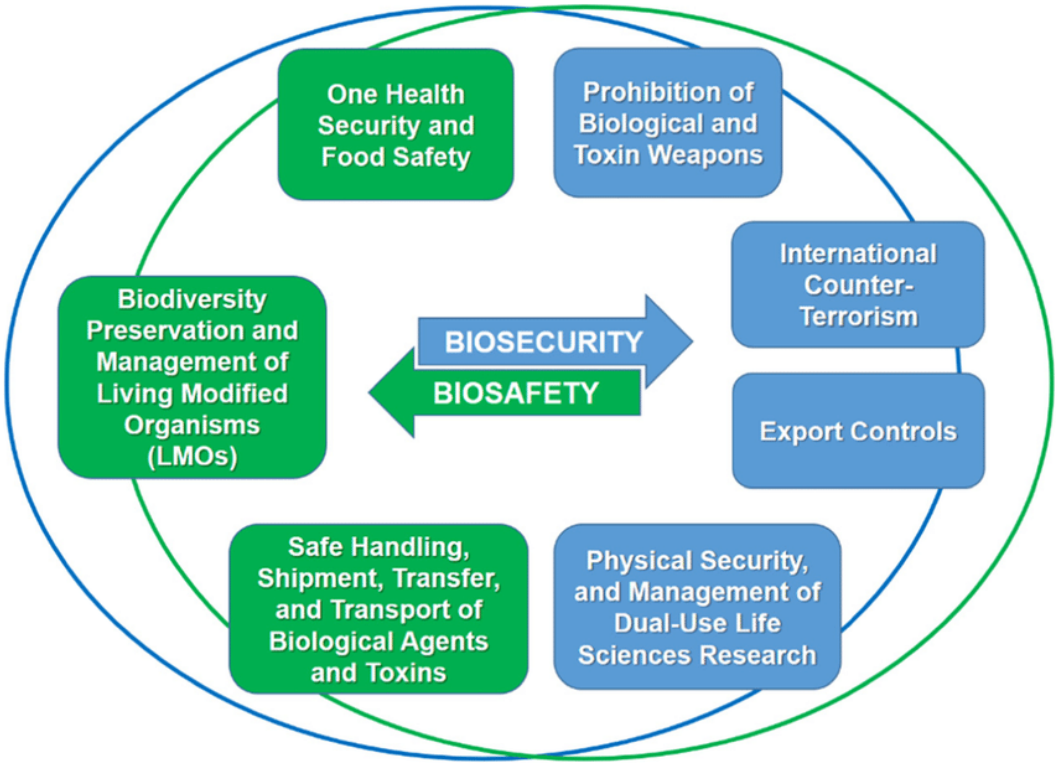
EURIZON H2020 project, grant agreement 871072

EURIZON FELLOWSHIP PROGRAMME: “Remote Research Grants for Ukrainian Researchers”

BIOSAFETY AND BIOSECURITY



Biosafety: Containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release.

Biosecurity: Principles, technologies and practices that are implemented for the protection, control and accountability of biological materials and/or the equipment, skills and data related to their handling. Biosecurity aims to prevent their unauthorized
access, loss, theft, misuse, diversion or release.

Picture: Novossiolova, Tatyana A., et al. "The Vital Importance of a Web of Prevention for Effective Biosafety and Biosecurity in the Twenty-First Century." One Health Outlook, vol. 3, no. 1, Sept. 2021. Crossref, https://doi.org/10.1186/s42522-021-00049-4

INTRODUCTION

Factors that have led to potential and confirmed exposures to biological agents

- absence or improper use of personal protective equipment;
- inadequate or ignored risk assessments;
- lack of standard operating procedures (SOPs);
- needlestick injuries and/or insufficiently trained personnel.

RISK ASSESSMENT

Risk is the combination of the probability that a hazard will cause harm and the severity of harm that may arise from contact with that hazard.

STEP 1: GATHER INFORMATION (HAZARD IDENTIFICATION)

- What biological agents will be handled and what are their pathogeni characteristics?
- What type of laboratory work and/or procedures will be conducted?
- What type(s) of equipment will be used?
- What type of laboratory facility is available?
- What human factors exist (for example, what is the level of competency of personnel)?
- What other factors exist that might affect laboratory operations (for example, legal, cultural, socioeconomic, public perception)?

RISK ASSESSMENT: DEFINITIONS

Initial risk: Risk associated with laboratory activities or procedures that are conducted in the absence of risk control measures.

Acceptable risk: The risk that is considered acceptable and allows work to proceed bearing in mind the expected benefit of the planned activities.

Residual risk: Risk that remains after carefully selected risk control measures have been applied. If residual risk is not acceptable, it may be necessary to apply additional risk control measures or to stop the laboratory activity.

STEP 2: EVALUATE THE RISKS

- How could an exposure and/or release occur?
- What is the likelihood of an exposure and/or release?
- What information gathered influences the likelihood the most?
- What are the consequences of an exposure and/or release?
- Which information/factor influences the consequences the most?
- What is the overall **initial risk** of the activities?
- What is an **acceptable risk**?
- Which **risks are unacceptable**?
- Can unacceptable risks be controlled, or should the work not proceed at all?

PRACTICAL TASK 1

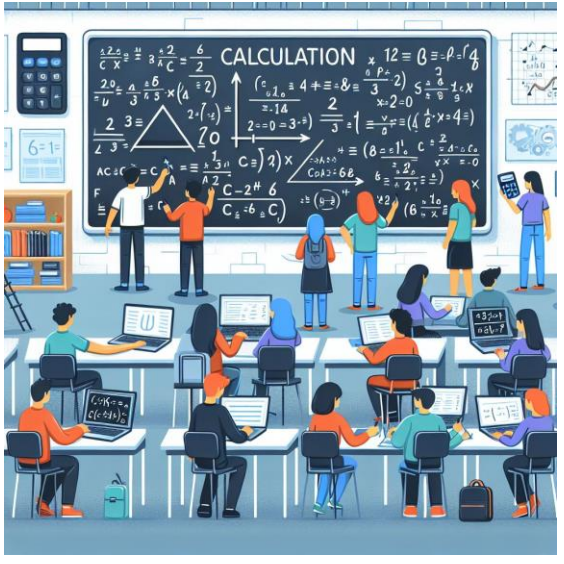
1. Design a biological study/experiment;
2. Identify the dangers in it (3-5);
3. Predict the consequences for each danger.

10 MINUTES

STEP 2: EVALUATE THE RISKS

Evaluation methods

- Statistical methods;
- Expert systems theory methods;
- Artificial neural networks.



PRACTICAL TASK 2
STEP 2: USING EXPERT SYSTEM THEORY TO EVALUATE THE RISKS

Each of you is an expert.

Each of you is asked to make your own subjective assessment of the probability of occurrence of each danger and its consequences on a scale from 0 to 10.

10 MINUTES

Frequency	Insignificant	Minor	Moderate	Severe	Catastrophic
Certain	5	10	15	20	25
Likely	4	8	12	16	20
Possible	3	6	9	12	15
Unlikely	2	4	6	8	10
Rare	1	2	3	4	5

Severity

ESTABLISH AN ACCEPTABLE RISK

It is important to note that risk can never be completely eliminated unless the work is not performed at all. Therefore, determining if the initial and/or residual risks are acceptable, controllable or unacceptable is a vital part of the risk evaluation process.

Each enterprise independently determines the acceptable level of risk so that it is proportionate to the situation and the resources of the enterprise.

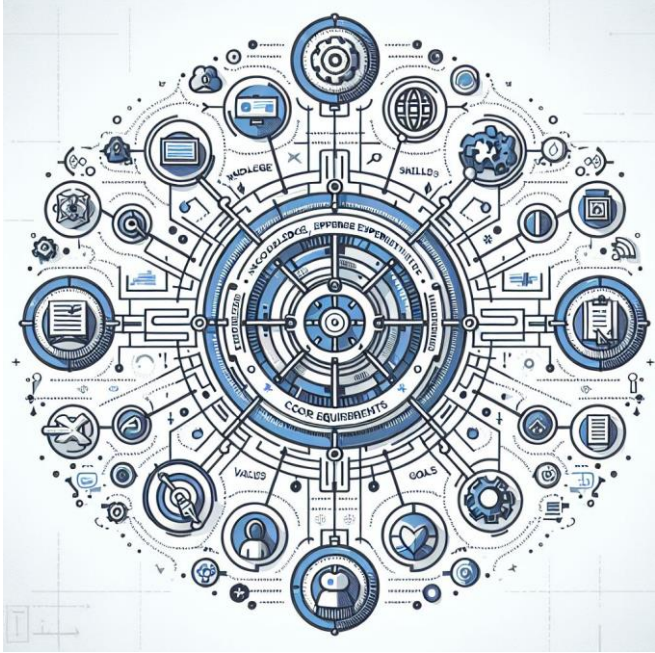
STEP 3: DEVELOP A RISK CONTROL STRATEGY

- What resources are available for risk control measures?
- What risk control strategies are most applicable for the resources available?
- Are resources sufficient to obtain and maintain those risk control measures?
- Are proposed control strategies effective, sustainable and achievable in the local context?

REVIEW RISKS AND RISK CONTROL MEASURES

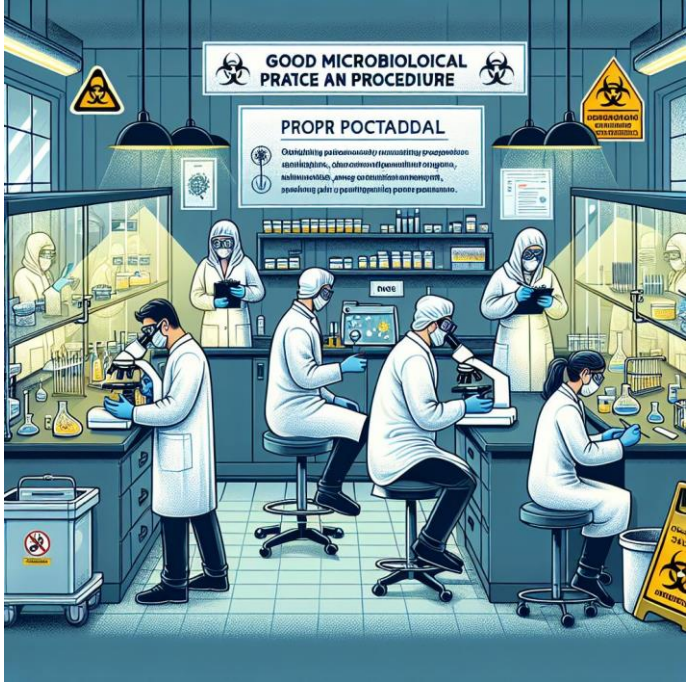
CORE REQUIREMENTS

Core requirements is the term used to describe a combination of risk control measures that are both the foundation for, and an integral part of, biolaboratory biosafety.



GOOD MICROBIOLOGICAL PRACTICE AND PROCEDURE

- **Best practice**
- **Technical procedures:**
  - Avoiding inhalation of biological agents;
  - Avoiding ingestion of biological agents and contact with skin and eyes;
  - Avoiding injection of biological agents;
  - Preventing dispersal of biological agents.

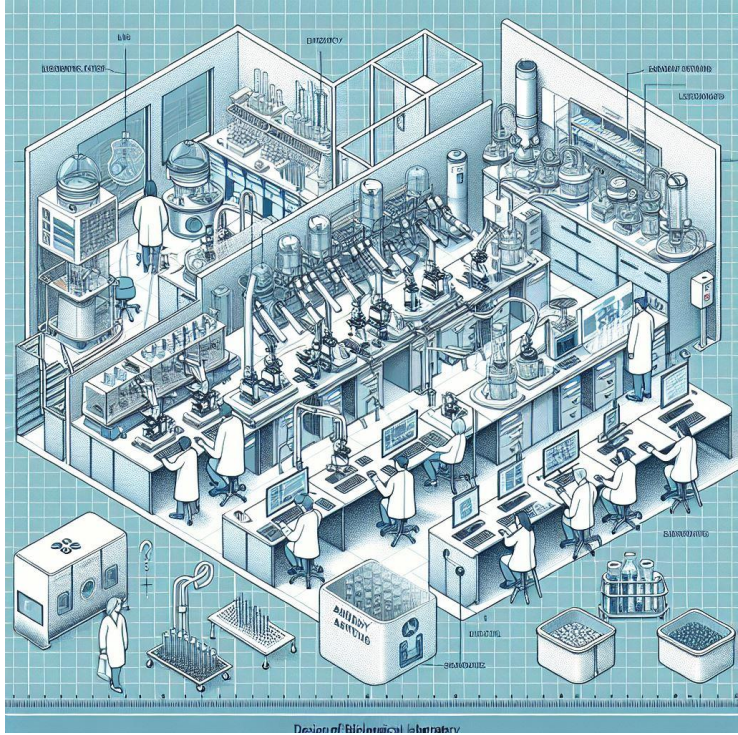


PERSONNEL COMPETENCE AND TRAINING

Human error and poor technical skills can compromise the best safeguards. Thus, competent and safety-conscious laboratory personnel, who are well informed on how to recognize and control laboratory risks, are essential for the prevention of laboratory-associated infections and/or other incidents

REQUIREMENTS FOR THE DESIGN OF BIOLOGICAL LABORATORIES

- Zoning and Separation;
- Airflow and Ventilation;
- Containment and Waste Management;
- Materials and Surfaces;
- Emergency Systems;
- Utility Systems;
- Lighting and Ergonomics;
- Monitoring and Access Control.



SPECIMEN RECEIPT AND STORAGE

- **Receiving specimens**
  - A specimen received by the laboratory must be accompanied by sufficient information to identify what it is, when and where it was taken or prepared, and which tests and/or procedures (if any) are to be performed
- **Specimens must be stored in containers that are:**
  - made of adequate strength, integrity and volume to contain the specimen;
  - leak-proof when the cap or stopper is correctly applied,
  - free of any biological material on the outside of the packaging,
  - correctly labelled, marked and recorded to facilitate identification, and
  - made of an appropriate material for the type of storage required.

DECONTAMINATION AND WASTE MANAGEMENT

- Chemical disinfection
- Autoclaving
- Incineration

PERSONAL PROTECTIVE EQUIPMENT

- Laboratory coats
- Footwear
- Gloves
- Eye protection
- Respiratory protection

OCCUPATIONAL HEALTH