



PRINCIPLES AND PRACTICES OF BIORISK MANAGEMENT

Monday, November 11th – Friday, November 15th, 2024

AGENDA

DAY 1 – MONDAY, NOVEMBER 11TH

9:00am – 12:00pm

Introduction to Biosafety

Biosafety entails the rigorous implementation of safety protocols to reduce or eliminate risks to laboratory personnel, building occupants, the general public, animals, and the environment from exposure to infectious agents, infected animals, or hazardous toxins within containment zones. This section offers a detailed exploration of biosafety principles, risk assessment methods, regulatory standards, and the formulation of robust biosafety programs.

Learning Objectives

- Understanding biohazards and laboratory associated infections
- Conduct Risk Assessments and Classify Biological Agents
- Navigate the Legal Framework in Canada
- Develop and Administer a Biosafety and Biosecurity Program

12:00pm – 1:00pm

Lunch Break

1:00pm – 2:00pm

Managing Emerging Infectious Diseases and Pandemics with a Focus on Biosafety and Risk Mitigation

2:00pm – 5:00PM

Infection Control Pathogen Transmission in Clinical, Experimental and Field Research Settings

The purpose of this talk is to characterize the gray areas in biosafety for field studies and clinical settings. Developing creative solutions to solve unique problems not relevant in traditional laboratory setting. Foster discussion among participants through real scenarios.

Learning Objectives

- Overview of microbiological hazards in healthcare and field research settings
- Considerations when assessing risk in these contexts

DAY 2 – TUESDAY, NOVEMBER 12TH

9:00am – 11:00am

Zoonotic Diseases and Biosafety

Due to the unpredictable behavior of animals and the potential for pathogen shedding, working with pathogens in live animals can significantly increase the risk associated with any procedure. Therefore, specific considerations must be given to the design of both the facility and the experiment when working with pathogens and toxins in animals.

Learning Objectives

- Understanding animal characteristics related to biosafety concerns
- Animal containment zone design considerations
- What is the unique infrastructure requirement?
- How to handle and restrain animals to avoid contamination and injury

11:00am -12:00pm

CRISPR Biosafety

Genome editing (also called gene editing) is a group of technologies that give scientists the ability to change an organism's DNA. These technologies allow genetic material to be added, removed, or altered at particular locations in the genome. Several approaches to genome editing have been developed. A recent one is known as CRISPR-Cas9, which is short for clustered regularly interspaced short palindromic repeats and CRISPR-associated protein 9.

Learning Objectives

- Learn various applications of CRISPR
- Understanding the biosafety and biosecurity concerns
- How CRISPR can be used in human subjects
- Non-human germline editing
- Germline editing and gene drive differences and local risk assessment

12:00pm – 1:00pm

Lunch Break

1:00pm – 1:45pm

Prion Biosafety

Prion diseases or transmissible spongiform encephalopathies (TSEs) are a family of rare progressive neurodegenerative disorders that affect both humans and animals. They are distinguished by long incubation periods, characteristic spongiform changes associated with neuronal loss, and a failure to induce inflammatory response.

Learning Objectives

- Learning about prion related diseases
- Understanding the unusual pathogen Prion Protein (PrP)
- Stringent decontamination methods
- Understanding prion blood borne transmission and required PPE

2:00pm – 3:00pm

Open Reading Frames (ORFs) for Infectious Agents: A Brief Overview

Open reading frames ORFs are critical in the study of infectious agents, aiding in the identification of key genetic elements responsible for infection and disease. However, research involving ORFs must be carefully managed to ensure biosafety and biosecurity, minimizing risks to public health and the environment.

Importance of ORFs in Infectious Agents

1. **Gene Identification:** ORFs help in identifying genes that encode for proteins essential for the survival, replication, and virulence of infectious agents.
2. **Vaccine Development:** Understanding ORFs can aid in the development of vaccines by identifying potential antigens.
3. **Drug Targets:** ORFs can reveal potential targets for antimicrobial drugs, helping to combat antibiotic resistance.

4. **Pathogenic Mechanisms:** ORF analysis can elucidate mechanisms of infection and immune evasion by pathogens.

Biosafety Implications

1. **Containment and Handling:** Working with infectious agents requires strict biosafety measures to prevent laboratory-acquired infections and environmental contamination. Understanding the genetic makeup, including ORFs, helps assess the risk level.
2. **Pathogen Manipulation:** Genetic manipulation of ORFs in infectious agents must be conducted in appropriate containment level (CL) laboratories. The level depends on the agent's risk group
3. **Accidental Release:** Knowledge of ORFs contributes to risk assessment and management strategies to prevent accidental release of genetically modified or naturally occurring pathogens.
4. **Biosecurity:** Genetic information, including ORFs, must be safeguarded to prevent misuse in bioterrorism. Regulatory frameworks ensure that research does not lead to the creation of more virulent or drug-resistant strains.

3:00pm – 5:00pm

Viral Vectors Biosafety

Viral vectors have become a fundamental tool among molecular biology researchers. It is important to understand how these tools came about and the potential implications of their use. Viral vectors are tailored to their specific applications, but must generally share a few key properties: Safety, Stability, Cell type specificity and Selection.

Learning Objectives

- How to identify lower and higher viral vectors
- How to identify lower risk and higher risk research projects
- Understanding the replication incompetency of viral vectors and why it is still harmful
- Learning what are cell tropisms, the nature of transgene, mutagenesis
- Safety features-reversion prevention

DAY 3 – WEDNESDAY, NOVEMBER 13TH

9:00am – 11:00am

Key Considerations for Regulatory Compliance

The Public Health Agency of Canada's team will provide an informative two-hour session focused on the engineering aspects of Containment Level 2 (CL2) and Containment Level 3 (CL3) laboratories. This talk will delve into key design and infrastructure requirements, including HVAC systems, security measures, and negative pressure controls, that are crucial for maintaining biosafety and containment. Additionally, the session will cover PHAC's inspection process, highlighting what inspectors look for during evaluations, common compliance challenges, and typical findings that may impact facility operations and regulatory status.

Learning Objectives:

1. Understand the key engineering and design requirements for CL2 and CL3 laboratories, including critical infrastructure such as HVAC systems, negative pressure controls, and security measures.
2. Gain insights into PHAC's inspection process, including the specific elements inspectors evaluate in CL2 and CL3 facilities.
3. Identify common compliance challenges and typical findings from PHAC inspections to better prepare for and address regulatory requirements.
4. Learn how to proactively maintain and improve lab infrastructure to meet Canadian biosafety standards and avoid non-compliance.

11:00am – 11:30pm

Critical Analysis of Backup Systems and their Weakest Links

This talk will delve into the key aspects of backup systems in containment laboratories, focusing on identifying potential vulnerabilities that could compromise safety and operational continuity.

The presentation will cover:

- The role of redundancy in critical systems (HVAC, power, security, etc.)
- Common failure points and overlooked vulnerabilities in these backup systems
- Case studies of real-world failures and lessons learned
- Recommendations for bolstering system resilience and reliability

11:30am – 12:00pm

Mastering AI for Efficient Data Analysis: Techniques for Extracting Critical Insights from Large Data Sets

This talk explores AI-driven data analysis techniques, focusing on the practical skills needed to extract valuable insights from large and complex data sets. Participants will learn to leverage machine learning, and data visualization tools.

Learning Objectives:

- Understand key AI and machine learning techniques for data analysis and their practical applications.
- Apply AI tools to efficiently analyze large data sets.

12:00pm – 1:00pm

Lunch Break

1:00pm – 1:45pm

Navigating the Future: Integrating Self-Driving Labs with Biosafety Protocols Learning Objectives

Introduction

- Overview of self-driving labs
- Importance of biosafety in laboratory settings
- The intersection of automation and biosafety

Self-Driving Labs: An Overview

- Definition and components of self-driving labs
- Key technologies (AI, robotics, IoT)
- Advantages of automation in research

Challenges of Integrating Self-Driving Labs with Biosafety

- Technical challenges (software, hardware integration)
- Ensuring compliance with biosafety regulations
- Risk assessment and mitigation

Technological Innovations Enhancing Biosafety

- Advances in biosafety equipment (e.g., automated containment systems)
- Role of AI in monitoring and maintaining biosafety
- Smart lab infrastructure and real-time data analytics

2:00pm – 3:00pm

Biological Safety Cabinets

Biological Safety Cabinets, (BSCs), also known as tissue culture hoods, are designed to provide personal, environmental and product protection when installed and maintained properly and appropriate practices and procedures are followed.

Learning Objectives

- Understanding the limitations and capabilities of different class and types of BSCs
- Understanding what causes turbulence and what affects laminar air flow
- Location and installation of BSCs
- Proper testing and certification
- How to demonstrate safe usage of BSCs

3:00pm – 4:00pm

Comprehensive Lab Safety: Integrating General, Chemical, and Ergonomic Best Practices for Biosafety Officers

This talk will provide a thorough understanding of the essential components of lab safety, focusing on general safety practices, chemical safety protocols, and ergonomic considerations. By integrating these diverse aspects, biosafety officers will gain practical insights into ensuring a safe and compliant laboratory environment. Attendees will learn to identify, assess, and mitigate risks across different domains, emphasizing the importance of a holistic approach to lab safety.

4:00pm – 5:00pm

Personal Protective Equipment

Proper Personal protective equipment (PPE) use would minimize the risk of exposure to various hazards. PPE is the last line of defence to protect personnel and to minimize the risk of transmitting pathogens and toxins to the public and the animal population.

Learning Objectives

- Understanding the various types and selection of proper PPE (gloves, lab coats, eyewear)
- How to prepare a respiratory protection program
- Equipment certification and special protection equipment

DAY 4 – THURSDAY, NOVEMBER 14TH

9:00am – 10:30am

Engineering Considerations for Containment Laboratories

Physical containment requirements are crucial for mitigating the risks associated with handling or storing pathogens, toxins, infected animals, or other regulated infectious materials. These requirements are achieved through specific physical barriers provided by engineering controls and facility design.

Learning Objectives

Understanding the Concept of Containment Barriers

- Comprehend the principles and importance of containment barriers in biological laboratories.

Controlling and Securing Access to Facilities

- Learn strategies for controlling and securing access to facilities to safeguard biological materials effectively.

Surface Finishes and Casework Assessment

- Evaluate the suitability of surface finishes and casework in maintaining a safe and clean laboratory environment.

Air Handling and Directional Air Flow

- Understand the role of air handling systems and the importance of directional airflow in preventing contamination.

Facility Services Required in Biological Laboratories

- Identify the essential facility services necessary to support safe biological laboratory operations.

Essential Biosafety Equipment

- Recognize and understand the function of essential biosafety equipment used in biological laboratories.

10:30am – 11:30am

Understanding Dual Use Research of Concern (DURC) and Dual Use in Life Sciences

This session provides an essential overview of Dual Use Research (DUR) and Dual Use Research of Concern (DURC), focusing on the ethical, regulatory, and security challenges in life sciences research. Dual Use refers to research that, while intended for beneficial purposes, can also be misused to cause harm. DURC, specifically, involves research that poses a significant risk of being misapplied in ways that could threaten public health, agriculture, the environment, or national security.

Participants will gain insight into:

- The definitions and distinctions between DUR and DURC.
- Historical examples and key cases where life sciences research has raised dual-use concerns.
- Regulatory frameworks and international guidelines, including the role of Canadian regulations in controlling DURC.
- Best practices for biosafety and biosecurity officers, researchers, and institutional review boards to identify and mitigate dual-use risks.
- Ethical considerations and responsibilities of researchers in addressing the dual-use potential of their work.

This session will highlight the importance of risk assessment and management strategies to ensure responsible conduct in life sciences research and will conclude with a discussion on global collaboration to address the challenges posed by DURC.

11:30am – 12:00pm

Change Control Management

In today's fast-paced research environment, being able to adapt to change is the only option. Within the research industry, legislations, technology, funding, conditions and requirements are always changing. As a result, an organization should work to embed change management and build organizational capabilities.

Learning Objectives

- Creating consistency and efficiencies in approach
- How to maintain and keep up to date your biosafety and biosecurity program
- Understanding the role of IBC when changes in the biosafety program is required

12:00pm – 1:00pm

Lunch Break

1:00pm – 3:00pm

Blood Borne Pathogens

Blood borne pathogens are infectious microorganisms in human blood and primary tissues that can cause disease in humans. These pathogens include, but are not limited to, hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV). It is essential to understand the mode of transmission and how to prevent diseases by applying good biosafety practices.

Learning Objectives

- Understanding profile of prevalent viral pathogens
- How to prepare protocols to mitigate exposure
- What to do following exposure to BBP
- Pre and Post Exposure Prophylaxis to BBP

3:00pm – 5:00pm

Medical Surveillance

The basic purpose of a medical surveillance program is to help prevent and detect illnesses related to the exposure to pathogens or toxins. The program can include physical exams, laboratory testing, data analysis, x-rays, lung capacity and other medical tests. This presentation will provide methodology to determine, establish and streamline an effective medical surveillance program.

Learning Objectives

- What are the common biological hazards, prevention methods and controls
- How to prepare a medical surveillance & pre/post exposure management program
- Exposure assessment and decision making of post-exposure emergency actions
- Risk assessment of biological exposure
- Pre-placement and medical evaluation
- Additional considerations for working with higher risk pathogens

DAY 5 – FRIDAY, NOVEMBER 15TH

9:00am – 9:45am

Bio-Waste and Other Hazardous Waste

Waste management is an integral component of a biosafety program, and comprises policies, plans, and procedures to address all aspects of waste management, including decontamination and disposal. Waste leaving the containment zone may be destined for disposal, movement or transportation to a designated decontamination area outside of the containment zone or transported off-site for decontamination via a third-party biohazardous waste disposal facility (e.g., incineration, steam sterilization).

Learning Objectives

- What are considered as biological waste
- Designations of biological waste and exemptions
- Standards for waste disposal
- Waste facilities and storage of biological waste
- Shipping, transporting and documentation

10:00am – 11:00am

Biosecurity and Deliberate Biological Threats

Biosecurity is a multidisciplinary field focused on protecting humans, animals, plants, and the environment from biological threats. These threats can come in various forms, including infectious diseases, invasive species,

bioterrorism, and accidental release of harmful biological agents. The goal of biosecurity is to implement measures that reduce the risk of exposure to these biological hazards, thereby safeguarding public health, agriculture, biodiversity, and the economy.

In recent years, biosecurity has gained prominence due to the increasing interconnectedness of our world, which facilitates the rapid spread of diseases and invasive species. Additionally, advancements in biotechnology have raised concerns about the potential misuse of biological materials. Effective biosecurity requires a coordinated approach involving government agencies, international organizations, scientists, healthcare providers, farmers, and the general public.

Learning Objectives

- Understand the Fundamentals of Biosecurity
- Recognize Key Biosecurity Threats
- Implement Biosecurity Measures
- Navigate Legal and Regulatory Frameworks
- Promote Biosecurity Awareness and Education
- Develop Risk Assessment and Management Skills
- Collaborate in Multidisciplinary Teams

11:00am – 12:00pm

Emerging and Pandemic Infections Consortium

The Emerging and Pandemic Infections Consortium (EPIC) at the University of Toronto is a leading initiative in understanding and managing emerging infectious diseases and pandemics. By integrating expertise from diverse fields, EPIC has developed comprehensive biosafety and health safety programs that serve as a model for other institutions.

Key lessons from EPIC include:

- **Developing Robust Biosafety Protocols:** Establish clear, thorough protocols to prevent and respond to infectious threats.
- **Regulatory Compliance:** Ensure adherence to national and international biosafety regulations and guidelines.
- **Risk Assessment and Management:** Conduct regular risk assessments and implement appropriate risk management strategies.
- **Training and Education:** Provide continuous training for staff on biosafety practices and emergency response.
- **Collaboration and Communication:** Foster collaboration between departments and maintain transparent communication channels.
- **Emergency Preparedness:** Develop and regularly update emergency response plans.
- **Continuous Improvement:** Implement a process for regular review and improvement of biosafety practices.

12:00pm – 1:00pm

Lunch Break

1:00pm – 3:00pm

Proactive Emergency Response by Design: Optimizing Preparedness through Strategic Planning

In this two-hour session, participants will explore the principles and methodologies behind designing a proactive emergency response framework. The session emphasizes the importance of embedding preparedness into laboratory and facility design from the ground up. Attendees will learn how strategic planning—focused on risk assessment, redundancy, communication, and the integration of cutting-edge

technologies—can significantly improve emergency readiness and response effectiveness. Topics include optimizing facility layout, integrating advanced monitoring systems, ensuring regulatory compliance, and enhancing coordination among internal teams and external responders. By the end of the session, participants will understand how a well-designed environment can mitigate risks and streamline crisis management, promoting safety, continuity, and resilience.

3:00pm – 5:00pm

A Guided Tour: Biosafety Inspections of Research Laboratories

Workplace inspections drive the mitigation of incidents, injuries and illnesses. Through an in-depth review of the laboratory, inspections help to identify risks and hazards and reveal non-compliance issues. A good inspection program is a key component of an integrated biosafety and biosecurity management program.

Learning Objectives

- Understanding the essentials elements of an internal inspection program
- Learning the critical elements to review in a laboratory
- How to plan and prepare for biosafety inspections
- Types of hazards found in laboratories
- Elements to include in a report