

Biosecurity

PUBLIC HEALTH AGENCY of CANADA
AGENCE DE SANTÉ PUBLIQUE du CANADA

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Overview

- Definitions
- Challenges
- Fundamentals
- Risk management
- Risk assessment
- Biosecurity components
- Biosecurity plan

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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

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
 - university setting in particular

Biosecurity Challenges

- Dual-Use characteristics
 - common techniques and projects may be employed for nefarious purposes
 - eg. antibiotic resistance in *B. anthracis*
 - key to assisting in 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 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

- determines which assets to be protected from which threat(s)
- ensures protection provided is proportional to threat
 - threat of theft
 - threat of destruction
- starts with a risk assessment

Biosecurity Risk Assessment

- need to evaluate assets
 - pathogens and experimental protocols
- need to evaluate the threat
 - is there a threat external to facility
 - is there a threat internal to facility
- need to evaluate the risk
 - given work with a particular pathogen, what is the risk

Asset Evaluation

- pathogens
 - what pathogens are present
 - review agent characteristics
 - route of transmission
 - life cycle stages
 - environmental stability
 - growth characteristics
 - slow grower vs. fast grower
 - ease of storage
 - potential to become endemic
 - economic impact

Asset Evaluation

- review potential for malevolent use
 - Australia group list
 - limited to agents of bioterrorist threat
 - does not include agents of public health consequence
 - physical location within facility
 - map

Asset Evaluation

- Experimental design and protocol
 - does planned experiment produce a pathogen with higher potential consequences?
 - higher “weaponization potential”?
 - does the experiment use equipment/technologies that may be desirable for malevolent use?
 - fermenters

Threat Evaluation

- most difficult to determine → little information usually exists on potential adversaries
- any reputable information should be used to identify threat
- threats can be
 - **outsiders:** those who may be aware of agents present in lab
 - no authorized access to facility
 - **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

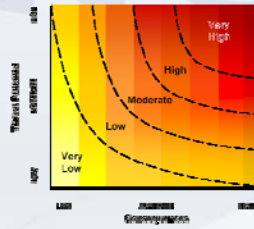
Risk Evaluation

Biological Facility Risk

•an expression of the relationship between threat potential and consequences for a particular event

-example: theft and subsequent use of biological material as a weapon

- Expert judgment contributes significantly to the analysis
- uncertainty inherent in the process



Threat Potential

•an estimate of the degree to which a particular adversary is willing and able to execute a particular event

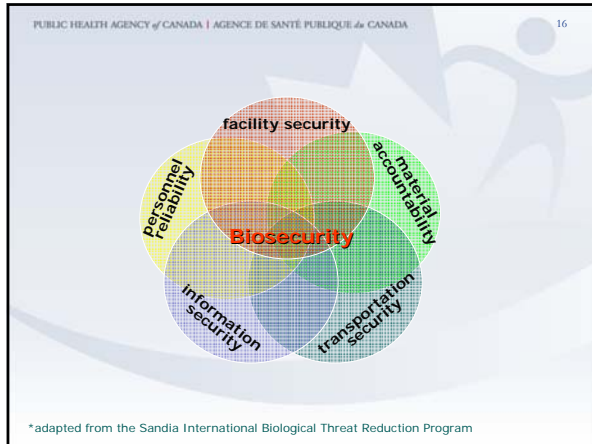
Consequences

•an estimate of the magnitude of a successfully executed event in deaths, illness, economic loss, symbolic and functional impacts

courtesy of Sandia International Biological Threat Reduction Program

Biosecurity Components

- facility security
- personnel security
- material handling and control measures
- transport security
- information security
- program management practices



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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

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Facility Security

- high risk
 - materials and experiments in a protected 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
 - involves CSIS
 - psychological assessment
- visiting scientist/student procedures

Personnel Security

- employee ID cards
 - specifies level of access
- visitor control
- training
 - lab staff
 - housekeeping & maintenance
 - management

Material Handling & Control Measures

- inventories
 - cannot account for each and every viable cell/virus particle
 - based on the number of containers
 - location
- control and access
 - biosafety
 - personnel
 - information
 - transfer/transport
- incident response

Transport Security

- need to ensure risk of theft of agent during shipment/movement is minimized
- is transport internal (within facility), domestic or international?
 - must follow domestic regulations
 - *Transportation of Dangerous Goods Regulations*, Transport Canada
 - must follow international regulations
 - International Air Transport Association (IATA)
 - International Civil Aviation Organization (ICAO)

Transport Security

- must determine security suitable for agent
 - chain of custody for high risk agents?
 - record of all individuals who have had contact with agent in transport
 - physical security in transshipment
 - personnel screening of individuals shipping and receiving, and all in between

Information Security

- information too sensitive for public consumption
 - to be controlled
 - marked/labeled accordingly
 - electronic versions to be restricted
 - networks to be assessed for security requirements
 - 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

- management commitment of resource allocation
- ensure resources are allocated proportionately to risk
- need to identify objectives of the biosecurity plan
 - determine what is “unacceptable” and “acceptable” risk
- design biosecurity system
 - physical security
 - facility biosecurity policies and standard operating procedures

Program Management Practices

- take responsibility for emergency response plans/incident response
- ensure on-going testing, verification and maintenance of security systems/programs
- training:
 - allocate funds and employee time

Summary

- Definitions
- Challenges
- Fundamentals
- Risk management
- Risk assessment
- Biosecurity components
- Biosecurity plan

Putting it all Together

- Develop a laboratory biosecurity plan
- plan should include:
 - facility/lab mission and statement
 - risk definitions
 - essential to develop threat potential vs. consequences chart
 - physical security measures
 - personnel management
 - material control and accountability
 - material transfer/transport security
 - information security
 - biosecurity program management
 - reporting structure and responsibilities
 - incident response plans and reporting

Resources

- http://www.phac-aspc.gc.ca/publicat/lbg-ldmbl-04/ch2_e.html
- <https://www.biosecurity.sandia.gov/>
