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THE NEED OF METHODOLOGICAL GUIDE FOR DEVELOPING STANDARDS

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Abstract. The development of a framework for international standard – the main idea of the WHO International EMF Project, is possible on the basis of activities by each representative in the standards harmonisation process. One of the possibilities to develop it is the creating of an international working group including specialists with different viewpoints. Other requirement for an agreement is to have universal terminological glossary in the field of standards. Very important point should be the developing a new methodological handbook showing the way of the studies for developing exposure limits to be carried out precisely. This handbook is possible to be prepared by the international working group. This guide should include all requirements of conducting experiments, epidemiological studies, human exposure and modelling studies, etc., to be used for developing exposure limits. Here, we are speaking for precise description of the exposure system, selection of the objects, control groups, controlling conditions, exposure assessment and dosimetry, etc. Such a handbook should contain all rules of GLP and QA, and it will have the purpose to minimise the uncertainties in research.

Keywords: electromagnetic fields, exposure limits, standard protocol, study design .

AIMS AND BACKGROUND

The idea is a methodological handbook to be created after reviewing the Eastern European literature where sometimes very poor dosimetric data could be found. Similar guide was issued in the 70's in Russia[1], and it was a very useful booklet to every researcher in the field of standards development. This handbook could be one possibility to settle the differences between the schools in developing exposure limits.

DISCUSSION

There are opportunities to reach an agreement between the west and east schools. We try to debate and to explain one such possibility what could give us a chance in this area.

The idea, discussed here, is the need of developing a new methodological handbook showing the way studies for developing exposure limits should be carried out precisely.

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First, we have to discuss and to reach an agreement for use of universal terminology in the field of standards. Such a terminological glossary should be prepared very fast because it would give an opportunity to speak in one language.

Second, we need to discuss the criteria for exposure limits: which energetic values should be used and how different dose parameters to be calculated from one to other and to have universal meaning. This is one of the possibilities to compare the exposure limits between different standards in the world.

Both the handbook and glossary are possible to be prepared by a working group from different countries. This methodological guide should include all requirements of conducting experiments, epidemiological studies, human exposure and modelling studies, etc., to be used for developing exposure limits. Here, we are speaking of precise description of the exposure system, selection of the objects, control groups, controlling conditions, exposure assessment and dosimetry, etc. Such a handbook should contain all rules of GLP and QA, and it will have the purpose to minimise the uncertainties in research.

This idea created after reviewing the Eastern European literature where sometimes very poor dosimetric data could be found.

As a basis for developing such a handbook could be the experience of IEEE, SCC 28 in the field of reviewing the literature. Additional basis could be the ICNIRP Guidelines, also several terminological standards in Europe and USA.

METHODOLOGICAL GUIDE (HANDBOOK). SOME REQUIREMENTS. NECESSARY PARAMETERS/CRITERIA

A group of requirements is presented below which should be applied to future papers and studies.

We shall make an attempt to present the requirements to the studies as sheets for the different characteristics – identified (groups of) elements and operations as well as warranties for their availability.

I. The working group can develop two groups of requirements status quo ante articula (maximal requirements), and common ones.

II. New conditions

The study of SAR or other dose parameter through stages of the irradiation process from a source (I/O) to the biological object, referred to a target (Bt) with biological properties, and the effects in the biological substrate (Bs) enables the realisation of a formal analysis of this process. There have to be used the scheme 'analytical description of the sequentially treated parameters', from source 'I' to 'Bt', and then – in the analysis of the data from where a deduction or synthesis of effect assessment is achieved aiming at exposure assessment. Each stage is assigned a set of elements. The operations between them are replaced with the

operations addition and multiplication between algebraic analogues of these elements. They are defined in an abstract (phase) space as points and discreet intervals. The simplest division of the elements of a function and an argument is through secularisation of the indices of the characteristic element what is assigned the given point of the phase space of the indices in this point. The following realisation of a limit transition enables the inclusion of the description of each stage in an analytical expression for mathematical description of quantities, the relationship between which is expressed quantitatively. The direct sequence of this 'complication' is the possibility to equalise a number of requirements for each stage of the experiment, data processing and objects monitoring, leading to the hygienic estimation.

III. Basic requirements to the protocol of the paper

1. The reproducibility and replicatibility of the design and results within the task are servicing as: To present the results through a quantity comparable (functional or in regression at least) with the basic metabolite rate (BMR), and particularly – via SAR with the measurements for the data being reduced to data obtained at one and the same distance to the object, determined only by the wave length and the biological target at equal configuration of electromagnetic 'lightening'.

2. To provide means and methodology for the control of quantitative and qualitative characteristics and criteria for availability and assessment of characteristic and parameter for the study en bloc; Bt and the falling (at Bt location) radiation – the occurring EMR as a sequence of it.

3. Metrological provision and processing of data for best quality assurance. Concerning any publication as an *articulo ipso facto*, we must be sure that the grade is guaranteed by low and achievable basic uncertainty for each result. Marking this quantity we have in mind the primary texts to which every method should conform literally.

4. The bases and ways of comparison, correlation with the mutual values and with those from other articles, standardisation and normalising must be clearly stated and quoted. The explicit statement of the basis for such procedures or at least a way of their verification is obligatory.

As to referring to the inferior limit of an expanded uncertainty,

$$U = ku_c,$$

in the ideal case we reach to a level of confidence of 95 to 97%. The realised statistics is always a finite string of data, so even at the normal Gaussian distribution we approximate by a finite function. Besides that this can always lead to great deviations, above the values of dispersion – eruption, the finite functions

theory provides the following possibilities:

A. Unilateral determination towards the probability of the distribution of the quantity:

(i) at summing by the module of the average square error (mod σ)

$$9\% < U = ku_c < 15\%$$

where k is the coverage factor.

(ii) at treating by mod (3σ)

$$5.196\% < U < 8.66\%$$

B. At determination of the whole interval of probability densities towards a given mod, $p\ (-3\sigma) \leq p \leq p\ (+3\sigma)$

$$3.67\% < U < 6.124\%.$$

For the rest should be evident that the respective standards are applied, e.g. ISO 30012-1:1999(E), ISO 14253-1,2:1998(E), etc.

After that the type of the study should be revealed.

5. Whether the study is an experiment when a situation is organised and actively realised, at which a given effect is searched for and is parameterised the studied system 'source–space', in which an EMR or a trace of irradiation originates or this is a scrutinising study, i.e. collection of data from measurement in a *status quo* – sampling in an EMR, etc.

6. It is possible to have parallelly an experimental process and scrutinising. Then it should be known which procedure is prevailing, which is the initial one, when and in what order they shift or are in parallel; the time of each shift. This is a casus that we would like to illustrate by a digest of our experience and together with that to show the upper limit for U.

7. It can turn out that the article presents studies of the class in question that are not dosimetric nevertheless supply such information, conforming with the requirements under the existing literature.

The detailing of those requirements by second descending hierarchical level contains:

A. Referring to the object (Bt): whether the effect of the irradiance is irreversible destroying the structures from tissue level downwards or there is a possibility for recovery of structures and infrastructures.

B. Referring to the issue (I), Bt and measurement equipment (ME): whether the basic metabolite rate (BMR) is disturbed – thermal irradiation or it is simply affected – non-thermally; for both it is important to state whether the overall metabolism is affected and/or chemism, i.e. whether there is actinic effect of EMF at a given exposure; whether the exposure is yet weaker – athermic or practically independent of the exerted on Bt effective power (P_{eff}) at frequencies falling in the so-called 'windows'. Other type of frequently evidenced impacts

are those with cooperative effects (the brain tissue of mice is resonantly activated but as a whole we have strong disturbance of the metabolic and chemical balance), induction of currents at irradiation in the near field and effects from primary external irradiation and induced cascades by decreasing frequency. The expansion of this nomenclature is a matter of knowledge.

C. Referring to I, Bt and ME as receiving and transmitting systems: to which type of antennae and other end devices for EMF propagation (e.g. waveguides) and how technically and which type of EMF generation is realised in each component – I, Bt, ME.

D. Referring again to Bt: whether the impact is on the activity of the organism or on the activity of its elements, on its chemism (e.g. opioids like a grade brain production); on systems of functional nature (e.g. cardio-vascular); syndromes are manifested (e.g. asthenic syndrome of the autonomic nervous system), behavioural disorders, etc.

Together with this description relating to the homeostasis and EMF attributed to each component (I, Bt, ME), the description of EMF is required, which we could name 'description by mutual local phasing of the electric and magnetic fields':

a) distance between receiver and transmitter in units wave length – near field, far field, the Fresnel zone or near inductive zone;

b) to what extent in the area around Bt, respectively ME, has changes in the propagation trace of irradiance. There are changes imposing transition from treating propagations in free space to treating local electric and magnetic fields in a function of the Poynting's vector;

c) to what extent the sensitive probe terminal is parallelly Hertz vibrator and Helmholtz probe; to what extent ME and Bt similarly perturbate the falling radiation/EMF;

d) to what extent the irradiance is from a single frequency emission; how many and which are the different frequency bands and how SAR is calculated out of the solution of the mono-frequency task;

e) with ME, how the occurrence of effects described after the Wiedemann–Franz law, i.e. the influence of a RF field at particular radiant heating on the metal conductivity in ME, is read;

f) how the dose and exposure are introduced as associated quantities, as well as the inherent errors; multi-frequency task or reading of harmonica (obertone, undertone);

g) characteristics of the impulse fields;

h) irradiance duration time; characteristics and energy parameters of irradiance interrupted during the time of the current study;

i) background determinations: natural background – levels by energy in the frequency band or elsewhere (why such selection) in unavailable technogenic

emissions; technogenic background; values for irremovable technogenic fields; levels by energy for the highest frequency, which can be determined by ME;

j) co-factors of chemical and physical nature and their parameters;

k) exposure type: direct actinic; leading off the energy by a waveguide; closed TEM-cell; long line; others, e.g. conjugated horns or other antennae;

l) description of an optimum curve path of a moving Bt and introduction of the sensitive terminal of a device to the point in EMF;

m) model of Bt by EMF with a view to selection and implementation of a statistical approach;

n) implemented measurement principle via a ME and its compatibility with the frequency and dynamic ranges.

CONCLUSIONS

The proposed inventory is a flexible hierarchically organised test table via which we can develop and deepen the level of conformity with the requirements through introducing more details.

The actual knowledge level selects sufficiently comprehensively each study, if average effective power and SAR can be defined and to outline, together with the reasons, the deviations or distortions and contortions or false assessments of these quantities.

It is reasonable that the database should have a central peak file and subordinate peripheral files. There should be also an algorithm for following up and enrichment (in descending order) of actual and new characteristics at description of the discussed studies; at each updating the peripheral files should be tested again with a view to a new selection – towards the center or towards the periphery.

Finally, there would be an agreement between different points of view if the two schools of specialists for developing standards reach a consent for including in the standards (or in the criteria for developing exposure limits): long-term effects, non-thermal, athermal effects, physiological and psychological parameters changed by the EMR exposure. Others for discussion are the 'windows', 'resonance', 'informational' effects, also those found in the CNS, cardiovascular, immune, autonomic nervous system.

General glossary and methodological handbook are one possibility to reach this agreement.

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