ASSESSING RISKS OF WORK WITH PATHOGENIC BIOLOGICAL AGENTS[1]

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Abstract. Biological safety is a matter of current interest and a priority on the RF national security agenda. Development of a methodological approach to biorisk management and reduction of the laboratory-acquired infections in research work with PBA is in progress. Development and application of a methodological approach to biorisk management in research work with PBA will serve as a basis for the development and implementation of management solutions to improve the efficiency of the current biosafety system.
Key words: biological risk assessment and management, pathogenic biological agents, laboratory-acquired infections.

The state biological safety system is an important part of the national security system; it includes a set of organizational and technical measures to prevent damage and protect people, society and the state against potential and current biological threats.

Today biological safety of the Russian Federation is a pressing issue and a priority on the RF national security agenda [3].

The Federal Government of the Russian Federation is paying close attention to the development and implementation of biological safety measures to protect our country. The Regulation of the Government of the Russian Federation №791 from October 27, 2008 approved The National System of Chemical and Biological Safety of the Russian Federation (2009-2013) federal special purpose program (hereafter – Program). One of the main objectives of the Program is to reduce the biological threats to the biosphere, technological sphere and ecological system and keep them at an acceptable level; special attention needs to be paid to risky biological facilities, namely organizations that deal with dangerous biological materials and agents.

This objective is urgent because over 160 organizations in the Russian Federation use infectious agents of hazard groups (HG) 1 and 2 [2] in their activities. The Federal Service for Consumer Rights Protection and Human Well-Being has registered over 9000 organizations that are licensed to carry out activities involving infectious agents and microorganisms of HG 3 and HG 4 [5].

Harmonization of sanitary regulations is especially important these days when the Customs Union is being created and Russia is joining the World Trade Organization (WTO) and the Organization for Economic Cooperation and Development (OECD). One of the main conditions for such harmonization is providing biological safety in research work with pathogenic biological agents (PBA) following the international standards.

[1] *Translated by Ksenya Zemnlyanova*

The world's scientific community has recently developed a consistent approach to providing biological safety in research work with PBA which is based on the concept of biorisk management which is reflected in the international [7, 9, 11, 13] and federal [8, 12] documents.

The Federal Service for Consumer Rights Protection and Human Well-Being has taken significant measures to develop and adopted regulatory documents and guidelines to assess health effects of chemical exposure.

Health risk assessment associated with chemical exposure includes such components as risk assessment, risk management and risk reporting. The following indicators are used in risk assessment: reference doses and concentrations for acute, subacute and chronic exposures, regional minimum risk levels, factors affecting carcinogenic potential, hygienic standards based on direct health effects, and dose/concentration-response values [14].

The biorisk assessment and management guidance database, however, has not been completed yet due to a major procedural challenge: the quantitative indicators that characterize PBA are not meaningful because the dose/concentration-response relationship does not hold true. When the microorganism concentration is above the infectious level, the severity of the infectious disease does not change, and some infectious diseases can be caused by single cells of pathogenic agents [15].

The report includes the guidelines for the development of a methodological approach to biorisk management that will help take into account all the factors in research work with PBA and minimize biological risks,

Using the standard Russian terms [1], 'risk' is a combination (spontaneous) of hazard probability (or frequency) and hazard severity; the WHO defines 'biological risk' [7] as 'the probability or chance that a particular adverse event (contamination as a result of contact with PBA), possibly leading to harm (laboratory-acquired infection), will occur'. Activities that involve PBA can possibly cause the following harm: contamination of laboratory personnel, accidental release of PBA into the atmosphere followed by animal and human contamination, unauthorized use of PBA in bioterrorism attacks and gas, solid and liquid waste pollution.

Since laboratory-acquired contamination has been occurring during the whole period of over a hundred years of pathogenic microorganism studies and its incidence significantly prevails over other types of harm [4, 6, 10], we will be looking at only one type of harm – laboratory personnel contamination - in our discussion of biorisk management in research work with PBA.

Based on the main provisions of the risk management approach, ensuring biosafety when working with PBA involves following four stages:

Planning and implementing activities

Identifying hazard

Assessing biorisks

Managing biorisks

The first stage consists of developing the goals and objectives of the planned activities, determining the sources of information, selecting the group of executives, identifying financial and physical resources, and preparing management decisions.

It is important to consider that design of the facility aimed for activities involving PBA is the key stage in ensuring biosecurity because this stage identifies the purpose of the facility and corresponding biosafety level, facility location, the size of sanitary protection zone, space and layout design, service systems engineering, and the type of equipment and devices. This approach that involves identifying hazards, assessing biorisks and developing biorisk management project decisions at the design stage with the account of the planned activities, properties of the used PBA, safety criteria and service systems reliability allows the determination of the minimum sufficient amount and efficiency level of special safety equipment that will provide biological safety of the facility.

At the hazard identification stage, possible PBA-related hazards are identified and the main sources of hazard are described. Using the standard Russian terms [1], 'hazard' is a potential source of harm. In the context of the matter under discussion, the hazards leading to contamination of laboratory personnel should be identified.

The sources of information to identify hazards include:

- Regulatory documents, local regulatory acts, device manuals, etc.;
- Results of the state sanitary and epidemiological inspection;
- Results of the operational inspection;
- Results of the workplace assessment;
- Results of the personnel audit (survey);
- Practical experience
- It is necessary to register the identified hazards. A sample register can contain the following identified hazards leading to laboratoy-acquired contamination:
- Contaminated animals (bites, scratches, contact with saliva);
- Aerosolized PBA (centrifugation, drying, pipetting, infected animals, breaking of the laboratory glassware);
- Physical objects with high potential energy (centrifugal bowl);
- Object with insufficient mechanical performance (laboratory glassware) or of dangerous shapes (needles, lancets);
- High-temperature flows and tanks under pressure (autoclave, УНОС, СТОС);
- Unsafe electric circuits;
- Violation of regulatory workplace requirements (lighting, microclimate);
- Psychological and emotional overload when working with PBA;
- Insufficient educational background, professional training, qualification, length of service and experience;
- Lack of attention and self-discipline, inadequate behavior;
- Violation of regulatory biological safety requirements;
- Poor health (physical, spiritual, social) as well as inappropriate age, gender and life style;
- Bad habits (excessive alcohol consumption, drug use);
- Ventilation system malfunction, poor air supply, insufficient personal protection devices.

Hazard identification is followed by selection of the area of activities – stopping the risk analysis due to its little significance or a more detailed assessment of the hazard realization risk in the form of an infectious disease. It is necessary to note that unidentifieid hazards are not subject to further analysis and are not considered in biorisk management.

In comparative assessment of biorisks, it is necessary to know their quantitative values which is particularly important when prioritizing the management decisions at the biorisk management stage, especially in case of limited financial resources.

The qualitiative biorisk assessment can be carried out using the following formula [1]:

$$R = \sum_{i=1}^{N} U_i P_i,$$

where R – biorisk;

Uí – harm (laboratory-acquired infectious disease);

Pí – harm probability;

N – number of discrete values of the possible harm

The following can be used as quantitative indicators of harm:

- Number and severity of infectious diseases;
- Period of temporary disability;
- Temporary disability allowance;
- Number of permanent professional disability cases;
- Level of professional incapacity for work, in percent;
- Total insurance expenses
- The following can be used to identify the probability of harm occurrence:
- Statistical data;
- Event tree analysis method
- Expert assessment

After the biorisk assessment results have been documented, it is necessary to develop and implement biorisk management recommendations in an organization in order to reduce to an acceptable level the risk of laboratory-acquired contamination which constitutes the next but not the last stage of biosafety assurance. Inspection of the implemented activities is followed by adjustment measures to ensure continuous (procedural) biorisk management.

The European Committee for Standardization (CEN) has developed and adopted a laboratory biorisk management standard which includes some sort of a plan to introduce a biorisk management system into a lab. It will serve as a basis for the development of an international biorisk management accreditation scheme planned by the World Health Organization.

Many countries use insurance as a financial mechanism that regulates the issues related to operational safety of an organization (including activities that involve the use of PBA) and possible harm.

The state doctrine of the Russian Federation provides for a series of the federal support measures to provide biosafety in the form of insurance against risks.

On January 1, 2012, Russia passed a new federal law making liability insurance that mitigates the financial consequences of an accident compulsory for owners of hazardous facilities. Unfortunately, the list of hazardous facilities the owners of which have to have compulsory insurance does not include organizations that work with PBA.

Consequently, the development and implementation of a biorisk management methodology for activities that involve PBA will be an innovative accomplishment that increases the effectiveness of the current biosafety system and helps obtain clear enough results that can be used when making adequate management decisions related to providing biosafety.

The development (adoption) of biorisk assessment methods and the Russian standards of biorisk management foractivities that involve PBA following the CWA 15793:2008 international standard is a pre-requisite for the implementation of a biorisk management concept activities involving PBA.

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