds to Limits

Considering the uncertainties in the data, ICNIRP applies a reduction ("safety") factor to establish the limits

- arriving at 10 mA m^{-2} for current density
- 0.4 W kg^{-1} for whole body SAR etc.

These reduction factors have been variously criticised as being too great or too small - they are the result of a value judgement (more uncertainty) and are acknowledged as being somewhat arbitrary.

Underlying all of this however, is a confidence that the chosen values will protect 'normal healthy' people from these adverse effects of EMF

Potentially Sensitive Groups?

As an example, for RF exposures

- Older people, infants, children, pregnant women and other adults taking certain medications. In addition, the performance of cognitively demanding tasks may also be vulnerable to increases in heat load or body temperature. People with cardiovascular system impaired by disease or medication are likely to be more susceptible to localised heating of tissues than people with normal cardiovascular physiology.

Other factors apply for ELF exposures

Differential Limits

ICNIRP's general (occupational) limits are reduced by a factor of 5 to:

- 2 mA m^{-2} current density in the CNS and
- 0.08 W kg^{-1} whole body SAR etc.

as applied for the general public and form the basis of the EC 1999 recommendations for protection of the general public from EMF – implemented within the member states of the EU.

Guidelines to Regulations

In the process of making regulations based on guidelines, the role of scientific uncertainty becomes less clear

- **Guidelines** are intended as a framework for radiation protection applying to all exposures and not just from specific sources or processes, are recommendations implicitly having voluntary status, and are accompanied by statements about uncertainty
- **Regulations** are prescriptive, legally binding and exposure limits are set out as 'RED and GREEN' no 'AMBER'

It is perhaps then not surprising that compliance issues come to the fore, not when guidelines are published, but when regulations appear

Regulations

Regulations can be promulgated in many ways.

Two general examples are:

- by using existing overarching legislation applying to health and safety in combination with codes of practice (or similar) that include quantitative restrictions based on the most recent advice from international or national experts groups
- by having specific EMF regulations that themselves include quantitative restrictions

Regulations

Up until now, the former approach has been common.

- Advantage is that when scientific bodies revise their advice - relevant codes of practice can be changed to incorporate new limits that reflect the most up-to-date scientific knowledge without recourse to changing the overarching legislation.

The 2004 European proposed regulations set out minimum standards for the protection of workers from EMF in the workplace and were based on the latter approach.

- Problem is that if the advice from scientific bodies changes (as is likely), then the legislation may contain restrictions that are at variance with current expert scientific advice (and possibly for some time).

EC EMF Regulations

Implementation of EC regulations is currently scheduled for April 2012 and what must be ascertained is what businesses are likely to be affected and to what degree.

General observations, from this European experience that could apply globally to any country are that:

Large industries - e.g. electricity supply and telecommunications

- Are generally are very aware, are preparing - are doing exposure assessments - funding research - collaborating with and/or contributing to international programmes WHO, COST, CENELEC, IEC etc. and generally have the knowledge and infrastructure to cope.

Medium and small commercial sectors

- May be unaware of the Directive and/or that it affects them, may not be prepared, may not know how to prepare and may not have the knowledge and infrastructure to cope without help.

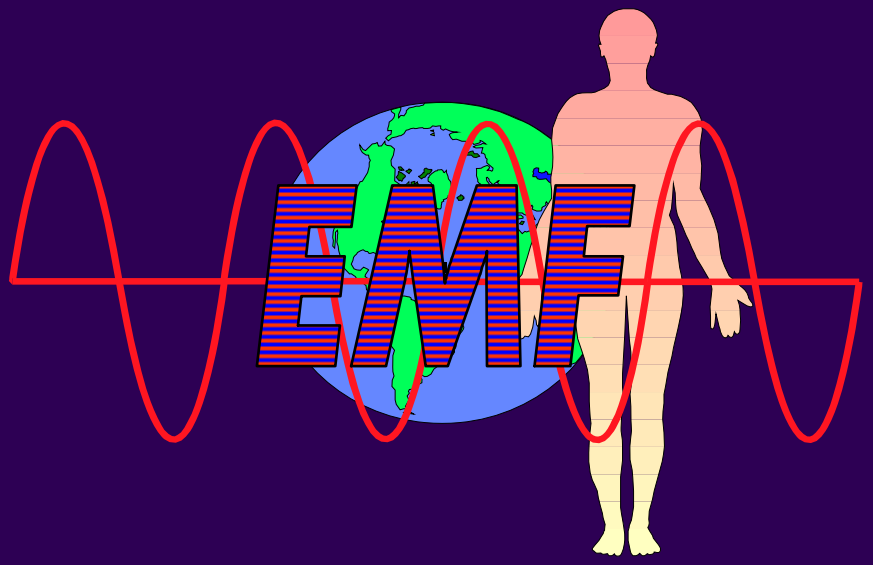
Exposure of MRI Staff

An important occupational source of exposure that has instigated urgent investigation in respect of regulatory compliance is that of medical and other support staff involved in medical resonance imaging procedures that may require them to be in close proximity to the MRI machines while in use.

Such occupational exposure situations are currently under scientific investigation (in part through EC funding) and are a topic included in COST Action BM 0704 on Emerging EMF Technologies

WHO's EMF Project

Much of the generation of EMF in society is related to technologies that span the globe, such as mobile telecommunications and electric power generation and distribution. Thus the health issues are global issues and internationally harmonised approaches are vital. This is the key role undertaken over the past 10+ years by WHO's International EMF Project.



Proportionality

A key principle in adopting precautionary approaches is proportionality.

- Proportionality (implying an assessment and balancing of benefits and costs) aids policy decisions . Where data permit, this can take the form of a quantitative health-economics analysis to point to the most efficient way to achieve a particular exposure reduction.
- Clarity on the scientific political, environmental, social, economic and other factors is important when selecting actions on the basis of precaution.

The Road Ahead
Exposure Guidelines

For scientific input, the WHO health risk assessments are key inputs to the further development of EMF exposure guidelines

- WHO has completed two EMF health risk assessments, one on static electric and magnetic fields (WHO 2005), the other on extremely low frequency electric and magnetic fields (WHO 2007).
- ICNIRP is currently revising its guidelines on limiting exposure to static magnetic fields (following consultation) and to time-varying electric and magnetic fields of frequencies up to 100 kHz.
- It is anticipated, that following publication of the INTERPHONE study results, and IARC carcinogenesis review of RF and a WHO health risk assessment of RF - ICNIRP will further develop its RF exposure guidelines.

Where to now?
A Transition?
Past – Present - Future

Basis in identifying critical effects and applying ‘reduction factors’

Mixture of human physiological data and animal data

For ELF – CNS ‘possible’ effects (weak electric fields – gated ion channels) but with large uncertainties

Further (rather arbitrary) ‘safety factors’ in setting general public levels

Where to now?
A Transition?
Past – Present - Future

For static magnetic fields – a movement towards levels at which clear (transient – but possibly affecting performance) effects in people are avoided (2 T – vertigo etc.) but with relaxation (subject to controls - speed of movement etc.) allowed up to a level (8 T) where there is no evidence of further effects but little known about the higher levels at which adverse effects in people might occur (related to flow potentials?).

Does this indicate a transition in approach that might also apply to time-varying ELF and RF fields – or not? – We await ICNIRP's recommendations.

What about Low-level Effects?

Important to continue to address – BUT unlikely to enable setting of quantitative limits on exposure.

For ELF, WHO's 2007 Health Risk Assessment concluded:

- Consistent epidemiological evidence – increased risk of childhood leukaemia and chronic exposure to low level ELF magnetic fields
- Evidence that the association is causal is weak and the impact on public health limited and uncertain
- Benefits of exposure reduction are unclear and so only low cost/no cost precautionary approaches are warranted

For RF – await the outcome of IARC's and WHO's assessments.

The Road Ahead
Precaution

In developing policies on precaution on EMF, different countries will apply different weight to scientific, social, political, economic and other factors. Therefore, it appears likely that individual countries will continue to develop their own national (and within a country, sometimes regional) approaches to policies on further precaution.

Continued international collaboration (most effectively within the WHO International EMF Project) towards a harmonised approach on precautionary policies appears so worthwhile

The Road Ahead
Uncertainty

Uncertainty is intrinsic to the scientific process and affects all stages of the road that takes us from EMF scientific research through EMF health risk assessment and the development of EMF exposure guidelines to regulations and relevant precautionary policies.

Strict adherence to established principles and procedures for carrying scientific research will minimise uncertainty and where possible it can be quantified.

Policy makers should be made aware of the scientific uncertainties underlying EMF exposure guideline values and scientists should not be asked to go beyond what evidence the science provides.