Welcome to our “Risk Groups, Containment Levels, Risk Assessments and PSDS” tutorial.

This tutorial will review the criteria by which organisms are categorized by risk, the level of containment required to handle the organisms safely, the risk assessment process which determines the containment level and a resource of safety data available from the Public Health Agency of Canada.

Links:
Narration:

Risk Groups.

Classification of organisms according to risk group, has traditionally been used to categorize the relative hazards of infectious organisms. The factors used to determine which risk group an organism falls into, is based upon the particular characteristics of the organism, such as:

Pathogenicity;
infectious dose;
mode of transmission;
host range;
availability of effective preventive measures;
availability of effective treatment.

These classifications presume ordinary circumstances in the research laboratory, or growth in small volumes for diagnostic and experimental purposes. Four levels of risk have been defined.

Links:
Risk Group 1

- Low individual and community risk
- Any biological agent that is unlikely to cause disease in healthy workers or animals.
- Immunocompromised individuals can become ill when infected with a risk group 1 organism

Narration:

Risk Group One.

Risk group one presents a low individual and community risk. It is also referred to as “BSL1”, “level one” or “RG1”. This group includes any biological agent that is unlikely to cause disease in healthy workers or animals. Immuno-compromised individuals can become ill when infected with a risk group one organism.

Examples of risk group one include:
cloning strains of E-coli;
Highly characterized tumor cell lines;
Tissues and fluids from healthy donors or animals;

Links:
Risk Group 2

- Moderate individual risk, low community risk
- Any pathogen that can cause human disease but, under normal circumstances, is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment.
- Laboratory exposures rarely cause infection leading to serious disease; effective treatment and preventive measures are available, and the risk of spread is limited.

Narration:

Risk Group 2.

Risk group two provides a moderate individual risk, and a low community risk. It includes any pathogen that can cause human disease, however, it is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment.; Laboratory exposures rarely cause infection which leads to serious disease; effective treatment and preventative measures are available; and the risk of spread to others is limited. Examples of risk group 2 include Clostridium and Salmonella.

Links:
Risk Group 3

- High individual risk, low community risk
- Any pathogen that usually causes serious human disease or can result in serious economic consequences but does not ordinarily spread by casual contact from one individual to another, or that causes diseases treatable by antimicrobial or antiparasitic agents.

Narration:

Risk Group 3.

Risk group 3 presents a high individual risk and a low community risk. It includes any pathogen that usually causes serious human disease or can result in serious economic consequences. It includes any pathogen that causes diseases treatable by anti-microbial or anti-parasitic agents. However, it does not ordinarily spread by casual contact from one individual to another. Examples of risk group 3 agents include mycobacterium tuberculosis and HIV.

Links:
Risk Group 4

- High individual risk, high community risk.
- Any pathogen that usually produces very serious human disease, often untreatable, and may be readily transmitted from one individual to another, or from animal to human or vice-versa, directly or indirectly, or by casual contact.

Narration:

Risk group 4.

Risk group 4 presents a high individual risk and a high community risk. It includes any pathogen that usually produces very serious human disease, often untreatable, and may be readily transmitted from one individual to another, or from animal to human or vice-versa, directly or indirectly, or by casual contact. Examples of risk group 4 include ebola virus and smallpox.

Links:
Risk Groups for Other Species

- Risk groups for infectious plant microorganisms
- Risk groups for infectious animal microorganisms
  - Aquatic animals
  - Terrestrial animals
- Required to handle the microorganisms at the highest risk group level prescribed even if the human risk group level is 1
- Obligation to protect plants, animals and ourselves

Narration:

Risk groups are assigned for organisms that infect plants and animals whether they are aquatic or terrestrial animals. We are required to handle any microorganism by the highest risk group level prescribed even if the human risk group level is 1. We have an obligation to protect plants and animals as well as ourselves.

Links:
Containment Levels

- Risk group does not prescribe handling
- Containment levels prescribe handling
- Containment system
  - Engineering controls
  - Operational controls
  - Technical controls
  - Physical controls
- There are 4 containment levels

**Narration:**

Containment Levels.

Classification of organisms according to risk group is not meant to prescribe handling procedures within in the laboratory. For example, the risk group system does not take into account the procedures that are to be employed during the manipulation of a particular organism. Containment levels are selected to provide the end-user with a description of the minimum procedures required for handling the organism safely in a laboratory setting.

In addition to the inherent characteristics of each organism as previously described, the containment system includes the engineering, operational, technical and physical requirements for manipulating a particular organism. These containment levels are applicable to facilities such as diagnostic, research, clinical, teaching and production facilities that are working at a laboratory scale.

There are four containment levels.

**Links:**
Containment Level 1

- Basic laboratory
- Functional laboratory
- Biological safety cabinets not required
- Open bench work
- Good microbiological practices
- Biomedical waste disposal
- Decontamination of liquids

**Narration:**

Containment Level 1 or CL1.

CL1 applies to any basic laboratory that handles agents that are rated as risk group 1 to humans, animals and plants. CL1 requires no special design features, beyond those suitable for a well-designed and functional laboratory. Biological safety cabinets are not required, however they are often used for sterility purposes. Work may be done on an open bench top, and containment is achieved through the use of practices normally employed in any basic microbiology laboratory. Decontamination of waste is required. Solids are packaged for biomedical waste pickup and liquids are decontaminated before disposal.

**Links:**
Containment Level 2

- Exposure hazards through ingestion, inoculation and mucous membrane route
- Not typically transmitted by airborne route
- Care not to generate aerosols
- BSCs and safety cups for centrifuges required
- PPE required
- Handwashing sinks
- Decontamination of waste

Narration:

Containment level 2 or CL2.

CL2 applies to any laboratory that handles agents that are rated as risk group 2 to either humans, animals or plants. CL2 laboratories are required where the primary exposure hazards are through the ingestion, inoculation and mucous membrane routes. Agents requiring CL2 facilities are not generally transmitted by airborne routes, but care must be taken to avoid the generation of splashes or aerosols, which can settle on bench tops and become an ingestion hazard through contamination of the hands. Primary containment devices such as biological safety cabinets and centrifuges with sealed rotors or safety cups are to be used as well as appropriate personal protective equipment, for example, gloves, laboratory coat and protective eyewear. As well, environmental contamination must be minimized by the use of handwashing sinks and decontamination facilities or equipment such as autoclaves. Decontamination of waste is required. Solids are packaged for biomedical waste pickup and liquids are decontaminated before disposal.

Links:
Narration:

Containment Level 3 or CL3.

CL3 applies to any laboratory that handles agents that are rated as risk group 3 to either humans, animals or plants. Agents requiring CL3, may be transmitted by the airborne route, often have a low infectious dose to produce effects, and can cause serious or life-threatening disease. CL3 emphasizes additional primary and secondary barriers to minimize the release of infectious organisms into the immediate laboratory and the environment. Additional features to prevent transmission of CL3 organisms are appropriate respiratory protection, HEPA filtration of exhausted laboratory air, and strictly controlled laboratory access.

Links:
Narration:

Containment level 4 or CL4.

CL4 applies to any laboratory that handles agents that are rated as risk group 4 to either humans, animals or plants. This is the maximum containment available. These agents have the potential for aerosol transmission, often have a low infectious dose and produce very serious and often fatal disease; there is generally no treatment or vaccine available. This level of containment represents an isolated unit, functionally and, when necessary, structurally independent of other areas. CL4 emphasizes maximum containment of the infectious agent by complete sealing of the facility perimeter with confirmation by pressure decay testing; isolation of the researcher from the pathogen by his or her containment in a positive pressure suit or containment of the pathogen in a Class III BSC; and decontamination of air and other effluents produced in the facility.

Links:
Risk Assessments.

Risk assessment is a critical step in the selection of an appropriate containment level for the microbiological work to be carried out. A detailed local risk assessment should be conducted to determine whether work requires containment level 1, 2, 3 or 4 facilities and operational practices. Individuals with varying expertise and responsibilities should be included in the risk assessment process and can include, among others, the facility director, laboratory supervisor, principal investigator, senior microbiologist, biosafety officer and biosafety committee.

Available information can be used as a starting point to assist in the identification of risk factors, including the recommended Risk Group of the organism. In addition to the Risk Group classifications, which are based on the risk factors inherent to the organism, the following factors associated with the laboratory operation should also be examined:

- potential for aerosol generation;
- quantity;
- concentration;
- agent stability in the environment or the inherent biological decay rate;
• type of work proposed for example in-vitro, in-vivo or aerosol challenge studies;
• use of recombinant organisms, specifically those with the following characteristics:
  • genes coding for virulence factors or toxins; host range alteration;
  • oncogenicity;
  • replication capacity; capability to revert to wild type.

Links:
Pathogen Safety Data Sheets

- Found on the PHAC website
- Lists organisms by species name
- Sometimes covers entire genus
- Generic PSDS for Risk Group 1 organisms has been created and is posted on the Biosafety SOP website

**Narration:**

Pathogen Safety Data sheets are found on the PHAC website where the list of sheets is ordered by species name. In some cases the PSDS covers all species within a genus. The following slides describe each of the sections found on a PSDS.

There are no PHAC PSDS sheets for risk group 1 organisms, however one has been created and posted on the Biosafety SOP website.

Please see the attached PDF containing the slides and notes for website addresses.

**Links:**

Biosafety SOP Website – [https://biosafety.mcmaster.ca/biosafety_sops.htm](https://biosafety.mcmaster.ca/biosafety_sops.htm)
Section 1 – Infectious Agent

- Name
- Synonym or Cross Reference
- Characteristics

Narration:

Section 1 - Infectious agent.

This section lists the species name of the pathogen, with alternative synonyms and cross references. It also includes characteristics of the organism, which may include classification categories such as gram-positive/gram-negative for bacteria or enveloped/non-enveloped for viruses.

Links:
Section II – Hazard Identification

- Pathogenicity/Toxicity
- Epidemiology
- Host Range
- Infectious Dose
- Mode of Transmission
- Incubation Period
- Communicability

**Narration:**

Section 2 – Hazard Identification.

*Pathogenicity and toxicity* refer to how sick the organism can make you. It describes the symptoms associated with exposure and infection. *Epidemiology* includes the characteristics of population infection and the associated risks. *Host range* describes the species that the pathogen is capable of infecting, whether or not it causes disease. *Infectious dose* describes the minimum amount and route of exposure that is required to establish an infection. *Mode of transmission* describes how one can become exposed to the pathogen. Examples include fecal-oral route, close contact and aerosolization through coughing. *Incubation period* describes the time from exposure or infection to the signs of clinical disease. *Communicability* describes how easily the pathogen can spread through a population.

**Links:**
Section III - Dissemination

- Reservoir
- Zoonosis
- Vectors

Narration:

Section 3 – dissemination.

Reservoir describes the hosts known to carry the disease. Examples of reservoirs include bats and raccoons as reservoirs for rabies. Zoonosis describes pathogens which cause disease in both humans and animals. Vectors describe intermediate hosts for transmission or lifecycle of the organism such as mosquitoes and nematodes.

Links:
Narration:

Section 4 – stability and viability.

*Drug susceptibility* describes the effectiveness of drugs against the pathogen. *Susceptibility to disinfectants* describes the effectiveness of disinfectants to be used for decontamination. *Physical inactivation* describes the physical methods (heat, dryness, pressure, irradiation) effective for inactivation of the pathogen. *Survival outside the host* describes how long and under what conditions a pathogen can remain viable when outside its host, for example, dried on surfaces.

Links:
Section V – First Aid / Medical

- Surveillance
- First Aid/ Treatment
- Immunization
- Prophylaxis

Narration:

Section 5 – First Aid, Medical.

*Surveillance* describes the clinical symptoms and tests that can be used to detect an infection.

*First aid and treatment* describe the measures to take upon exposure to the pathogen.

*Immunization* lists the vaccines available for the pathogen.

*Prophylaxis* lists the pre-emptive measure to take to protect you against infection.

Links:
Section VI – Laboratory Hazards

- Laboratory acquired infections
- Sources / Specimens
- Primary Hazards
- Special Hazards

Narration:

Section 6 – Laboratory Hazards.

*Laboratory acquired infections* describe the known infections that were caused in the workplace. *Sources and specimens* describe the sources of pathogens known to be involved in laboratory acquired infections. *Primary hazards* describe the laboratory hazards or scenarios which pose a risk for an exposure and their routes. *Special hazards* describe additional hazards that pose a risk for exposure.

Links:
Section VII – Exposure controls and personal protection

- Risk group classification
- Containment requirements
- Protective clothing
- Other precautions

Narration:

Section 7 – Exposure controls and personal protection.

*Risk group classification* gives the risk group of the organism. *Containment requirements* outline the necessary laboratory features and operational practices required to handle the organism safely. *Protective clothing* describes the personal protective equipment needed. *Other precautions* describes additional precautions required that are specific to this pathogen.

Links:
Section VIII – Handling and Storage

- Spills
- Disposal
- Storage

**Narration:**

Section 8 – Handling and Storage.

*Spills* describes the minimum actions to take to safely clean up a biological spill. *Disposal* describes the required actions prior to disposal of cultures and contaminated wastes. *Storage* describes how to safety store the pathogen.

**Links:**
Section IX – Regulatory and Other Information

- Regulatory information
- Updated
- Prepared by

Narration:

Section 9 - Regulatory and Other Information.

Regulatory information describes the government agencies which regulate the handling and transfer of the pathogen. There may be permits that are required for movement, transport, import or export of the pathogen.

Links:
Creating a PSDS

- Required for any microorganism or toxin that is pathogenic to humans
- Use same section headings
- Provide references
- A generic PSDS for risk group 1 material is posted on the SOPs webpage on the Biosafety Website

Narration:

Creating a PSDS.

A pathogen safety data sheet is required for any microorganism or toxin that is pathogenic to humans. Most, if not all human pathogens are already captured on the PHAC PSDS website. If you require a PSDS and there is none available, please first contact the biosafety office. If there are none available, it is recommended that you create your own and use the same section headings and provide references for each. A generic PSDS for risk group 1 material is posted on the SOPs webpage on the biosafety website.

Links:

Biosafety SOP Website: https://biosafety.mcmaster.ca/biosafety_SOPs.htm
ePathogen Database

- PHAC has created an online pathogen database thousands of entries
- Use this database to determine the risk group of your organism
- ATCC and DSMZ risk group ratings are not Canadian organizations and often do not correlate with Canadian risk group levels
- Contact the Biosafety Office prior to ordering

Narration:

ePathogen Database

The Public Health Agency of Canada has created an online database of microorganisms which contains thousands of entries. Please use this database to verify the risk group of your organisms. Please note that while ATCC and DSMZ do provide risk groups or biosafety levels for the organisms that they sell, they are not Canadian organizations and their ratings often do not correlate with Canadian risk group levels. This can be problematic when attempting to import. Please contact the Biosafety Office before ordering. There is an online form on the biosafety website to assist in this process.

Links:

ePathogen Database: https://health.canada.ca/en/epathogen
Narration:

In summary,

Risk groups (1-4) consider the inherent hazardous properties of an organism
Risk assessments are used to determine the containment level required to handle the organism safely and includes the risk group plus other information associated with the proposed work
Containment Levels 1-4 provide increasing levels of physical and operational protection to handle biohazardous materials safely
A PSDS provides important information about the organism, safe handling and disposal.
The ePathogen database should be consulted prior to obtaining any microorganism.

Links:
Thank you for your participation.

https://biosafety.mcmaster.ca

Narration:
Thank you for your participation.

Links:
McMaster Biosafety Website - https://biosafety.mcmaster.ca