


**Biosecurity**

PUBLIC HEALTH AGENCY of CANADA  
AGENCE DE SANTÉ PUBLIQUE du CANADA

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## What is Biosecurity?

- Biosafety
  - Aims to prevent the **accidental** release of pathogens and toxins to lab workers, the general population and the environment
- Biosecurity
  - Aims to prevent the **deliberate** theft or diversion of high-risk biological agents for malicious use (bioterrorism, bio-weapons)
- Common strategy:
  - To implement graded levels of protection based on risk management

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*"Biosafety aims to protect people from dangerous pathogens, while biosecurity aims to protect pathogens from dangerous people."*

R. Salerno & D. Estes, Sandia, 2003

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## Biosecurity

- You may be thinking that because you do not work with CL3 or CL4 organisms that you are "safe"...
- Clostridium botulinum
- Salmonella typhi
- Shigella dysenteriae
- Vibrio cholerae
- Clostridium perfringens epsilon toxin producing
- Enterohaemorrhagic E. coli
- Clostridium perfringens toxins
- Shiga toxin
- Staphylococcus aureus toxins
- Cholera toxin
- Clostridium tetani (warning list)
- Legionella pneumophila (warning list)
- Yersinia pseudotuberculosis (warning list)

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## Biosecurity Challenges

- Nature of the material
  - Self-replicating
  - Used in small quantities
  - Often cannot be easily quantified
  - Contained materials are generally not detectable using "scanning" technologies
- Laboratory Culture/Environment
  - Biological research community not generally accustomed to a secure environment
    - Open nature of university setting

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## Biosecurity Challenges

- Dual-Use Characteristics
  - Common techniques and projects may be employed for nefarious purposes
    - Eg. Antibiotic resistance in *B. anthracis*
      - Key to assisting countermeasures
      - May be used to alter resistance of bacterium to ensure population vulnerability.

## Biosecurity Fundamentals

- Not feasible to protect all assets against all threats
- Most biological agents can be isolated from nature
- Theft of biological agents extremely difficult to detect
- Must ensure biosecurity measures do not disrupt day-to-day activity
  - User input is required

## Biosecurity Fundamentals

- Control of some pathogens is necessary
  - How this is achieved must be carefully considered
- Management must identify the protection objectives and allocate resources
- Where to allocate financial resources
  - Risk assessment and risk management

## Risk Management

- Starts with a Risk Assessment
- Determines which assets to be protected from which threats
- Ensures protection is proportional to threat:
  - Threat of theft
  - Threat of destruction

## Biosecurity Risk Assessment

- Evaluate assets
  - Pathogens and experimental protocols
- Evaluate the treat
  - Is there a threat external to the facility?
  - Is there a threat internal to the facility?
- Evaluate the risk
  - Given the work with a particular pathogen, what is the risk?

## Asset Evaluation

- Review potential for malevolent use
  - Australia group list
    - [http://www.australigroup.net/en/control\\_list/bio\\_agents\\_additions\\_in\\_italica.htm](http://www.australigroup.net/en/control_list/bio_agents_additions_in_italica.htm)
      - Bioterrorist threat not agents of public health consequence
  - Physical location within facility
- Experimental design and protocol
  - Does experiment produce a pathogen with higher potential consequences?
  - Does experiment use equipment/technologies that may be desirable?
    - Fermentors

## Threat Evaluation

- Most difficult to determine → little information
- Use any reputable information to identify threat
- Threats can be:
  - Outsiders: those who may be aware of agents present in lab
    - No authorized access
  - Insiders: those with authorized access
    - Most likely threat
    - May be an employee who is:
      - Disgruntled
      - Financially desperate
      - Personally threatened
      - Psychologically unstable
      - Motivated by other factors

## Risk Evaluation

### •Biological Facility Risk

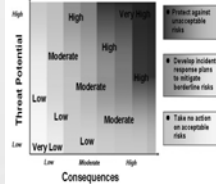
- Relationship between threat potential and consequences
  - Ex: theft and subsequent use of biological material as a weapon
- Expert judgment
- Uncertainty inherent in the process

### •Threat Potential

- Estimate of the degree to which a particular adversary is willing and able to execute a particular event

### •Consequences

- An estimate of the magnitude of a successfully executed event in deaths, illness, economic loss



## Biosecurity Components

- Facility security
- Personnel security
- Material handling and control measures
- Transport security
- Information security
- Program management practices

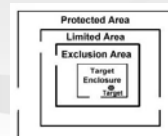
## Facility Security

- Low risk
  - Materials and experiments in a protected area (includes storage)
    - One level of secure access
- Moderate Risk
  - Materials and experiments in limited area (includes storage)
    - Two levels of secure access

## Facility Security

### •High risk

- Materials and experiments in a exclusion area (includes storage)
  - Three levels of secure access
  - Control and restriction of visitors
  - Detailed entry/exit records



## Personnel Security

- Need to ensure suitability and reliability based on risk
- May include:
  - Review and verification of personal information
  - Criminal background check
  - Credit history
  - Security screening
  - Psychological assessment
- Visiting scientist/student procedures
- Employee ID cards
  - Specifies level of access
- Visitor control
- Training
  - Lab staff
  - Housekeeping and maintenance management

## Material Handling & Control Measures

- Inventories
  - Cannot account for each and every viable particle
  - Based on the number of containers
  - location
- Control and Access
  - Biosafety
  - Personnel
  - Information
  - Transfer/transport
- Incident Response

## Transport Security

- Minimize risk of theft of agent during transport
- Is transport within facility, domestic or international?
  - Must follow domestic regulations
    - Transportation of Dangerous Goods Regulations, Transport Canada
    - International Air Transport Association (IATA)
    - International Civil Aviation Organization (ICAO)
- Determine suitable security for agent:
  - Chain of custody
    - Record of all individuals who have had contact with the agent
  - Physical security
  - Personnel screening of individuals shipping and receiving and all in between

## Information Security

- Information too sensitive for public consumption
  - To be controlled
    - Marked/labelled accordingly
    - Electronic versions to be restricted
      - Networks, fax and phone
- Types of information
  - Risk assessments
  - Sensitive experimental protocols and results
  - Facility design
    - Biocontainment
    - Security
    - Access authorizations
  - Personnel records
  - Financial records

## Program Management Practices

- Resource allocation
- Ensure this is proportionate to risk
- Identify objectives of the biosecurity plan
  - What is "unacceptable" and "acceptable" risk
- Design biosecurity system
  - Physical security
  - Biosecurity policies and SOPs

## Biosecurity Plan

- Is a plan that aims to prevent the deliberate theft or diversion of high-risk biological agents for malicious use
- The plan should include:
  - Facility/lab mission and statement
  - Risk definitions
    - Essential to develop threat potential vs consequences chart
  - Risk assessment (define threats, vulnerabilities, countermeasures)
  - Physical security measures
  - Personnel management
  - Material control and accountability
  - Material transfer/transport security
  - Information security
  - Incident response plans and reporting

## Biosecurity in Universities

- This is difficult...
- Important for researchers to know and dialogue with their staff
- Keep good inventories
- Restrict access to labs

## Resources

- [http://www.phac-aspc.gc.ca/publicat/lbg-ldmbl-04/ch2\\_e.html](http://www.phac-aspc.gc.ca/publicat/lbg-ldmbl-04/ch2_e.html)
- <https://www.biosecurity.sandia.gov/>
- [http://www.australiagroup.net/en/control\\_list/bio\\_agents\\_additions\\_in\\_italica.htm](http://www.australiagroup.net/en/control_list/bio_agents_additions_in_italica.htm)