BIOSAFETY & BIOSECURITY NEWSLETTER

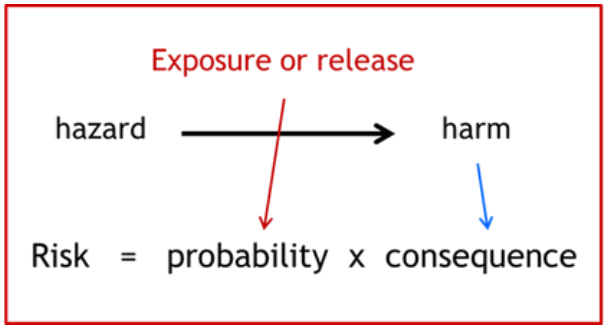
OFFICE OF RESEARCH INTEGRITY
ORI

Spotlight on Biological Risk Assessment

A comprehensive biological risk assessment (RA) must be conducted for each organism and sample type handled in a research project to determine the appropriate containment measures to prevent exposure or release. The specific laboratory procedures included in the project must also be considered. Biological risk assessments are conducted within a Risk analysis framework that includes risk assessment, risk management and risk communication.

IMPORTANT CONCEPTS

HAZARD: Biological agents that have the potential to cause adverse effects (harm) to personnel and/or humans, animals, and the wider community and environment following exposure or release.



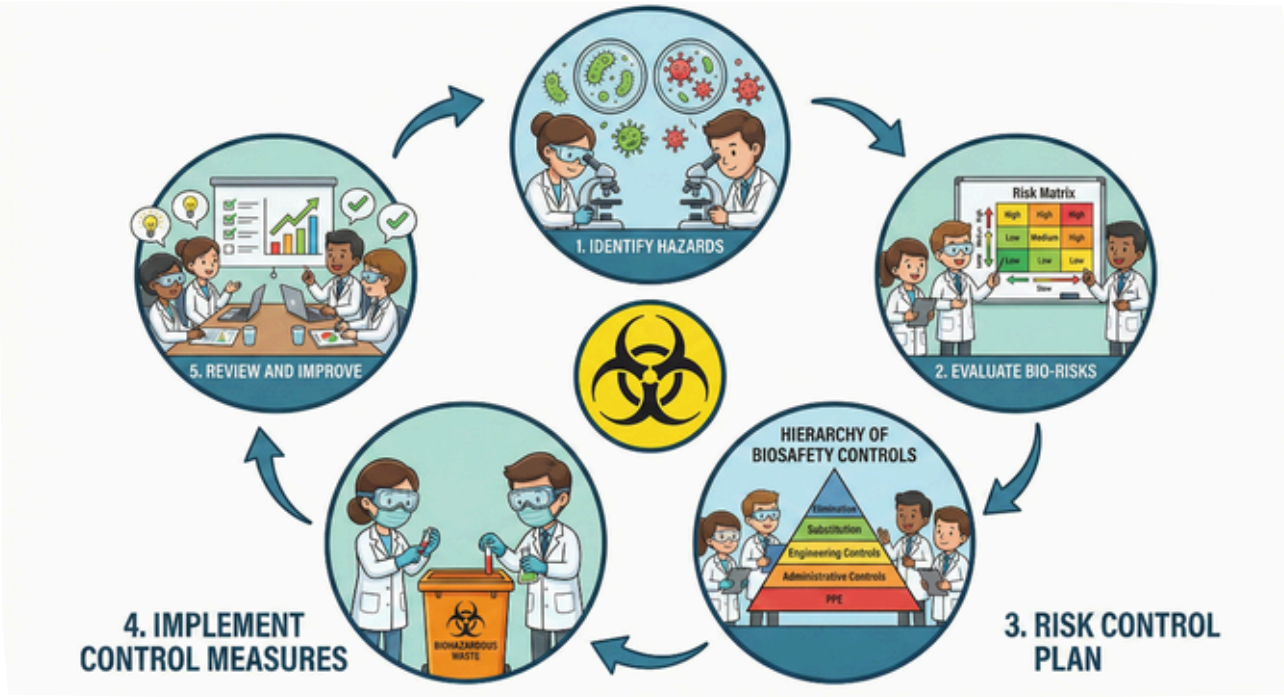
A hazard ≠ A risk

The probability and consequences of exposure to the hazard must be considered to determine the level of risk associated with it.

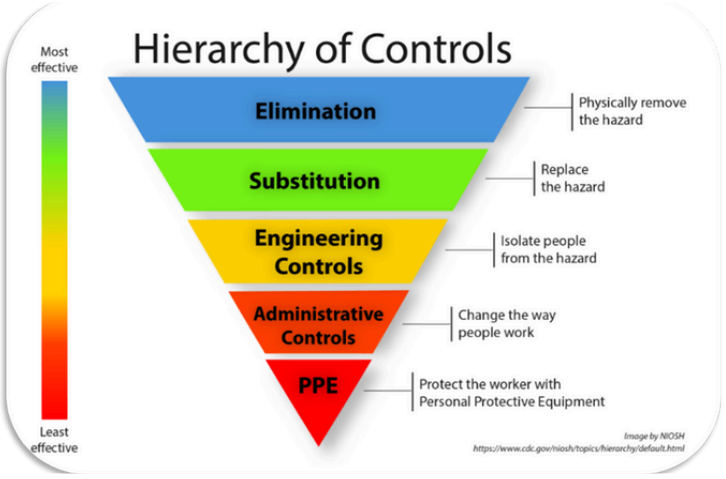
RISK: The combination of the probability that exposure to or release of a hazard can take place and the severity of the harm (consequence) that may arise from exposure to that hazard.

The Hazard or Risk Group of a pathogen ≠ Biosafety level at which it should be handled

Biological Risk Assessment Process



This image was produced by Gemini AI, using the prompt "Draw an informal picture of a biological risk assessment cycle with the following five steps: 1. Identify hazards, 2. Evaluate risks, 3. Risk control strategy, 4. Implement risk management 5. Review and improve. Include cartoons of scientists wearing lab PPE at each step. Start with Step 1 at the top of the cycle and follow with step 2. Step 2 is followed by step 3, etc. Include a risk matrix in step 2. Include the hierarchy of biosafety controls in step 3. Include the universal biohazard sign in the centre of the cycle."

	STEP	KEY CONSIDERATIONS
RISK MANAGEMENT	Identify hazards: gather information	• What? Characteristics of the biological agent. • How can exposure or release occur? Type of procedures (each step) and generation of aerosols. Does the planned procedure change the risk? • Where will work be done? Type of available lab facility & equipment. • Who? Level of personnel competence. What can go wrong? • Other factors that affect lab operation (legal, regulatory)?
	Evaluate the risks	• What is the likelihood of exposure or release? • What are the consequences of exposure or release? • What is the overall initial risk? • Are risks acceptable or unacceptable?
	Develop a risk control strategy/ plan	Which resources are available for risk control? Are the resources sufficient to reduce initial risks to acceptable risks and allow work to proceed safely (low residual risk)? Use the Hierarchy of Controls to determine which actions will best control exposures. Initial risk → Residual risk Risk control measures 
	Select and implement risk control measures	• Core biosafety requirements plus additional control and containment measures for medium and high risks. • Training and communication are essential.
	Review the effectiveness of controls	• Inspection, review and audit of processes and documentation. Consider new info about biological agents, changes in lab activities or equipment & new risk control measures. • Document RA & findings, and update or improve risk management strategy.
RISK COMMUNICATION		
	Takes place throughout the entire process, steps 1 to 5	• Goal: To guide all stakeholders to understand the risk assessment methodology, the results and the risk management decisions. Includes training, development of standard operating procedures (SOPs), signage (OH&S aspects), reporting of incidents, etc.

Updated forms: Animal Diseases Act Section 20 permit applications

Please note that the Directorate of Animal Health's Section 20 Permit Office has updated its guideline document and application forms. The new forms (Version 25/1) must be used from January 2026 (no applications on the previous forms will be accepted from January 2026). Please find the updated application and amendment application forms on the Department of Agriculture website: https://www.nda.gov.za/index.php/publication/429-research-approval-section-20

All new project applications and amendment applications must be submitted in **Word** format to Lisa Williams (lisa.williams@uct.ac.za) for review and insertion of the UCT designated authority's contact details. Section 20 applications must be signed by the ORI Director, after which Lisa will submit the application form to the Section 20 Office, together with all the supporting documents.

The Office of Research Integrity wishes everyone a safe and peaceful festive season and a joyful holiday.

Contacts

Please feel free to contact us in the ORI should you have queries related to biosafety and biosecurity. Your queries can be directed as follows:

- Dr Sarita Groenewald (sarita.groenewald@uct.ac.za) for GMO facility registrations and imports, biosafety audit responses, the South African biosafety and biosecurity regulatory framework and questions about biosafety compliance.

- Ms Lisa Williams (lisa.williams@uct.ac.za) for Section 20 permits applications and follow-up and Section 20 amendment applications.

If you want to enquire about import permits relating to the Department of Health, please contact Dr Blessing Silaigwana (blessing.silaigwana@uct.ac.za).

What you can do

Share this newsletter with colleagues and students in your department.

Visit our revamped webpages and let us know if they are useful, or missing something.

Share resources with us. Please let us know if you have come across a useful resource that improves, simplifies, or provides scientific evidence for your own biosafety and biosecurity management so we may add it to our repository.

Remember to submit Section 20 permit and amendment applications to the ORI for review and final signature (the Department of Agriculture (DOA) won't process an application without our sign-off!).