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Title:	**Risk Assessment of Biological Agents**		
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1.0 PURPOSE

Biosafety and biosecurity risk assessments are essential processes aimed at identifying potential hazards such as pathogens, toxins, equipment, animals, and procedures in order to assess associated risks and implement effective mitigation strategies. These assessments play a crucial role in determining whether existing measures align with the risk and help apply the requirements of the Canadian Biosafety Standards (CBS). The process involves scientific, policy, and expert judgment considerations, addressing various objectives, including creating awareness of biological hazards, identifying individuals at risk, prioritizing risks and control methods, assessing CBS containment and operational requirements, developing an overall risk management plan, evaluating the adequacy of existing mitigation measures, and identifying training needs.

2.0 PROCEDURE

A thorough risk assessment is imperative before commencing any laboratory work, particularly for tasks requiring registration and biosafety approval. Qualitative biological risk assessments involve subjective professional judgments due to uncertainties or limited scientific data, often relying on incomplete information. Recognizing the inherent limitations and assumptions in the process is crucial, as acceptable risk perceptions vary. It is essential to acknowledge that absolute risk is never zero, and potential human error remains a factor. Identifying hazards is the initial step, with a comprehensive approach incorporating data from various sources. The five-step process involves (i) identifying hazards, (ii) assessing activities leading to exposure, (iii) considering personnel training and experience, (iv) prioritizing risks based on likelihood and severity, and (v) implementing controls while establishing plans for managing exposures if they occur.

Identifying hazards associated with infectious or biohazardous agents

- Potential for infection, determined by common transmission routes such as ingestion through contamination from surfaces/fomites to hands and mouth, percutaneous inoculation from cuts, needle sticks, non-intact skin, or bites, direct contact with mucous membranes, and inhalation of aerosols.
- The volume and concentration of organisms being handled.
- Intrinsic factors specific to the agent, including pathogenicity, virulence, strain infectivity/communicability, mode of transmission (which may differ from natural transmission), infectious dose or LD50 for toxic materials.
- Genetic modifications affecting risk (e.g., expression of oncogenes or siRNAs to knockdown tumor suppressors).
- Risk of forming replication competent viruses with recombinant viral vectors,
- Type (stage) of the agent (e.g., presence or absence of cell wall, spore versus vegetation, conidia versus hyphae for mycotic agents).
- Invasiveness of the agent (ability to produce certain enzymes).
- Origin of the material being handled (e.g., human tissues or cell lines that may harbor pathogens).
- Availability of vaccines and/or prophylactic interventions, and resistance to antibiotics.

Each of these factors contributes to the overall risk assessment of working with a particular agent or material.

Considerations for assessing potential risks in a laboratory setting

- The facility's characteristics, including containment levels, layout (open floor plan versus separate areas or rooms), available space, workflow organization, and the presence of equipment.
- Evaluation of equipment conditions, such as uncertified Biological Safety Cabinets (BSCs), damaged centrifuge tubes, poorly maintained autoclaves, overfilled sharps containers, and the usage of Bunsen burners.
- Recognition of activities that may lead to the generation of aerosols and droplets. Aerosols, often undetectable, may result from routine laboratory procedures, particularly those associated with the manipulation of needles, syringes, sharps, inoculation needles, loops, pipettes, and various specimens and cultures. Examples of procedures linked to infectious aerosol generation include manipulating needles and syringes, aspirating and transferring body fluids, or using centrifugation.
- Disposal of contaminated items into biohazardous waste
- Cleaning up spills
- Utilization of animals
- Handling sharps
- Production of large volumes or concentrations of potential pathogens or agents
- Improper use or maintenance of equipment
- Examples of possible risks include reduced dexterity or reaction time for workers wearing gloves, compromised breathing ability when using N95 respirators, or the use of ill-fitting personal protective equipment (PPE).

- Additionally, the act of working alone in the laboratory does not inherently pose a biological danger. However, it is the responsibility of the supervisor to be aware of instances when an individual is assigned to work alone. Since the decision to have an individual work alone is facility-specific, a thorough risk assessment should be conducted, considering all safety considerations such as the nature of the work, physical safety, laboratory security, emergency response, potential exposure or injury, and other laboratory-specific issues.

Proper attention to these factors is crucial in developing effective risk management strategies within a laboratory environment.

Considering the competencies and experience of laboratory personnel

- Age, recognizing that younger or less experienced employees might be at a higher risk.
- Genetic predisposition and nutritional deficiencies, as well as immune and medical status, encompassing underlying illnesses, the use of immunosuppressive drugs, chronic respiratory conditions, pregnancy, non intact skin, allergies, and the use of medications known to affect dexterity or reaction time.
- Education, training, experience, and overall competence of the personnel.
- Stress, fatigue, mental status, and excessive workload, as these factors can impact performance and safety.
- Perception, attitude, and adherence to safety precautions, which influence the overall safety culture in the laboratory.
- Awareness of the most common routes of exposure or entry into the body, including skin, mucous membranes, lungs, and mouth, to tailor safety measures accordingly.

Assessing and prioritizing risks

- Likelihood of occurrence:
    - Almost Certain: Expected to occur.
    - Likely: Could happen at some point.
    - Moderate: Possibility exists but is not likely.
    - Unlikely: Possibility exists but is rare.
    - Rare: Possibility exists but is highly improbable.
- Severity of consequences:

  Consequences may be influenced by the duration and frequency of exposure, as well as the availability of vaccines and appropriate treatment. Examples of potential consequences for individual workers include:
    - Asymptomatic infection
    - Toxicity, oncogenicity, allergenicity
    - Infection, either acute or chronic
    - Illness requiring medical treatment
    - Development of diseases
    - Fatality

Establishing, implementing, and assessing controls to minimize the risk of exposure

- Engineering Controls:
    - Utilize primary containment methods such as Biological Safety Cabinets (BSC), sharps containers, centrifuge safety cups, splash guards, and safer sharps.
    - Implement secondary containment through building design features, including directional airflow or negative air pressure, handwashing sinks, closed doors, and double door entry.
- Administrative and Work Practice Controls:
    - Enforce strict adherence to safe lab practices.
    - Follow standard operating procedures diligently.
    - Emphasize frequent handwashing.
    - Wear Personal Protective Equipment (PPE) only in the designated work area.
    - Minimize aerosol generation.
    - Prohibit eating, drinking, smoking, and chewing gum.
    - Limit the use of needles and sharps, and forbid the recapping of needles.
    - Minimize splatter by using lab "diapers" on bench surfaces and covering tubes with gauze when opening.
    - Monitor and ensure the appropriate use of housekeeping, decontamination, and disposal procedures.
    - Implement a "clean" to "dirty" workflow.
    - Adhere to recommendations for medical surveillance and occupational health, including immunizations, incident reporting, first aid, and post-exposure prophylaxis.
    - Provide comprehensive training.
    - Establish and implement emergency response procedures.
- Personal Protective Equipment (PPE):
    - Use gloves when handling potentially contaminated materials, containers, equipment, or surfaces.
    - Utilize laboratory coats and gowns to prevent exposure of street clothing, and employ gloves or bandages to protect nonintact skin.
    - Consider additional respiratory protection if deemed necessary based on risk assessment.

Risk assessment is a continuous process that necessitates at least an annual review to accommodate changes in emerging pathogens, technologies, and personnel. To maintain the effectiveness of the risk management system, consider the following practices:

- Regularly review reports detailing incidents, exposures, illnesses, and near-misses.
- Identify root causes and problematic areas, and implement necessary changes while offering follow-up training to address identified issues.
- Routinely revisit and update the risk assessment process to align with evolving conditions and knowledge, fostering an adaptive and robust safety culture within the laboratory.

Additional Resources

- **Pathogen risk assessment template**
- **Local risk assessment- Canadian biosafety Guidelines**

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01	Director Research Facilities	December 11, 2023
03		
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