Biosafety and biosecurity in a microbiological laboratory in Russian Federation

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Russian Research Anti-Plague Institute (RusRAPI) “Microbe”

- RusRAPI “Microbe” is the successor of the “special laboratory”, founded in 1897 by the Emperor Nikolay II on an isolated island near Saint-Petersburg in order to develop methods to fight plague. 15 November 1918 the institute had been transferred to Saratov.

- Belongs to the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor) – Federal agency dealing with public health issues

Broad complex of activities:

- Research projects concerning epidemiology, microbiology, immunology and laboratory diagnostics of dangerous infectious diseases (plague, anthrax, cholera, tularaemia, brucellosis, viral pathogens)
- Development of protocols, standards, manuals
- Coordination of national scientific and practical activities concerning public health
- Development and production of diagnostic kits and vaccines
- Training of specialists
- Handling outbreaks of dangerous infectious diseases
In a broad sense – Federal policy for biosafety (Presidential decree of 01 November 2013 № 2573 «Basics of state policy in the field of chemical and biological safety of the Russian Federation for the period up to 2025 and beyond»)

Functioning of a complex federal system of chemical and biological safety on the territory of Russian Federation:
Categorization, prognostication, prevention and countering of chemical and biological threats, emergency response.

In a narrow sense - protection of personnel and contacts at the level of the institution/laboratory.

System of biomedical, organizational, and technical measures aimed at protection of working personnel, people and environment from pathogenic biological agents
The existing system of biosafety is based on the legal system of Russian Federation


- regards sanitary and epidemiological welfare as one of the main conditions of implementation of constitutional rights of citizens for health protection and favorable environment.

**Sanitary and epidemiological welfare of citizens** – is the state of health of the population and the state of environment, that brings no harm to citizens and assures favorable conditions for their life.

**Safe conditions for human beings** – is the state of the environment without dangers of harmful effects upon human beings.
Federal level Regulatory documents

- Sanitary regulations on handling pathogens belonging to the I-II groups of pathogenicity (i.e. particularly dangerous pathogens)

- Sanitary regulations on handling pathogens belonging to the III-IV groups of pathogenicity (less dangerous)

- Sanitary regulations on accounting, transportation and storage of pathogenic microorganisms

- Regulatory documents on certain species of microorganisms

- Regulatory documents on certain research/diagnostic methods
Sanitary regulations on handling pathogens belonging to the I-II groups of pathogenicity

Compliance with requirements of this document is mandatory for all legal entities and individuals conducting the following types of activities with pathogens:

- Diagnostic (testing biological and environmental samples for detection, isolation and identification of pathogens or their fragments, nucleic acids, antigens and antibodies against them);

- Experimental (all types of activities using pathogens, their products, toxins and poisons of biological origin);

- Production (activities on producing vaccines, sera, immunoglobulins, etc., using microorganisms and their products);

- Zoological and entomological (including gathering field samples of biological and environmental origin, and their transportation).
Sanitary regulations on handling pathogens belonging to the I-II groups of pathogenicity

Compliance with the requirements in the following sections:

- Personnel;
- Rooms and equipment;
- Samples decontamination, waste management;
- Personal protective equipment;
- Handling infected animals and vectors;
- Incident management

+ Compliance monitoring procedures
+ Annexes
Sanitary regulations on handling pathogens belonging to the I-II groups of pathogenicity

Annexes:

- Decontamination of various objects;

- Classification of pathogenic biological agents, causing diseases in humans;

- Types of personal protective equipment for handling pathogens in laboratories, examination and treatment of patients;

- Monitoring the efficiency of steam sterilizers;

- Maintenance of air filters in exhaust and supply ventilation systems, monitoring their protective efficiency;

- Biological safety cabinets

- Support systems (fencing building structures, sewerage, water supply, heating, electric power supply)

- Decontamination of samples for immunological and genetic analyses
Laboratory network of Rospotrebnadzor

Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor) includes a network of public health laboratories.
Engineering and technical systems for biosafety

- Fencing building structures;
- Ventilation and air extraction systems;
- Microbiological safety cabinets;
- Special water supply and sewerage systems;
- Centralized wastewater disinfection systems
Standard operational procedures (SOPs)

- Describe every possible part of work in the microbiological laboratory

- Are based on the acting regulatory documents

- Are adapted to every specific location / institution / laboratory
National system of accreditation for microbiological laboratories

National accreditation system in Russia treats biological safety and security as one of the basic criteria to comply when the accreditation is obtained or prolonged.

The majority of Russian microbiological laboratories, performing diagnostics of infectious diseases, have the ISO-17025 accreditation.
Same national requirements (complying with international) for any institutions and laboratories, regardless of their affiliation, are Authorization documents are issued by the Rospotrebnadzor

For the institution:

- License for work with pathogenic microorganisms, agents of infectious diseases

For every department (laboratory):

- «Sanitary and epidemiological conclusion» with a thorough description of specific activities with specific species of pathogens
National system of training personnel for dealing with infectious diseases agents

- Doctors / biologists / research associates
- Laboratory technicians
- Junior medical staff

Certified training courses, performed by institutions having a license for education

Education course lasts up to 4 months

Very practical direction of training:
Epidemiology, cultivation and identification of bacterial and viral agents, handling infected animals, diagnostic express-methods
Sharing experience with specialists from other countries

Cooperation, training and sharing experience for specialists from other countries

Near abroad:

Belarus, Kazakhstan, Kyrgyzstan, Uzbekistan, Tajikistan, Turkmenistan, Armenia, Azerbaijan

Far abroad:

Republic of Guinea, Socialist Republic of Vietnam
Requirements for ensuring biological safety are the same:

- For traditional, stationary laboratories;

- For mobile laboratories
Biological safety in the mobile laboratories

- Headquarters
- Sanitary microbiology lab (BSL-2)
- Bacteriology lab (BSL-2)
- Detection lab (BSL-3)
- Support
- Animal models lab (BSL-3)
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