PHILOSOPHY OF STANDARDS IN EASTERN EUROPE AND IDEAS FOR STANDARDS HARMONIZATION

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I. INTRODUCTION

In this presentation I would like to compile the thoughts belonging to certain scientists and philosophers known all over the world related to hygienic standards through my views. As a beginning I would like to discuss the term "norm" (which is the basis for developing "exposure limits" and "standards") on the basis of ideas quoted by V.P.Petlenko, M.L.Reznik yet in 1977 in the Proceedings of the Institute of Occupational Hygiene, Moscow.[3]

The term "norm" is not new for medical philosophy. The health and disease issue, norm and pathology has been a focus for physicians from Hypocrite to nowadays. It is sufficient to quote more than 200 existing definitions of "norm" and "pathology". The WHO did set recently a unique definition for the term "health" – basis for definitions for "norm" and "pathology". A. Kettle introducing the term "average human" could be assumed as one of the founders of the new science on standards in the 19th century with the implementation of statistics. This "average human" should possess average physical, moral and intellectual characteristics and each deviation from them is considered an anomaly. This definition underlies the originating average statistical term "norm" and the related philosophical approach is a part of Kant's aesthetic theory. Of course, with the time the quantitative assessment methods undergo a sophisticated development – from the arithmetical average value to quite significant probability-statistical data.

At present the mathematical methods enable the determination with substantially good precision of different human parameters related to human health and activity. Nevertheless, even now, modern theoretical medicine assigns a critical evaluation to the average statistical understanding of "norm". Besides averaging physiological indicators, the average statistical assessment does not account for the novelty, which could prove to be a development tendency of the living system. Assessing the "normal" we do not assess "abnormality" from the viewpoint of progressive or regressive purposefulness.

The opposite approach based on individual physiological characteristics of the organism or their comparison with the so-called "prime" at the age of 20–25 is also under criticism.

The failures to define the term "norm" are determined mainly by the complexity of the interactions within the organism and with the environment.

The parallel usage of the terms "norm" and "standard" ("or limits") also provides problems at assessment of the interactions. The norm is objective, individual, dynamic, corresponding to optimal status of the organism. The term "standard" is associated with subjective contracting acts between specialists (conventions), it is related to elaboration of standards, models, patterns, and is conventional. Subjectivism results in approaches at setting norms (limits) – the differences in some hygienic standards reach tens and hundreds times.

At present in the "standard" the variety of the phenomena is deliberately brought to schemes allowing the stipulation of one or other interaction processes. The degree of closeness of the exposure limits (standards) to objective norms could be addressed depending on the set of phenomena covered or stipulated by the standards.

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The standard reflects the degree of knowledge on the subject and the norm – its real state. Consequently the task for development of scientifically based standards lies in maximal approximation to real norms.

In fact, there is no such science as "normology". Nevertheless it has its methodology – from the understanding of the term "norm" to proceed to development of a system of philosophical principles of the norms theory. The modern norm theory should compile data from physics and engineering, medico-biological, natural sciences, social sciences (the latter for juridical, ethical, esthetical norms).

It should not be forgotten that in the course of transformation of environment the adaptation-accommodation abilities of the organism could lay behind environmental changes.

II. PHILOSOPHY OF SOME EASTERN EUROPEAN STANDARDS

1. Terms and definitions

"Risk" is the term moving the research of developing exposure limits for different hazards, also concrete for electromagnetic fields (EMF). I am not going here to advance the theory of risk, and to discuss the ways and methods of risk assessment. I want to mention only, for instance, what is risk of exposure to ionizing radiation - a synonym of a probability of a harmful effect. There are opinions discussed in the Eastern European Countries (EEC) to use the same method to develop exposure limits for EMF exposure as that used for ionizing radiation. As a result, some precautionary approaches are used now in some countries similar to these suitable for ionizing radiation. Also, the fundamental dosimetric quantity in radiological protection is the absorbed dose. This is the energy absorbed per unit mass and its unit is the J/kg, similar to the unit "specific absorption" for non-ionizing EMF exposure.

The most important in the conception for developing standards not only in the EEC is the threshold conception, which is still in dispute for ionizing radiation. This means that in the Eastern European standards Threshold Limit Values (TLVs) and Maximal Permissible Levels (MPLs) are established.

TLV is ***the hazard's value which produces periodically or for the whole lifetime effect on humans without causing somatic or mental disorders (including latent or timely compensated conditions) or other alternations of health state out of the limits of adaptation reactions, which could be detected by the current methods at the moment or in a further period of life of the present or future generations***. Thus the compliance with TLV should preserve (avoid changes in) the average life expectancy, physical development indices, higher nervous activity state, work capacity, behavior, reproductive function, capacity for adequate adaptation to the environment, biochemical and functional human constants.

2. Types of standards

An additional question is one or two tier standards. The conception in EEC for developing standards is to use two types of exposure: occupational and environmental (for the general population). There is, also, discussion about the possibility to separate an additional exposed group – non-occupational exposure using different safety factor settled between those for the occupational and for the environmental exposure. The exposure of the general population also is divided into exposure at home (in dwellings), outside the buildings (living area), and at places where temporary exposure may occur (agricultural lands, parks and gardens, places for recreation, etc.).

One different example is the approach used in the Polish standards. Three zones have been introduced to evaluate exposure of different people: dangerous, intermediate, and safety zones. The maximal admissible levels of exposure (similar to the TLVs) are applied for the dangerous and intermediate zones, the first one for short time exposure, the second - for longer time (more than 2 hours). The Czech standard also is dealing with different duration of exposure – short time, middle time intervals, and long-term, also applicable for different part of the population. The Russian,

Bulgarian standards for occupational exposure, are developed for limits used for every exposure duration. In the latter, time (and the energy) can be calculated using equations discussed below.

One approach is common for most standards – TLVs exist for every type of exposure, MPEs should be calculated depending on duration of the exposure.

3. Methods for developing standards.

I think, this will be strange for more of you but that is the philosophy of thinking of more of the Eastern European scientists working in the field of developing exposure limits. Here, I would like to present you now the publication of Prof. Savin from the Institute of Occupational Health in Moscow, used as a philosophy in most Eastern European countries for hygienic standardization [5]. Following this paper, the following changes have to be taken into account when assessing the exposure:

1. Qualitative changes in the course of biological processes.
2. Quantitative changes in the state of biological processes out of the physiological standard levels and resulting in the decrease of human compensation capacity to respond to environmental hazards or to overcome unusual psycho-physiological conditions.
3. Occurrence of additive effects of exposure with cumulative characteristics, leading at long term exposure to changes in the biological processes exceeding the permissible quantitative indices.

The following classification of the thresholds of electromagnetic radiation exposure by biological indicators is given in the same publication:

5	Zone of harmful exposure
4	Zone of extreme effects
	Adverse effect threshold
3	Zone of adaptive response
2	Indifferent zone
	Threshold of radio wave sensibility (biological effect)
1	Below threshold-level

According to the publication of Prof. A.G.Subbota [7], which is also widely used for the hygienic standardization in Eastern Europe, the most informative indices for radio frequency injury are:

a. disorders of the CNS;

b. suppressed interchange of gases;

c. functional disorders of gastric secretion (signs of gastritis);

d. marked functional disorders of cardiovascular system (dyastonia, ECG changes);

e. long term functional changes and changes in the blood element composition;

f. marked decrease of human resistance to infections and other environmental factors (heat, cold and others);

g. constant metabolic disorders;

h. continuous hormonal functional disorders (menstrual disorders, changes in the fertility and offspring indices).

Structural changes in human system, such as cataract, epithelial degeneration of testicles, ulcer etc. should be considered as obvious indices.

Similar philosophy was used in standardization from Prof. Shandala (Kiev), Prof. Paltzev (Moscow), and from some East European researchers. Only the definitions of the adverse effect (the MPE level) are on different level on the scale presented above. [2]

The TLVs and the MPE levels for electromagnetic (EM) exposure in most of the EEC standards have been developed on the basis of a complex of methods: hygienic, clinical-physiological, epidemiological and experimental methods.

A short description and cause of using these methods are:

- hygienic methods: to evaluate the parameters of the exposure, including the duration of the exposure;
- clinical-physiological methods: to evaluate clear manifested harmful effects and changes in the physiological functions;
- epidemiological methods: to establish the future (secondary) effects;
- experimental methods: to study the biological effects of the EM radiation.

Different experimental methods are the main ones for developing limits because of the non-specific functional and pathological changes in the organism.

Hygienic methods include two groups of methods for exposure assessment – exposure measurements and dosimetry. The exposure assessment can be made using the following:

spot methods - based on single measurements of the incident EMF parameters at the assessed work place or at men's residences;

dosimetric methods - they comprise personal dosimetry during the work shift, evaluation of the time duration for an individual or for a group with homogeneous exposure, direct dose measurements, etc. Direct dosimetry includes methods for assessment of the energetic loading of the organism, induced currents, whole-body or localized SAR, etc.

Prof. Paltsev in [2] speaks, also, about three different zones of biological reactions of the organism:

- biological effects;
- a progress of adaptive and cumulative processes as a manifestation of adverse effects on the systems;
- pathology.

The exposure limit for adverse effect should be the border dividing the zones of active adaptation and pathology.

When the absorbed energy is considered, different methodology for studying the exposure limits of EMF exposure is used in dependence on the wavelength:

- with a wavelength essentially exceeding the size of the biological object – frequency up to 30 MHz;
- with a wavelength much less than the size of the body;
- with a wavelength commensurable with the size of the body or with the sizes of different parts or organs – frequency between 30 MHz up to 10 GHz and above.

The exposure limits for adverse effect evaluated on the basis of extrapolation and by numerical methods of calculating the induction currents/absorbed energy in phantoms are a better approximation than the direct transfer of data from animals to human body. The uncertainty of such extrapolations could reach to 50-100%, while for animal extrapolation it reaches 1-2 orders. [3]

What does non-thermal effect mean? It exists when whole body temperature rise is not observed. The heat distribution could be non-uniform, and “hot spots” could be available in field strengths below those causing thermal effect.

The interaction mechanisms of the EMF exposure of biological tissues have essential meaning for evaluation of exposure limits. Fundamental manifestation of such interaction is the heating of the tissue.

4. Safety factors

Now, short debate regarding safety factors (coefficients of hygienic reserve, as the term is in the EEC). Historically, and as the most used value of the safety factor, is 1:10. In the EEC there were ideas for the low frequency ranges where the electric and the magnetic field strengths have to be evaluated separately, a factor of $\sqrt{10} \approx 3$ was proposed for exposure limit to every field. When simultaneous exposure of the two field components E and H is available, an additional coefficient of $\sqrt{2}$ had to be multiplied with the first one. The final safety factor for exposure limits for frequency up to 300 MHz becomes about 5.

In most of the Eastern European standards, the safety factors are 1:10 for occupational exposure, and 1:50 for the general population. For non-occupational exposure (occupational exposure in working area, but for people not engaged with EMF sources), the discussion is whether a safety factor of 1:20 to 1:50 to be applied.

Little is being done on combined effects of EMF and various other physical, chemical and other hazards of the environment. There are few standards (Russia, Bulgaria) where attention on combined effects of EMF and ionizing radiation or hyperthermal conditions has been taken into account using an additional safety factor of 1:10.

5. The "dose approach" in standardization

The "dose approach" – "the energetic loading of exposure" is the most often used term in the EEC standards. Historically, it was accepted in the late 60-s and the early 70-s in some EEC – Poland, Czechoslovakia, the Soviet Union. This approach comprises to evaluate together the measured values of EMF – field strengths (electric E, and magnetic H), power density S, with the duration of exposure T in hours or in minutes. The energetic loading values are defined as $E^2.T$, $H^2.T$ or S.T, and they are in direct proportion to the incidental electromagnetic energy. If the angle of the incidental energy to the long axis of the human body, and its section area would be taken into account, it is possible to connect these values with the whole body or local SARs.

Prof. Savin in 1979 [6] discusses the basis of the dose approach: the MPE has similar to hyperbolic dependence to the duration of the exposure. In the same guide Subbota and Tchuchlovin [8] give a simple equation for dose evaluation:

$T = \frac{W}{kP}$, where T is the duration, in min; P is the power density measured; k is a coefficient related to other exposure characteristics (efficiency); W is the incidental energy density.

Fig. 1. Dose-effect relationship.

The dose approach gives the possible exposures to different sources of radiation to be added for persons working in several workplaces, for persons exposed to different frequencies and field strengths, or for different exposure duration (for instance - 24 hours). Most of the Eastern European standards describe methods for summing the exposures.

Here, it is presented a figure from Kudrashov et al. [1] shown a type of dose-effect relationship dividing the thermal from non-thermal effects (Fig. 1).

Many countries have their own standards (or parts of standards) dealing with intermittent or pulse electromagnetic radiation. The rationales of most of them are the data of studies having shown higher biological activity to exposure to pulse radiation than to continuous waves. Some of the standards introduce special types of radiation depending on the sources: rotating, scanning antennae. Most of the evaluations are made on the basis of the existing sources of radiation, not only on biological evidence.

III. CONSIDERATIONS FOR STANDARDS HARMONIZATION

Now, let go to standard harmonization.

I will not discuss now the way for such a process. We will do this on many meetings and joint projects between specialists from different countries and schools. Now we are going step by step to this framework that WHO Project gives us the possibility to develop.

The first step to harmonization is to change the approaches for developing exposure limits. Because of political reasons insufficient emphasis is placed yet on the requirement that the exposure limits should not be an obstacle to scientific-technical development and implementation of new technologies. The hygienic science is regarded as a social science and although there is no centralized financing of medicine any more, the political and historical heritage does not permit the thinking to turn to new approaches to norms.

Yet globally the environmental exposure is distinguished from occupational exposure. It is time to consider the approach for assessment the physical factors for 24-hour exposure, to proposed by the European Union Directive for Physical Agents, in 1992 [4] There, the overall strategy is founded on the obligation to reduce the hazards to the lowest attainable level. This strategy defines three hazard zones:

1. Black zone (banned) – for EMF it must be the forbidden zone where whole body SAR is above 0,4 W/kg;
2. Grey zone – where EMF have to be monitored or where precautionary approach have to be applied;
3. The White zone – safe zone where general population can be exposed to EMF up to 0,08 W/kg.

The top border of the white zone is the threshold level where exists a probability for adverse effect if human body staying without any protection or for a long time. Below it people can live safely without any harmful effects. The upper boundary of the gray zone where is the beginning of the black one, is the threshold limit value for occupational exposure.

This will lead to a more precise assessment of biological effects as, particularly for EMF often the outdoor and home radiation values are higher (or the duration is longer) than occupational values.

Standard harmonization is possible if we settle the differences in:

a) Terminology;
b) Measurement and exposure assessment;
c) Dosimetry;
d) Standard protocols for hygienic and biological investigations;
e) Criteria for developing exposure limits;
f) Methods (as a complex) for different type of biological research;
g) Philosophy of limits, etc.

To get this aim (standard harmonization) we propose the following activities:

- to organize a working groups for discussing terminology, different criteria of standards; criteria for evaluating established health effects, uncertainty factors, etc.;
- find a common viewpoints and tangents between different criteria of standards and to use it for an international proposal in future. That is the reason to discuss the problems of measuring, exposure assessment and dosimetry as parts of setting terminology, methodology and criteria;
- to create expert groups in different topics of standardization which can work in workshops, meetings, by Internet also;
- to organize meetings for discussing the socially-responsible standards and approaches, industrial concerns, scientific evidence, safety factors, non-thermal and long term effects; political pressure; demagogic principles, economical situation and standard development process;
- to support new research studies which can find some decisions connected with criteria for standardization and for exposure limits;
- to review a part of the Russian and other literature in Slavonic languages connected especially with philosophy, rationale and criteria for creating RF standards; some significant studies to be replicated in other countries;
- find more specialists from the East to be involved in the process of an international harmonization of standards.

Most of these issues we are going to discuss here, at the meeting in Bulgaria.. We hope this process can be shortened if we all have agreement with such activities, also between different scientists in the world.

Here, we want to present an example (in Appendix 1) showing how to reach the space (orthogonal, 3-dimentional) where the same or similar approaches are used from the two discussed school of standardization.

IV. CONCLUSION

In conclusion I would like to mention that the Eastern European countries have introduced EMF norms in the early 60s. The results of the studies have been discussed annually at workshops and meetings of specialists from the different countries. Often norms have been elaborated through joint projects involving two and more countries.

The applied methodology in eastern countries has its shortcomings. First of all, ranging medical indicators and those of changes in organs and systems of the organism first hides the comprehensive mechanisms of EMF interaction with tissues and cells, although the knowledge of interaction mechanisms cannot always lead to correct development of regulations. Nevertheless, essentially most regulations in these countries are based not only on short-term and thermal effects, but also on long-term and non thermal effects, which should be the basis for setting norms globally as well. This is the only way to help persons with the so-called “hypersensitivity” which phenomenon could prove to be very serious for future generations. In fact there is a tendency for consideration of long-term effects in the West standards (example IEEE/ANSI).

Finally, we are scientists and expressions like “there is no animal of the kind” are not serious. That is why we should not accept categorically the statements of some scientists:

- we do not believe in long-term effects;
- SAR is the only a quantity which enables us to determine the effects of exposure to RF/MW radiation;
- only the thermal effects are reliable at electromagnetic impact;
- we don’t believe in relationship between EMF and cancer;
- epidemiological studies nowadays are not serious, etc.

Instead of using categorical expressions for negation or confirmation of our theses, we would better seek a way to understanding between different standardization schools. We have now the possibility to do this because of the new global political situation, and the EMF Project is the opportunity to think positive on this process.

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Appendix 1

Example

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Let us illustrate a harmonization of biological criteria with an example related to marked thermal effects, visible on Fig. 1 [1].

Let us consider a case of EMF effect when thermal release exceeds the organism abilities to provide thermal comfort (area of S-like increase of the effect in the "dose-effect" curve).

In this case it is possible to show that the development of thermal effects towards growing intensities of EMF (S.t ≥10 mW.h/cm^2) is with substantial dispersion about and below the limit 100% (MPE), and has several alternatives for recognizing the next state of the organism: most often an indefiniteness is reached, which can be revealed only through selected additional experiments. Further, in semi-quantitative evaluations and in "dose-effect" terms the difference between standardizing is up to 10 W/m^2 (1 mW/cm^2) and the reaction at higher values can be expressed as protective, described through parameters or in destructive changes. If it is described analytically, the expression will be similar to that for a sea wave breaking against a low beach (Fig. 2).

What should the adopted philosophy be, so that it would be suitable for further global harmonization?

Standardization philosophy leads to the necessity of unity in the diversity and to equity in the variety. Such convergence type provides to the globalized community united civilization and technologies. Unfortunately we are not yet ready for hygienic standardization conforming to national and regional, race-specific biological features. As already mentioned, the initial difference of 1000 times by maximal admissible level between Eastern and Western standards decreases but at present this is not an intentionally controlled process. The East proceeds from very weak exposures with slow effect accumulation towards intensified exposures with increasing effects still staying within the frames of the concept for specific non-thermal EMF effect. Western hygienic standards lately evolve following the opposite direction.

On the other hand more and more teams developing standards "move" from short-term to long-term exposures and the discussed East European standards comprise also short-term evaluations at least as a design.

Fig. 2. Sea waves breaking.

It seems that there is a possibility to cover the hygienic measurement data with two phase spaces, where the hygienic evaluations would be quantitatively comparable. Those two coordinate systems could have a common origin as the bases used by both East and West for biological background of the indicators which turn into “health zone” parameters, described by the hygienic standard are practically the same. In the field of dose assessments this is a scale issue: dose values are graded into intervals by intensity and exposure duration. For example, depending on the interval dimension, it contains distinguished or united elements. For harmonization purposes we can replace the uniting of elements from such a set with summing by “general quality” index – exposure degree or intensity. The latter is a sum by qualitative or quantitative characteristics. Let us assume the “quality intensity” (“effect depth”) to lie within the whole interval of variables (e.g. energy index of exposure). Let us as well limit the set “dose-effect” only to a signal from falling EMF irradiating the measuring device at a distance of “R” (where the exposed individual works or resides) and the re-irradiated EMF from the area borders through which the power density is determined by effective values. Let the argument be the signal amplitude – effective intensity of total radiation – a function of the “reverse distance”, $1/\sqrt{(\lambda R)}$, where λ is the wavelength. Our previous studies [a poster in San Antonio, Dec.2000] show that this amplitude has a resolution in (conditional) real and imaginary components; for 80% of the possible amplitudes in the interval λ from 0.0073 to 1500 m [9], the components are positive, i.e. their imaging points in the “dose-effect” space fall in one octant. These points gather on their three coordinates in subclusters with different magnitude and density, clouds of hierarchical order with negative index (Fig. 3).

Fig. 3. The “dose-effect” space.

Let us select a projection in Hilbert or at least Hausdorf space, in which the generalized indefiniteness principle in a subspace or evolute of the basic (vector, interval) space is valid. Depending on the differentiation of the initial points in the projected group as a function of the exposure intensity m, the selected summing by unlimited number of elements (eventually of all recognized points) provides an infinite row, which sum can be presented by Bessel functions of I type and “m” order [10, 11]. We receive a function of differentiation of magnitudes of electromagnetic impacts with close values of S[$\mu W/cm^2$]. Because of the difference in the argument magnitude, which is the hygienic limit itself for two types of standards based on thermal effect and another type respectively on specific, these Bessel functions have resolutions by differently presented arguments. The latter means that the threshold doses (those that should be adopted as hygienic norms) fall into different intervals of measured power density (S). In these intervals the exposure intensity as a quantity is a solution of different differential equations. For them it is characteristic that the integration is not random but on precisely defined borders – the intensities could not be randomly selected. If we use the energetic doses for comparison, each pair of biological indicators, for which we would pursue approximation and harmonization of the two groups of hygienic standards of the East and the West, the difference between them would represent the length of a segment, for which it is the easiest to use quadratic form of impact intensity.

The selected example illustrates the following internal requirement of the standard harmonization procedure:

a) specialized studies selection, which should not be trivial or random but with strictly harmonizable characteristics – standard measurement, dosimetry and study protocols; pre-set group of biological indicators;

b) all standards should involve a parameter of the type energetic parameter of electric or magnetic field or of the energetic loading of the organism, i.e. quantity of absorbed energy per kg or g tissue live weight;

c) approach (philosophy)

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