



Managing Biohazards

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Managing Biohazards

About Me ...

- Canadian Registered Safety Professional
- Clinical Laboratories
- Research Laboratories
- Systems-Based Experience



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Where are you from?

What questions do you want answered today?





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Biohazard (bi·o·haz·ard) - *noun*

- A biological agent, such as a virus or a condition that constitutes a threat to humans, especially in biological research or experimentation.
- The potential danger or harm from exposure to such an agent or condition.



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Pathogen (path·o·gen) - *noun*

- An agent that causes disease, especially a living microorganism such as a bacterium, virus or fungus.

The American Heritage® Stedman's Medical Dictionary



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Toxin (tox·in) – *noun*

- A poisonous substance, especially a protein, that is produced by living cells or organisms and is capable of causing disease when introduced into the body tissues but is often also capable of inducing neutralizing antibodies or antitoxins.

The American Heritage® Stedman's Medical Dictionary

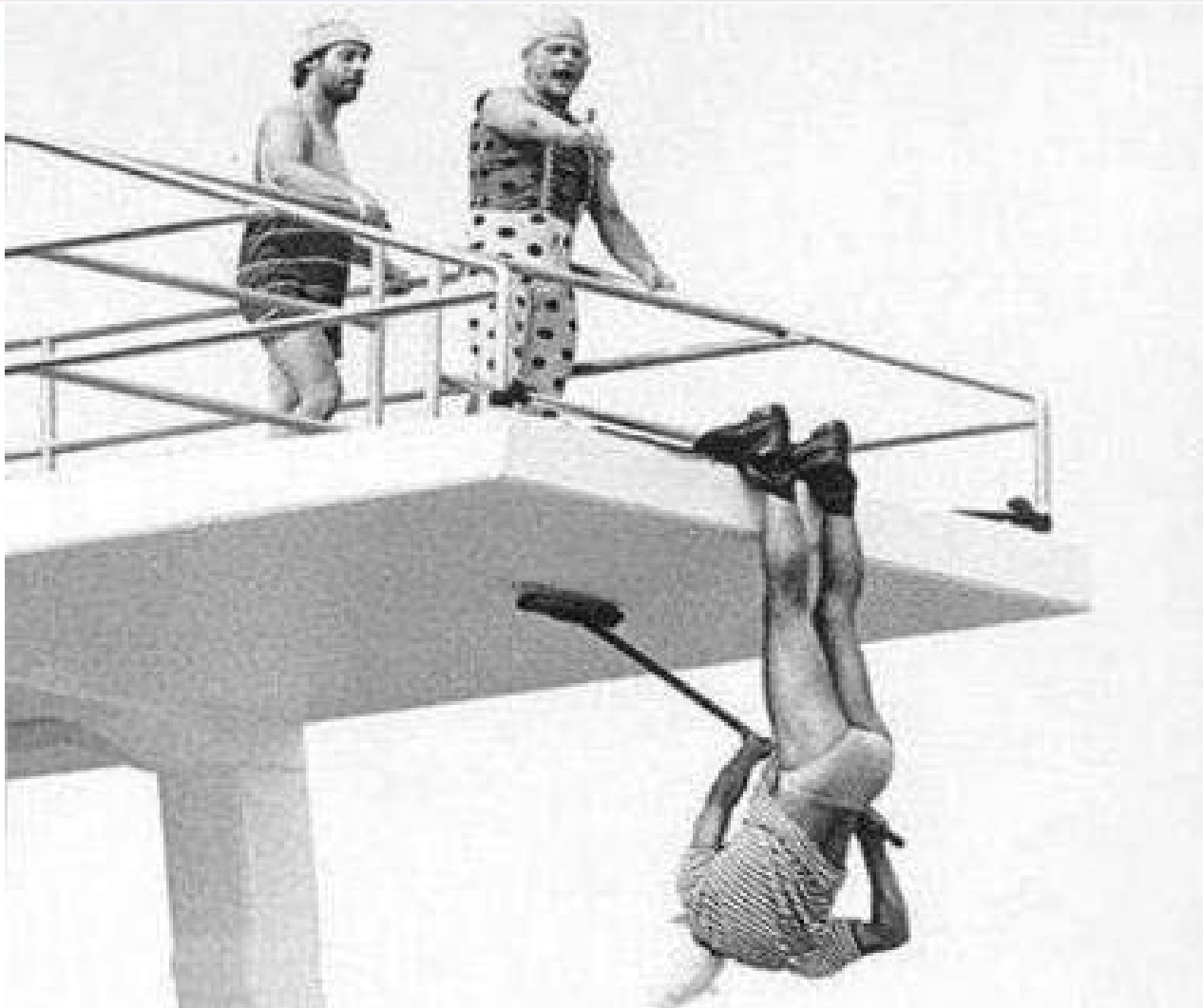


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Why is there so much interest in
biohazards?



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Who wants biohazards managed?

Canadian Federal

- OLS-PHAC / CFIA / Transport Canada

Canadian Provincial

- MOL / MOE

Canadian Public

- Everybody





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Laboratory Biosafety Guidelines

3rd Edition – 2004

- Mandatory when importing human pathogens and toxins.
- Voluntary for non-importing facilities.

Means about 4000 of the approximately 7500 facilities are voluntary.



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What do they expect from you?

Due Diligence plus Hazard Control

equals

Protection of the Health & Safety of the Public

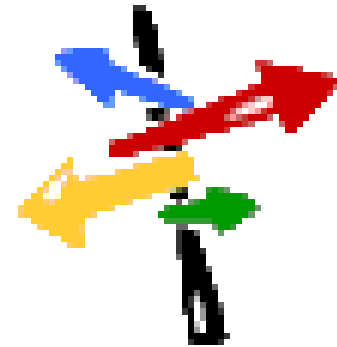


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Due Diligence / Hazard Control

Take Every Precaution Reasonable in the Circumstances ...

- Risk Assessments
- Evaluate the Controls
- Implement and Measure
- Documents & Records

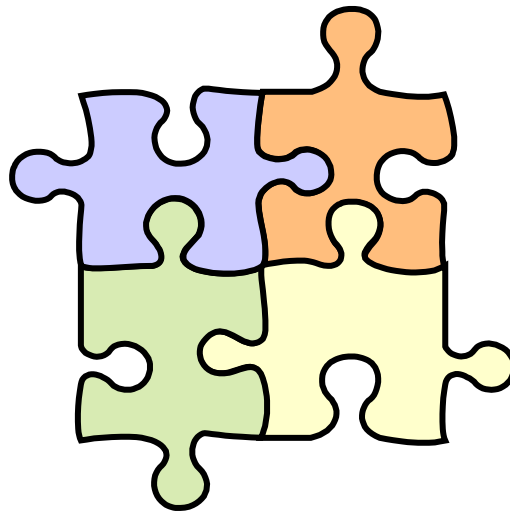




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What system will manage biohazards?

How do I prove I am managing biohazards?





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The Human Pathogens & Toxins Act

Was Bill C54

- but perished on September 7, 2008

Now Bill C-11

- was introduced on February 9, 2009

Moving along briskly now but still in draft form.



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Whereas the Parliament of Canada ...

Recognizes the objective of protecting the health and safety of the public;

Recognizes that certain human pathogens and toxins pose risks to the health and safety of the public;





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Whereas the Parliament of Canada ...

Recognizes that a lack of full scientific certainty regarding the risks posed by certain human pathogens and toxins is not to be used as a reason to postpone measures that protect the health and safety of the public;





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And Whereas the Parliament of Canada ...

Recognizes that human pathogens and toxins evolve and can be altered and that new human pathogens and toxins appear continually, therefore creating unique challenges in meeting the objective of protecting the health and safety of the public.





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The Purpose of the Act

To establish a safety and security regime to protect the health and safety of the public against the risks posed by human pathogens and toxins.

What human pathogens and toxins do they refer to?



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The Schedules of the Act

Schedule 1 – Toxins

Schedule 2 – Risk Group 2 Human Pathogens

Schedule 3 – Risk Group 3 Human Pathogens

Schedule 4 – Risk Group 4 Human Pathogens

Schedule 5 – Prohibited Human Pathogens & Toxins



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But first – the exemptions!

The Act does not apply to a human pathogen or toxin that is in an environment in which it naturally occurs if it has not been cultivated or intentionally collected or extracted, including a human pathogen or toxin that ...



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- Is in or on a human suffering from a disease caused by that human pathogen or toxin,
- Has been expelled by a human suffering from a disease caused by that human pathogen or toxin,
- Is in or on a cadaver, a body part or other human remains,
- Or is covered by the Food and Drug Act or the Assisted Human Reproduction Act.



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What are the main requirements of the Act?

1. Licence authorizing controlled activities
2. Security clearances for certain areas
3. Biological Safety Officer



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The Licence

Licences will contain authorization for controlled activities in a facility.

These activities are subject to any conditions that the Minister considers appropriate to protect the health and safety of the public.



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The Licence will also contain

- Holder's name
- Period in effect
- Description of the facility
- Description of areas subject to security clearances
- Toxins or human pathogens in controlled activities



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Activities that require a Licence

1. Possessing or handling or using
2. Producing
3. Storing
4. Permitting access
5. Transferring
6. Importing or exporting
7. Releasing or abandoning
8. Disposing





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Activities that do not require a Licence

Transportation of Dangerous Goods Act

Or

Export and Import Permits Act



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Security Clearances

- Certain areas of the facility may require a security clearance to access pathogens or toxins
- Issued by the Minister only
- Can appeal a denied security clearance
- Requirements will be set out in regulations



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Biological Safety Officer (BSO)

- Required of every applicant for a licence
- May cover multiple laboratories in a facility
- Less stringent qualifications for Risk Group 2
- More stringent qualifications for Risk Group 3/4
- BSO qualifications & responsibilities may be part of the regulations



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Conditions/requirements of controlled activities will vary according to the Risk Group

1. Risk Group 2 Requirements Least Stringent
2. Risk Group 3/4 Requirements Most Stringent



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Risk Group 2 Requirements

Licence meant to be simple

- On-line application

Biological Inventories

- Produce if requested by OLS-PHAC

Security Clearances

- Not required at this time



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Risk Group 2 Requirements (cont'd)

Transfers within facility

- Ensure compliance to LBGs

Imports

- Permits required under present system

Exports

- Due Diligence to ensure receiver is compliant to WHO standards



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Risk Group 2 Requirements (cont'd)

Biosafety & Biosecurity

- Follow Lab Biosafety Guidelines

Biological Safety Officer

- Every licence holder requires one

Disposal

- Ensure method renders material non-viable or non-functional



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Risk Group 2 Requirements (cont'd)

Compliance Inspections

- Risk-based spot inspections by OLS-PHAC
- Due Diligence says to self-audit regularly
- Generate records of self-audits
- Generate documentation of your system



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Risk Group 3/4 Requirements

Licence

- Apply in writing, not on-line
- Sensitive information of pathogens or toxins
- Provide biosecurity plan to OLS-PHAC
- On-site inspection by OLS-PHAC before issue



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Risk Group 3/4 Requirements (cont'd)

Biological Inventories

- Produce for licence application
- Include quantity, concentration, location, use and storage
- Changes reported to OLS-PHAC



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Risk Group 3/4 Requirements (cont'd)

Security Clearances

- Screening requirements are key biosecurity aspect of regulations
- Required to have access
- Required for non-scientific staff



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Risk Group 3/4 Requirements (cont'd)

Transfers within facility

- Ensure receiver is compliant to LBGs before receiving permission from OLS-PHAC
- Notify OLS-PHAC transfer successful

Imports/Exports

- Must use present system



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Risk Group 3/4 Requirements (cont'd)

Biosafety & Biosecurity

- Follow Lab Biosafety Guidelines
- May require special possession and handling requirements as a condition of licence

Biological Safety Officer

- Qualifications and responsibilities more stringent than Risk Group 2 BSO



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Risk Group 3/4 Requirements (cont'd)

Disposal

- Ensure method renders material non-viable or non-functional

Compliance Inspections

- Regular (annual) on-going by OLS-PHAC



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Your questions?

Your concerns?

