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A Reference Guide
The Multi-Facets of a Biorisk Assessment

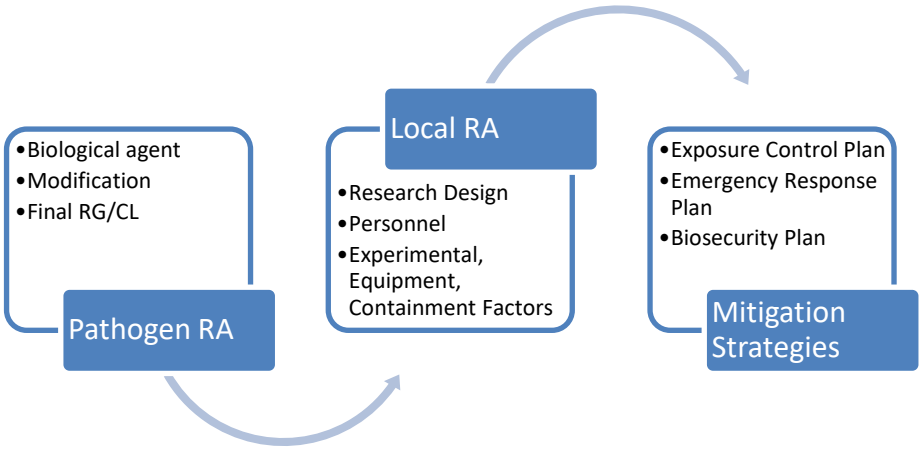
This is a useful tool to help your staff understand the issues that are addressed in the risk assessment and demonstrate due diligence

The comprehensive risk assessment (RA) comprises both the pathological and local risk assessment as defined and required by the Public Health Agency of Canada (PHAC). Historically this was addressed through use of the Project Specification Form, Containment Check List, and site visits.

The Risk Assessment is to be completed in conjunction with the review of the:

- **Biorisk Assessment Process (BRAP),**
- **Biosecurity and the Evolving Concerns Regarding Dual Use Guide (BSDU), and**
- **Biosecurity and Dual Use Research of Concern - Identification, Evaluation and Mitigation Guide (BDURC).**

It applies to all research conducted under the supervision of the named researcher and the listed grants/contracts.



The outcome of the risk assessment is the development of mitigation strategies. These are stand alone and supporting documents that must be available to all users on a regular basis. Should animal use be involved the associated exposure control must be on file with ACVS.

These documents will be reviewed annually and expires four years after its creation. Revisions are to be undertaken as required during this period.

If confused, do not hesitate to contact UO Biosafety team

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The goal is to have this be relevant to your research

Although the risk assessments primary goal is to identify and mitigate risk, the other facets of the process are often not recognized. In undertaking a risk assessment, many of the requirements for compliance to the standards of good science and those set by regulatory bodies are reviewed and documented.

The Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) are mandated to mitigate any potential risk by requiring a risk assessment to be undertaken and the appropriate measures (administrative, procedural and engineering) to be implemented. The Canadian Environmental Protection Act also regulates "living organisms", and through the "New Substances Notification Regulation" sets requirements for an assessment of the potential risk.

Risk analysis involves not only identifying the hazards but evaluating the hazards, in terms of probability of occurrence and determining the impact should the hazard not be addressed. The ultimate objective is to implement appropriate measures to reduce the risk, if required. When applied to biological agents (human, animal, zoonotic or plant pathogens) the risk may be increased or reduced, depending on the nature of the experimental work, containment available and a variety of influence factors, which will be discussed shortly.

The benefits of undertaking a risk assessment are:

- Ensuring the health and safety of lab personnel and those who could be exposed;
- Preventing the accidental release or contamination of research samples; and
- Helping demonstrate due diligence and compliance.

Other benefits include:

- Identification of training and supervision needs;
- Evaluation of procedural changes;
- Justification for space and equipment needs;
- Evaluation of security controls; and
- Evaluation of emergency planning, including spill response.

Frequency of Risk Assessment:

The preferred timing of a risk assessment coincides with:

- planning the research project,
- a significant change in the project (new employees, new infectious or potentially infectious agents, new procedures or techniques, new equipment, relocation activities, or during/after renovations), or
- annually (more frequent depending upon nature of risk).

Qualifications for a Risk Assessor:

The principal investigator (PI) and their employees are in the best position to evaluate the potential or existing risks associated with their research and laboratory practices. The qualifications required by these individuals and others mandated to undertake a risk assessment are:

- understanding the relationship between personnel, operational procedures, agent specific risks, work flow, and facility design, etc.;
- having the knowledge of hazards associated with biological agents (pathogenicity, infectious dose, mode of transmission, environmental stability, etc.);
- having the knowledge of procedures and techniques which present risks; and
- having the knowledge of containment requirements, national standards and guidelines.

Activities and Tools to Assist in a Risk Assessment:

- reviewing published materials (MSDS/PSDS, scientific journals, published safety manuals, manufacturer's bulletins, newsletters, equipment manuals, etc.),
- reviewing laboratory records (incident/accident, equipment maintenance, training, compliance monitoring, etc.),
- laboratory inspection (daily monitoring by employees, periodic walk through, formal inspections/audits, etc.),
- laboratory supervision (new procedures, new employees, new equipment, work-flow, etc.),
- consulting biosafety professionals [biosafety officers, infection control specialists, experts in specific fields (technical/procedural, virologists, bacteriologist etc.)], and
- reviewing reports of laboratory associated infections (LAI).

Factors Affecting Risk:

The main areas that need to be considered when undertaking a risk assessment are:

1. agent characteristics
2. personnel
3. experimental factors
4. equipment and PPE factors
5. environmental factors

1. Agent Characteristics

Not all agents pose the same degree of risk, and depending upon the nature of the risk engineering or procedural changes can greatly reduce the risk. The analysis may become more challenging in the cases of emerging pathogens, genetically modified organisms, or when vectors are involved (Appendix A).

There are 11 risk factors that need to be considered, and these address the agent's characteristics and potential impacts under certain environmental conditions, or when modifications are introduced. These are summarized below, while the "Risk Assessment Associated with Agent Characteristics" (Appendix B) outlines in greater detail the influencing factors.

Pathogenicity/virulence	Infectious Dose	Mode of transmission
Transmissibility	Environmental Stability	Host Range
Endemicity	Economic Considerations	Vectors
Recombinants	Availability of Prophylactic and therapeutic treatments	

2. Personnel

Although engineering, procedural and administrative controls can help mitigate risks; the degree of understanding, diligence and compliance by the individual can under mind these primary controls. The health status of an individual can greatly influence the outcome of a personnel exposure. In order to identify and minimize the risk of human error or exposure, a number of factors should be considered.

- level of training and experience (in general, specific to the procedure or agent, practical, etc.),
- competency level and demonstration of due diligence,
- personnel's health status,

  [University of Ottawa Biosafety Health Assessment Form (confidential) should be completed for each individual user and discussed with the Associate Director of Health and Wellness]
- allergies (determines vaccination restrictions),
- availability of prophylaxis and first aid, and
- use of personal protective equipment (PPE).

3. Experimental Factors

Numerous experimental procedures can introduce the potential for risk. Often each procedure is viewed as only one step in the process, and not reviewed independently for the potential of risk. These include:

- aerosol generating activities (pipetting, vortexing, centrifuging, etc.),
- potential for self-inoculation (recapping needles, disposal of sharps, etc.),
- concentration of samples,
- nature of samples (clinical, pure culture, previously manipulated, etc.),
- volume of pathogens,
- animal use (species, potential viral shredding, bites, scratches, etc.),
- cell line characteristics,

- toxin production,
- vector use,
- contingency plans (exposure, spill, accidental release, equipment failure, etc.)
- unique techniques (cryogenics, cell sorting, etc.), and
- decontamination/disposal procedures

4. Equipment and PPE Factors

The last factor to consider is how equipment may actually increase the risk of an exposure or spill. Factors to consider are:

- use of PPE
- equipment maintenance (frequency and status),
- periodic decontamination (incubators, centrifuge, etc.),
- training and correct operation of equipment (compliance to manufactures recommendations),
- equipment specific hazards (centrifuges, homogenizer, autoclaves, cryostats, etc.),
- standard operating procedures,
- biosafety containment equipment considerations, and
- location within lab or adjoining labs.

5. Environmental Factors

The environment can be considered the work area, laboratory, and facility. Should a release of the agent occur which impacts the larger general environment, an additional risk assessment will be required. Factors to be considered are modes of transmission, environmental stability and spread of contaminated material. From a laboratory perspective issues to be considered are:

- level of containment (required vs. available),
- factors affecting containment (air flow, pressurization, certification, etc.),
- impact of external activities (construction, traffic flow, new routes of egress, etc.),
- biosecurity (access and inventory control),
- lab facility conditions (clean, non-porous benches, etc.),
- availability and status of emergency support (first aid, eye wash, spill kits, etc.),
- access by public (students, visitors, trades personnel, etc.), and
- housekeeping and trades personnel (training, procedures, etc.).

The Final Step (Implementation and Documentation):

All activities summarized above identify and analyze the risks. To attain the goal of a risk assessment, one must identify and implement changes which reduce the hazard. When the ideal solution is not

feasible (due to financial, operation or logistical constrains), the risk can be reduced to an acceptable level by other means, and alternate equivalent measures which address risks must be implemented.

Keep the completed template for your records. It is important to document and review your findings in such fashion for a variety of reasons:

a. to track the steps taken to identify and reduce risks,
b. to provide a point of reference for future assessments, thus will greatly reduce future time requirements,
c. to justify restricting assessments to just those elements which have changed, and
d. to provide records which demonstrate due diligence and compliance.

Appendix A: Products of Biotechnology

Products of biotechnology may include Genetically Modified Organisms (GMOs), viral vectors, and synthetic biological devices and systems. Although the risk group and containment level may have been determined for a particular pathogen, modifications to a pathogen that increase risks posed by the pathogen may result in changes to specific physical containment or operational practice requirements. The following are a list of questions to keep in mind.

- Does the modification alter pathogenicity or virulence or decrease the effectiveness of anti-infective agents?
- Does the modification alter pharmacological activity (e.g. resistance to antibiotics)?
- Does the modification delete genetic material or introduce novel genetic material with potentially adverse effects (e.g., insertion of an oncogene)?
- Does the inserted gene encode a toxin or a relatively uncharacterized toxin?
- Can the modification alter the host range or cell tropism?
- Does the modification create novel mechanisms or undesirable traits in transgenic animals?
- Does the modification produce attenuated strains of recombinant pathogens that have lost virulence factors?
- Does the modification produce host bacterial or viral vectors with limited ability to survive outside the laboratory?
- Is the genetically modified organism (GMO) replication competent?
- Can there be novel hazards of the GMO that may not be well characterized?
- Are potentially pathogenic factors associated with the donor nucleic acid segment?
- What are the properties of the donor nucleic acid segment?
- If the modification has resulted in a form of attenuation, how extensively has this strain been utilized without incident and/or has the attenuation been proven in animal models?
- Does the modification have an effect of increasing or decreasing the efficacy of available treatment or prophylaxis?

Appendix B: Risk Factor Assessment

Risk Factor	Risk Group 1	Risk Group 2	Risk Group 3	Risk Group 4
Pathogenicity/Virulence	Unlikely to cause disease, low individual and community risk	Mild or moderate disease, moderate individual risk, low community risk, any pathogen that can cause disease but under normal circumstances, is unlikely to be a serious hazard to a healthy laboratory worker, the community, livestock or the environment	Serious livestock, poultry or wildlife disease; high individual risk, low community risk: any pathogen that usually causes serious disease or can result in serious economic consequences or does not ordinarily spread by causal contact form one individual to another	Severe livestock, poultry or wildlife disease / high individual risk, high community risk, also causes human disease, any pathogen that usually produces very serious and often fatal disease, often untreatable and may be readily transmitted form one individual to another, or from animal to human or vice-versa, directly or indirectly, or by casual contact.
Infectious dose	Not applicable (not known to cause disease)	Variable or high (1,000-5,000 organisms or greater)	Medium (10 –1,000 organisms)	High (1-10 organisms)
Mode of Transmission / Route of Infection	Not applicable (not known to cause disease)	Primary exposure hazards are through ingestion, inoculation and mucous membrane route (not generally through the airborne route)	May be transmitted through airborne route; direct contact; vectors	Readily transmitted, potential for aerosol transmission
Ability to Spread / Transmission / Communicability	Not applicable (not known to cause disease)	Geographical risk of spread if released form the laboratory is limited, very limited or no transmission is relatively limited	Geographical risk of spread if released form the laboratory is moderate, direct animal to animal or human to human transmission occurs relatively easily – transmission between different animal species may readily occur	Geographical risk of spread if released form the laboratory is widespread
Environmental Stability	Not applicable	Short term survival (days); can survive under ideal conditions	Resistant (days to months)	Highly resistant (months to years) e.g. spores
Host Range	Not applicable (not known to cause disease)	Infects a limited number of species	Infects multiple species	Infects many species of animals

Endemicity	Enzootic	Generally enzootic (some low-risk exotics, or reportable diseases)	Exotic or enzootic but subject to official control	Exotic
Economic aspects of introduction and/or release into the environment of the Canadian public	No economic and /or clinical significance	Limited economic and/or clinical significance	Severe economic and/or clinical significance	Extremely severe economic and/or clinical significance
Availability of prophylactic and therapeutic treatments	Not applicable (not known to cause disease)	Effective treatment and preventive measures are available	Prophylactic and /or treatments may or may not be readily available (or of limited benefit)	Prophylactic and/or treatments are not usually available
Vectors	Not applicable (not known to cause disease)	Do not depend on vectors or intermediate hosts for transmission May depend on vectors or intermediate host for transmission	May depend on vectors or intermediate host for transmission	May depend on vectors or intermediate host for transmission
Recombinants	The recombinant is a risk group 1 organism; modifications have not changed the risk	The recombinant is a risk group 2 organism; modifications have not changed the risk - DNA from risk group 2 or 3 organism is transferred into risk group 1 organism: but not the whole genome. - DNA from risk group 4 organism is transferred into risk group 1 organism (only after demonstration of a totally and irreversible defective fraction of the organism genome is present in the recombinant. - The recombinant is a risk group 3 or 4 organism, however, the modification has resulted in proven attenuation.	The recombinant is a risk group 3 organism; modifications have not changed the risk - The recombinant is based on a risk group 2 organism, however, the modifications have increased the risk group 3 organism.	The recombinant is a risk group 4 organism; modifications have not changed the risk - DNA form risk group 4 organism is transferred into risk group 1 organism in absence of demonstrations of lack of virulence or pathogenicity.