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Bridging policy and practice: Implementing the WHO Laboratory Biosecurity Guidance

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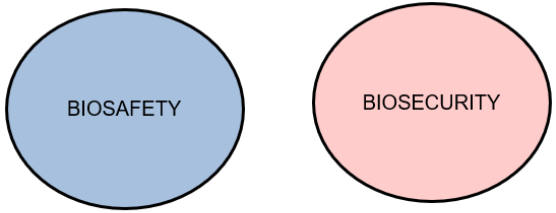
«Biosafety and laboratory biosecurity are a continuum that is fundamental to safe and secure operation and management of laboratories»

Dr. Kazunobu Kojima, WHO

The gap – bridging policy and practice

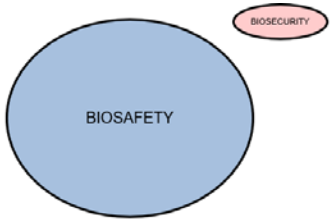
- Disconnect between national policy and laboratory operations
- Variability in capacity and enforcement
- Lack of standardized implementation mechanisms
- Lack of technical capacity and trained personnel
- Limited awareness and engagement of stakeholders
- Underestimated significance of biosecurity in institutions concerned
- No prioritization of resources (financial, personnel)

The interplay of biosafety and biosecurity

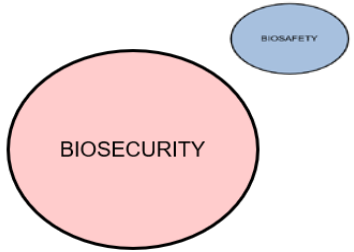


Two separate things

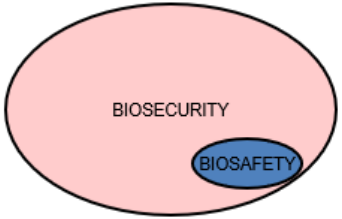
Is the same



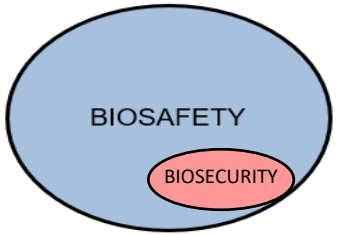
Biosafety is much more important than Biosecurity and is a separate element



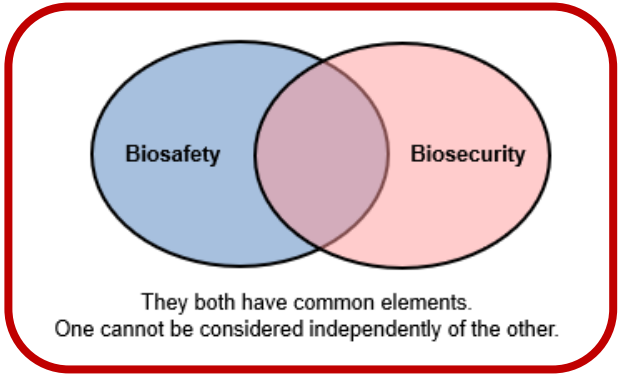
Biosecurity is much more important than Biosafety and is a separate element



Biosafety is an element of Biosecurity and less important

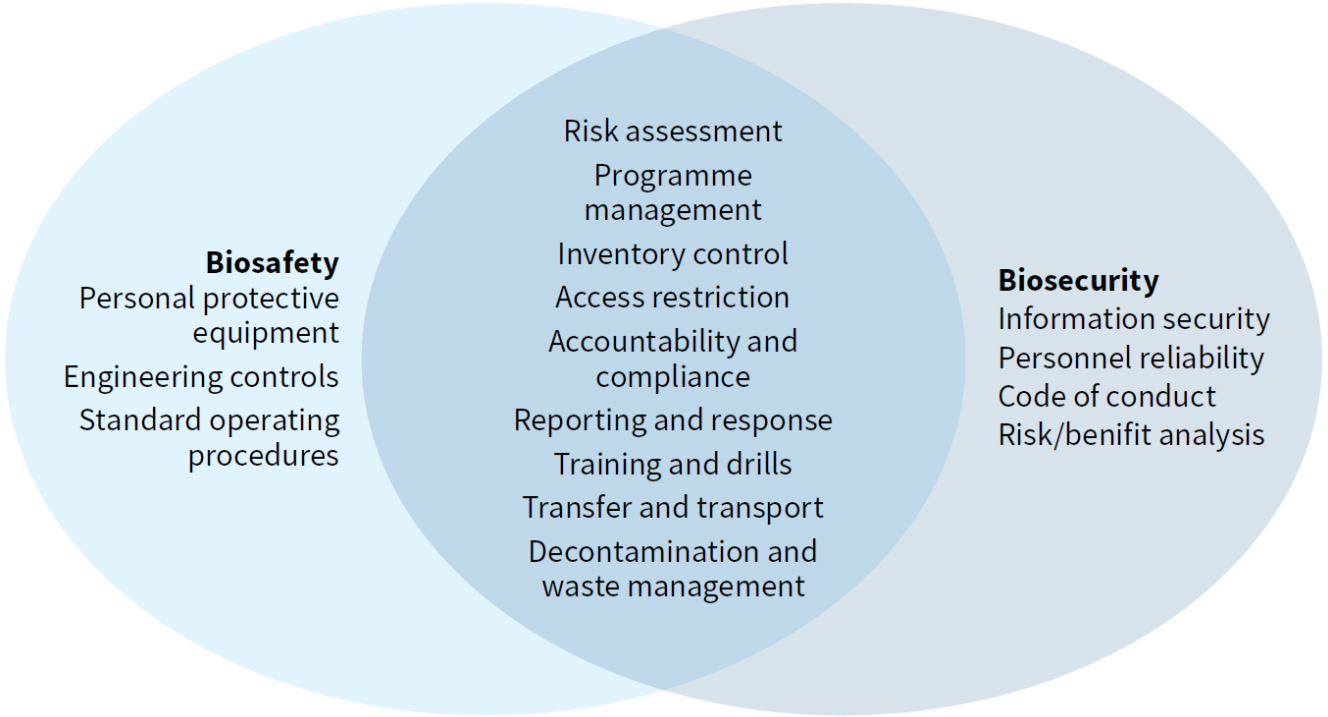


Biosecurity is an element of Biosafety and less important



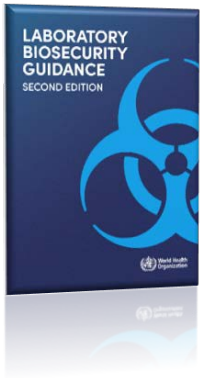
They both have common elements.
One cannot be considered independently of the other.

Biosafety – biosecurity: complementary pillars of laboratory biological risk management



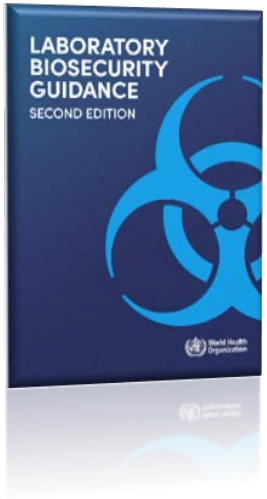
WHO Laboratory Biosecurity Guidance, 2024

WHO Laboratory Biosecurity Guidance



- Published in 2024
- Complements the Laboratory Biosafety Manual (LBM4)
- Enables biological risk management for secure and safe operations
- Provides comprehensive, scalable, and sustainable approaches to biosecurity in laboratory settings globally
- Covers high-consequence research and work with high-consequence materials and other biosecurity-relevant material

Key updates



- Stronger emphasis on risk-based approaches reinforcing the context-specific risk assessments to define biosecurity measures
- Integration of cybersecurity and artificial intelligence
- Integration of dual-use concerns and emerging technologies
- Expanded personnel reliability and insider threat mitigation
- Strengthened focus on culture of responsibility and biosecurity culture and governance

Two-tier system

National level oversight:

- Set broad biosecurity policies, laws, and standards (e.g. list of high consequence materials)

Institutional level oversight:

- Implement and adapt national policies to specific local contexts
- Institutional biosafety committee – Biosafety professionals - PI

Hybrid approach combining top-down and bottom-up mechanisms

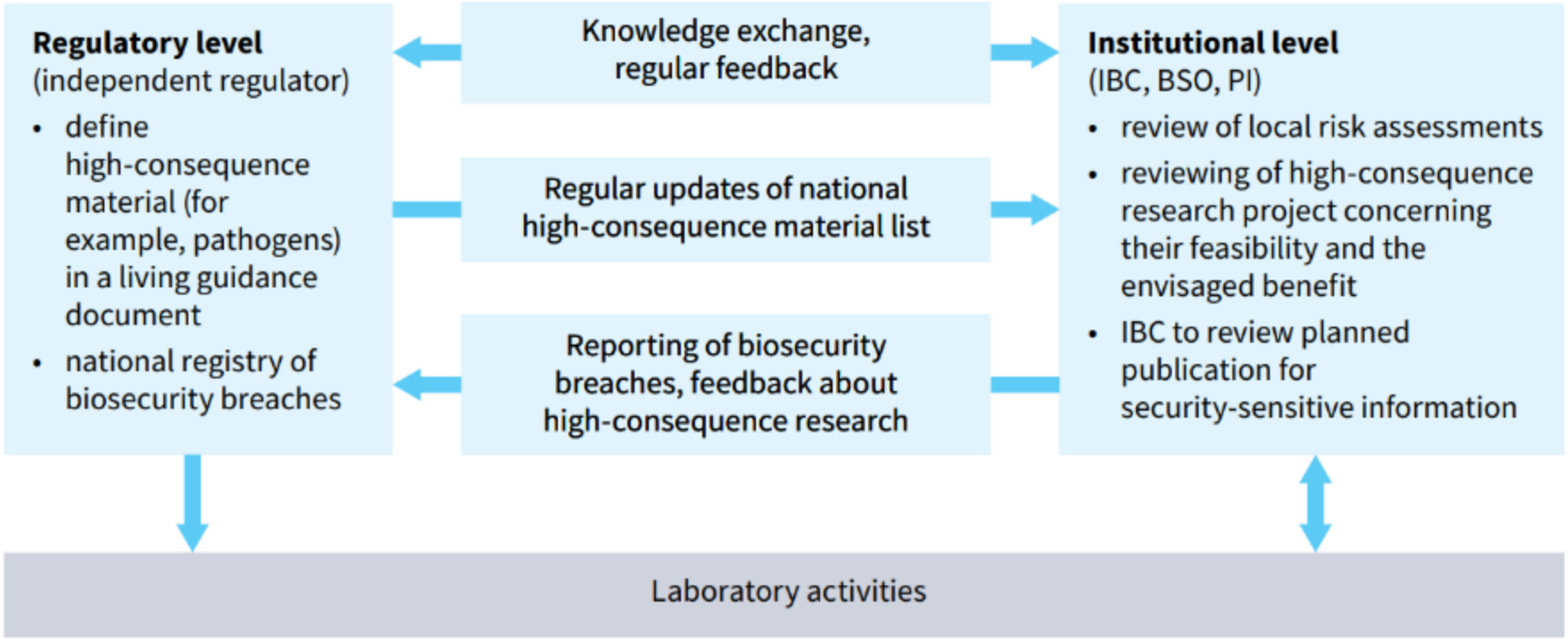


Fig. 8.1. Schematic overview of a two-tier system for national regulation of high-consequence research and material

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Strategies for effective implementation on an institutional level

- Establish of a robust institutional governance
- Conduct comprehensive biosecurity risk assessments
- Implement risk control measures
- Promote a culture of biosecurity
- Strengthen training and capacity building
- Ensure effective communication and reporting
- Align with national and international regulations

Foster a culture of biosecurity

- Leadership and commitment including top-down endorsement
- Biosecurity specific code of conduct including principles on responsible science
- Education, training and awareness
- Psychological safety and no blame culture
- Incident reporting systems inclduing root-cause analysis
- Peer engagement and accountability
- Continuous improvement culture

Institutional biosafety committees

- Serve as a bridge between policy and lab-level implementation
- Review and approve biosecurity relevant activities and biosafety practices
- Review and oversee work involving high-consequence materials and dual-use evaluations
- Support risk assessments
- Promote a culture of responsibility and compliance

Biosecurity incident reporting systems

Purpose: to create a standardized approach for reporting and investigating biosecurity incidents, accidents and near misses:

- early detection and response
- **non-punitive environment** where personnel feel safe reporting
- open dialogue and regular debriefings where lessons are learned - not blame assigned
- identification of patterns and threats to enable targeted risk assessment and improved prevention

Tools for institutional implementation

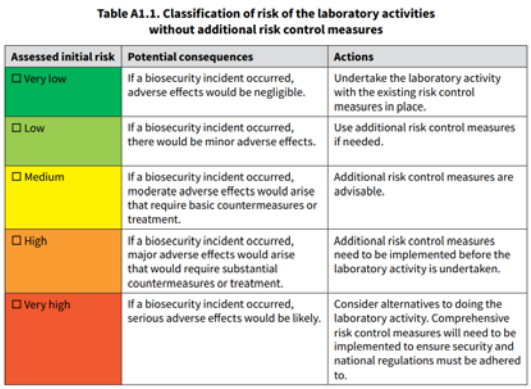

Table A1.1. Classification of risk of the laboratory activities without additional risk control measures

Assessed initial risk	Potential consequences	Actions
☐ Very low	If a biosecurity incident occurred, adverse effects would be negligible.	Undertake the laboratory activity with the existing risk control measures in place.
☐ Low	If a biosecurity incident occurred, there would be minor adverse effects.	Use additional risk control measures if needed.
☐ Medium	If a biosecurity incident occurred, moderate adverse effects would arise that require basic countermeasures or treatment.	Additional risk control measures are advisable.
☐ High	If a biosecurity incident occurred, major adverse effects would arise that would require substantial countermeasures or treatment.	Additional risk control measures need to be implemented before the laboratory activity is undertaken.
☐ Very high	If a biosecurity incident occurred, serious adverse effects would be likely.	Consider alternatives to doing the laboratory activity. Comprehensive risk control measures will need to be implemented to ensure security and national regulations must be adhered to.

- Risk assessment framework: structured methodology to identify and evaluate biosecurity risks (template)
- Institutional biosafety committee: definition of roles and responsiblities (terms of reference template)
- Emergency response tool to help plan the emergency response
- Detailed information about biosecurity risk control measures (e.g. personnel, physical security, inventory control, information security etc.)

Challenges

- Resistance to change, lack of institutional support
- Cultural and organizational barriers
- Perceived lack of relevance
- Balancing security with research freedom
- Shortage of skilled personnel
- Limited resources
- Inconsistent or absent regluations hinder effective and uniform implementation on an institutional level

Key takeaways

- Risk-based approach is central
- Leadership and governance are crucial
- Biosecurity is a shared responsibility
- Training and awareness make or break success
- Reporting systems enable continuous improvement
- Bridging gaps requires national and institutional alignment

Thank you for your attention!

Acknowledgment: Dr. Kazunobu Kojima

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