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**THE INTERNATIONAL APPROACH OF THE BIORISKS MANAGEMENT IN
THE AREA OF LABORATORY BIOSAFETY AND BIOSECURITY**

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Abstract. *It was studied an international approach of creating biorisks management system in sphere of laboratory biosafety and biosecurity. It was established that the basis of the laboratory biosafety and biosecurity is biorisks management system – model AMP (assessment, mitigation and performance). This system is part of the management system, which ensures the development and implementation of policies concerning biological risks and their management in the laboratory. The key factors are the commitment of senior management and the emphasis on continuous improvement, created by the CWA 15793 requirements – Laboratory biorisk management (CEN, 2011).*

Keywords: *laboratory biosafety, laboratory biosecurity, biorisk, biorisks management system*

Biosafety is the development of practical methods of protecting humanity, animals and the environment from dangerous biological agents in the circulation and working with them [1, 2]. And biosecurity is a system of measures applied to reduce the risks associated with both intentional and unintentional (due to technological accidents and violations) removal or release of dangerous biological materials [1, 2].

Problems of biosafety and biosecurity are relevant in veterinary medicine, especially in institutions where the staff is working with live pathogens (research and diagnostic laboratories and companies of bioindustry). Existing risks of emergence and spread of infectious diseases through the territory of Ukraine increase their importance, which requires consistent actions of science and practice on development, streamlining of production and use of means of control and prevention of these diseases.

The purpose of research. Explore the international approach to biorisks management system in the area of laboratory biosafety and biosecurity.

Material and methods of research. In the process used materials of training course have been used "Management in the area of biosafety," which is a part of the World educational program of biological risk management (Global Biorisk Management Curriculum - GBRMC), which is managed by Sandia National Laboratories [3]. There was Conducted analysis of international regulatory documents concerning the biosafety of laboratory [4], laboratory biosecurity [5], biorisks management in laboratory conditions [6]. In the work was used statistical and analytical methods for the analysis of documentation.

Results. In the Instruction on biological safety [4] it was noted that laboratory biosafety is principles of storage, technologies and practice which are implemented for the prevention of **unintended** exposure of pathogens and toxins, or their accidental release. The concept of laboratory biosafety process includes protection from infections and laboratory chemicals that can cause severe illness. Then, as laboratory biosecurity is a protection, control and accountability of biological materials in laboratories which are directed at preventing of unauthorized access, loss, theft, misuse, diversion or **intentional** distribution [5]. The concept of biosecurity in the laboratory covers the provision of protection, control and accounting of biological agents and toxins in laboratories in order to prevent their loss, theft, misuse, sabotage, unauthorized access or deliberate unauthorized release. Therefore each laboratory that works with infectious diseases of animals and birds, and a person has to develop its own programs of biosafety and biosecurity, whose purpose is to minimize the negative influence of biologically dangerous objects on the health of people, animals and the environment. Examples of measures to ensure biosafety and biosecurity in laboratory conditions are shown in Fig. 1.

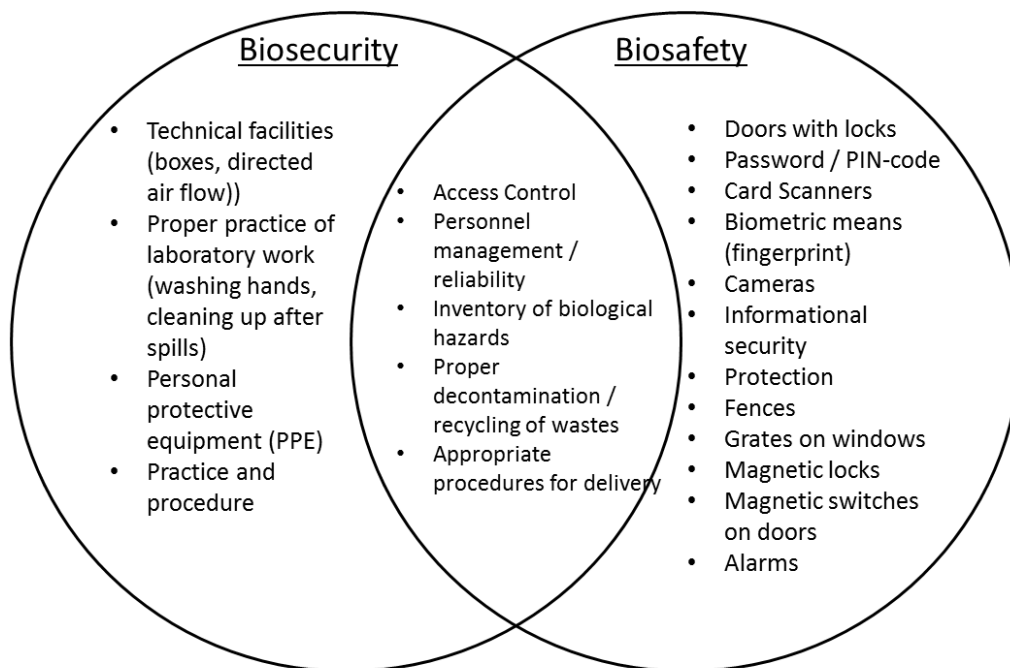


Fig. 1. Examples of measures to ensure of laboratory biosafety and biosecurity

The basis of the of laboratory biosafety and biosecurity is biorisks management system. **Biorisk** is a risk of health and life which is associated with the influence of pathogens of biological nature (biological materials and/or infectious agents) within laboratories; while biosafety and biosecurity are considered as the whole. Unit is a combination of harmful impact and potential scale of consequences of harmful effects in cases where the source of such exposure is a biological agent or toxin [1, 3, 7].

The main components of **biorisks management system** in the area of laboratory biosafety and biosecurity by international requirements (**CWA 15793 - Laboratory biorisk management (CEN, 2011)**) are: biorisks **assessment**, **mitigation** of biorisks and **performance** - the model **AMP**.

- **assessment** of biorisks is process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the

adequacy of any existing controls, and deciding whether or not the risks are acceptable;

- **mitigation** of biorisks is actions and control measures that are put into place to reduce or eliminate the risks associated with biological agents and toxins;

- **performance** is implementation of the entire biorisks management system, including evaluating and ensuring that the system is working the way it was designed. Another aspect of performance is the process of continually improving the system.

Therefore **biorisks management system** in the area of laboratory biosafety and biosecurity is a part of the control system which provides the development and implementation of policies concerning biological risks and their management in the laboratories [6]. There is an approach of the management system in the basis of the biorisks management main components of which are shown in Fig. 2.

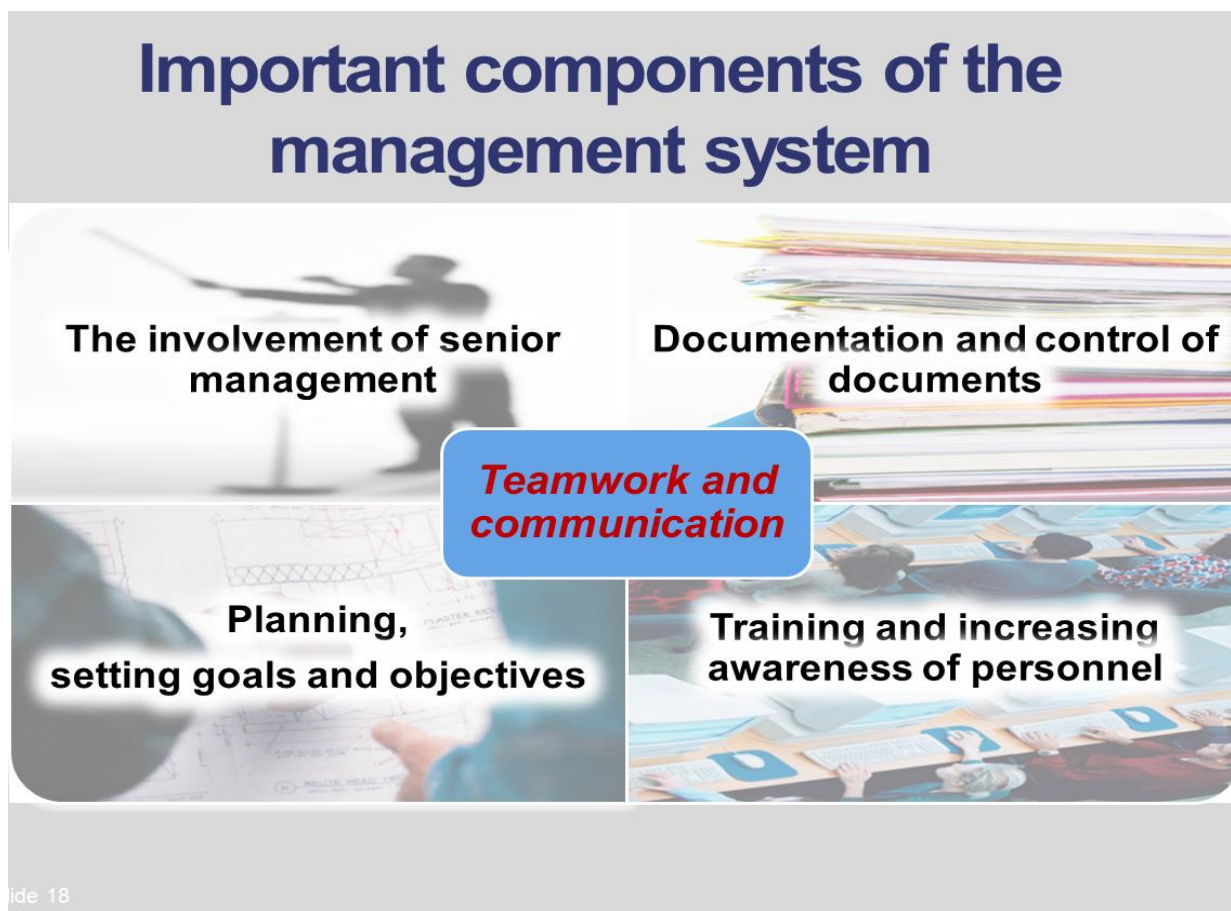


Fig. 2. The main components of the management system

From this figure we see that the key factors in the development and implementation of successful management system in the area of laboratory biosafety and biosecurity is the senior management commitment and the focus on continuous improvement.

The basis of the international management system of laboratory biorisks (**CWA 15793 - Laboratory biorisk management**, [4]) laid **Instruction WHO of biological protection and biological safety of laboratories** [5, 6]. The given system:

- is a complex **basis** for the program of biosecurity and biosafety (biorisk);
- is designed for all types of laboratories working with biological materials;
- is **available** on the website of CEN:
ftp://ftp.cenorm.be/CEN/Sectors/TCandWorkshops/Workshops/CWA15793_September2011.pdf;
- complies with international standards of quality (ISO 9000), Environmental Protection (ISO 14000) and occupational health and safety (OSHAS 18001);
- has a recommended character;
- does not apply to a particular country, that is, the possible harmonization with national and local legislation;
- is allowed organizations to determine the best ways to perform tasks.

Biorisk management committee is created for controlling the biorisks in every laboratory, and on the level of laboratory division is a group which is composed of persons competent in the control of biorisks and other representatives (if necessary). The commission may be the same as commission of management and control of biosafety. The activities of these committees and groups is governed by the provisions of **CWA 15793 - Laboratory biorisk management (CEN, 2011)** [4].

Conclusions

1. Basis of laboratory biosafety and biosecurity is biorisks management system.
2. AMP (assessment, mitigation and performance) is a simple, but effective biorisks management model in the area of laboratory biosafety and biosecurity.

3. Biorisks management system in the area of laboratory biosafety and biosecurity is a part of the management system, which ensures the development and implementation of policies concerning biological risks and its management in the laboratory.

4. Key factors of successful development and implementation of biorisks management system in the area of laboratory biosafety and biosecurity is a senior management commitment and focus on continuous improvement.

5. CWA 15793 - Laboratory biorisk management (CEN, 2011) is a complex basis for the creation of laboratory biorisks management system which are developed through international cooperation.

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МІЖНАРОДНИЙ ПІДХІД З УПРАВЛІННЯ БІОРИЗИКАМИ У СФЕРІ ЛАБОРАТОРНОЇ БІОБЕЗПЕКИ ТА БІОЗАХИСТУ

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***Анотація.** Вивчено міжнародний підхід з створення системи управління біоризиками у сфері лабораторної біобезпеки та біозахисту. Встановлено, що основу лабораторної біобезпеки та біозахисту складає система управління біоризиками - модель ОЗВ (оцінка, зниження та виконання). Дана система являє собою частину системи управління, що забезпечує розробку і здійснення політики організації з питань біологічних ризиків та управління ними в лабораторіях, ключовими факторами є зобов'язання вищого керівництва та акцент на постійному удосконаленні, створюється за вимогами CWA 15793 - Laboratory biorisk management (CEN, 2011).*

***Ключові слова:** лабораторна біобезпека, лабораторний біозахист, біоризик, система управління біоризиками*

МЕЖДУНАРОДНЫЙ ПОДХОД К УПРАВЛЕНИЮ БИОРИСКАМИ В СФЕРЕ ЛАБОРАТОРНОЙ БИОБЕЗОПАСНОСТИ И БИОЗАЩИТЫ

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***Аннотация.** Изучен международный подход к созданию системы управления биорисками в сфере лабораторной биобезопасности и биозащиты. Установлено, что основу лабораторной биобезопасности и биозащиты составляет система управления биорисками - модель ОСИ (оценка, снижение и исполнение). Данная система представляет собой часть системы управления, что обеспечивает разработку и осуществление политики организации по вопросам биологических рисков и управления ими в лабораториях, ключевыми факторами являются обязательства высшего руководства и акцент на постоянном совершенствовании, создается по требованиям CWA 15793 - Laboratory biorisk management (CEN, 2011).*

***Ключевые слова:** лабораторная биобезопасность, лабораторная биозащита, биориск, система управления биорисками*