

PREVENTIVE MEDICINE: URGENT ASPECTS OF RISK ANALYSIS

Universal Decimal Classification (UDC) 614.3

ON THE DEVELOPMENT OF THE SYSTEM OF RISK-BASED SUPERVISION IN THE FIELD OF SANITARY AND EPIDEMIOLOGICAL WELFARE OF THE POPULATION AND CONSUMER PROTECTION

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In order to fulfill the legal requirements for the transition to the new risk-based model of the state control (supervision) in the Federal Service for Consumer Rights Protection and Human Welfare, the methodical approaches to the classification of economic entities and activities of potential risk of injury have been developed. The risk assessment takes into account the frequency of violations of sanitary legislation, the severity of the consequences of these violations for the health and extent of negative effects, which is estimated in terms of population under the influence of the economic entity. Algorithms and methods for calculating the exposed population: workers, consumers, including consumer food products, non-food products and services; residents of settlements under the negative impact of air pollution, water and soil, have been developed. Regional and federal registries of objects for sanitary and epidemiological supervision are formed.

Testing of the risk-based approaches in the regions allowed excluding the low risk harm objects when forming the audit plans for 2016, due to what the number of planned inspections all over country was reduces by more than 20%.

The basic directions of further improvement of the risk-based model of sanitary and epidemiological surveillance: its extension to the system of technical regulation and consumer protection; scientific substantiation of its volume, content and laboratory support of the scheduled inspections of objects belonging to different classes of health risk; improving procedures and methods for evaluating the effectiveness and efficiency of risk-based supervisory activities; creation of an effective system of risk communication between the sanitary and epidemiological surveillance, economic entities, public organizations and associations and civil society.

Key words: risk-based sanitary and epidemiological supervision, the population under exposure.

The Federal Law № 246-FZ signed by the RF President on July 13, 2015 makes significant amendments and changes to the Federal Law of December 26, 2008 № 294-FZ "On the Protection of Legal Entities' and Individual Entrepreneurs' Rights when Exercising State Control (Supervision) and Municipal Control". The new Law excludes small business enterprises from the scheduled inspections (exceptions apply); moreover, it introduces the new state control (supervision) model based on risk-oriented

approach. The Law requires that the risk-based approach when exercising state control (supervision) be implemented in the course of scheduled inspections starting 2018.

Rospotrebnadzor is the federal government agency that has developed and tested the scientific approaches to the risk-based model of the supervisory activity, and has taken a lot of organizational steps to foster its implementation [1].

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The guidelines on the classification of the objects of sanitary and epidemiological supervision by the potential health risks [5] – a document approved by the Decree № 1302 of 26.12.2014 – identifies four classes of risk to the economic entities – extremely high, high, average, and low.

Potential risk is determined with the help of the principals used all over the world by the federal supervisory authorities [2, 8-11]:

- health risk is developed as a result of the violation of the legal requirements to the sanitary and epidemiological well-being and customer rights protection;

- Violation of the legal requirements to the sanitary and epidemiological well-being and customer rights protection determines the probability of environmental, product and service safety degradation and related probability of damage to the health of the general public, employees, and consumers affected by the supervised entity;

- Assessment of the potential health risk is carried out in respect of a specific activity of the legal entity or individual entrepreneur; here, the class of hazard is assigned to the economic entity based on the most hazardous activity;

- The procedure and criteria used to assign a class of hazard (in terms of health risks) to the economic entity are uniform for all the legal entities and individual entrepreneurs regardless the type of economic activity and form of ownership;

- Company rating by class of hazard is the basis for scheduling inspections and supervisory activities. The frequency of scheduled inspections for the entities which do not present extremely high or high risk may vary even for the entities in the same class of hazard;

- Urgency and priority of inspections within the same class of hazard depend on the results of past supervisory activities concerning a specific organization including the results of laboratory studies. Consequently, the “degree of legitimacy” of an economic entity may influence the frequency of scheduled supervisory activities.

The class of hazard by potential health risk is viewed as a characteristic of the supervised entity established with the account for:

- Frequency of sanitary violations when carrying out a specific type of activity (determined as 95%-percentile of the frequency of violations per 1 inspection visit according to a 3-year review of the sanitary activities of all the RF constituent territories);

- Health effects which may result from the violation of the requirements;

Scale of negative consequences assessed by size of the population exposed to the activities of an economic entity (1).

$$R_j = p_{kj} u_{ij} N_{kj}, \quad (1)$$

where R_j – health risk from j -th activity p_{kj} – probability of a sanitary violation under the k -th article of the j -th type of activity of the sanitary law; u_i – harm associated with the i -th violation of law; N_{kj} – size of the population under exposure to the consequences of the law violation under the k -th article of the j -th type of activity. The risk for the LE (legal entities) and IE (individual entrepreneurs) concerning the j -th type of activity is calculated as the sum of risks from all the supervised entities of this economic entity.

The first two components (p and u) are defined based on the federal state statistics and mathematical modelling of the causal relationship in “law violation – health indicators”; they characterize a specific economic activity, and are shared by the entities involved in this type of activity.

The third component (N) is unique to the object; it characterizes the scale of its impact and contributes significantly to the potential level of risk. For example, if the violations of mandatory requirements to the microbial or chemical composition of drinking water are the same, the source of water that feeds a settlement with a population of 1 million people forms a substantially larger population risk than the source that feeds 10 thousand people.

In order to correctly assess the population under exposure, we developed and tested the guidelines which define the procedures and methods for calculating the number of people under exposure:

- Employees of enterprises and organizations;
- Customers, including consumers of food, non-food products and services;
- Residents of settlements impacted by air pollution, water bodies, soil.

The challenge in defining the population under exposure is selecting the indicators which, with a certain degree of generalization, without unnecessary details, but consistently and reasonably, will be able to define the exposed population:

We proposed the following:

- calculate the number of employees, including those working in hazardous and dangerous working conditions, using the data provided by the

economic entities themselves, or taking into account the average of the number of employees in hazardous working conditions

- determine the number of customers using the data provided by the economic entities on the number of places at which the service is provided;

- determine the number of consumers of goods (food and non-food) based on the data on the volumes of produced or sold goods provided by the economic entities or from other data sources, or in accordance with the parameters of similar study targets.

- calculate the number of people in the area impacted by air pollution and soil contamination, based on the estimated size of the sanitary protection zone in accordance with Chapter VII of SanPiN 2.2.1 / 2.1.1.1200-03, as well as the density of the population in the area of the facility location. In the event of availability of results on the calculated dispersion of harmful impurities from the facilities in violation with the sanitary requirements for air quality, the population under exposure is defined as the number of people living in the area described by the outer contour line IMAC (taking into account the aggregate substances).

In the absence of the results of dispersion calculation, the number of people impacted by air pollution is defined according to the formula (1):

$$N = 3\pi r^2 \rho 10^{-6} + N_{\text{нцз}} = 9,42r^2 \rho 10^{-6} + N_{\text{нцз}} \quad (1)$$

where $\rho = 3,14$;

N – number of people impacted by air pollution, million;

r – size of the standard sanitary protection zone, m;

ρ – density of population, people/km²;

$N_{\text{спз}}$ – number of people residing in the sanitary protection zone, million people,

10^{-6} – conversion coefficient m² to km².

More precise calculation methods can still be used, for example, calculation of air pollution dispersion, calculation of waste blending-dilution and adding contamination to the water use line, etc. [3].

When calculating the number of people impacted by the facility under observation, it is important to account for the level of human contact with the hazardous factor (duration of contact, level of consumption per unit of time). We have developed an approach formalized in equations 2 and 3:

$$M = NT, \quad (2)$$

where M – a factor that describes the average annual number of people exposed to and the level of contact with the hazardous factor produced by the facility under supervision, million people; N – population (workers, consumers of goods and services, residents) exposed to the hazardous factor produced by the facility under supervision, million people; T – dimensionless coefficient that takes into account the average annual exposure time or the amount of consumption. The general formula to calculate the ratio, taking into account exposure time:

$$T = \frac{t_1}{24} \times \frac{t_2}{365}, \quad (3)$$

where t_1 – duration of human contact (employees, consumers residents) with a hazardous risk factor produced by the facility under supervision throughout the day, hour,

t_2 – number of days per year of the possible human contact (employees, customers, residents) with the hazardous risk factor produced by the facility under supervision, days.

The number of people exposed to water pollution is determined only for those facilities under supervision which have the sources of waste disposal, including water drains, into the water bodies used for drinking, domestic water supply, as well as for medical, health and recreational purposes.

For the economic entities (facilities under supervision) which have waste disposal and established standards of permissible waste, the number of people under exposure to water pollution is defined as:

a) upon availability of general-use water intake located downstream from the site of sewage, as the total population powered from this intake. It is necessary to take into account the population of all the water-use places to the line of wastewater dilution at the MAC level. The time of potential contact – twenty-four-seven.

б) upon unavailability of general-use water intake, it is necessary to take into account the number of people using the water body for the recreational purposes. The number of people is defined by the maximum capacity of the recreation zone. The time of potential contact – during the recreational season.

The coefficient that takes into account exposure time for the economic entities (facilities under supervision) that have waste disposal is

defined based on day-and-night presence throughout the year ($t_1=24$, $t_2=365$) and equals $T=1$.

The number of people exposed to soil pollution is calculated only for the entities that have a waste storage site and defined based on the size of the sanitary protection zone using the same method as for air pollution. The time of potential contact – twenty-four-seven.

We have prepared the reference material to facility the evaluation of the population exposed to hazardous factors in healthcare, education, recreation organization, entertainment, arts, sport, personal services, etc.

When implementing a risk-based model, it is important to develop regional and federal registers of legal entities and individual entrepreneurs involved in the activities that are subject to sanitary and epidemiological supervision and consumer rights protection [4].

Currently, the federal register contains information about more than 694.4 thousand legal entities and individual entrepreneurs, and 1.24 million economic entities subject to supervision and located in all the 85 RF territories. The register is “live”; it needs to be constantly updated, corrected, and improved. At the same time, the register is a unique database for a number of analytical conclusions and assessments.

In that way, implementation of the adopted approaches to classification of the entities under supervision based on the regional data in Irkutsk, Krasnoyarsk, and Perm regions has shown that grouping of the entities under supervision into 6 classes rather than into 4 classes as was suggested when the model was just being developed, makes differentiation of the entities based on potential health risks and determination of the frequency of scheduled inspections more flexible (Table 1) [6].

Table 1

Classification of the entities under supervision by potential health risk

Class of hazard	Characteristic of the health risk	Health risk	Scheduled inspections
class of hazard 1	Extremely high	$>1 \cdot 10^{-3}$	Ongoing (at least once every 6 months)
class of hazard 2	High	$10^{-4} < R \leq 1 \cdot 10^{-3}$	At least once every 2 years, but not more than once a year
class of hazard 3	Significant	$10^{-5} < R \leq 1 \cdot 10^{-4}$	At least once every 3 years, but not more than once a year
class of hazard 4	Average	$10^{-6} < R \leq 1 \cdot 10^{-5}$	Not more than once every 3 years
class of hazard 5	Moderate	$10^{-7} < R \leq 1 \cdot 10^{-6}$	Not more than once every 5 years
class of hazard 6	Low	$R < 10^{-7}$	Exempt from scheduled inspections

In full concordance with current law, the frequency of scheduled state inspections (supervisory activities) is decreasing from the upper-level risk category to the lower-level category.

The entities in the ‘extremely high’ class of hazard are subject to ongoing state sanitary and epidemiological control (inspection) which involves permanent presence of authorized officials on the site of the entity under supervision implement the activities aimed at preventing, identifying, and eliminating the violations of mandatory requirements to the economic activities at the facility.

The entities in the ‘high’ and ‘significant’ classes of hazard are subject to the maximum and minimum frequency of scheduled state sanitary and epidemiological activities (inspections).

The entities in the ‘average’ and ‘moderate’ classes of hazard are subject only to the maximum

frequency of scheduled state sanitary and epidemiological activities (inspections).

The entities in the ‘low’ class of hazard are exempt from the scheduled state sanitary and epidemiological activities (inspections).

The frequency of scheduled inspections for the entities in the 2nd and 3rd classes of hazard can be changes as follows:

- If as a result of on-site inspections for the past five years, the relative frequency of violations of sanitary legislation is lower than the average calculated for the same period, then the frequency of inspections is minimum,

- If as a result of on-site inspections for the past five years, the relative frequency of violations of sanitary legislation is higher than the average calculated for the same period, then the period between scheduled inspections is assigned with a minimum frequency;

Analysis of the potential health impact imposed by the economic entities in the 4 regions

helped us draw some interesting preliminary conclusions.

For example, comparison of the calculated potential health risks showed that among all the healthcare facilities (except for kids' health caps and dentist offices), the highest risk is associated with federal multi-field hospitals or federal

hospitals with an in-patient department (more than 1000 beds) servicing more than 80 thousand people per year (including the clinic visits) ($R > 10^3$) (табл. 2). Nevertheless, the healthcare facilities may be referred to the group of entities subject to ongoing supervision.

Table 2

Generalized classification of therapeutic and prophylactic institutions (85.11-85.14, except for children's sanatoria)*

Class of potential hazard	Description of the entity under supervision conducting the economic activity
class 1	Federal-level or regional-level multidisciplinary hospitals with inpatient units (more than 1000 beds), total population served – more than 80 thousand per year (including visits to clinics)
class 2	Multidisciplinary hospital with inpatient units (300 to 1000 beds) with a total population served from 10 to 80 thousand (including visits to clinics)
class 3	LPU without infectious and surgical units (less than 300 beds) with a total population served from 1000 to 10 thousand people
class 4	Healthcare institutions without infectious and surgical units with the total number of the population served at least 100 to 1000 thousands of people a year
class 5	Clinics and dispensaries without inpatient units with the total number of visits of less than 100 visits per year
class 6	none

* hereinafter - the resource analysis results Irkutsk, Lipetsk, and Omsk regions, Krasnoyarsk and Perm territories.

Multidisciplinary hospitals with inpatient care (300-1000 beds) servicing from 10 to 80 thousand people (including clinic visits) bear high health risks ($10^{-4} < R \leq 10^{-3}$). Medical institutions without infectious and surgical units, less than 300 beds capacity, servicing from one thousand to ten thousand people, present significant health risks. Similar facilities with a smaller service area (from

100 to 1000 people) are classified as 'average risk' facilities, etc.

Similar generalizations allowed determination of some parameters of industrial entities which differ by the level of risk and may be referred to different classes (Table 3); general education institutions (Table 4), food stores (Table 5), etc.

Table 3

Preliminary classification of industrial enterprises by the level of health risk

Class of potential hazard	Description of the entity under supervision conducting the economic activity
class 1	Industrial enterprises referred to class 1 according to the sanitary classification, located in the areas with a population density of over 200 people/km ² , own wastewater outlets and/or waste storage sties. Harmful and dangerous workplace conditions for employees
class 2	Industrial enterprises referred to class 1 according to the sanitary classification, located in the areas with a population density of over 200 people/km ² , own wastewater outlets and/or waste storage sties. Industrial enterprises referred to class 1 according to the sanitary classification, located in the areas with a population density of over 200 people/km ² , no own wastewater outlets and/or waste storage sties. Industrial enterprises referred to classes 2 and 3 according to the sanitary classification, located in the areas with a population density of over 200 people/km ² , own wastewater outlets and/or waste storage sties. Harmful and dangerous workplace conditions for employees
class 3	Industrial enterprises referred to classes 2 and 3 according to the sanitary classification, no own wastewater outlets and waste storage sites. Hazardous workplace conditions.
class 4	Industrial enterprises referred to class 4 according to the sanitary classification, no own wastewater outlets and waste storage sites. Hazardous workplace conditions.
class 5	Industrial enterprises referred to class 5 (sanitary protection zone does not exceed 50 m)
class 6	Industrial enterprises outside of residential areas, no hazardous workplace conditions

Table 4

Preliminary classification of secondary educational institutions by the level of health risk

Class of potential hazard	Description of the entity under supervision conducting the economic activity
class 1	none
class 2	General educational institution, more than 1500 students. General education institution, more than 1000 students на территориях с нарушением гигиенических требований к качеству питьевых вод и атмосферного воздуха
class 3	General educational institution, 500-1500 students
class 4	General educational institution, 50-500 students General educational institution, less than 50 students, имеющие собственные котельные и источники питьевого водоснабжения
class 5	General educational institution, less than 50 students
class 6	none

Table 5

Preliminary classification of food outlets, including beverages and tobacco products, by the level of health risk

I class	none
2 class	Trade in food products, beverages and tobacco, the size of population receiving the service - about 14 thousand a year or more. Have workshops on the preparation of semi-finished products.
3 class	Trade in food, beverages and tobacco, the size of population receiving the service - from 1 to 14 thousand people. Have workshops for the preparation of semi-finished products.
4 class	Trade in food, beverages and tobacco, the size of population receiving the service - from 500 to 1000 people
5 class	Trade in food, beverages and tobacco, the size of population receiving the service - from 100 to 500 people per year
6 class	Trade in food, beverages and tobacco, the size of population receiving the service - less than 100 people per year

It is noteworthy that the above results were obtained through the analysis of assessment conducted on the bases of limited data (we analyzed approximated 6 thousand legal entities and individual entrepreneurs, and 11 thousand facilities operated by them). Testing of the suggested approaches as exemplified by the complete federal register will probably make room for adjustments in the classification features of the entities from different classes by type of economic activity.

At the same time, the suggested methodological approaches and obtained classification results were used as recently as in 2015 by the regional offices of Rospotrebnadzor in order plan and schedule control-and-supervisory activities with the account for potential health risks [7].

The number of scheduled inspections countrywide has dropped by approximately 20%. Low-risk entities were exempted from planned supervision if in the previous three years they had not significantly violated the sanitary law. A reduction in scheduled inspections related mostly to the food outlets, transportation, food production,

city services, and public services. At the same time, the entities of extremely high, high, significant and average risk regardless the type of economic activity were included in the inspection plan in most regions.

A risk-based model used by Rospotrebnadzor is still developing. To improve it, it is necessary to:

- Consolidate the procedure for determining the class of hazard based on the produced health impact following its testing in all the regions of Russia;
- Identify based on the results of the supervisory activities the risks that need to be reduced and prevented for the purposes of sanitary and epidemiological wellbeing;
- Create a record-keeping system for the cases of personal injuries due to violations of the sanitary law;
- Develop a complete list of mandatory uniformly interpreted sanitary and epidemiological requirements to the current economic activities, buildings, facilities, installations, tec.;
- Scientifically validate and develop an administrative regulation on the volume, content,

and laboratory support of scheduled inspections of the entities referred to different classes of hazard;

- Expand risk-based supervision to include technical regulation and consumer rights protection;

Improve the procedure and evaluation of the results and efficiency of risk-oriented supervision;

Provide additional training to the inspection employees on risk assessment and risk management;

Create an effective system of risk communication between the sanitary and epidemiological agencies, economic entities, community organizations, and NGOs.

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