

## Part 3. Biosafety and emergent diseases

UDC 619:613/614:616:578/579

### FUNDAMENTAL OBLIGATIONS AND RIGHTS OF BIOSAFETY COMMISSIONS IN THE ORGANIZATIONS WHICH WORK WITH PATHOGENIC AGENTS

Danilova I. S.

National Scientific Center 'Institute of Experimental and Clinical Veterinary Medicine',  
Kharkov, Ukraine, e-mail: irrulik@ukr.net

**Summary.** Biosafety is the system of preventing large-scale losses for the living systems directed on the maintenance of ecological balance and human health.

The pathogenic microorganisms and products of their vital functions which are agents of infectious diseases regardless of their origin and the methods of their receipt are the basic sources of biological danger for the population, animals, plants and the environment.

Each institution should develop its own biosafety programs for the following purposes:

- minimization of the negative influence of biohazards;
- prevention of the dangerous biological materials releasing;
- protecting of the experimental samples.

In each institution, the main points of the control over the compliance with the biosafety and biosecurity systems should be necessarily assigned to the Regime Commission or Biosafety Commission.

Based on this, each institution that works with the microorganisms of II–IV pathogenicity groups should have its regulations on the Regime Commission about the monitoring compliance with biosafety and biosecurity regimes when working with pathogenic microorganisms. It is noted that the provisions should include 3 sections: general provisions, obligations, and the rights of Regime Commission.

This article determines the basic provisions, rights, and responsibilities of the regime commissions from different departments. The main principles and approaches of 'Regulations on the Policy Commission on monitoring compliance with biosafety and biosecurity regime when working with pathogenic microorganisms' are also shown in this article.

**Keywords:** biosafety, veterinary medicine, laboratory, regime commission, pathogenic agents

**Introduction.** Biosafety is the ensuring of safety measures to reduce the risk of losses, thefts or applications of microbiological agents or toxins which could lead to the criminal or improper use of one or another agent as a biological weapon.

To prevent the release of biological hazard material that can harm the health of people, animals, plants, and the environment; as well as to defend the integrity of experimental materials, every institution that conducts scientific research using the pathogens of infectious diseases of livestock and poultry should develop its own biosafety programs. In the United States, Canada, and the European Union there are special committees on biosafety, genetic safety, biological ethics, and environmental safety aimed to maintain the biological security in a single facility or unit.

Most institutions in the CIS countries have only regime commissions that are directly responsible for biosafety and biosecurity.

**The aim** of this work is to investigate, analyze and define the basic obligations and rights of biosafety commissions among the organizations that work with II–IV pathogenicity groups of microorganisms.

**Results and discussion.** According to the order № 183 of the Ministry of Healthcare of Ukraine 'About the regime of working with pathogenic microorganisms' from 12.14.1992, each institution or laboratory that works with microorganisms of II–IV pathogenicity groups should have its regulations about monitoring of compliance to biosafety and biosecurity regimes when working with pathogenic microorganisms by the regime commission. This document should include three sections: general provisions, obligations, and rights of regime commission.

General provisions must include the following ones:

1. Regime commissions must be created in all institutions of the Ministry of Healthcare of Ukraine and other departments that work with the hazardous

material or with material that is suspected to be infected by pathogenic microorganisms.

2. Regime commissions in all institutions and departments must be created *on the basis of* the order of the head of institution, organization or department.

3. Regime commissions must work according to the relevant orders, instructions or applications.

4. The composition of the regime commission (5–6 members) should be confirmed by the order of the institution head. Commission must include specialists of the highest degree that have great skills in working with pathogen agents and in providing of antiepidemic measures. The head of the institution or his deputy in science, labor service or in the planning of the institution epidemiological readiness may hold a post of the Commission Head.

5. The head of the Regime Commission is responsible for executing of the regime inside the institution. In cases of his absence, Head's Deputy becomes a responsible person.

6. The head of the institution is responsible for executing of regime obligations.

Obligations of Regime Commissions:

1. To provide control measures for regime executing when working with pathogen microorganisms in different institutions regardless of their department participation.

2. To control obedience to orders in regime from the higher-level authority and the Head of the institution.

3. To render methodical assistance and to control activities of Regime Commissions in institutions regardless of their department participation and territory of activity.

4. To arrange necessary materials and documents for special echelons to gain the rights of working with pathogen materials or probably pathogen ones.

5. To evaluate methodical recommendations, instructions, projects of the laboratories to be built or reconstructed, and other documents for checking them by criteria of antiepidemic regime.

6. To register each occurrence of emergency when working with microorganisms of II–IV pathogenicity groups and to make accident reports to the higher-level authority regime commissions.

7. To determine and represent measures of accident liquidation to the Head of the institution.

Regime Commissions have the following rights:

1. To demand accomplishment of work standards with microorganisms of II–IV pathogenicity groups.

2. To involve other employees in the performance of Regime Commission work in accordance with manager's order.

3. To make an application for Heads of institutions and higher-level authority Regime Commissions about following questions:

- hiatus of certain employees to work with microorganisms of II–IV pathogenicity groups after systematic accepting of emergencies, or after the emergency with drastic consequence;

- prohibition of application of the methods that may be unsafe for medical stuff;

- hiatus of certain laboratories to work with pathogen agents.

4. If the Head of Regime Commission forbids working with pathogen organisms in the laboratory, he sends the direction to the Head of Institution that commits him to issue an order to review the activity of the laboratory. The copy of this order must be sent to the Regime Commission. In extreme case, related to the emergency or other situation, Regime Commission closes down the laboratory. The copy of this order must be sent to the state administration.

NSC 'IECVM' has its own 'Statute of the regime commission' related to the control of biosafety and biohazard regimes when working with pathogenic microorganisms in the laboratories of NSC 'IECVM'. It was ratified by the order of the Head, from 28.02.2014 with the signatures of members of regime commission and given under the Common Stamp of the Institution. It clearly determines the composition of Regime Commission, and regulations that are responsible for biohazard and biosafety modes accomplishment, as well as rights and obligations of NSC 'IECVM' Regime Commission.

**Conclusions.** Personnel reliability, its build-up oriented at the biosafety questions and strict observance of all procedures for defense from pathogens are wise and defend using of scarce resources. Most likely, these measures have greater influence at defending of important materials from using with the aim of sabotage than expensive measures of physical safety. Routine examination and renewal of set rules for pathogens and toxins defending, examination of safety measures for preventing their incorrect and sabotage use, documenting of storage, moving, using and disposal, all that is the passport to success of Regime Commissions for control of biohazard and biosafety in each institution that works with II–IV pathogenicity groups of microorganisms.

References

- Verkhovna Rada Ukrainy (1994) 'Law of Ukraine № 4004-XII from 24.02.1994 «About supporting of sanitary and epidemiological public well-being»' [Zakon Ukrainy № 4004-XII vid 24.02.1994 «Pro zabezpechennia sanitarnoho ta epidemichnoho blahopoluchchia naseleennia»], *News of the Verkhovna Rada of Ukraine [Vidomosti Verkhovnoi Rady Ukrainy]*, 27, art. 218. Available at: <http://zakon3.rada.gov.ua/laws/show/4004-12>. [in Ukrainian].
- Verkhovna Rada Ukrainy (2000) 'Law of Ukraine № 1645-III from 06.04.2000 «About population defense from infectious diseases»' [Zakon Ukrainy № 1645-III vid 06.04.2000 «Pro zakhyst naseleennia vid infektsiinykh khvorob»], *News of the Verkhovna Rada of Ukraine [Vidomosti Verkhovnoi Rady Ukrainy]*, 29, art. 228. Available at: <http://zakon3.rada.gov.ua/laws/show/1645-14>. [in Ukrainian].
- Ministry of Health of Ukraine (1992) Order № 183 from 14.12.1992 'About regime work with pathogen microorganisms' [Prikaz № 183 vid 14.12.1992 'O rezhime raboty s patogennymi mikroorganizmami']. Available at: <http://www.uazakon.com/document/tpart11/isx11594.htm>. [in Russian].
- Salerno, R. M., Gaudioso, J. and Brodsky, B. H. (2007) *Laboratory biosecurity handbook*. Boca Raton: CRC Press. ISBN 9780849364754.
- U.S. Department of Health and Human Services (2009) *Biosafety in microbiological and biomedical laboratories*. 5<sup>th</sup> ed. HHS Publication No. (CDC) 21-1112. Available at: <http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf>.