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HARMONIZATION OF SAFETY NORMS FOR DIFFERENT SPHERES OF HUMAN ACTIVITY

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The article develops a harmonized approach to regulating safety in different spheres of human activity based on risk analysis. We suggest two stages of harmonization: at the first stage, it is necessary to prepare the scientific basis for the harmonization of hygienic norms for different spheres of human activity. The next stage consists in the harmonization of safety norms and other hygienic standards of different countries. On the basis of this approach, we put forward: 1) general universal safety norms for professional workers and for the population; 2) key safety norms and other levels of safety-related levels of decision making for a number of modern controlled sources of negative impact basing on the universal safety norms.

Key words: *Risk assessment, risk index, methodology, safety norm, harmonization, decision making principle.*

For decades, along with their technologies, traditional industries have been developing and improving sectoral safety systems for both their personnel and the population in general. For instance, the nuclear industry established the norms of radiation safety back in the 1920s and is constantly improving them. The present-day radiation safety standards are by two orders of magnitude more stringent than the original norms.

The improvement of safety systems in different spheres of human activity is still highly relevant and should be continued. This is explained by the fact that up until now, for different sources of harmful impact, safety norms (SN) and other safety-related decision making levels have been adopted on the basis of heterogeneous approaches and different risk or exposure indices. Those indices are hardly if at all comparable with each other. In this situation it is hard to expect them to be optimal. As for the recently developed spheres of human activity (e.g. the application of nanomaterials), the issue of safety is still under development.

One of the main recommendations of national and international environmental groups and safety organizations is to harmonize regulatory acts in these spheres [3]. The lack of such harmonization, which is observed even now, is a serious obstacle for the development of international cooperation and trade [4].

Our approach to such harmonization consists of two stages. First, it is necessary to prepare the scientific ground for SN harmonization between different spheres of human activity, bridging the existing gaps. The second stage presupposes international

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harmonization of safety norms and other safety decision making levels between different countries. In this approach, the first stage may serve as a scientific ground for international harmonization.

Materials and methods. Types of situations and categories of the impact of risk sources

To further develop the decision making system based on risk assessment, it is practical to identify three types of impact situations:

· Planned impact situation, when a new source of impact is installed and put in operation, or a new potentially hazardous material is about to be used in production or released for household use;

· Emergency impact situation, which may follow the planned impact situation due to a breakdown, sabotage or another unexpected occurrence, e.g. a natural phenomenon (earthquake, volcano eruption, a major forest (peat-bog) fire, etc.).

· Current impact situations including the existing sources of impact which should be taken under control (car exhaust fumes, coal and gas electric power station emissions containing pollutants, etc.).

Furthermore, it is necessary to distinguish between professional impacts of risk sources and the impact on the population.

Key principles of safety control. The key principle of establishing safety norms for any controlled source of adverse impact is formulated as follows: preventing deterministic effects and limiting stochastic effects to achieve a sufficiently low, or acceptable, level of risk.

The safety norms preventing deterministic effects are based on the findings of toxicity studies. Such studies define the threshold for the impact of harmful substances (deterministic effect threshold), and the value of safety norms is set below this threshold.

The safety norm established on the basis of risk assessment refer to the limitation of stochastic effects. This concerns the so-called involuntary risk, i.e. the risk coming from a source of impact to which people are related to as 'third persons' and from which they do not get any benefit or advantage. As for the personnel of hazardous production facilities, their professional risk may also not be considered as voluntary. For the personnel, the risk levels are set at a higher level than that for the population, and they usually receive some kind of compensation for the higher risk.

Here we do not consider the voluntary risk such as the risk of the usage of cars. Neither do we consider the potential risks of medical procedures that apply, for example, sources of ionizing radiation or medical procedures intended for obtaining a therapeutic or diagnostic effect.

In order to make decisions on human safety on the basis of risk analysis, it is necessary to establish an appropriate system of risk levels and of levels of decision making. Apart from the basic and derivative safety norms, this system includes different kinds of reference levels, levels of negligible risk (*de minimus*), levels of intervention in case of emergency, etc.

According to the accepted practice in different spheres of human activities, safety norms are established on the basis of gender and age averaged risk indices, since specific safety norms for different groups of the population would lead to a significant complication of the safety system.

To achieve harmonization, it is necessary to adopt a common approach to establishing safety norms. These are the key conceptual conditions of this approach:

1. It is necessary to develop a general methodology of risk assessment which can lay the basis of the development and justification of specific methods (for ionizing radiation, harmful chemical substances, nanomaterials and other specific sources of harm).

2. It is necessary to adopt unified and universal safety norms, which, in turn, serve as the basis for specific (sectoral) safety norms for particular sources of harm, with those risk or impact indices that are, or will be in future, used in practice (as a rule, for each source of impact its own set of indices is used). For this purpose, the most appropriate risk index is se-

lected. Following the accepted practice, safety norms are adopted on the basis of gender and age average.

At hazardous production facilities, additional working regulations may be adopted for specific critical groups of people (e.g. pregnant women).

The procedure of adopting safety norms on a unified basis of risk assessment that we propose looks as follows. At its core, there are basic universal safety norms for the personnel of hazardous production facilities and for the population. Those are common for all controlled hazards, including cases of their joint impact.

On this basis, basic sectoral safety norms are developed for individual sources of harm. They are expressed in those indices (specific risk indices or exposure dose indices), which are at present widely used in practice or will be selected for practical application or upon the revision of the current indices for other sources of harm. For instance, for industrial safety, the risk index is the probability of death (heavy injury) per annum resulting from an occupational accident.

On the next level, there are the derivative safety norms which local sanitary and hygienic authorities or departments need to control: the level of impact, environment pollution or the contamination of consumer goods (atmosphere, water, ground, production premises, foodstuffs, etc.). These safety norms are expressed in indices that can be easily measured and controlled by the available means. As a rule, these indices correspond to the maximum one-time and daily average concentration of the harmful substance in question.

Selection of the risk index. The currently used safety norms in different spheres of human activity are developed on the basis of different approaches using different indices of harmful impact or risk, and are hard to compare with each other. For instance, the Radiation Standards (RS) use indices specific for the impact of ionising radiation (effective exposure and its global average risk indices). These indices are specific for radiation risk, so its standards cannot be directly correlated with safety norms in other spheres [1,2].

Chemical safety standards, as a rule, are still adopted in terms of maximum permissible concentration in the atmosphere or in water on the basis of toxicity approach and the threshold dependence between exposure and effect.

To protect the population and the workers of hazardous production facilities, some organizations have adopted safety norms (risk limits) in terms of individual intensity of death risk (annual probability of death) r. Obviously, such standards and such risk index cannot be used for risk sources with a delayed presentation of adverse health effects, e.g. for ionizing radiation or chemical contaminants with potential oncogenic and/or genetic effects. For instance, due to the lengthy latent period of radiogenic solid cancer (lasting from 5-10 to 30-50 years), the average number of disease-adjusted life years per one case of radiogenic lethal cancer $L^{l.c.}$ is by far lower than the average loss of life years in case of immediate death $L^{i.d.}$ as a result of an accident. The same can be said about chemical oncogenesis.

According to the estimation of the International Commission on Radiological Protection (ICRP) [1], the average global value of $L_{av}^{l.c.}$ is 15 years, $L^{i.d.}_{av.}$ is 35 years, and this value for the population of Russia $L^{i.d.}_{av.}$ is 35-40 years. The number of the lost life years $L^{i.d.}$ for any particular country can be easily calculated using the available means of risk assessment.

Therefore, cases of death caused by different risk sources can cause different degrees of loss expressed in lost life years, i.e. they are not, in fact, equivalent. For this reason, we cannot accept as sound the adoption of safety norms for different sources of harm in terms of death risk, or the comparison of death probability indices, or the number of deaths.

To establish the unified universal safety norms and other decision making levels on the common basis of risk assessment, the most appropriate risk index is the special risk index $\hat{A}$. Conceptually, it is calculated as the product of the intensity of exposure (dose) d to a chronic (continuous) impact (in its general definition) or, in other words, average annual exposure to the source of impact in question, and loss g_D (lost year of healthy life) of the exposure unit *D*.

Let us assume that there exists a continuous (chronic) impact of a harm source with exposure rate d(e), where e is the current age. Then, the relative annual damage Â (e) at the age of e is equal to

$$\hat{A}(e) = d(e) \cdot g_D(e), \quad (1)$$

where $g_D(e)$ is the loss caused by an exposure unit; it is calculated for a single exposure dose received at the age of *e* [5-7]. The dimensions of quantities *d* and g_D are respectively [[exposure]/year] and [year/[exposure]], where the dimension (dose) of the exposure is calculated for each specific source of impact. Here we use the general notion of 'exposure' as the degree of impact of each controlled risk source in question.

The risk index Â has the dimension of [year/year] (a lost year of healthy life related to a year of exposure to the source of risk). In the statistically average sense, Â is the part of this year that is lost as a result of a year-long exposure to the risk source in question, i.e. Â may be considered as ***relative loss***. In reality, the loss of healthy life years is subsequent to this exposure. Considering this, Â may be conventionally considered a non-dimensional value (a proportion of the year).

Using a mathematical probabilistic definition, Â is the expected value of loss expressed in the number of lost years of healthy life of the annual exposure to risk source.

Risk index Â*(e)* is the most convenient index for comparing and controlling risks. It describes the full loss in lost life years of annual exposure to a risk source, and has additive property. No other risk index has this property. Apart from age ***e***, it can depend on gender or other factors. To adopt safety norms and other decision making levels, the value of risk index Â*(e)* is averaged over gender and age.

Key universal safety norms. We propose adopting the following values of $\hat{A}_n$ as basic universal safety norms to limit the chronic impact of controlled risk factors:

$$\hat{A}_n = \begin{cases} 0.006 \text{ for professional workers,} \\ 0.0004 \text{ for the population.} \end{cases}$$

These values were chosen so as to correspond to the present-day radiation safety norms for the normal operation of production facilities or for sources of ionizing radiation. Experience shows that these norms provide for a rather high level of human health protection for individuals who work with sources of ionizing radiation in their normal mode. Besides, the sphere of radiation safety has the most detailed coverage of the use of risk assessment for the adoption and justification of SN.

Universal level of negligible risk *(de minimus).* We suggest adopting the level of $\hat{A}_{d.m.}$ equal to

$$\hat{A}_{d.m.} = 10^{-5}. \quad (3)$$

Key sectoral safety norms. The transition from the basic universal safety to basic sectoral safety norms for specific sources of harmful impact can be achieved by this simple formula

$$d_n = \hat{A}_n / gD, \quad (4)$$

where d_n is a general denotation of basic sectoral safety norms expressed in corresponding units of exposure and calculated through the basic universal safety norm $\hat{A}_n$. Below we specify quantities g_D and d_n for several controlled sources of harmful impact.

Here and elsewhere, the term 'sectoral' refers to a single specific factor; in the case of hazardous chemicals it refers to a specific substance for which it is necessary to define individual norms.

Basic radiation safety norms. For ionizing radiation, we use D_p, the exposure dose of this radiation, as the degree of its impact on human health (absorbed, equivalent or effective dose, depending on the sphere of application). For this risk source, $\hat{A}$ is calculated as

$$\hat{A} = dp \times gp. \qquad (5)$$

In the expression (5), in accordance with the modern radiation regulation practice, we should use the effective exposure dose and its coefficients [1]:

$$dp = d_E,\ gp = g_E, \qquad (6)$$

where d_E is the rate of the effective dose (effective dose per annum), g_E is the well-known average coefficient of risk for ionizing radiation, which was changed slightly in the latest ICRP recommendations [1]:

$$g_E = \begin{cases} 0.6 \text{ year/Sv for professional exposure,} \\ 0.8 \text{ year/Sv for the population.} \end{cases} \qquad (7)$$

This coefficient already factors in all effects of ionizing radiation exposure, such as lethal and nonlethal cancer, and genetic diseases.

By using expressions (6) and (7), and taking into account the fact that the norms in effective exposure dose indices restrict radiation risk somewhat more stringently than the risk expressed in the coefficients of the risk of effective dose (with a reserve of approximately 2) [1], we obtain the currently used basic radiation safety norms in the form of maximum permissible effective dose $d_{E,n}$:

$$d_{E,n} \approx \begin{cases} 20 \text{ mSv/year for professional exposure,} \\ 1 \text{ mSv/year/ for the population.} \end{cases} \qquad (8)$$

This result could have been expected, as the values of basic universal safety norms were selected to correspond to modern radiation safety norms.

Basic industrial safety norms (limitation of the risk of death/injuries caused by occupational accidents)

For a risk source of immediate impact (industrial accidents that may present a hazard to the personnel and the public at large), the generally accepted quantity used as the exposure rate is risk intensity r (the probability of death (heavy injury) per annum). For such source of risk, the expression for risk $\hat{A}$ is as follows:

$$\hat{A} = r \times g_r, \qquad (9)$$

where $g_D \equiv g_r$ is the healthy life years lost as a result of an accident. The age average value of $g_r^{av.}$ is equal to 30 and 40 years for the personnel and the population, respectively. From the general definition of the sectoral SN (4) we get

$$d_n \equiv r_n = \begin{cases} 2.0 \cdot 10^{-4}\text{/year for professional exposure,} \\ 1.0 \cdot 10^{-5}\text{/year for individual members of the public.} \end{cases} \qquad (10)$$

Sectoral safety norms for hazardous chemicals. As a rule, the norm for the exposure-effect dependence for chemical atmosphere pollutants is set against the exposure ε_x, a time integral (total) of the concentration of this pollutant C_x in the atmosphere $\varepsilon_x = \int C_x\,dt$. Its dimension is [year*mkg/m^3)]. The annual exposure (or rate of exposure) e_x is calculated through exposure ε_x for the time period Δt using the formula $e_x = \varepsilon_x/\Delta t$, *and* has the dimension of [year*mkg/m3/year], i.e. its dimension corresponds to the dimension of the average annual concentration of the pollutant in the atmosphere. With this measure of the impact of the chemical pollutant, the expression for $\Re$ index is written as follows:

$$\Re = ex \cdot gx, \qquad (11)$$

The currently used basic safety norms for specific hazardous chemicals are based mainly on the findings of toxicity studies. The application of risk analysis for the improvement of chemical safety norms is under development and it is moving toward the harmonization of these norms [3]. Important examples of calculated values of loss L (lost life years) for chemical atmosphere pollutants can be found in the literature. Here, in order to demonstrate the application of $\Re$ for the regulation of chemical exposure risk, we consider only fine aerosols $PM_{2.5}$ (with the diameter of particles of 2.5 μm or less) emitted by industrial sources. Basing on the data set forth in paper [8], we can calculate that for $PM_{2.5}$ the mean value of coefficient $g_D \equiv g_x$ is equal to

$$g_x = \begin{cases} 0.0004 \text{ years/(year}\cdot\mu\text{m/m}^3\text{) for professional workers } (PM_{2.5}), \\ 0.0005 \text{ years/(year}\cdot\mu\text{m/m}^3\text{) for the population } (PM2.5). \end{cases} \qquad (12)$$

According to the general definition of the

$$d_n \equiv c_n(PM_{2.5}) \approx \begin{cases} 15\ \mu\text{m/m}^3 \text{ for professional workers,} \\ 1.0\ \mu\text{g/m}^3 \text{ for the population.} \end{cases} \qquad (13)$$

of the average annual concentration of this atmosphere pollutant:

Sectoral levels of negligible risk. Basing on the universal definition of this level by the formula (3), it is easy to calculate the sectoral levels of negligible risk. This can be done by following the same procedure as for sectoral SN, i.e. by calculating them by the formula $d_{d.m.} = \Re_{d.m.} / g_D$. As a result we obtain:

$$d_{d.m.} \equiv \begin{cases} d_{E,d.m.} \approx 10 \text{ mcSv/year} & \text{(ionizing radiation),} \\ r_{d.m.} = 3\times10^{-7} \text{ / year} & \text{(accidents),} \\ c_{d.m.}(PM_{2.5}) = 0.02\ \mu\text{g/m}^3 & \text{(atmosphere pollution).} \end{cases} \qquad (14)$$

These sectoral levels of negligible risk are at the same risk level in terms of risk indicator $\Re$.

Complex safety regulation. In practice, there may be situations when the personnel of a production facility or some groups of population are exposed to the impact of two or more controlled sources of harm. This can be ionizing radiation and some hazardous chemicals, including nano-scale ones. In such situations, especially when each individual impact meets the sectoral safety norm, their aggregate impact may be rather intensive and exceed the set criteria for safety norms, it is necessary to impose additional restrictions on the impact of such sources.

When two or more controlled harm factors are involved, the safety-related decision making may be executed on the basis of the same key principles of decision making, including the unified approach to the adoption of safety norms.

The special risk index Â (see formula (1)) permits calculating the aggregate value of annual risk $Â_{å}$ for all active controlled sources of harm:

$$Â_{å} = å_i \, Â_i, \qquad (15)$$

$Â_i$ is the mean value of the special risk index of the ***i***-th source of harmful impact. Safety-related decision making is executed by adhering to the simple ratio

$$Â_{å} = å_i \, Â_i \, £ \, Â_n \qquad (16)$$

and is achieved by complex optimization of the impact rates of all sources of harmful impact in question conditioned on (16). A criterion of optimality is the minimal consolidated loss, which equals to the total cost of risk reduction and residual health damage expressed in economic measures. All active sources of harmful impact are included in the total.

To achieve an optimal rate of impact in practice, it is necessay to have risk assessment methodologies for each relevant source of harmful impact that permit calculating the necessary age- and gender-specific risk indices and then obtaining their mean values.

Conclusion. We have proposed a unified approach to the adoption of safety norms and other safety decision making levels using risk analysis in different spheres of human activity. On the basis of this approach, we have proposed unified universal safety norms for professional workers and for the population. Basing on such universal safety norms, we have derived basic safety norms and other safety-related decision making levels for cases of exposure to a number of currently existing controlled sources of negative impact.

We suggest using this unified approach in the framework of modern risk assessment methodology to harmonize decision making regulation. The key step in this unified approach is the development of proposals on universal safety norms and other safety-related decision making levels.

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