

BASIS FOR THE DEVELOPMENT OF STANDARDS

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ICNIRP Statement

GENERAL APPROACH TO PROTECTION AGAINST NON-IONIZING RADIATION

Health Physics 82:540-548 (2002)
www.icnirp.org



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FUNDAMENTALS OF ICNIRP GUIDELINES

- Procedures and criteria are defined *a priori*
- Restrictions are **based on science**.
No consideration for economic or social issues
- **Only established effects** are considered

The guidelines are developed in such a way as to be general, and **flexible**. They can be adapted in principle to any realistic condition of exposure



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STEPS IN THE DEVELOPMENT OF GUIDELINES

- Critical review of the literature
- Identification of health and biological effects relevant for health
- Identification of the critical effect
- Establishment of basic restrictions
- Derivation of reference levels



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REVIEW OF THE LITERATURE

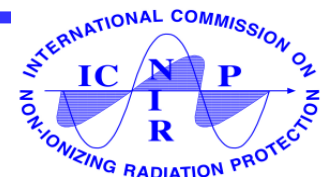
Any single observation or study may indicate the possibility of a health risk related to a specific exposure.

However, risk assessment requires information:

- From studies that meet **quality criteria**
- From the **totality** of science



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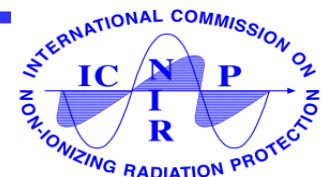
EVALUATION PROCESS

The evaluation process used by ICNIRP consists of three steps:

- **Evaluating** single studies in terms of their relevance
- **Reviewing** all the information for each health effect
- **Combining** the outcomes into an overall evaluation



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OVERALL EVALUATION

A decision must be made whether the available evidence allows the identification of an exposure hazard, i.e. an adverse health effect that is caused by an NIR exposure.

By this identification, the effect becomes “established”.

Science-based exposure limits are set with regard to established effects



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RANKING OF EVIDENCE

EVIDENCE

≠

PROOF

humans

animals

BIOLOGICAL EFFECT

≠

HEALTH EFFECT

ASSOCIATION

≠

CAUSALITY

biological models
Dosimetry

Courtesy of B. Veyret



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ESTABLISHED EFFECTS

Effects are considered as **established** based on:

- Quality of the studies (peer review)
- Consistency
- Replicability
- Cause-effect relationship



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Publication in an international journal is not necessarily a guarantee

Received March 31, 2000; accepted April 3, 2000.

<u>April</u>						
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THE CRITICAL EFFECT

If several effects occur, it may be possible to rank them according to the exposure level at which each effect becomes relevant.

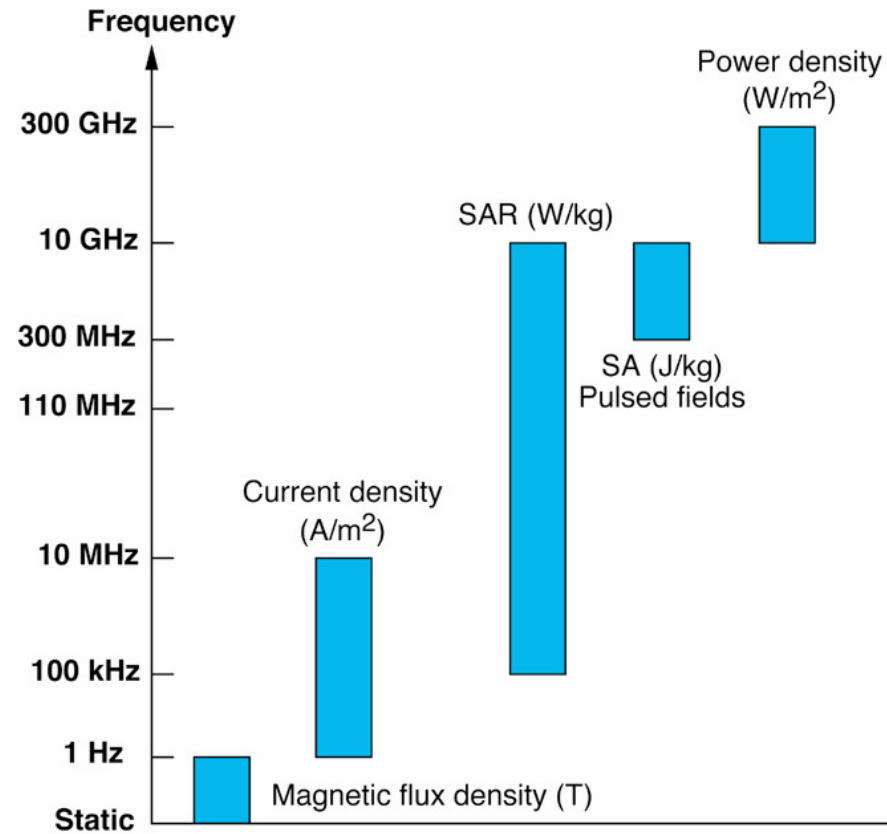
The **critical effect** is the established adverse health effect that is relevant at the **lowest level of exposure**



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BIOLOGICALLY EFFECTIVE QUANTITIES



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THE TWO-LEVEL SYSTEM

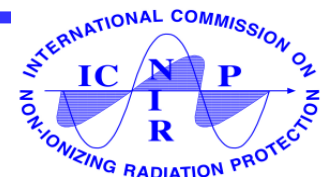
- **Basic restrictions**
in terms of biologically effective quantities
- **Reference levels**
in terms of an external exposure metric

Exposure below reference levels ensures compliance with basic restrictions, since the relations between them have been developed under worst-case conditions.

If the reference level is exceeded, the basic restriction is not necessarily exceeded.



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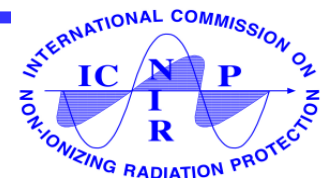


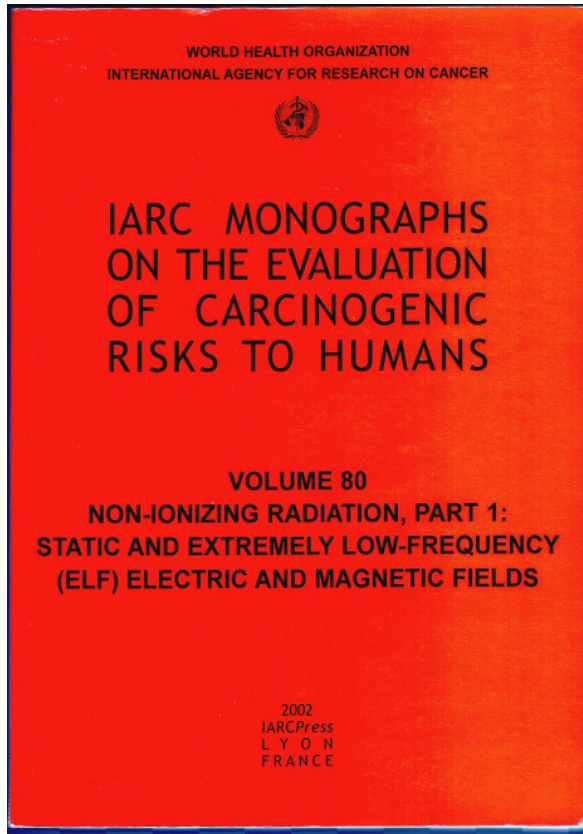
SEQUENCE OF ACTIONS

- Identification of gaps and research agenda WHO
- Syntesis of overall knowledge ICNIRP
- Evaluation of carcinogenicity IARC
- Overall evaluation of health hazard WHO-ICNIRP
- Revision of standards ICNIRP

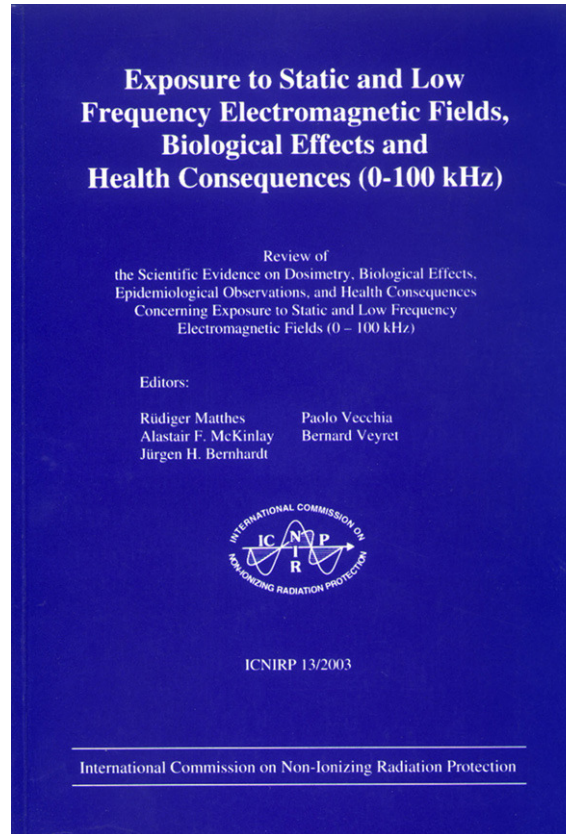


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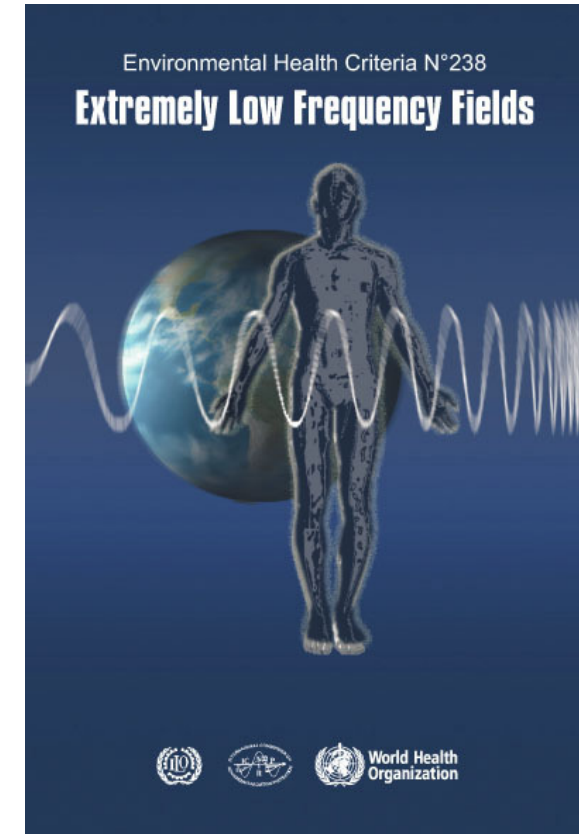




IARC 2002



ICNIRP 2003



WHO 2007



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SYSTEMS OF PROTECTION

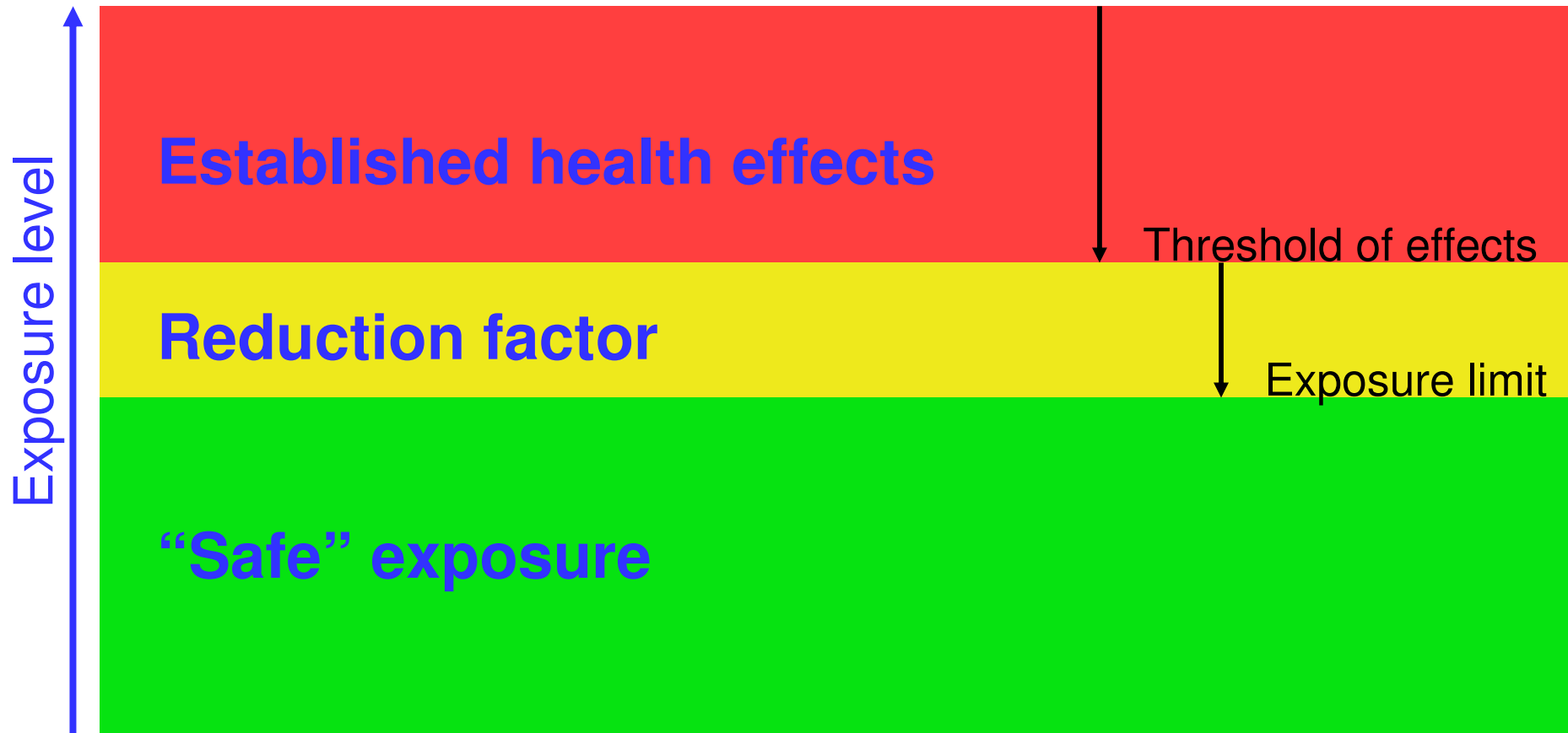
- **Health threshold based systems**
Adequate for well established, threshold effects
- **Optimization systems**
Adequate for no-threshold known hazards
- **Precautionary measures**
Adequate for suspected, not established hazards



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OBSERVABLE HEALTH EFFECTS



ESTABLISHED EFFECTS FOR ELF FIELDS

- ↪ Induction of internal electric fields and currents
- ↪ Stimulation of electrically excitable tissues

The effects are related to the internal electric field (V/m)
or the internal current density (A/m²)



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ESTABLISHED EFFECTS FOR RF FIELDS

- ↪ Absorption of electromagnetic energy
- ↪ Increase of body temperature (general or local)
- ↪ Thermal effects

Thermal effects are related to SAR, i.e. to the energy absorbed per unit time and per unit body mass (W/kg)

ABSENCE OF OBSERVABLE HEALTH EFFECTS

Situations may exist where no relevant effect occurs within the range of experimental conditions

"All things are poisons, for there is nothing without poisonous qualities...it is only the dose which makes a thing poison".

Paracelsus (1493-1541)

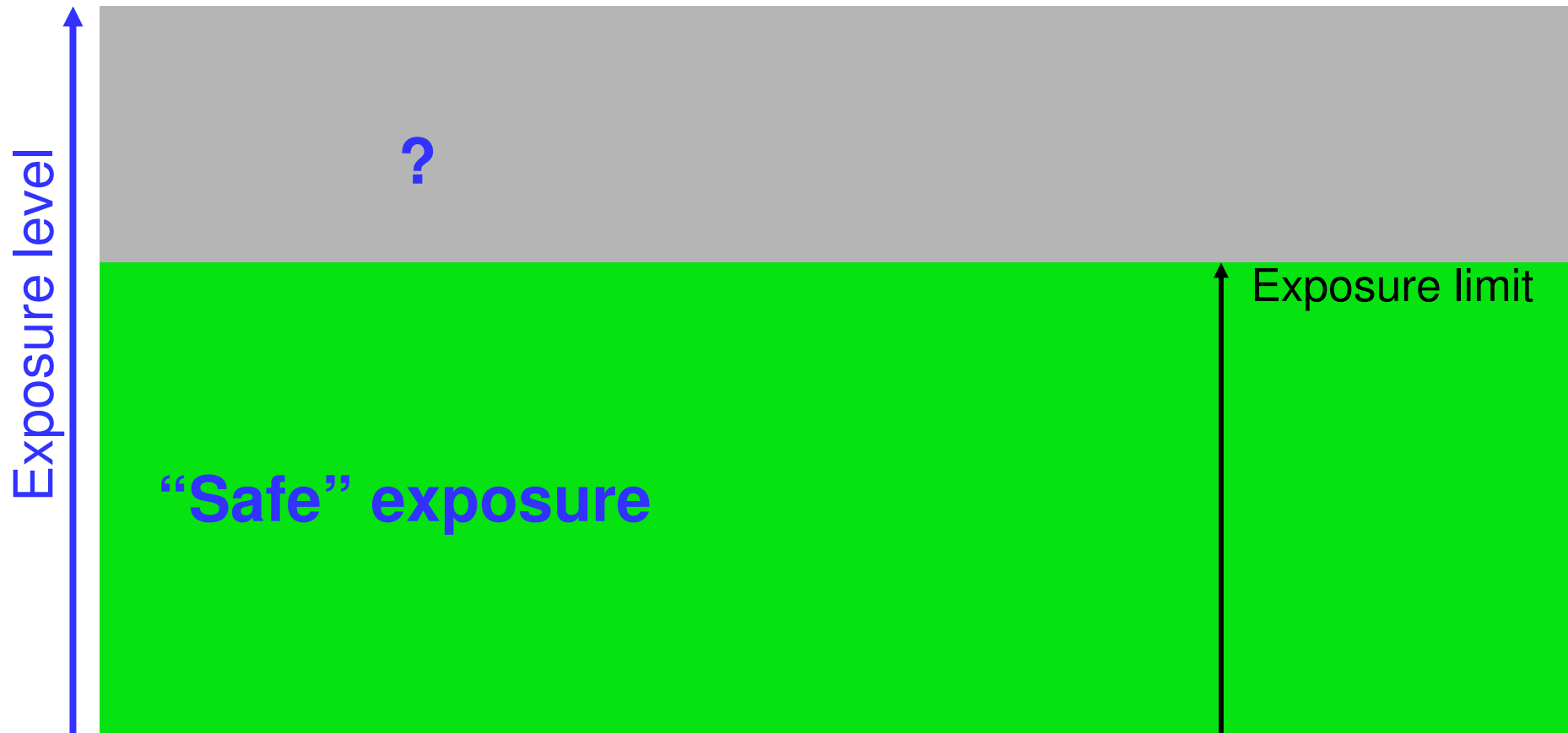
Restrictions may be based on maximum NOAEL (No Observable Adverse Effect Limit)



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NO OBSERVABLE ADVERSE EFFECT LIMIT



ICNIRP ON LONG-TERM EFFECTS

ELF

In the absence of support from laboratory studies, the epidemiological studies are **insufficient** to allow an exposure guideline to be established.

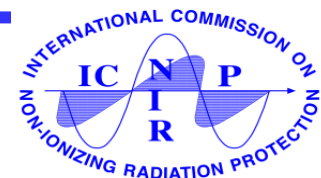
RF

Although there are deficiencies in the epidemiological work, [...] the studies have yielded **no convincing evidence** that typical exposure levels lead to adverse reproductive outcomes or an increased cancer risk in exposed individuals.

ICNIRP Guidelines, 1988



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WHAT IF LONG-TERM EFFECTS WERE ESTABLISHED?

If available data permit the identification of an adverse effect, but not the detection of a threshold, **other risk reducing strategies** will have to be used.

[...] ICNIRP should also attempt to analyze the risk in terms of levels of consequences that could be quantified. The **acceptability** of such risks would, however, be based also on social and economic considerations, and as such, fall outside the remit of ICNIRP.

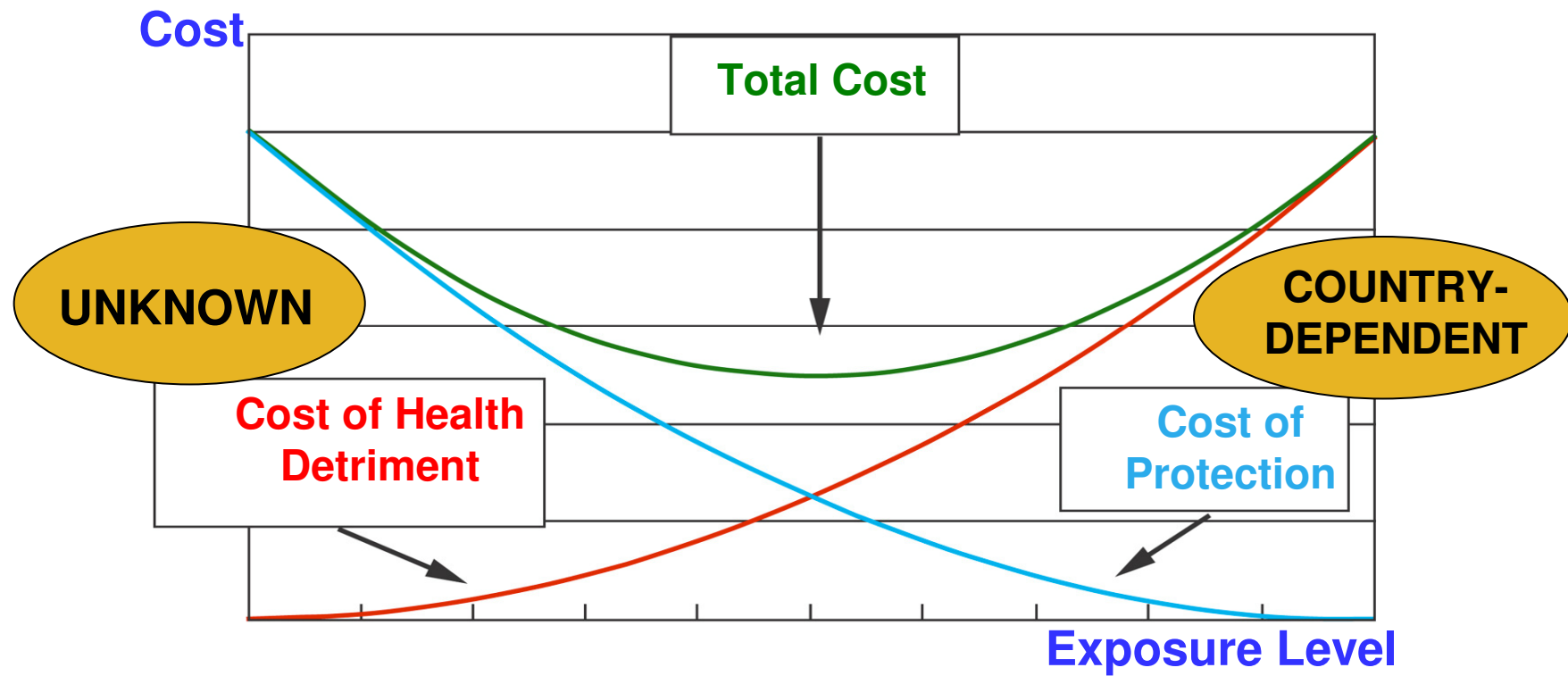
ICNIRP 2002



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ALARA FOR EMF?



WHAT IN CASE OF HYPOTHESIZED EFFECTS?

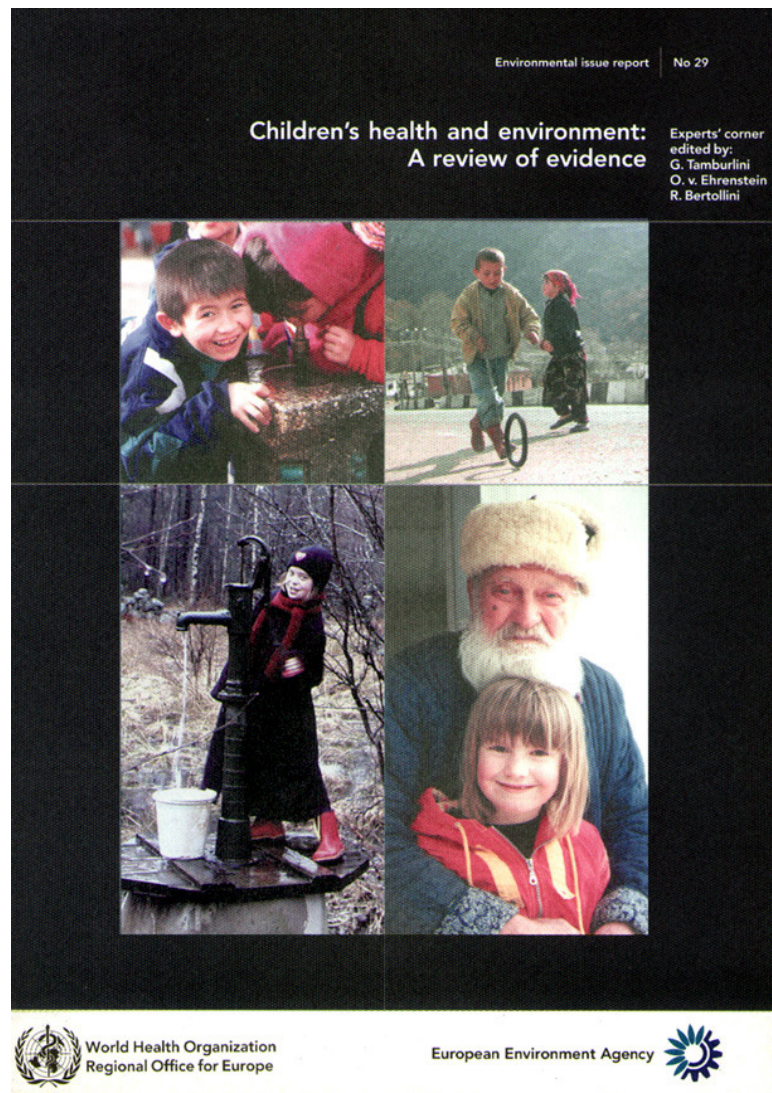
The role of ICNIRP, as a scientific body, is to provide a scientific evaluation of:

- the strength of evidence supporting the hypothesis (i.e. the credibility of the effect)
- the health impact in case the effect were real.



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Electromagnetic fields

Assuming that the association is causal, the number of cases in excess would be in the order of 1%. [...]

Whether or not this is to be considered acceptable (keeping in mind that the association is not proven) is an ethical matter, requiring a thorough and transparent discussion among different stakeholders.

(p. 89)

2002, 222 pages



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Health is a state
of complete physical,
mental, and social
well-being and
not merely the
absence of disease
or infirmity.



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