Annex 2 Risk assessment template

Although a qualitative approach to combining likelihood and severity parameters in a risk matrix is provided as a risk evaluation method here, it is important to note that quantitative (for example, simple numerical scoring schemes to complex mathematical models) and hybrid (semi-quantitative) methods can also be used for risk evaluation. Laboratories should use a risk evaluation/assessment method that best meets their unique needs, without excluding the possibility of developing customized evaluation approaches, scoring methods and definitions of the parameters.

While this template was primarily developed for biosafety risk assessment, it can also be used for general safety risk assessment of laboratory activities, especially when the biosafety and general safety risks are interlinked, for example, sample collection and transport, where appropriate and applicable.

Institution/Facility name	
Laboratory name	
Laboratory manager/Supervisor	
Project titles/Relevant standard operating procedures (SOPs)	
Date	

If using this template, complete all sections following the instructions in the grey boxes. The instructions and bullet points in the grey boxes can be copied into the text boxes beneath the instructions and used as prompts to gather and record the necessary site-specific information. The grey instruction boxes can then be deleted, and the text remaining will form a risk assessment draft. This draft must be carefully reviewed, edited as necessary and approved by the risk assessment team members.

STEP 1. Gather information (hazard identification)

Instructions: Provide a brief overview of the laboratory work and summarize the laboratory activities to be conducted that are included in the scope of this risk assessment.	
Describe the biological agents and other potential hazards (for example, transmission, infectious dose, treatment/preventive measures, pathogenicity).	
Describe the laboratory procedures to be used (for example, culturing, centrifugation, work with sharps, waste handling, frequency of performing the laboratory activity).	
Describe the types of equipment to be used (personal protective equipment (PPE), centrifuges, autoclaves, biological safety cabinets (BSCs)).	
Describe the type and condition of the facility where work is conducted.	
Describe relevant human factors (for example, competency, training, experience and attitude of personnel).	
Describe any other factors that may affect laboratory operations (for example, legal, cultural, socioeconomic).	

STEP 2. Evaluate the risks

Instructions: Describe how exposure and/or release could occur.	
What potential situations are there in which exposure or release could occur?	
What is the likelihood of an exposure/release occurring? • Unlikely: not very possible to occur in the near future • Possible: feasible to occur in the near future • Likely: very possible to occur in the near future	
What is the severity of the consequences of an exposure/release (negligible, moderate, severe)?	

Instructions: Evaluate the risk and prioritize the implementation of risk control measures. Circle the initial (inherent) risk of the laboratory activities before additional risk control measures have been put in place.
Note:

- *When assigning priority, other factors may need to be considered, for example, urgency, feasibility/sustainability of risk control measures, delivery and installation time and training availability.*
- *To estimate the overall risk, take into consideration the risk ratings for the individual laboratory activities/procedures, separately or collectively as appropriate for the laboratory.*

		Likelihood of exposure/release		
		Unlikely	Possible	Likely
Consequence of exposure/release	Severe	Medium	High	Very high
	Moderate	Low	Medium	High
	Negligible	Very low	Low	Medium
Laboratory activity/procedure		**Initial risk (very low, low, medium, high, very high)**	**Is the initial risk above the tolerance level? (yes/no)**	**Priority (high/medium/low)**

Select the overall **initial** risk.	☐ Very low	☐ Low	☐ Medium	☐ High	☐ Very high
Should work proceed without additional risk control measures?	☐Yes ☐No				

STEP 3. Develop a risk control strategy

Instructions: *List any requirements that have been prescribed by international and national regulations, legislation, guidelines, policies and strategies on biosafety and biosecurity.*	
Describe the measures required by national legislation or regulations (if any).	
Describe the measures advised by guidelines, policies and strategies (if any).	

Instructions: Describe the resources available for risk control and consider their applicability, availability and sustainability in the local context including management support.	
Are resources sufficient to secure and maintain potential risk control measures?	
What factors exist that may limit or restrict any of the risk control measures?	
Will work be able to proceed without any of the risk control measures; are there alternatives?	

STEP 4. Select and implement risk control measures

*Instructions: Describe where and when risk control measures are needed, the level of **residual** (remaining) risk when these risk control measures are in place, and an assessment of the availability, effectiveness and sustainability of the risk control measures.*

Laboratory activity/procedure	**Selected risk control measure(s)**	**Residual risk (very low, low, medium, high, very high)**	**Is the residual risk above the tolerance level? (yes/no)**	**Are risk control measures available, effective and sustainable? (yes/no)**

*Instructions: Evaluate the **residual** risk that remains after risk control measures have been selected to determine if that level of risk is now below the tolerance level and whether work should proceed.*
*Circle the **residual** risk of the laboratory activities after risk control measures are in place.*

		Likelihood of exposure/release		
		Unlikely	Possible	Likely
Consequence of exposure/release	Severe	Medium	High	Very high
	Moderate	Low	Medium	High
	Negligible	Very low	Low	Medium

Overall **residual** risk:	☐ Very low	☐ Low	☐ Medium	☐ High	☐ Very high
If the residual risk is still above the risk tolerance level, further action is necessary such as additional risk control measures, based on the initial risk evaluated in STEP 2, redefining the scope of work such that it falls below the risk tolerance level with existing risk control measures in place or identifying an alternative laboratory with appropriate risk control strategies already in place that is capable of conducting the work as planned.					
Should work proceed with selected risk control measures?	☐Yes ☐No				
Approved by (Name and title)					
Approved by (Signature)					
Date					

Instructions: Describe how to communicate risks and risk mitigation strategies to personnel. Provide a mechanism of communication within the laboratory. Describe the process and timeline for ensuring that all identified risk control measures are purchased, have associated SOPs and training has been completed before starting the laboratory work.	
Communication of the hazards, risks and risk control measures	
Purchase (and budgeting) of risk control measures	
Operational and maintenance procedures	
Training of personnel	

STEP 5. Review risks and risk control measures

Instructions: Establish a periodic review cycle to identify: changes in laboratory activities, biological agents, personnel, equipment or facilities; changes in knowledge of biological agents or processes; and lessons learnt from audits/inspections, personnel feedback, incidents and/or near misses.	
Frequency of the review	
Person to conduct the review	
Describe updates/changes	
Personnel/procedures to implement the changes	
Reviewed by (Name and title)	
Reviewed by (Signature)	
Date	

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