15 years ESJ
Special edition

Combining Biosafety Experts' Evaluations and Workers' Perceptions to Disclose Biological Risks in Biomedical Laboratories

Dionysios Vourtsis, MSc, PhDc
Efstathia Papageorgiou, Professor
Anastasios Kriebardis, Professor Emeritus
George Albert Karikas, Professor Emeritus
Department of Biomedical Sciences,
University of West Attica, Athens, Greece
Gijsbert van Willigen, PhD
Medical Center, Leiden University, Leiden, Holland
Kostas Kotrokois, Assistant Professor
Georgios Dounias, Professor
Department of Public Health Policies,
University of West Attica, Athens, Greece
Petros Karkalousos, Associate Professor
Department of Biomedical Sciences,
University of West Attica, Athens, Greece

Doi:10.19044/esj.2025.v21n37p68

Submitted: 05 July 2024
Accepted: 27 August 2024
Published: 15 January 2025

Cite As:
Vourtsis D., Papageorgiou E., Kriebardis A., Karikas G.A., van Willigen G., Kotrokois K., Dounias G. & Karkalousos P. (2025). *Combining Biosafety Experts' Evaluations and Workers' Perceptions to Disclose Biological Risks in Biomedical Laboratories.* European Scientific Journal, ESJ, 21 (37), 68. https://doi.org/10.19044/esj.2025.v21n37p68

Abstract

Objectives: This paper focuses on examining the biological risks in biomedical laboratories of public hospitals in Athens, Greece, by combining expert evaluations and laboratory workers' perception. It also aimed to review how personnel managed biological materials, assess the level of safety awareness and training of workers, and propose hazards mitigation actions according to local legislation and international biosafety guidelines. **Materials**

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

and Methods: A total of 36 biosafety level 2 (BSL-2) laboratories in 20 hospitals were evaluated for biosafety containment specifications and adherence to biosafety procedures. The study was conducted as a cross-sectional survey using a checklist and a detailed health and safety (H&S) questionnaire, focusing on biosafety and biorisk management. An expert biosafety officer inspected and completed a checklist for each laboratory (n=36) across the 20 hospitals. Additionally, 415 lab professionals completed a biosafety-specific health and safety questionnaire. **Results:** Both the checklists and questionnaires revealed that, although some positive findings were observed, a significant percentage of laboratories lacked effective management of biological agents and materials overall. The main deficiencies identified included restricted access, safety equipment, standard operating procedures (SOPs), biorisk management systems, risk assessments, biosafety manuals, biosafety officers, accident reporting, and biosafety training programs. **Conclusion:** The significant shortcomings in some areas of engineering and administrative controls, as well as in the implementation of Greek and European biosafety legislation, demonstrate that the laboratories do not fully comply with internationally accepted BSL-2 standards. Therefore, there is an urgent need for more comprehensive and proactive measures, adequate biosafety training for workers, and stricter enforcement of existing laws and directives to ensure the safety of laboratory professionals, the community, and the environment.

Keywords: Biorisk management, Biosafety, Biological risk assessment, Biomedical laboratories, Laboratory personnel awareness, Biosafety legislation

Introduction

Biomedical laboratories are undeniably important and valuable in every healthcare system (Farr & Shatkin, 2004; Kessel, 2014; Brown et al., 2015). However, if containment measures and procedures are not properly followed and enforced, these labs can pose biological risks to both personnel and the environment. Such risks, present in all types of diagnostic samples or materials, combined with the handling and analysis procedures, could result in an ongoing threat of Laboratory-acquired infections (LAIs) and breaches of containment. Numerous LAIs have occurred worldwide, potentially exposing workers to dangerous infections through aerosols, spills, needle sticks, splashes, and equipment malfunctions (Pike, 1976; Sewell, 1995; Wurtz et al., 2016; Blacksell et al., 2023). Therefore, ensuring that samples and materials containing infectious biological agents are safely received, handled, transported, and stored requires the establishment of proper mitigation measures in accordance with best practices in adequately equipped and

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

contained facilities (NIH, 2024) as part of a biosafety regime. Biosafety is the scientific discipline that involves the containment principles, methods, and procedures used to describe and regulate the unintended exposure or release of biological agents (WHO, 2020).

The "Biorisk Management System" is an approach that can assist in controlling and mitigating these risks to a manageable level for lab personnel, the community, and the environment. Biorisk management is a strategy for monitoring lab safety and security risks (WHO, 2014; Salerno & Gaudioso, 2015), enhancing lab operations and activities, and managing risks more effectively (ISO 35001:2019). As a result, overall safety can be improved, providing a safe working environment for lab staff. An essential component of a Laboratory Biorisk management system is risk assessment, because:

- According to the EU Directive 2000/54/EC and Greek legislation (Presidential Degree 102/2020, on the protection of workers from dangers associated with exposure to biological agents at work), any activity where there may be a risk of exposure to biological agents requires a risk assessment (Article 3).
- Every organization that handles biological agents has an obligation to its employees and the community to conduct a risk assessment related to its activities (WHO, 2020).

When conducting a risk assessment in every laboratory, the information gathered is used to identify the risks (Vourtsis et al., 2022) by combining the hazard's possibility with its consequences (WHO, 2010; WHO, 2020; Gribble et al., 2015). **Based on this facility-specific risk assessment, and in accordance with European and Greek legislation, as well as international guidelines, including BMBL 6th ed. (CDC, 2020) and WHO 3rd ed. (WHO, 2004), biomedical laboratories must be constructed and operated at the BSL-2 level.**

The next step is to minimize these risks to a tolerable or controllable level and prevent LAIs (Sandia National Laboratories, 2014). Proper control measures should be implemented, such as the **hierarchy of controls system**. By using the following three steps of the hierarchy of controls system (CDC, NIOSH, 2021), the transmission channels of biological agents can be efficiently inhibited, providing laboratory personnel with a safe working environment:

- **Engineering Controls** involve the containment of materials used in the lab through architectural and mechanical design. The purpose is to protect the environment both inside and outside the lab. Examples of containment include the physical separation of the lab from traffic flow within the building to reduce the risk of exposure to passing individuals, self-closing lab doors, biological safety cabinets (BSC),

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

safety centrifuge, and HVAC (Heating, Ventilation, and Air Conditioning) systems..

- **Administrative controls** are measures to control risks, including local and international policies, standards and guidelines, good microbiological practices and procedures (GMPP), standard operation procedures (SOPs), and the education and training of lab staff. Good microbiological practices and procedures are general behavior and practices relevant to all types of lab activities involving biological agents and should always be followed (WHO, 2020). Without them, the risk cannot be adequately controlled, even if all other control measures are in place. Another important aspect of lab safety is the safety culture and training of lab staff, which must be adopted, supported, and developed by top management to eliminate or reduce biological hazards to an acceptable level for lab professionals, the community, and the environment (Tun, 2017).
- **Personal Protective Equipment (PPE)** is worn by laboratory employees to protect them from exposure to biological materials and substances. In general, PPE includes gloves, lab coats, face shields, face masks, respiratory protection, safety glasses, goggles, hoods, shoe covers, gowns, and other specific items. All of these materials and safety elements must be provided to lab staff and should be legally accessible according to each laboratory's management (Bathula & Rakhimol, 2017). PPE can be an effective line of defense but must be proportionate to the local risk assessment.

Materials and Methods

Risk can be defined using qualitative, semi-quantitative, and quantitative methods (Raafat & Sadhra, 1999). The present study was designed as a cross-sectional survey, combining methods and sources, including a qualitative method (experts' evaluation using a checklist) and a subjective risk survey of the lab staff (questionnaires). It aimed to examine the biological risks in these biomedical labs and assess the level of biosafety regulations, knowledge, and practices among lab workers. Data collection on the biological risks in 36 laboratories across 20 public hospitals in Athens, Greece, was conducted between March 2021 and June 2022. The data were analyzed using SPSS software version 29 (Academic license), and descriptive statistics were used to summarize the findings.

Research Design

The study was divided into the following two parts:
1. Biosafety Experts' Evaluation (Checklist)

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

A custom checklist was developed based on available literature, including the checklist for BSL-2 laboratories from BMBL 6th ed., 2020, and the Self-Audits checklists from the WHO Biorisk Programme Management monograph, 2020. A total of 36 biomedical BSL-2 laboratories in 20 public hospitals were evaluated by a trained and accredited biosafety officer. The officer completed the checklist through on-site observations and discussions with laboratory directors and personnel, focusing on lab containment, procedures, PPE, emergencies, and biosafety education. The 45 checklist items were divided into four main sections:

A. Facilities and Technical Containment Measures (18 items)
B. Administrative measures, Laboratory Practices, and Procedures (11 items)
C. Personal Protective Equipment (PPE) (7 items)
D. Emergencies (9 items)

2. Combining the Results of the Biosafety Expert with a Subjective Risk Survey of the Laboratory Staff (H&S Anonymous Questionnaire)

A specific biosafety H&S anonymous questionnaire was administered to 415 laboratory workers (including medical laboratory doctors, technologists, assistants, biologists, and biochemists) at the same biomedical labs where the biosafety experts' checklist was completed. The questionnaire was filled out by staff in their workplaces, specifically in the microbiology, biochemistry, and hematology hospital labs. The questionnaire was also developed based on a review of the literature, BMBL 6th ed., 2020, and WHO Biorisk Programme Management monograph, 2020. It consisted of 15 main questions, divided into 77 sub-questions and two main sections:

- Six main questions gathered general information about the type of lab, the profession of the laboratory staff, and the biological materials handled.

The remaining nine questions were focused on gathering information about biosafety measures and procedures in the laboratory, addressing the last three steps of the hierarchy of controls (i.e., engineering controls, administrative controls, personal protective equipment), as well as emergency procedures and biosafety education practices. All questions were answered with a **Yes** or **No** response to the specified items.

Results

1. Biosafety Experts' Evaluation (Presentation of the Checklist Results)

Descriptive Statistics

Table 1. Facilities and Technical Containment Measures (Engineering Controls)

A. Facilities and Technical Containment Measures			
		Count	**Count %**
A.1 There is an access control to the laboratory, only to authorized personnel	YES	17	47.2%
	NO	19	52.8%
A.2 At the entrance of the laboratory, there is signage and information of the Biosafety Level	YES	3	8.3%
	NO	33	91.7%
A.3 The main entrance door of the laboratory has an automatic closing mechanism	YES	15	41.7%
	NO	21	58.3%
A.4 There are separate locker rooms and storage areas for the belongings of the laboratory staff	YES	29	80.6%
	NO	7	19.4%
A.5 The administration and the secretariat are separated from the laboratory analysis areas	YES	33	91.7%
	NO	3	8.3%
A.6 Blood collection is carried out in a specified, separate, and sufficient size area	YES	35	97.2%
	NO	1	2.8%
A.7 Doors - Windows of the laboratory: They can be closed correctly during analysis	YES	34	94.4%
	NO	2	5.6%
A.8 Laboratory surfaces, floors, and benches are intact, made of durable material and easy to clean and disinfect	YES	31	86.1%
	NO	5	13.9%
A.9 The laboratory seats have a stable base, their material is not fabric, and is easy to disinfect	YES	27	75.0%
	NO	9	25.0%
A.10 Air conditioning checks are carried out regularly and are recorded	YES	34	94.4%
	NO	2	5.6%
A.11 There are one or more certified Biological Safety Cabinets (BSCs)	YES	20	55.6%
	NO	16	44.4%
A.12 There is a safety centrifuge (with separate cover for each rotor)	YES	18	50.0%
	NO	18	50.0%
A.13 There is an autoclave for sterilization inside the laboratory area	YES	18	50.0%
	NO	18	50.0%
A.14 The washbasins are located near the exit of the laboratory area	YES	28	77.8%
	NO	8	22.2%
A.15 There is the possibility of using them hands-free, with automatic operation	YES	6	16.7%
	NO	30	83.3%
A.16 The storage of biological agents is carried out in a safe manner and in a suitable place	YES	34	94.4%
	NO	2	5.6%
A.17 Reagents are stored safely and in a suitable place	YES	36	100.0%
A.18 The luminosity and space in the laboratory are sufficient to safely carry out analytical procedures, including maintenance and disinfection	YES	34	94.4%
	NO	2	5.6%

The initial part of the checklist, Facilities and Technical Containment Measures, focuses on the engineering controls used to contain biological materials in the lab, which involves both the architectural and mechanical design of the laboratory.

One of the standout concerns was the lack of controlled access to the labs in the majority of hospitals (47.2%) and the limited number of self-closing mechanisms on entrance doors (41.7%). These findings are particularly

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

alarming, as unauthorized access to lab areas could lead to potential contamination, compromise the integrity of lab equipment, and pose significant risks to patients and staff. Additionally, the lack of adequate labelling and information on biosafety levels (91.7%) was a notable shortcoming. Proper labelling and the dissemination of information are essential to raising staff awareness of biosafety protocols and containment measures, which is especially critical in healthcare settings where biological materials and hazards exist. The limited availability of safety centrifuges with separate covers for each rotor (50.0%) raised concerns about emergency preparedness. Similarly, the number of autoclaves (50.0%) for sterilization within the lab area highlighted the need for safer disinfection methods, as autoclaves are vital for sterilizing equipment and materials to prevent cross contamination and ensure biosafety.

On the positive side, the presence of designated changing and storage areas for lab staff in the majority of laboratories (80.6%), the separation of administration areas from lab areas in almost all labs (91.7%), and the fact that blood collection was conducted in a specified, separate, and adequately sized area (97.2%) were favorable aspects. These spaces help minimize the risk of cross-contamination between laboratory personnel and administrative spaces, enhancing overall biosafety within the labs and ensuring the safety of both patients and healthcare workers. In almost all laboratories (94.4%), doors and windows were securely closed during the procedures, which is a fundamental condition for containment, as gaps or vulnerabilities in the laboratory's physical barriers can compromise security measures. The presence of durable, easily cleanable surfaces for lab countertops and equipment in 86.1% of labs was also a positive sign. Such surfaces are essential for effective disinfection and maintaining a clean working environment. Other positive findings include:

- Lab seats had a stable base and could be easily disinfected (75%)
- Air conditioning operation checks were carried out regularly and recorded (94.4%)
- One or more certified Biological Safety Cabinets (BSC) were present (55.6%)
- Washbasins were located near the exit of the laboratory area (77.8%), although only 16.7% were equipped for hands-free, automatic operation
- The storage of biological agents (94.4%) and reagents (100%) was conducted safely and in appropriate locations
- The luminosity and spaces were sufficient for safe analytical procedures in the laboratory, as well as for maintenance and disinfection (94.4%).

Table 2. Administrative measures, laboratory practices, and procedures (Administrative Controls)

B. Administrative measures, laboratory practices, and procedures			
		Count	**Count %**
B.1 Risk Assessment is carried out for all laboratory procedures (P.D. 102/2020)	YES	1	2.8%
	NO	35	97.2%
B.2 There is a Biosafety Manual	YES	2	5.6%
	NO	34	94.4%
B.3 There is an authorized Biosafety officer	YES	1	2.8%
	NO	35	97.2%
B.4 The laboratory is certified or accredited	YES	10	27.8%
	NO	26	72.2%
B.5 The laboratory has written working protocols (SOPs) for all performed practices and procedures to minimize or eliminate risks, especially those that may cause splashes, droplets, aerosols, or leaks	YES	21	58.3%
	NO	15	41.7%
B.6 It is not allowed to eat, drink, smoke, and apply cosmetics in the workplace	YES	35	97.2%
	NO	1	2.8%
B.7 Laboratory benches and work surfaces are disinfected after any possible leakage of potentially infectious materials and at the end of each day's work, following the appropriate protocols and procedures	YES	36	100.0%
B.8 Hands are washed after each contact with biological agents and before leaving the laboratory	YES	36	100.0%
B.9 Introductory and continuing training and information on potential hazards at work and Safe Laboratory Practices are provided to all staff	YES	10	27.8%
	NO	26	72.2%
B.10 Housekeeping and support staff receive appropriate training	YES	16	44.4%
	NO	20	55.6%
B.11 Waste Management is carried out in accordance with the Greek legislation (Law 4042/2012 and KYA 146163/2012)	YES	36	100.0%

The evaluation of the checklist for Administrative Measures, Procedures, and Laboratory Practices in the laboratory provides valuable information about the level of biosafety protocols, policies, standards, and guidelines in the laboratory environment, as well as the education and training of the laboratory staff.

The absence of a risk assessment process for lab procedures (97.2%) was a critical gap in biosafety practices. Risk assessment is the cornerstone of any biosafety program, helping to identify, evaluate, and mitigate potential hazards. Without this foundational step, laboratories may operate without a clear understanding of the risks involved, potentially jeopardizing the safety of both patients and healthcare workers. Additionally, the lack of a Biosafety Manual (94.4%) and an authorized Biosafety Officer (97.2%) indicated a deficiency in comprehensive biosafety procedures and expertise within the laboratories. These components are pivotal for establishing and maintaining

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

effective biosafety programs, and their absence is a significant concern. The lack of a biosafety manual suggests a deficiency in documented safety guidelines, making it challenging for staff to consistently follow standard biosafety practices. Creating and implementing a biosafety manual, adapted to the needs of each laboratory, is imperative for establishing clear safety procedures. Furthermore, the absence of a licensed biosafety officer in all labs is a notable gap. The Biosafety Officer plays a key role in overseeing biosafety practices, providing guidance and ensuring compliance with safety standards. Without a licensed biosecurity officer, maintaining a proactive approach to biosafety could be difficult, making the appointment of a qualified professional to this role crucial for effective safety management.

Only some labs (27.8%) were certified or accredited, suggesting a lack of a formal recognition for adherence to specific quality and safety standards, as safety and quality complement each other. Certification or accreditation can serve as external validation of quality and safety measures and should be sought to enhance biosafety credentials. Few labs (27.8%) provided their staff with introductory and continuing training on potential workplace hazards and safe lab practices. This lack of commitment to staff training is not aligned with biosafety best practices, which emphasize that staff should be well-informed and capable of effectively mitigating risks. Adequate training is crucial for ensuring that healthcare workers are aware of and can follow safety protocols when working with biological materials, signifying a missed opportunity to enhance safety practices. Furthermore, the lack of training for support staff (44.4%) was another negative aspect. Ensuring that all staff members, including support staff, are trained in biosafety measures is essential to overall safety and reflects a holistic approach to biosafety that extends beyond the lab staff.

On the positive side, other results were:

More than half of the labs (58.3%) had documented SOPs to minimize risks associated with lab procedures. SOPs are essential for providing step-by-step guidance on safety protocols, particularly for procedures involving potential splashes, droplets, aerosols, or leaks. The absence of SOPs in some cases highlights a gap in standard security practices, and their development for specific lab procedures should be a priority.

The prohibition of activities such as eating, drinking, smoking, or using cosmetics within the labs (97.2%) was a positive observation. These activities can introduce infectious agents and pose a risk to personnel. Strict rules should always be followed to maintain a clean and safe working environment. The proper disinfection of all lab benches and work surfaces (100%) demonstrated a commitment to maintaining a healthy lab environment and preventing cross-contamination, especially after potential spills.

Moreover, proper hand hygiene practices were robust and adequately enforced in the labs (100%), emphasizing hand washing after any contact with biological agents and before leaving the lab. Additionally, all laboratories (100%) complied with Greek legislation on waste management regulations. Proper waste management is vital to preventing the spread of biohazards and maintaining a safe environment, and the high compliance rate in this aspect indicates a commitment to responsible waste management practices.

Table 3. Personal Protective Equipment (PPE)

C. Personal Protective Equipment			
		Count	**Count %**
C.1 Appropriate Personal Protective Equipment is sufficient and worn	YES	35	97.2%
	NO	1	2.8%
C.2 The type of Personal Protective Equipment is proportional to the risk assessment	YES	3	8.3%
	NO	33	91.7%
C.3 There are procedures for using, applying, and disposing of Personal Protective Equipment in the laboratory	YES	14	38.9%
	NO	22	61.1%
C.4 The laboratory coats are buttoned and can only be used inside the laboratory	YES	10	27.8%
	NO	26	72.2%
C.5 There is a procedure and equipment (e.g., hangers) for laboratory coats to be worn when entering the laboratory and removed before leaving for any reason	YES	7	19.4%
	NO	29	80.6%
C.6 There is a policy when to change laboratory coats with clean ones	YES	4	11.1%
	NO	32	88.9%
C.7 The disinfection and washing of the laboratory coats is done at home and not in specific areas of the Hospital or in an external laundry	YES	24	66.7%
	NO	12	33.3%

PPE is equipment worn by laboratory professionals to protect themselves from exposure to biological materials. It is an important line of defense and must be proportionate to the local risk assessment (Bathula & Rakhimol, 2017).

The alignment of the type of PPE with the findings of the risk assessment was observed in only a very small fraction of labs (8.3%), and there was no policies regarding when to change lab coats with clean ones (11.1%). This indicates that only a limited number of labs considered the specific risks associated with their laboratory procedures when selecting and using PPE. For optimal safety, it is vital to match the choice of PPE with the identified risks, ensuring that personnel are adequately protected during all operations. There is room for improvement in this aspect to increase the effectiveness of PPE selection. Regarding the procedures for the use, application, and disposal of PPE in the lab, only some labs (38.9%) had established procedures. Well-defined procedures are essential to ensure that PPE is properly worn, used, and disposed of. The absence of such procedures in the majority of labs indicates a possible gap in coherent and standardised PPE practices.

A noteworthy observation indicated that lab coats were buttoned and worn only within the laboratory area in a small percentage of labs (27.8%), and there were no procedures and equipment (e.g., appropriately positioned hangers) for ensuring that lab coats were used exclusively within the laboratory (19.4%). These practices are not aligned with biosafety principles, as they prevent possible contamination of personal clothing and ensure that laboratory coats are confined to the workplace. This demonstrates a lack of understanding of the importance of minimizing the spread of infectious agents and preventing contamination beyond the laboratory environment. Additionally, the decontamination and washing of lab clothes was mostly done at home, rather than in designated areas of the hospital or through an external laundry service (66.7%). This practice increases the risk of cross-infection outside the lab and hospital setting, which is crucial for effective infection control.

The only positive result indicated that almost all labs (97.2%) had an adequate supply of PPE. This demonstrates a strong commitment to staff and patient safety and is a key component of biosafety.

Table 4. Emergencies

D. Emergencies			
		Count	**Count %**
D.1 There is a plan to deal with emergencies and accidents	YES	31	86.1%
	NO	5	13.9%
D.2 There is an alternative energy supply for lighting and the laboratory equipment	YES	34	94.4%
	NO	2	5.6%
D.3 There is a fire safety system and specific escape signs in case of an emergency	YES	34	94.4%
	NO	2	5.6%
D.4 There is an eyewash system in case of an accident	YES	2	5.6%
	NO	34	94.4%
D.5 There is a First Aid Kit	YES	7	19.4%
	NO	29	80.6%
D.6 There are obvious electrical hazards in the laboratory	YES	7	19.4%
	NO	29	80.6%
D.7 Emergency telephone numbers are indicated in the laboratory areas	YES	9	25.0%
	NO	27	75.0%
D.8 There is an Occupational Doctor, and Preventive health checks for employees are carried out	YES	27	75.0%
	NO	9	25.0%
D.9 Accident report: There is a system for reporting and managing occupational accidents related to exposure to biological agents and materials	YES	21	58.3%
	NO	15	41.7%

The section of Emergency Preparedness assesses the presence of basic safety measures for emergency plans in laboratory facilities.

The absence of eyewash systems (5.6%) and the limited presence of first aid kits (19.4%) raised concerns about the ability to respond adequately to accidents and injuries, particularly those involving hazardous materials. Eyewash stations are vital for immediate treatment in case of eye contact with

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

biological agents, and their absence represents a significant gap in emergency preparedness. First aid kits are essential for providing immediate medical attention in case of minor injuries. Only a small percentage (25.0%) of labs had emergency contact numbers posted on site. Easily accessible emergency contact numbers are crucial for rapid response to critical situations. Additionally, only half of the labs (58.3%) had an incident and accident reporting system specifically related to exposure to biological agents and materials. This system is vital for documenting and managing workplace accidents and incidents.

It is encouraging that most labs (86.1%) had an Emergency Response Plan. In a healthcare setting, preparedness for various emergency scenarios is crucial. Without a clear plan in place, laboratories may not respond effectively to critical situations, potentially putting staff, patients, and the public at risk. Almost all labs (94.4%) had alternative energy sources for lighting and laboratory equipment. This readiness is critical during power outages or electrical failures, as ensuring uninterrupted power supply is essential to maintain critical operations in healthcare facilities, especially during emergencies. Additionally, almost all (94.4%) of the laboratories had a fire safety and evacuation system, which is a positive indicator of preparedness for fire-related emergencies. Fire safety measures are vital in healthcare settings, where the safety of patients and staff is paramount. Many labs (75.0%) had a contract with an occupational doctor and carried out preventive health checks for employees, suggesting an enhancement of the health and well-being of the laboratory workforce. Moreover, the majority of labs (80.6%) had no visible electrical hazards, indicating adherence to electrical safety standards.

B. Comparative Analysis of Experts' Evaluation (Checklists) and Staff's Perception (Questionnaires)

Summarizing key findings from both sources and identifying any notable differences or similarities

In comparing the questionnaire and checklist results for laboratories, it is important to note that the questionnaire provides more detailed qualitative information, while the checklist, which focuses on binary yes/no responses, offers a more structured assessment. Tables 5-8 contain the positive (Yes) answers from questionnaires and checklists for all the questions investigated. The column "EU and Greek Legislation" includes the articles of EU and Greek laws relevant to each question. The differences in positive answers between the questionnaire and checklist were investigated statistically using the McNemar test. The McNemar test is similar to Chi-square test but is more suitable for the data. It is applied to 2x2 contingency tables, like the data where the answers Yes/No were compared based on each common question from the questionnaire and checklist. If the P-value from the McNemar test is below

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

0.05, the positive ("Yes") answers from the questionnaire and checklist in Tables 5-8 differ significantly in statistical terms for that particular question.

Table 5. Comparing the Facilities and Technical Containment Measures (Engineering Controls) *The P-value has been calculated using the McNemar test and shows the statistical significance of the differences in **Yes/No** answers between the questionnaire and checklist for each question in the table.*

A. Technological Measures for the Reduction of Biological Risks					
Questionnaire Questions	**Questionnaire Count %**	**Checklist Count %**	**P-value of McNemar test**	**Checklist Question**	**EU/Greek Legislation**
7.1 Restricted access	48.9%	47.2%	0.013	A1	ANNEX V, A8
7.2 Signage at the entrance	10.6%	8.3%	1.000	A2	ARTICLE 6.2
7.3 Automated door closing mechanism	34.5%	41.7%	0.001	A3	
7.4 The doors and windows of the laboratory could be closed	23.1%	94.4%	0.000	A7	
7.5 Laboratory management is separated from laboratory analysis procedures	52.0%	91.7%	0.000	A5	
7.6 There are separate sanitary and rest areas for laboratory personnel	50.8%	80.6%	0.096	A4	ARTICLE 8.1
7.7.1 Air conditioning operation checks are carried out regularly and recorded	31.8%	94.4%	0.000	A10	
7.8 Special insulation and durable construction of Floors, Walls, and Ceiling of the laboratory	14.0%	86.1%	0.000	A8	ANNEX V, A7
7.9 Construction of the surface material of laboratory benches made of HPL, or other type of durable material	29.6%	86.1%	0.000	A8	ANNEX V, A7
7.10 Laboratory surfaces and floors are easy to clean and disinfect	69.6%	86.1%	0.001	A8	ANNEX V, A6 / A10
7.11 There is an Autoclave in the laboratory area	21.9%	50.0%	0.031	A13	
7.12 There are biological safety cabinets (BSC), Class I or II	31.8%	55.6%	0.001	A11	ANNEX V, A3
7.12.1 An annual inspection of the proper functioning of the BSCs is carried out	19.5%	55.6%	0.000	A11	
7.13 The washbasins are located near the exit of the laboratory	28.4%	77.8%	0.000	A14	
7.14 Ability to use the washbasins hands-free, with automatic operation or with the use of the legs	4.1%	16.7%	*	A15	
7.15 There is an eyewash and emergency shower system	6.0%	5.6%	1.000	D4	ARTICLE 8.1

*McNemar test could not be calculated

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

Regarding the Facilities and Technical Containment Measures, both the results from the questionnaires and the checklists showed that a significant percentage of laboratories had deficiencies in:

- Access control: restricted access (48.9% and 47.2%), signage at the entrance (10.6% and 8.3%), and automated door-closing mechanisms (34.5% and 41.7%) for questionnaires and checklists, respectively.
- Availability of autoclaves (21.9% and 50.0%) and BSCs (31.8% and 55.6%) for questionnaires and checklists, respectively.
- Washbasins with automatic operation (4.1% and 16.7%) and eyewash and emergency shower systems (6.0% and 5.6%) for questionnaires and checklists, respectively.

On the positive side, laboratory surfaces and floors were easy to clean and disinfect (69.6% and 86.1%), lab procedures were separated from management (52.0% and 91.7%), and sanitary and rest areas for laboratory personnel (50.8% and 80.6%) for questionnaires and checklists, respectively.

Table 6. Comparing the Administrative measures, laboratory practices, and procedures
P-value has been calculated by the McNemar test and shows the statistical significance of the differences of Yes/No answers between the questionnaire and checklist for each question in the table.

B. Administrative measures and laboratory procedures					
Questionnaire Questions	**Questionnaire Count %**	**Checklist Count %**	**P-value of McNemar test**	**Checklist Question**	**EU/Greek Legislation**
8.3 Samples are taken in a separate area of the laboratory administration	73.7%	97,2%	0.006	A6	
8.6 Regular disinfection of workplaces and benches	70.8%	100%	*	B7	ANNEX V, A10
8.7.1 Avoiding smoking, eating, or drinking in the laboratory	62.7%	97%	0.002	B6	ARTICLE 8.1
8.7.3 Washing hands after each contact with biological agents and before leaving the laboratory	68.4%	100%	*	B8	
9.2 Risk Assessment is performed for all laboratory procedures	28.4%	2.8%	0.625	B1	ARTICLE 3.1
9.3 There is a Biosafety Manual	21.4%	5.6%	1.000	B2	
9.4 The laboratory has written working protocols (SOPs) for all procedures	35.9%	58.3%	0.115	B5	ARTICLE 8.1
9.5 There is an authorized Biosafety officer	10.8%	2.8%	1.000	B3	
9.8 Centrifugation of samples is carried out in a safety centrifuge with a separate rotor covers	33.3%	50.0%	0.302	A12	
9.12 Waste Management is carried out in accordance with the current Greek legislation (Law 4042/2012 – Joint Ministerial Decision 146163/2012)	69.6%	100.0%	*	B11	ARTICLE 6.2
13. Theoretical and practical Biosafety training programs are provided to all staff	28.2%	27.8%	0.146	B9	ARTICLE 9

*McNemar test could not be calculated

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

There was a lack of compliance with the recommended biosafety measures related to the Biological Hazard Management System. Both the questionnaires and checklists indicated a significant percentage of labs with the following issues: written risk assessments were rarely performed (28.4% and 2.8%), there were no Biosafety Manuals (21.4% and 5.6%), few written working protocols (SOPs) for procedures (35.9% and 58.3%), very few assigned Biosafety officers in the labs (10.8% and 2.8%), and limited Biosafety training programs (28.2% and 27.8%). The centrifugation of samples was also rarely carried out in a safety centrifuge with separate rotor covers (33.3% and 50.0%).

On the positive side, it was important to note that both the questionnaires and checklists indicated that waste management was carried out in accordance with current Greek legislation (69.6% and 100.0%). Hand washing was performed after each contact with biological agents and before leaving the lab (68.4% and 100%), workplaces and benches were regularly disinfected (70.8% and 100%), and smoking, eating, or drinking in the lab was avoided (62.7% and 97%).

Table 7. Comparing Personal Protective Equipment (PPE)

The P-value has been calculated using the McNemar test and indicates the statistical significance of the differences in Yes/No answers between the questionnaire and checklist for each question in the table.

C. Personal Protective Equipment (PPE)					
Questionnaire Questions	**Questionnaire Count %**	**Checklist Count %**	**P-value of McNemar test**	**Checklist Question**	**EU/Greek Legislation**
10.1 There are sufficient Personal Protective Equipment (PPE)	63.9%	97.2%	0.000	C1	ARTICLE 8.1
10.2 The selection of PPE is made by the management or the supervisor of the employees	40.7%	8,3%	0.289	C2	
10.3 The choice of PPE is made by the employee himself	62.7%	8.3%	0.001	C2	
10.5 Laboratory coats are worn, buttoned, and with long sleeves	78.3%	27.8%	0.000	C4	
10.6 There is a policy when to change lab coats	16.4%	11.1%	0.687	C6	
10.8 There are written protocols for the application and removal of PPE	24.6%	38.9%	0.013	C3	
10.10 There is an Occupational Doctor and Medical Examinations are carried out for preventive control	34.9%	75.0%	0.001	D8	ARTICLE 14

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

There were deficiencies in the selection and use of PPE, such as: the selection of PPE was not made by the management or the supervisor of the employees, nor was it based on a risk assessment (40.7% and 8.3%); there was no specific policy on when to change lab coats (16.4% and 11.1%); and there were no written protocols for the application and removal of PPE (24.6% and 38.9%) for questionnaires and checklists, respectively.

On the positive side, there was sufficient PPE available (63.9% and 97.2%) for questionnaires and checklists, respectively.

Table 8. Comparing Emergencies
P-value has been calculated using the McNemar test and shows the statistical significance of the differences in Yes/No answers between the questionnaire and checklist for each question in the table.

D. Emergencies					
Questionnaire Questions	**Questionnaire Count %**	**Checklist Count %**	**P-value of McNemar test**	**Checklist Question**	**EU/Greek Legislation**
11.2 There is a plan in place to deal with emergencies and accidents	34.2%	86.1%	0.000	D1	ARTICLE 6.2
11.3 Accidents Reporting - There is an Occupational Accident Reporting System	25.5%	58.3%	0,115	D9	ARTICLE 10
11.5 There is a First Aid Kit	23.6%	19.4%	0.754	D5	
11.6 Emergency telephone numbers are indicated in the laboratory premises	30.8%	25.0%	1.000	D7	

In relation to emergency preparedness, both sources identified deficiencies in emergency procedures and preparedness, specifically in accidents reporting (25.5% and 58.3%), the availability of a first aid kit (23.6% and 19.4%), and the presence of emergency telephone numbers on laboratory premises (30.8% and 25.0%) for questionnaires and checklists, respectively.

Discussion

Checklist Results

The findings from the Checklist results across all four sessions highlighted both positive and negative areas that need immediate attention and improvement. **Laboratories should view these findings as opportunities to enhance engineering and administrative controls, PPE, and emergency preparedness.** Addressing these gaps should be a priority for all labs to improve biosafety. This precautionary approach is essential for maintaining a safe working environment and ensuring the protection of both staff and the environment. More specifically:

- **In Session A (Facilities and Technical Containment Measures):** While the layout, separation, and luminosity of lab areas were sufficient, gaps were detected in engineering control measures,

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

including access control, labelling and information of the Biosafety Level at the entrance, and the acquisition of critical equipment, such as safety centrifuges and autoclaves.

- **In Session B (Administrative measures, Laboratory Practices and Procedures):** Labs demonstrated strengths in some areas of administrative controls, such as good lab practices and procedures, hand hygiene, disinfection of laboratory surfaces, and waste management. However, significant gaps were found in performing risk assessments for lab procedures, the absence of a biosafety manual and authorized biosafety officers, continuing training, and the information of lab and housekeeping personnel, underscoring the need for enhanced guidance. It is essential to ensure that these procedures are consistently followed and staff members are adequately trained to understand and implement them.
- **In Session C (Personal Protective Equipment):** While the majority of labs demonstrated a strong commitment to the availability of PPE, many areas for improvement remain. These include the need for standardized procedures for the use of PPE, the alignment of PPE with risk assessments, and the development of formal policies for changing and disinfecting lab coats. These improvements will contribute to enhanced biosafety practices in lab facilities.
- **In Session D (Emergencies);** Laboratories demonstrated preparedness in some aspects, such as emergency plans, alternative energy supply, fire safety systems, and occupational health services. However, notable gaps were identified in other areas, including the lack of eyewash systems, first aid kits, visible emergency contact numbers, and an incident and accident reporting system. Addressing these gaps is essential to enhance emergency preparedness.

Comparison of the Checklist and Questionnaire Results

When comparing the checklist and questionnaire results, both sources highlighted common challenges and areas for improvement in biosafety practices related to engineering and administrative controls, PPE, and emergency preparedness. These findings help address perceived and actual workplace hazards:

- **Issues were identified in the implementation and enforcement of national Greek legislation**, not only by competent authorities, but also by the administration of hospital organizations. Specifically, several items referenced in Presidential Decree 102/2020 were rarely implemented, according to both checklist and questionnaire results. These items include restricted access (ANNEX V, A8 – Table 5, 7.1), signage at the entrance (ARTICLE 6.2 - Table 5, 7.2), eyewash and

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

emergency shower systems (ARTICLE 8.1 - Table 5, 7.15), risk assessments for all laboratory procedures (ARTICLE 3.1 - Table 6, 9.2), SOPs for all procedures (ARTICLE 8.1 - Table 6, 9.4), biosafety training programs for all staff (ARTICLE 9 - Table 6, 13), and an accidents reporting system (ARTICLE 10, Table 8, 11.3).

- This study, in line with other studies (Tziaferi et al., 2011), also validated the importance of incorporating staff perception and expert evaluation to improve the efficiency of risk management in laboratory environments and the enforcement of applicable regulations. These factors should be considered in future research studies involving hospital staff in the risk evaluation process. However, the observations and responses from lab staff highlighted the difficulty in evaluating risks, as **there was not always alignment between questionnaire and checklist results for laboratories.** Limited staff awareness of biosafety issues led to both overestimation and underestimation of risks. Experts may have also overestimated or underestimated current risk levels in their capacity as external evaluators. Differences in risk perception between lab staff and experts, in this case, the biosafety officer, are a known phenomenon when using questionnaires as an audit methodology. These differences can occur at various levels of risk, such as risk magnitude, likelihood, and severity. Such disparities may stem from factors like educational level, work experience, risk attitude, and professional knowledge level of laboratory workers compared to the expert. Lab staff, who work daily in the audited laboratory, may find it more challenging to recognize deviations or the absence of SOPs and procedures, lab layout issues, etc. The expert, however, visits the laboratory only once per year to perform an audit and is more likely to notice every deviation from SOPs or procedures. Therefore, it would be beneficial to have not only internal audits by the lab staff but also audits by an external expert every 1-2 years. **The observed disparities in perceived risk estimation between subjective staff questionnaires and expert evaluations underscore the importance and crucial need for biosafety training.** Such training should be designed to clarify employees' perceptions of risk and offer suggestions for improving safety.

Recommendations

There is a significant need for more comprehensive and proactive measures, as well as adequate training and education for all workers, to reduce the risks of exposure to hazardous biological materials and agents. In the face of a constantly evolving landscape of biological risks and threats, it is essential to raise biosafety practices to higher standards.

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

Using the results of this study, actions can be formulated to improve biosafety safeguards by creating a Biorisk Management System in biomedical labs and enhancing the biosafety culture among laboratory professionals in Greece. It is hoped that the findings of this study will encourage employers to adopt a more proactive approach and invest the necessary resources to enhance biosafety.

Recommendations for Biomedical Laboratories to improve Biosafety at the International BSL-2 Level:

1. **Development and Effective Implementation of a Structured and Sustainable Biorisk Management System (ISO 35001:2019);** This system should be based on management's strategic commitment, resources, and a continuous improvement mindset through a cycle of planning, implementing, and reviewing (European Committee for Standardization, 2011; WHO, 2011). It could improve lab operations and activities, assist in meeting quality standards (ISO 15189:2022; 15190:2020), and fulfill legal requirements (WHO, 2016).
2. **Conduct risk assessments with the 5-step methodology** as described in the WHO Laboratory Biosafety Manual, 4th ed. (WHO 2020), or utilize a custom procedure for biomedical labs, such as the one proposed in Annex I.
3. **Develop written SOPs for all lab procedures.**
4. **Designate an Appointed Biosafety Officer in Every Hospital**; This officer should be authorized by the administration to oversee biosafety and biosecurity programs. Competent biosafety professionals are essential to labs and organizations, serving as a crucial element of global health security and vital for preparedness and response to infectious disease outbreaks. This is also emphasized in:
    - WHO LBM 4ed. (2020), Biosafety Programme Management monograph: "A biosafety officer should be appointed to provide advice and guidance to personnel and management on biological safety issues. The role and knowledge of the biosafety officer is vital to the development, implementation, maintenance, and continuous improvement of a biosafety and biosecurity programme."
    - ISO 35001 (2019) Biorisk Management Standard: "A competent individual(s) shall be designated to provide advice, guidance, and assurance on biorisk management issues."
    - WHO External Evaluation Tool (2005) (Action Package Prevent 3 – Biosafety & Biosecurity): "Biosafety officers certified and stationed at all laboratories that handle dangerous pathogens."

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

5. **Elaboration of Introductory and Continuous Training Programs:** These programs increase awareness and responsibilities to create a safety culture regarding biological risks. Education and training are essential for the proper implementation of biosafety procedures and emergency response. Training should be organized by management in collaboration with the Biosafety officer. Furthermore, to enhance regional and national biosafety, there is a need to form a local team of experts to educate and train biosafety professionals.
6. **Ongoing Collaboration and Partnerships with International Organizations (WHO, CDC, and ECDC), Biosafety Associations, and Individuals with Expertise**: No single governmental authority can effectively manage biological risks and infectious biological incidents alone. There is a growing trend towards increased integration and cooperation among multiple stakeholders, including international organizations (WHO, CDC, and ECDC), biosafety scientific associations, academia, research institutions, and individual experts. These stakeholders could play a crucial role at both local and international level in:
    - Networking and collaborating to advance biorisk management practices and procedures, and sharing information about failures and implemented solutions.
    - Creating a safety culture and raising awareness of risks among biosafety professionals to ensure safe, secure, and responsible work with biological materials and agents.
    - Promoting biorisk management practices and procedures.
    - Educating and certifying skills of biosafety officers and laboratory professionals.

Particularly, WHO, CDC, and ECDC can be important partners for government authorities, providing support and assistance in developing and implementing cost-effective and sustainable key national biosafety strategies, guidelines, and legislation for safe work with biological agents at all containment levels, considering specific circumstances and goals. They could also assist with the use of the Joint External Evaluation Tool in compliance with the GHSA (Global Health Security Agenda) and IHR (International Health Regulations) in assessing biosafety capability and addressing security deficiencies. Finally, adopting the international biosafety and biosecurity standards and guidelines of WHO, CDC, and ECDC, and aligning risk control measures with them, could ensure that best practices are followed, thereby improving biosafety in these labs to the international BSL-2 level.

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

Conclusion

While there were some positive findings, much work remains to be done to ensure effective biosafety levels in these types of labs. The results indicate that few labs had an effective biorisk management system in place, and there was a low biosafety culture within the organizations. The administration did not appear to be fully aware of its responsibilities in performing risk assessments and providing introductory and continuous training to the lab staff. **Therefore, it is evident that in many of the biomedical labs assessed, there were issues with the implementation of national Greek legislation, which did not fully comply with internationally accepted BSL-2 standards, such as those of the WHO, CDC, and ECDC.**

By implementing the above recommendations to improve biosafety at the international BSL-2 level and the Recommended Risk Assessment for Biomedical Laboratories (ANNEX I), along with enforcing existing laws and directives, a valuable tool and armamentarium will be developed for any hospital, diagnostic, and research area. The expected results may significantly impact the biosafety awareness of laboratory staff and the implementation of Greek legislation. **The most favorable outcome will be enhanced protection for lab staff, the community, and the environment from potentially dangerous biological materials and lab-acquired infections.**

Implications

The findings of this study have several implications for laboratory workers and employers:

1. The need for increased education and training on biosafety practices.
2. The need for improved laboratory engineering and administrative control measures, along with the necessary resources to support and oversee them.

Declaration for Human Participants: The study was conducted in accordance with the ethical guidelines outlined by the Declaration of Helsinki. The questionnaires were anonymous, and informed consent was obtained from the participants regarding the study's purposes, their voluntary participation, and their ability to withdraw the questionnaire at a later stage. In the first stage, the study protocol and questionnaire were approved by the Ethical Committee of the University of West Attica (UniWA) on 16-11-2020, with acceptance number 89760/06-11-2020. Prior to visiting the labs, written permission was obtained from the scientific committee of each hospital where the laboratories were located, and the confidentiality of the facilities was strictly maintained and ensured throughout and after the study.

Conflict of Interest: The authors reported no conflict of interest.

Data Availability: All data are included in the content of the paper.

Funding Statement: The project is financially supported by ELKE Uniwa (Special Account for Research Funds of the University of West Attica).

References:

1. Bathula, S. R. & Rakhimol, A. (2017). Global Trends in biorisk Management. BioRisk, 12, 1–23. https://doi.org/10.3897/biorisk.12.12156
2. Blacksell, S. D., Dhawan, S., Kusumoto, M., Lě, K., Summermatter, K., O'Keefe, J., Kozlovac, J. P., Almuhairi, S. S., Sendow, I., Scheel, C. M., Ahumibe, A., Masuku, Z. M., Bennett, A., Kojima, K., Harper, D. R., & Hamilton, K. (2023). Laboratory-acquired infections and pathogen escapes worldwide between 2000 and 2021: a scoping review. The Lancet Microbe. https://doi.org/10.1016/s2666-5247(23)00319-1
3. Brown, C.S., Zwetyenga, J., Berdieva, M., Volkova T., Cojocaru R., Costic, N., Ciobanu, S., Hasanova, S., van Beers, S., & Oskam, L. (2015). New policy-formulation methodology paves the way for sustainable laboratory systems in Europe. Public Health Panor. 2015; 1(1):41-7.
4. Centers for Disease Control and Prevention (CDC) (2020). U.S. Department of Health and Human Services. Public Health Service. National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories. 6th ed. Available at: https://www.cdc.gov/laboratories/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf (Accessed: 27 July 2024)
5. Centers for Disease Control and Prevention (CDC) & National Institute for Occupational Safety and Health (NIOSH) (2021). Hierarchy of Controls. Available at: https://www.cdc.gov/niosh/learning/safetyculturehc/module-3/2.html (Accessed: 27 July 2024)
6. Directive 2000/54/EC (2000). Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32000L0054&from=EN (Accessed: 27 July 2024)

7. Farr, J.M. & Shatkin, L. (2004). Best jobs for the 21st century. JIST Works. p. 460. ISBN 978-1-56370-961-6.
8. Gribble, L.A., Tria, E.S., & Wallis, L. (2015). 'The AMP Model,' in Salerno, R.M. and Gaudioso, J. (ed.) Laboratory Biorisk Management: Biosafety and Biosecurity, Boca Raton: CRC Press, Taylor & Francis Group, pp. 31-42.
9. International Organization for Standardization (ISO) (2019). ISO 35001:2019. Biorisk management for laboratories and other related organizations. Availab le at: https://www.iso.org/standard/71293.html (Accessed: 27 July 2024)
10. International Organization for Standardization (ISO) (2020). ISO 15190:2020. Medical laboratories – Requirements for safety. Available at: https://www.iso.org/standard/72191.html (Accessed: 27 July 2024)
11. International Organization for Standardization (ISO) (2022). ISO 151 89:2022. Medical laboratories – Requirements for quality and compet ence. Available at: https://www.iso.org/standard/76677.html (Accessed: 27 July 2024)
12. Kessel, M. (2014). Neglected diseases, delinquent diagnostics. Science Translational Medicine, 6(226). https://doi.org/10.1126/scitranslmed.3008194
13. National Institutes of Health (NIH) (2024). NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). DEPARTMENT OF HEALTH AND HUMAN SERVICES, National Institutes of Health. Available at: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf (Accessed: 27 July 2024)
14. Pike, R.M. (1976). Laboratory-associated infections. Summary and analysis of 3921 cases. Health and Laboratory Science vol 13, page 105-114.
15. Presidential Decree 102/2020 (Government Gazette 244/A'/07.12.20 20) (2020). Available at: https://www.et.gr/api/DownloadFeksApi/?fek_pdf=20200100244 and https://www.gov.gr/sdg/work-and-retirement/health-and-safety-at-work/independent-authority-labour-inspectorate/obligations-of-companies (Accessed: 27 July 2024)
16. Raafat, H. & Sadhra, SS. (1999). In: Sadhra SS, Rampal KG, editors. Occupational health: risk assessment and management. 4th ed. Oxford (UK): Blackwell Science Ltd; 1999. pp. 177–193.
17. Salerno, M.R. & Gaudioso, J. (2015). 'Introduction: The Case for Biorisk Management,' in Salerno, M.R. and Gaudioso, J. (ed.)

Laboratory Biorisk Management: Biosafety and Biosecurity, Boca Raton: CRC Press, Taylor & Francis Group, pp. 1-23.
18. Sandia National Laboratories (2014). Laboratory Biosafety and Biosecurity Risk Assessment Technical Guidance Document. Available at: https://internationalbiosafety.org/wp-content/uploads/2019/08/Laboratory-Biosafety-and-Biosecurity-Risk-Assessment.pdf (Accessed: 27 July 2024)
19. Sewell, D. L. (1995). Laboratory-associated infections and biosafety. Clinical Microbiology Reviews, 8(3), 389–405. https://doi.org/10.1128/cmr.8.3.389
20. Tun, T. A. (2017). Biomedical Laboratory: its safety and risk management. Journal of Experimental & Biomedical Sciences/Biomedical Science Letters, 23(3), 155–160. https://doi.org/10.15616/bsl.2017.23.3.155
21. Tziaferi, S., Sourtzi, P., Kalokairinou, A., Sgourou, E., Koumoulas, E., & Velonakis, E. (2011b). Risk assessment of physical hazards in Greek hospitals combining staff's perception, experts' evaluation and objective measurements. Safety and Health at Work, 2(3), 260–272. https://doi.org/10.5491/shaw.2011.2.3.260
22. Vourtsis, D., Papageorgiou, E., Kriebardis, A., Karikas, G. A., Van Willigen, G., & Karkalousos, P. (2022). A swift risk analysis for COVID-19 testing facilities using rapid tests. One Health & Risk Management, 3(4), 48–66. https://doi.org/10.38045/ohrm.2022.4.05
23. Weinstein, R. A. & Singh, K. (2009). Laboratory-acquired infections. Clinical Infectious Diseases, Volume 49, Issue 1, 1 July 2009, Pages 142–147,. https://doi.org/10.1086/599104
24. World Health Organization (WHO) (2004). Laboratory Biosafety Manual. 3rd ed. Available at: https://www.who.int/publications/i/item/9241546506 (Accessed: 27 July 2024)
25. World Health Organization (WHO) (2005). International Health Regulations, Joint external evaluation tool – third edition. Available at: https://www.who.int/publications/i/item/9789240051980 (Accessed: 27 July 2024)
26. World Health Organization (WHO) (2010). Responsible life sciences research for global health security, A guidance document. Available at: https://www.who.int/publications/i/item/WHO-HSE-GAR-BDP-2010.2 (Accessed: 27 July 2024)
27. World Health Organization (WHO) (2011). Laboratory Quality Management System:

handbook, Available at: https://www.who.int/publications/i/item/9789241548274 (Accessed: 27 July 2024)

28. World Health Organization (WHO) (2014). Training Report, Hands-on Training Workshop on Cell Culture Techniques for the Laboratory Diagnosis of Polio/Enteroviruses and Measles/ Rubella in the Western Pacific Region. Available at: https://apps.who.int/iris/bitstream/handle/10665/208735/RS_2014_GE_11_HOK_eng.pdf?sequence=1 (Accessed: 27 July 2024)
29. World Health Organization (WHO) (2016). Development of national laboratory policies, Best practices document and facilitators' guide. Available at: https://www.who.int/europe/publications/i/item/WHO-EURO-2017-5659-45424-65013 (Accessed: 27 July 2024)
30. World Health Organization (WHO) (2020). Laboratory Biosafety Manual. 4th ed. Available at: https://www.who.int/publications/i/item/9789240011311 (Accessed: 27 July 2024)
31. World Health Organization (WHO) (2020). Laboratory biosafety manual, 4th edition: Biosafety programme management. Available at: https://www.who.int/publications/i/item/9789240011434 (Accessed: 27 July 2024)
32. Wurtz, N., Papa, A., Hukić, M., Di, A., Leparc-Goffart, I., Leroy, E. M., Landini, M., Sekeyová, Z., Dumler, J. S., Bădescu, D., Busquets, N., Calistri, A., Parolin, C., Palù, G., Christova, I., Maurin, M., La Scola, B., & Raoult, D. (2016). Survey of laboratory-acquired infections around the world in biosafety level 3 and 4 laboratories. European Journal of Clinical Microbiology & Infectious Diseases, 35(8), 1247–1258. https://doi.org/10.1007/s10096-016-2657-1

ISSN: 1857-7881 (Print) e - ISSN 1857-7431

Appendix

Recommended Risk Assessment for Biomedical Laboratories

1. Comprehensive Hazard Identification: The initial step is the thorough and comprehensive identification of biological hazards within the laboratory. This process should involve biosafety experts and laboratory staff. All possible sources of hazards must be considered, including patient samples, infectious agents, and laboratory equipment.
2. Holistic Risk Profile: Once risks have been identified, a holistic risk profile must be developed. This includes assessing the full range of hazards, such as biological, chemical, radiological, and physical hazards. Risks should be categorized based on their potential impact on patients, healthcare workers, visitors, and the environment.
3. Advanced Risk Modeling: Apply advanced risk modeling techniques to quantitatively assess risks by calculating the likelihood and severity of potential incidents and hazards. Leverage historical data, incident reporting systems, and predictive analytics to enhance the accuracy of the risk assessment. This data-driven approach allows for more effective prioritisation of the risks. Adopt global standards by aligning risk control measures with international biosafety and biosecurity guidelines from organizations like the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and the European Centre for Disease Prevention and Control (ECDC) to ensure best practices are followed.
4. Multi-layered Risk Mitigation: Develop and implement multi-layered controls to mitigate risks. This includes a combination of technical controls (e.g., HVAC, containment facilities, and equipment), administrative controls (e.g., policies, procedures, and training), and personal protective equipment (PPE).
5. Continuous Monitoring: Implement a real-time monitoring system to continuously assess and update risk profiles. This includes monitoring the emergence of new infectious diseases and advances in biomedical technologies. Regular risk assessments must be part of institutional policy.