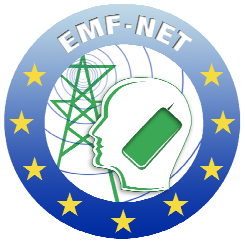

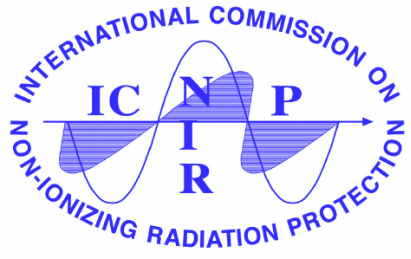

Workshop On Current Trends in Health and Safety Risk Assessment of Work-Related Exposure To EMFs
14-16 February 2007, Milan, Italy

The Role of Uncertainty in Measurements and Calculations in the View of Risk Assessment Required from Directive 2004/40/EC or other Regulation

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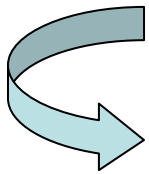
DEFINITION OF UNCERTAINTY

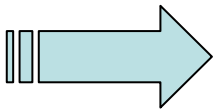
- *uncertainty is a parameter associated with the results of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand*
(International Vocabulary of Basic Terms in Metrology – VIM)

- practical assessment shall be made according to the ISO 13005 *"Guide to the Expression of Uncertainty in Measurement"*



uncertainty plays an important role in the assessment of human exposure to EMF since it affects the results of measurements and numerical calculations

COMPARISON WITH EXPOSURE LIMITS



how to deal with uncertainties in the comparison with exposure limits, when dealing with workers' exposure assessment?

is still an open question!!

"PHYSICAL AGENTS" DIRECTIVES

Directive 2004/40/EC on the protection of workers from exposure to EMF

the problem of uncertainty in the compliance judgment is not discussed

Directive 2003/10/EC on the protection of workers from exposure to noise indicates that *the assessment of the measurement results shall take into account the measurement inaccuracies* ***determined in accordance with metrological practice*** (Art. 4 -Determination and assessment of risks)

WHO POSITION

In the *"Framework for developing health-based EMF Standards"* (*www.who.int*), WHO points out:

- standards developed by relevant bodies such as IEC, ISO, CENELEC, IEEE, ITU provide technical advice on how to conduct **compliance measurements**
- **uncertainty** in measurements for compliance purposes is a practical problem best handled by organizations responsible for the development of compliance methods
- better technical measurement techniques and computational dosimetry are available, and when properly incorporated in guidelines, these will reduce **uncertainty**

no practical advice from:

- **prEN 50499** *"Determination of workers exposure to electromagnetic fields"* (M/351)

  how to take measurement uncertainty into account is awaiting guidance from the EU Commission

- **prEN 50413** *Basic standard on measurement and calculation procedures for human exposure to electric, magnetic and electromagnetic fields (0 Hz – 300 GHz)* (M/305, also fulfills M/351)

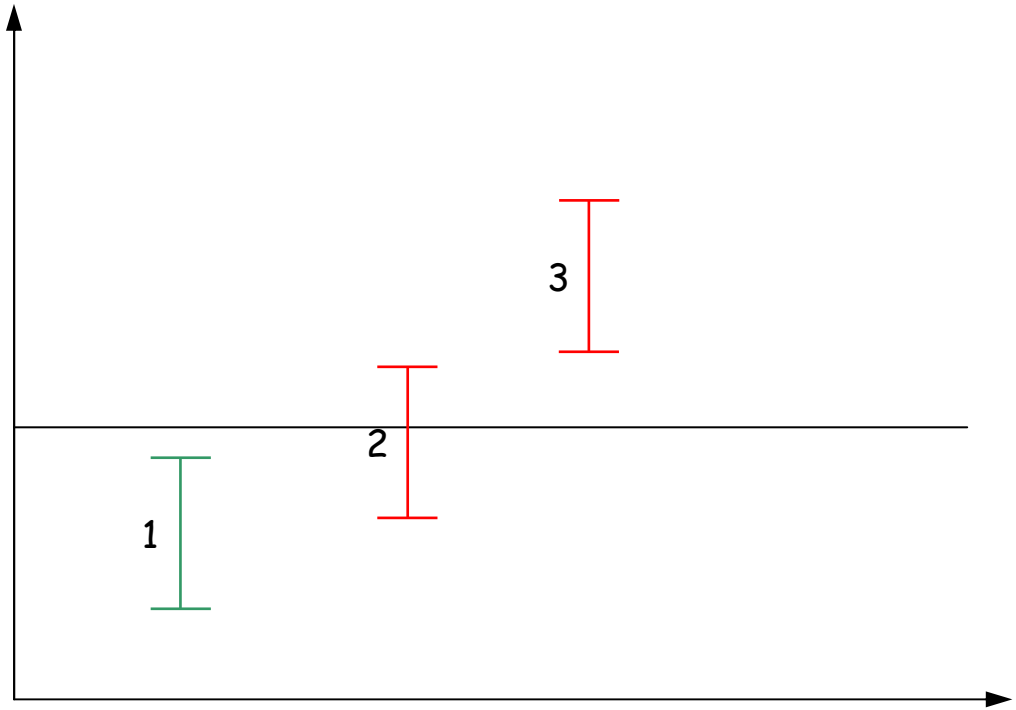
At the moment, only standards applicable to emission of products give practical advice on how to treat uncertainty, but criteria are not always uniform

Few standards require the uncertainty to be quantitatively included in the comparison with the limit of exposure

- **EN 50366, 2003:** Household and similar electrical appliances - Electromagnetic fields - Methods for evaluation and measurement

- **IEC draft 62233 ed.1, 2003:** Measurement methods for low frequency magnetic and electric fields of domestic appliance with regard to human exposure

EN 50366 - Inclusion of uncertainty in the comparison with the limit of exposure: three possible outcomes

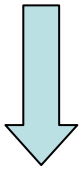


to establish whether an appliance produces only fields below the limit, the measurement uncertainty has to be added to the result and the sum has to be compared with the limit

to establish whether an appliance produces fields over the limit, the measurement uncertainty has to be subtracted from the result and the difference has to be compared with the limit

The most common indication in standards is however:

uncertainty must be assessed and recorded but measurements or calculation results shall be directly compared with the limits, ***provided that overall uncertainty is less than or equal to recommended or permissible values:***



shared uncertainty budget approach

(not always directly mentioned)

introduced first by **CENELEC Standard EN 50364, 2001** on Electronic Article Surveillance (EAS), Radio Frequency Identification (RFID) and similar applications

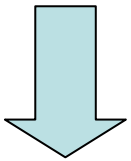
SHARED UNCERTAINTY BUDGET

According to EN 50364, the *shared uncertainty budget* (or *shared risk*) approach shall be used:

- if the total assessed uncertainty is less than or equal to permissible/reasonable pre-defined values

or

- if the assessment is proven to always overestimate the exposure



the actual measured or calculated values must be used for comparison with exposure guidelines

SHARED UNCERTAINTY BUDGET

The *shared risk* approach, as originally intended in the EMC testing, is applicable when the end user, or the Authority responsible for control, makes a judgement of compliance and ***takes some of the risk that the product may not meet the specification***

Generally acceptable in non-safety critical performance

The application to the verification of human exposure compliance should be considered acceptable only in the case of an explicit indication from Authorities responsible of controls and application of sanctions

Nevertheless, to support the *shared uncertainty budget approach*, it is invoked the presence of **safety factors** in the setting of basic restrictions and reference levels in the protection guidelines

CENELEC EN 50364, 2001: Limitation of human exposure to electromagnetic fields from devices operating in the frequency range 0 Hz to 10 GHz, used in **Electronic Article Surveillance (EAS), Radio Frequency Identification (RFID) and similar applications**.

CENELEC EN 50357, 2001: Evaluation of human exposure to electromagnetic fields from devices used in **Electronic Article Surveillance (EAS), Radio Frequency Identification (RFID) and similar applications**.

CENELEC EN 50360, 2001: Product standard to demonstrate the compliance of **mobile phones** with the basic restrictions related to human exposure to electromagnetic fields (300 MHz - 3 GHz).

CENELEC EN 50385, 2002: Product standard to demonstrate the compliance of **radio base stations and fixed terminal stations for wireless telecommunication** systems with the basic restrictions or the reference levels related to human exposure to radio frequency electromagnetic fields (110 MHz - 40 GHz) - **General public**.

CENELEC EN 50384, 2002: Product standard to demonstrate the compliance of **radio base stations and fixed terminal stations for wireless telecommunication systems** with the basic restrictions or the reference levels related to human exposure to radio frequency electromagnetic fields (110 MHz - 40 GHz) – **Occupational**.

WHAT IS THE RATIONALE FOR ICNIRP SAFETY FACTORS?

"Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz)".

The following general variables were considered in the development of safety factors for high-frequency fields:

- *effects of EMF exposure under severe environmental conditions (high temperature, etc.) and/or high activity levels*
- *the potentially higher thermal sensitivity in certain population groups, such as the frail and/or elderly, infants and young children, and people with diseases or taking medications that compromise thermal tolerance*

ICNIRP SAFETY FACTORS (#2)

The following additional factors were taken into account in deriving reference levels for high-frequency fields:

- *differences in absorption of electromagnetic energy by individuals of different sizes and different orientations relative to the field*

- *reflection, focusing, and scattering of the incident field, which can result in enhanced localized absorption of high-frequency energy*

no direct mention of uncertainty in exposure assessment

In standard EN 50392, 2005: "*Generic standard to demonstrate the compliance of electronic and electrical apparatus with the basic restrictions related to human exposure to electromagnetic fields (0 Hz - 300 GHz)*", it is introduced the concept of uncertainty penalty

(prEN 50500 Measurement procedures of magnetic field levels generated by electronic and electrical apparatus in the railway environment with respect to human exposure)

if measurement uncertainty of the applicable assessment method is 30 % or more, the applicable limit for verification of compliance must be reduced by a specific factor (uncertainty penalty):

$$L_m \leq \left(\frac{1}{0,7 + \frac{U(L_m)}{L_m}} \right) L_{lim}$$

prEN 50445, 2006: *Product family standard to demonstrate compliance of equipment for resistance welding, arc welding and allied processes with the basic restrictions related to human exposure to electromagnetic fields (0 Hz – 300 GHz)* **(M/351)**

- shared risk approach is explicitly adopted
- the **uncertainty penalty concept** introduced by EN 50392 (measurements), is extended to calculations **if permissible uncertaintes are not fulfilled**

$$L_m \le L \cdot \left(\frac{1}{1 - \frac{U_p}{100} + \frac{U_m}{100}} \right)$$

- **prEN 50444, 2006:** *Basic standard for the evaluation of human exposure to electromagnetic fields from equipment for arc welding and allied processes* **(under M351)**
- **prEN 50505, 2006:** *Basic standard for the evaluation of human exposure to electromagnetic fields from equipment for resistance welding and allied processes* **(under M351)**
- **IEC 62369-1 Ed.1 2006:** *Evaluation of human exposure to electromagnetic fields from Short Range Devices (SRDs) in various applications over the frequency range 0-300 GHz.*

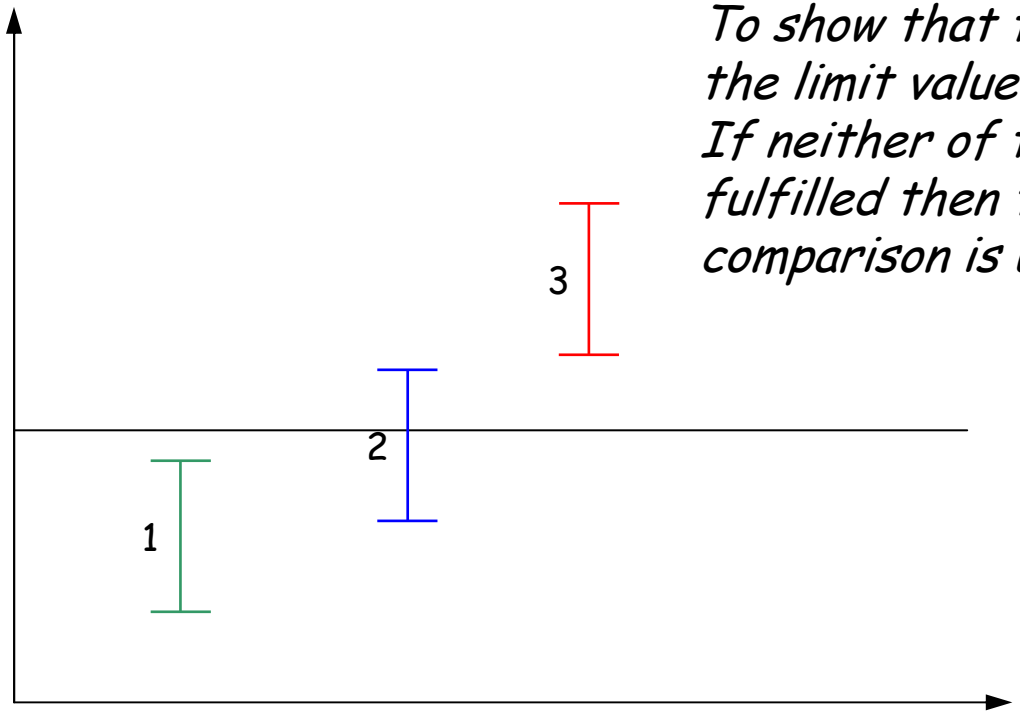
  Part 1: Fields produced by devices used for Electronic Article Surveillance, Radio Frequency Identification and similar systems

give as options:

- the shared uncertainty budget approach, completed with the uncertainty penalty concept
- direct inclusion of uncertainty in the comparison with limits (similar to criteria from EN 50366)

prEN 50444, 50505 - Something has changed with respect of EN 50366:

To show that the actual value is below the limit value: $X + U \leq L$
To show that the actual value is above the limit value: $X - U > L$
If neither of the above conditions is fulfilled then the result of the comparison is uncertain



Condition 2 is always uncertain

WHICH VALUES FOR PERMISSIBLE UNCERTAINTIES ?

- EN 50392 (Electronic and electrical apparatus, generic standard)
- EN 50383 (Base stations, basic standard)
- EN 50361 (Mobile phones, basic standard)
- prEN 50475 (Broadcasting system, basic standard)

criterium of +/- 30 %

WHICH VALUES FOR PERMISSIBLE UNCERTAINTIES ? (#2)

- EN 50357 (EAS)
- prEN 50445, prEN 50505, prEN 50444 (arc and resistance welding)

Frequency	Measurement	Numerical modelling
< 10 kHz	+58%, -37% (+/- 4 dB)	+/- 50%
10 kHz – 1 MHz	+41%, -30% (+/- 3 dB)	+/- 50%
1 MHz – 30 MHz	+41%, -30% (+/- 3 dB)	+/- 40%
30 MHz – 1 GHz	+100%, -50 % (+/- 6 dB)	+/- 40%
1 GHz – 30 GHz	+100%, -50 % (+/- 6 dB)	+/- 50%

Practical considerations

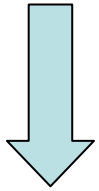
- the minimum recommended permissible uncertainties for field measurements are of the same order of magnitude of typical performance of instrumentation
  - **good possibility of determination of actual uncertainty**

- computational permissible uncertainties seem to be optimistic if compared with realistic evaluations:
  - Bahr A. et al. - *ICNIRP Workshop, Berlin 2006:*

$$\pm 12.2 \text{ dB} \rightarrow +307\%, -75\%$$

- no guide for evaluation of uncertainty is available

Report on Recommendation on Bioelectromagnetics research (EMF-NET project)



it is emphasized the poor reliability of numerical dosimetry results, and the need of experimental verification both for in vitro and in vivo experiments

EXAMPLE OF ITALIAN REGULATION

Prime Minister Decree of 8 July 2003 (Limits of exposure for the protection of population from EMF in the frequency range 100 kHz – 300 GHz)

adopted the *shared risk criteria*:

if measurement uncertainty is limited to a maximum value of ± 3 dB, field levels can be directly compared with exposure limits

measurements with uncertainties greater than ± 3 dB have to be considered suggestive and can be used when they differ from exposure limits of a quantity greater than uncertainty itself

The question is again:

how to manage uncertainty in workers' exposure assessment and compliance verification with 2004/40/EC ?

CONCLUDING SUGGESTIONS

- should criteria be uniform ?

CONCLUDING SUGGESTIONS (MEASUREMENTS)

- quantitative inclusion of uncertainty in the comparison is welcome, provided that conservative approach is adopted for uncertain situations

- *shared uncertainty budget* approach should be practicable if explicitly recommended by Authorities, and provided that maximum permissible uncertainties are more restrictive than what accepted in product standardization
  - **(less than or equal ± 3 dB ?)**

CONCLUDING SUGGESTIONS (NUMERICAL CALCULATIONS)

- **to get valuable results, application of calculation should be limited to standard and traceable worst-case conditions**

in this case, provided a strong conservative nature of calculation, realistic high values for permissible uncertainties could be accepted, in a *shared risk* approach