



INTRODUCTION OF BIOSECURITY



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Laboratories**

LEARNING OUTCOMES

At the end of this module, participants will be able to:

- ▶ identify the five pillars of biosecurity in the laboratory (C1)
- ▶ follow the general procedures (entry & exit control, inventory, labeling, etc.) pertaining to biosecurity (P2)
- ▶ value the importance of biosecurity in the laboratory (A3)

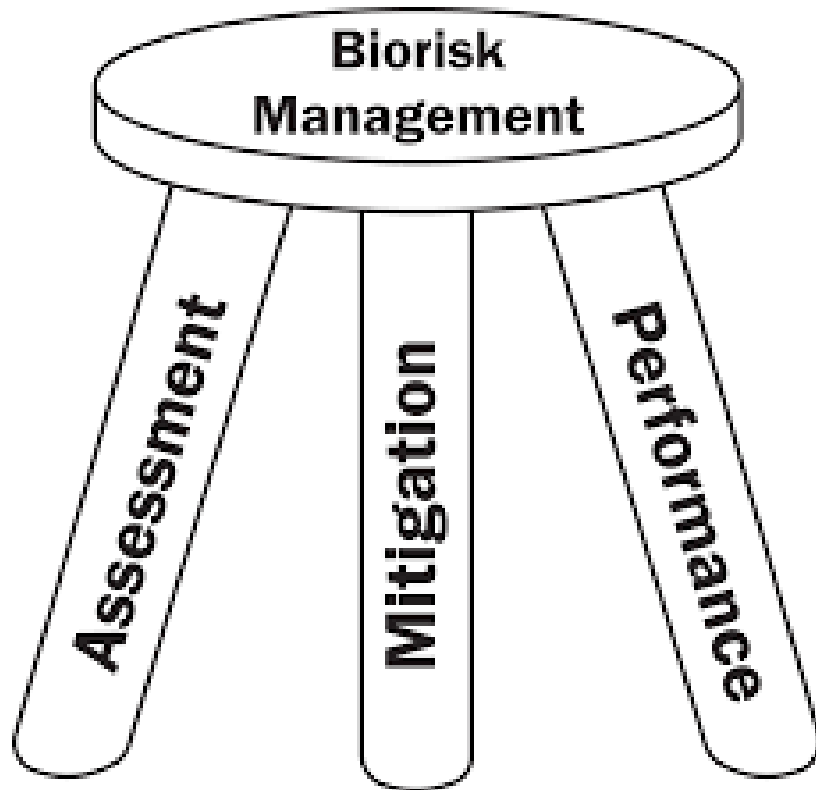
MODULE OUTLINE

- ▶ The concept of Biosecurity
- ▶ Biosecurity threat
- ▶ The FIVE pillars of Biosecurity

What is biosecurity?
Single word - keyword

► Mentimeter

Laboratory Biosecurity



- ▶ Laboratory biosecurity describes the protection, control, and accountability of valuable biological materials (VBM) in laboratories, to prevent unauthorized access, loss, theft, misuse, diversion, or intentional release.

Biological materials (viruses, bacteria & toxins)

- ▶ Viruses, bacteria, and other types of microorganisms that can multiply
- ▶ Toxins (are also biological materials)
- ▶ Characteristics (challenge):
 - ❖ Small amounts can have severe consequences
 - ❖ Detection is difficult
 - ❖ Relatively easy to obtain
 - ❖ inexpensive to produce



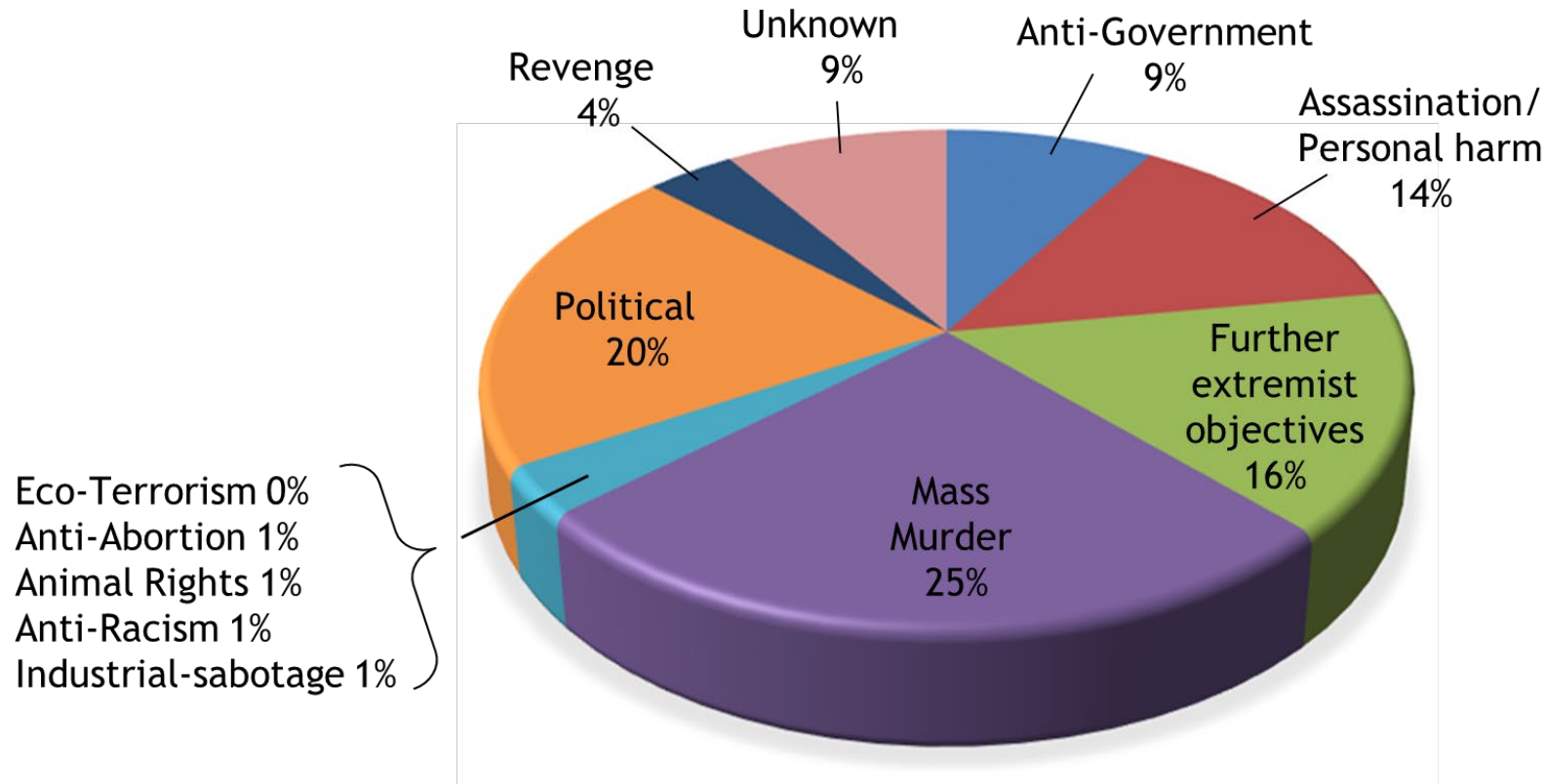
Where can you find biological materials?

- ▶ Laboratories
 - ❖ Animal and public health
 - ❖ Research
 - ❖ University
 - ❖ Clinical/diagnostic
 - ❖ Vaccine production
- ▶ Culture collections and repositories
- ▶ Environment
- ▶ People and animals
- ▶ Waste



Malicious Motives

35 legitimate incidents involving biological agents
from 1960 to 2016



Jane's Terrorism and Insurgency Centre <https://www.ihs.com/jtic>

National Consortium for the Study of Terrorism and Responses to Terrorism (START). (2016). Global Terrorism Database [Data file]. Retrieved from <https://www.start.umd.edu/gtd>

What are the consequences of Biosecurity risk?

- ▶ Biosecurity is about “**protecting pathogens from bad people**”
- ▶ What do you think would be the problem if a person with a malicious motive has access to the VBM?



Biosecurity Threat: Outsiders

Outsiders are people without authorized access to bioscience facilities wanting to commit malicious acts

- ▶ Terrorists
- ▶ Criminals
- ▶ Activists/protestors
- ▶ Scientific competitors

Biosecurity Outsider Threat (Example 1)

Location: Oregon, USA

Perpetrator: Rajneeshees - 1984

Motive:

- ▶ To interfere with a local election. The group attempted to incapacitate voters

Organism:

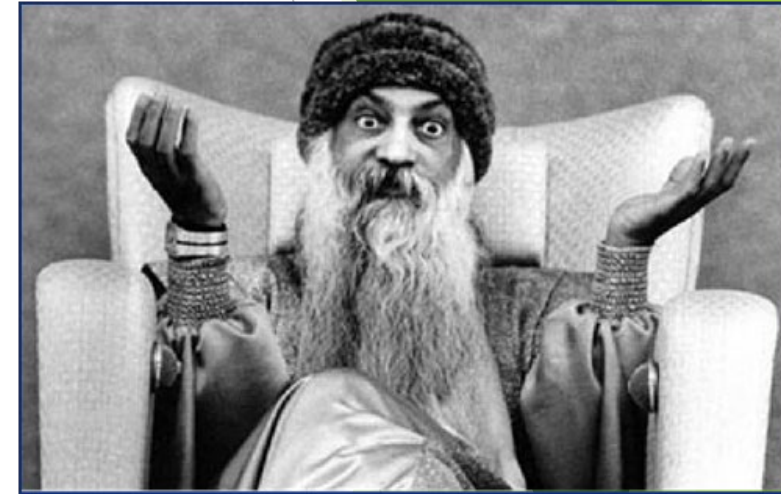
- ▶ *Salmonella* spp (ordered from a culture collection)

Dissemination:

- ▶ Contaminated restaurant salad bars

Outcome:

- ▶ Infected 751 individuals (45 were hospitalized)
- ▶ “First and still the largest germ-warfare attack in U.S. History”



Bhagwan Shree Rajneesh

Biosecurity Outsider Threat (Example 2)

Location: Tokyo, Japan

Perpetrator: Aum Shinrikyo - 1990s

Motive:

- ▶ The Aum Shinrikyo religious group used biological agents to contaminate anti-Aum Shinkrikyo activists and locals

Organism:

- ▶ Vaccine strain of *Bacillus anthracis*
- ▶ Inactive strain of *Clostridium botulinum*

Dissemination:

- ▶ Aerosolized and disseminated biological agents

Outcome:

- ▶ Due to ineffective dispersal, clogged spray device, and inactivation of spores by sunlight, the agents were inactive and did little harm to people except for making them nauseous and to lose their appetite.



Biosecurity Threat: Insiders

Insiders are people with authorized access to bioscience facilities who use their access/knowledge to commit malicious acts

- ▶ Blackmailed or coerced employees
- ▶ Disgruntled employees
- ▶ Criminals
- ▶ Research theft: intellectual property, data, materials, or cultures

Biosecurity Insider Threat Examples

Location: Texas, USA

Perpetrator: Diane Thompson

- ▶ Clinical laboratory technician

Motive:

- ▶ Possibly revenge against former boyfriend and cover-up by infecting co-workers

Organism:

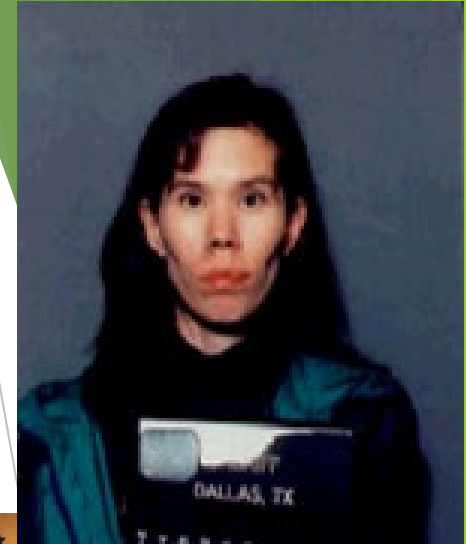
- ▶ *Shigella dysenteriae* Type 2 (acquired from the clinical laboratory of the St. Paul Medical Center where she worked)

Dissemination:

- ▶ Contaminated pastries in the tea-break room

Outcome:

- ▶ Infected 12 of her coworkers
- ▶ Arrested, convicted, 20 years jail sentence



Biosecurity Insider Threat Examples

Location: Japan

Perpetrator: Dr. Mitsuru Suzuki

- ▶ Physician with training in bacteriology

Motive:

- ▶ Revenge

Organism:

- ▶ *Shigella dysenteriae* and *Salmonella typhi* (stolen from Japan National Institute of Health)

Dissemination:

- ▶ Sponge cake, other food sources

Outcome:

- ▶ Later implicated in 200 to 400 illnesses
- ▶ 4 deaths
- ▶ Official investigation started after an anonymous tip to the Ministry of Health and Welfare
- ▶ Charged with infecting people, but not with causing death



Biosecurity Insider Threat (Example)

Location: More than 60 Locations in USA

Perpetrator: Bruce Ivins (FBI agent)

- ▶ Research Scientist

Motive:

- ▶ Unknown

Organism:

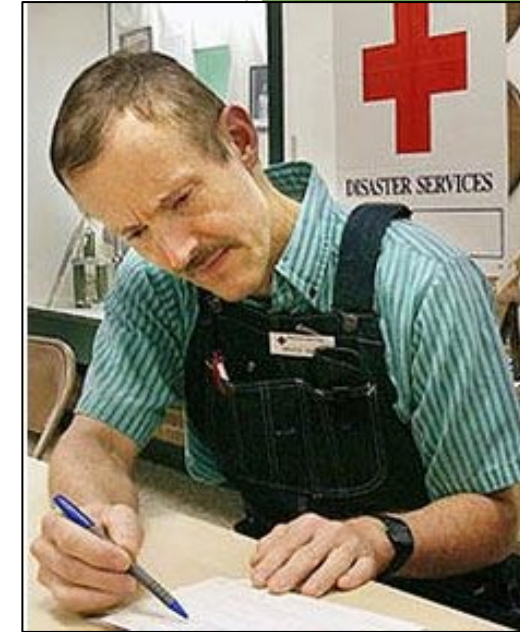
- ▶ *Bacillus anthracis* (stolen from a USA research laboratory)

Dissemination:

- ▶ 7 letters sent through the postal system

Outcome:

- ▶ 22 confirmed cases of anthrax
- ▶ FBI unveils evidence against Ivins
- ▶ Ivins died of an apparent suicide
- ▶ Financial impact \$320M (2001)



ANTHRAX INVESTIGATION

**FBI Discusses Microbial Forensics—
But Key Questions Remain Unanswered**

Well, if you believe Malaysia is safe from biosecurity threat .. Think again!

Location: Malaysia

Perpetrator: Yazid Sufaat

- ▶ Biochemist (California State University, Sacramento, USA)
- ▶ Served in the Malaysian Army as a medical technician, rising to the rank of Captain

Motive:

- ▶ Member of the Extremist Islamist terrorist organization, Jemaah Islamiyah from 1993. (arrested in 2001)

Organism:

- ▶ *Bacillus anthracis* (anthrax) - Green Laboratory Medicine

He was arrested in 2017 under the Prevention of Terrorism Act 2015 (POTA), and released after 2 years in prison



Should we worry about bioterrorism in Malaysia?



Antiviral Research 57 (2003) 113–119



Nipah virus—a potential agent of bioterrorism?

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Received 19 March 2002; accepted 18 September 2002

Abstract

Nipah virus, a newly emerging deadly paramyxovirus isolated during a large outbreak of viral encephalitis in Malaysia, has many of the physical attributes to serve as a potential agent of bioterrorism. The outbreak caused widespread panic and fear because of its high mortality and the inability to control the disease initially. There were considerable social disruptions and tremendous economic loss to an important pig-rearing industry. This highly virulent virus, believed to be introduced into pig farms by fruit bats, spread easily among pigs and was transmitted to humans who came into close contact with infected animals. From pigs, the virus was also transmitted to other animals such as dogs, cats, and horses. The Nipah virus has the potential to be considered an agent of bioterrorism.

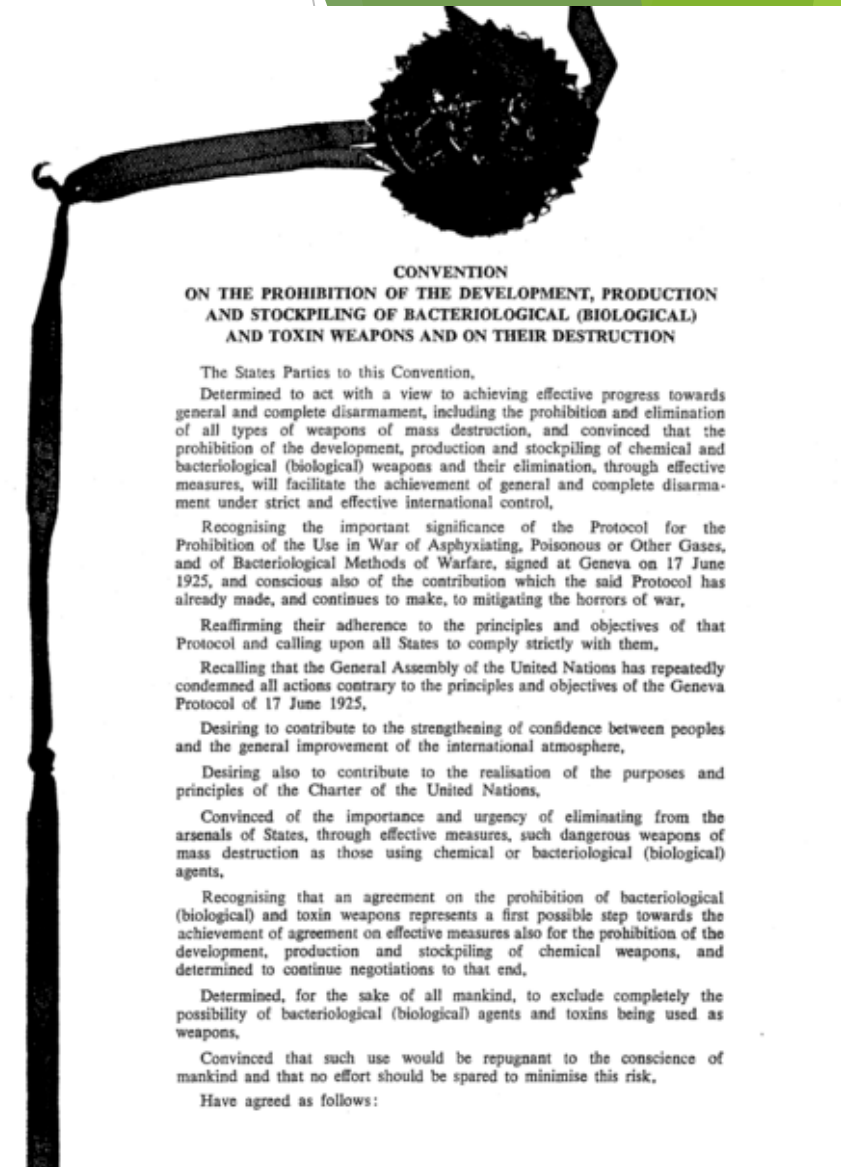
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Any regulatory requirement?

- ▶ United Nations Security Council Resolution 1540 (UNSCR 1540) - 2014
- ▶ Acceded/Ratified the treaty by 184 states including Malaysia
- ▶ Malaysia is bounded by the treaty and should follow the articles
- ▶ Biological & Toxin Weapons Convention (BTWC) - Bill 2015 (pending approval by Parliament)
- ▶ Meanwhile, Malaysia has drafted a Regulation on BTWC Bill 2015



Laboratory Biosecurity Risk - Case study

Activity:

- ▶ Form groups among yourself
- ▶ Carefully read the case provided
- ▶ Discuss the case among your group members
- ▶ Identify the biosecurity risk(s) in the case

Case study 1

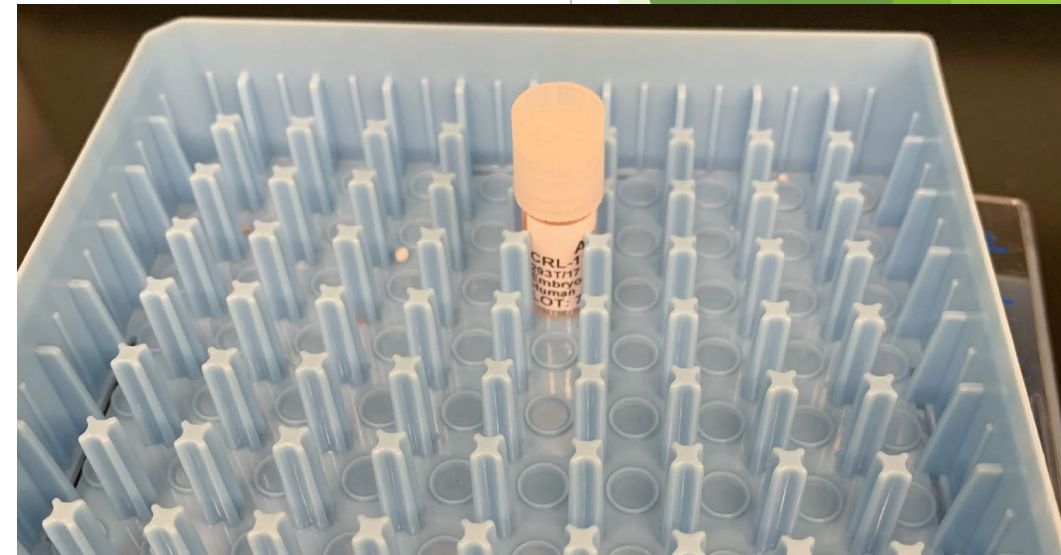
You are a new student walking alone in a Research Institute to explore the place. At the end of the corridor is a biosafety level 2 laboratory conducting human virus research.

What could be the potential problem with the facility and what should be done?



Case study 2

You are a senior student and one morning you were the first person to enter a research laboratory. You noticed a tube containing human embryonic kidney HEK293 cell line newly bought in from ATCC. The cell line that was shipped in dry ice costs RM3000. Realizing the value of the cell line, why do you think the tube was left exposed on the bench?



Case study 3

Your friend is working on a national project on vaccine development for a human pathogen. He likes to work on his data in a café nearby his house. One day, he left his laptop on the table and went out to chat on his phone just as you walked into the café. What kind of information do you think could be obtained from his unattended laptop?



Case study 4

Body fluid samples were collected from an Ebola patient in a very rural area in Africa. The trained logistic rider delivers the sample to a guy waiting at the entrance of the National Reference Laboratory. Is there any indication that the rider is carrying VBM that could make him a target for people with malicious motives?



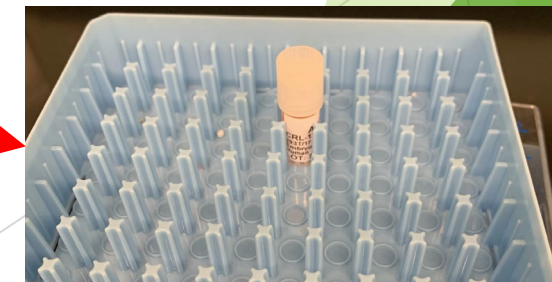
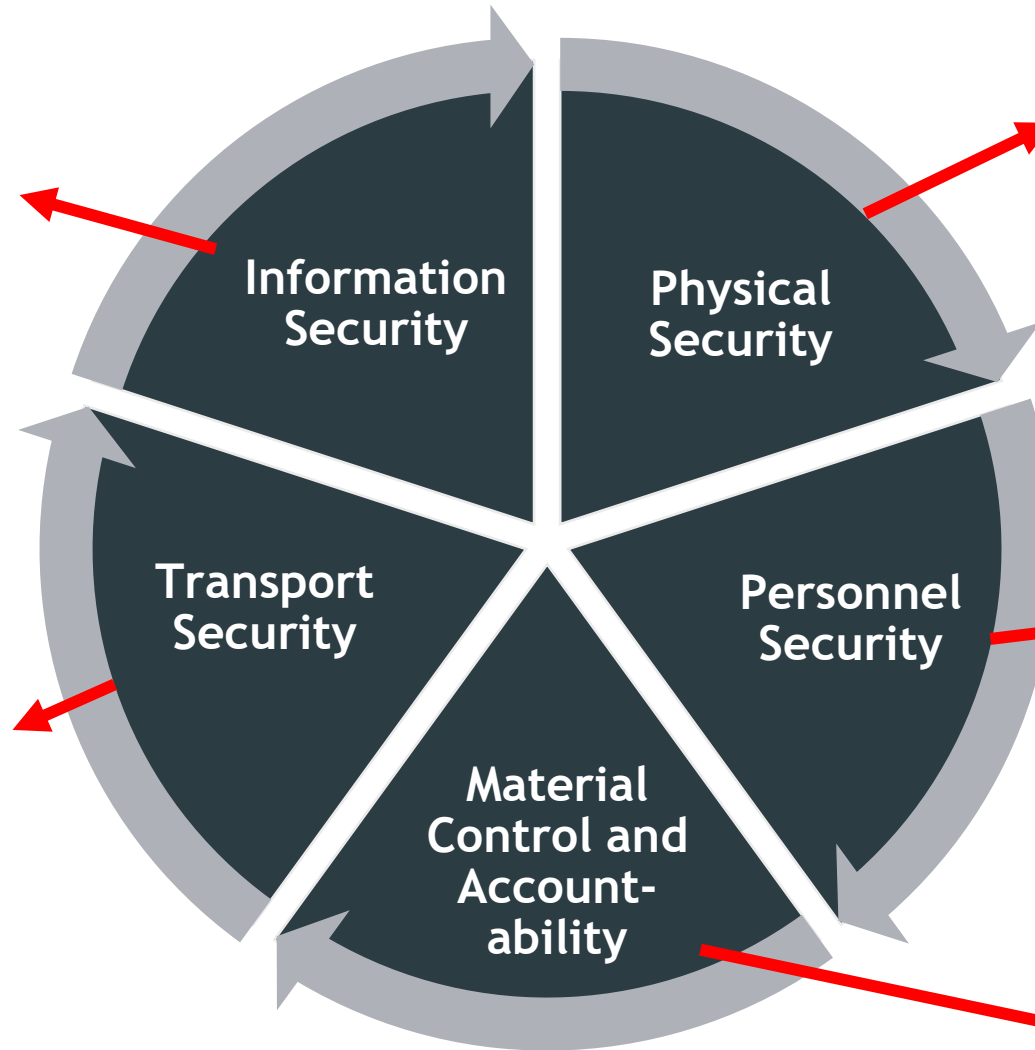
Case study 5

You were a new student walking along the corridor of a research institute when you saw this notice on the door. Curious to know how the BSL-4 laboratory functions, you tried to open the door. What could happen if the door actually opened?



Elements in Laboratory Biosecurity

LECTURE

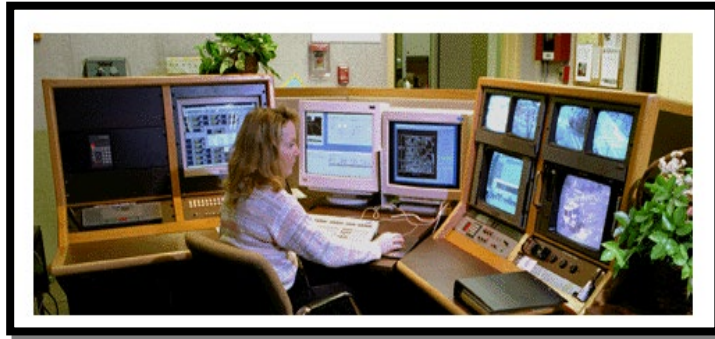


Physical Security

Pillar 1: Physical Security is a combination of measures taken to protect laboratories and their assets from physical intrusion

Principles of Physical Security:

- ▶ Detection
- ▶ Delay
- ▶ Response



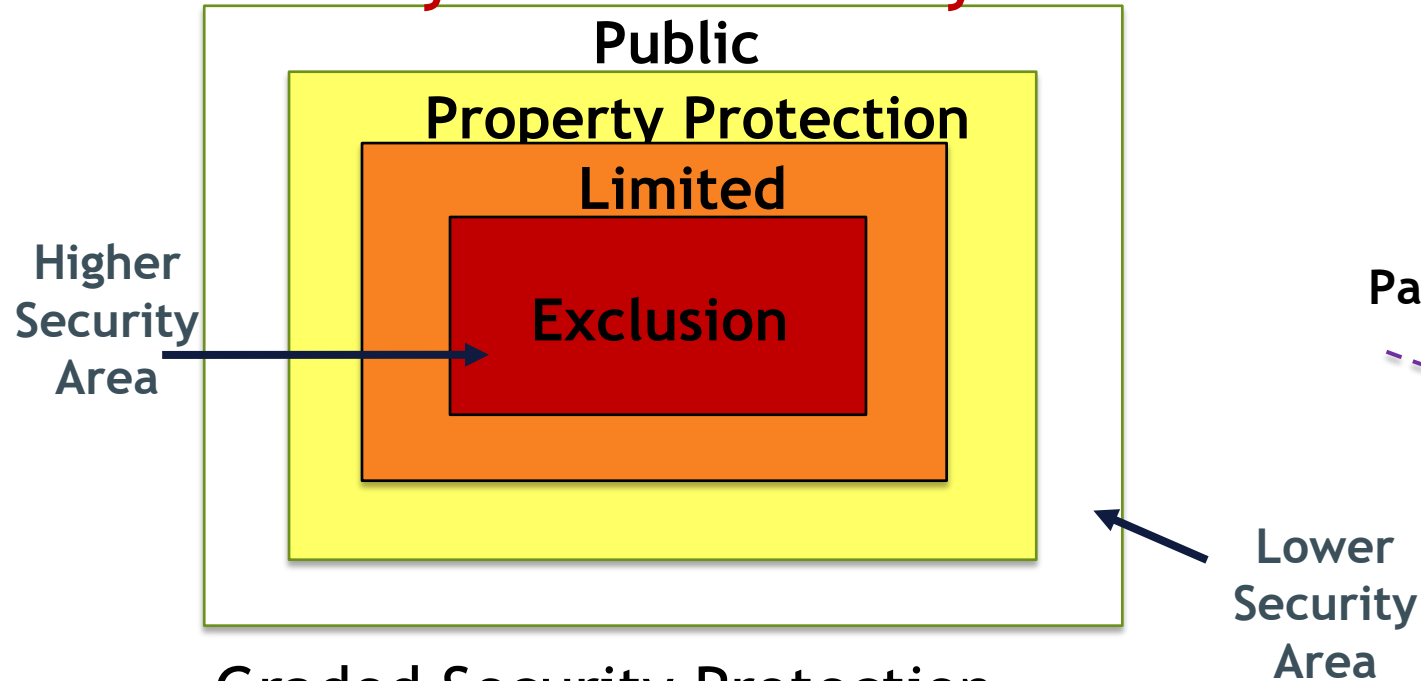
Other important aspects of physical security are **Access Control** and **Deterrence**

Access Control is used to determine and control entry and exit from secured areas. Examples are locks and request-to-exit (REX) mechanisms



Key Concepts in Biosecurity Risk Mitigation

Layers of Biosecurity

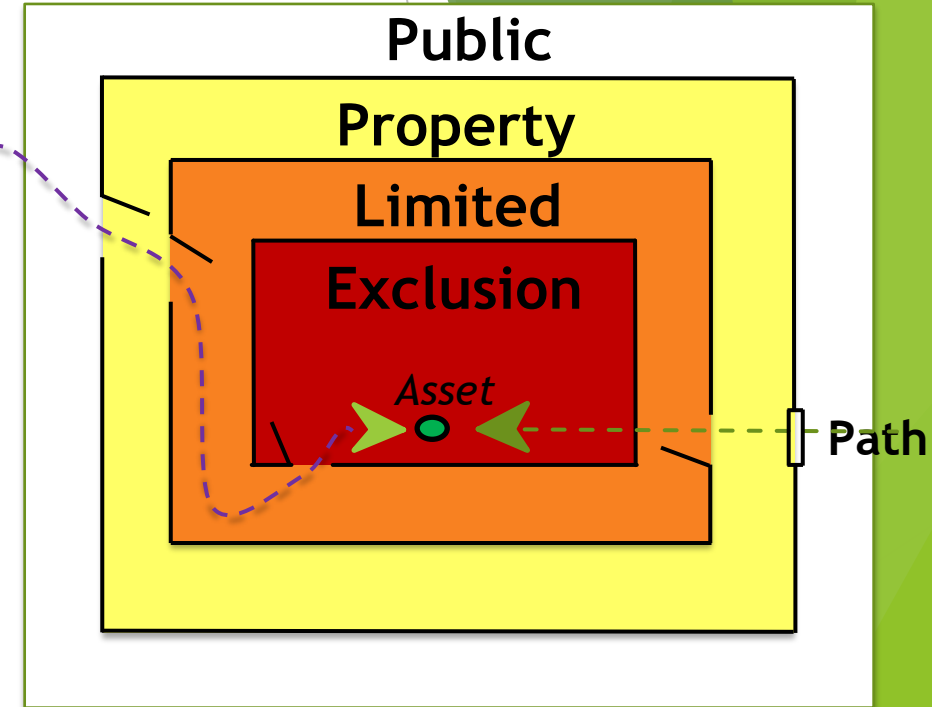


Graded Security Protection

Different areas of a facility will have **different levels of security** based on risk.

Security **increases** as you move from outside to inside the facility.

Path 1



Balanced Security

Balanced security = no weak path

As a student, what do you think is your responsibility in Physical Security?



Material Control & Accountability

Pillar 2: **Material Control & Accountability** is an awareness of:

- ▶ The assets in the laboratory
- ▶ The location of the assets
- ▶ The person responsible for the assets

What type of biological **materials/assets** should be controlled, accounted for, and secured?

- ▶ Only well-characterized strains?
- ▶ Closely related strains?
- ▶ Genetic material?
- ▶ Reagents?
- ▶ Experimental Results?
- ▶ Sequence Information?
- ▶ Waste?
- ▶ Animals?
- ▶ Others?

What material/information should we keep track of?

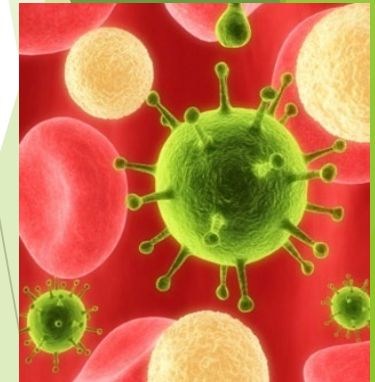
Agent

Quantity

Form

Detail

Scope



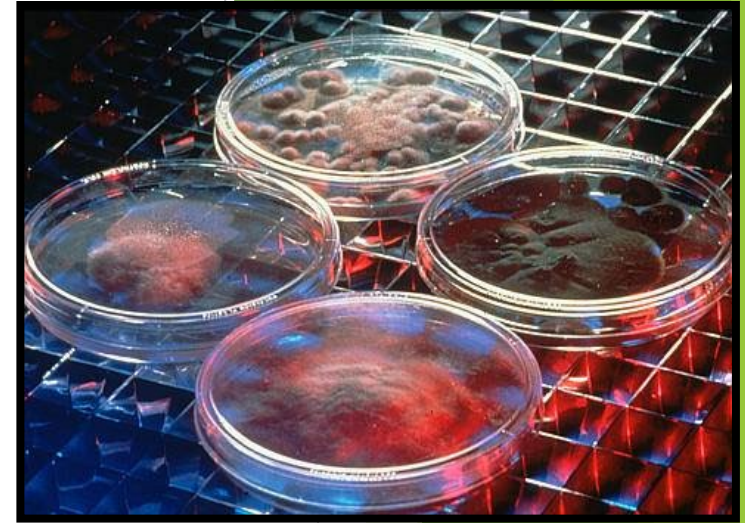
Control

- ▶ Engineered / Physical
- ▶ Administrative
- ▶ Procedural
- ▶ Containment is part of material control
 - ❖ Containment Lab / Freezer / Ampoule
- ▶ Procedures are essential for material control
 - ❖ For both normal and abnormal conditions

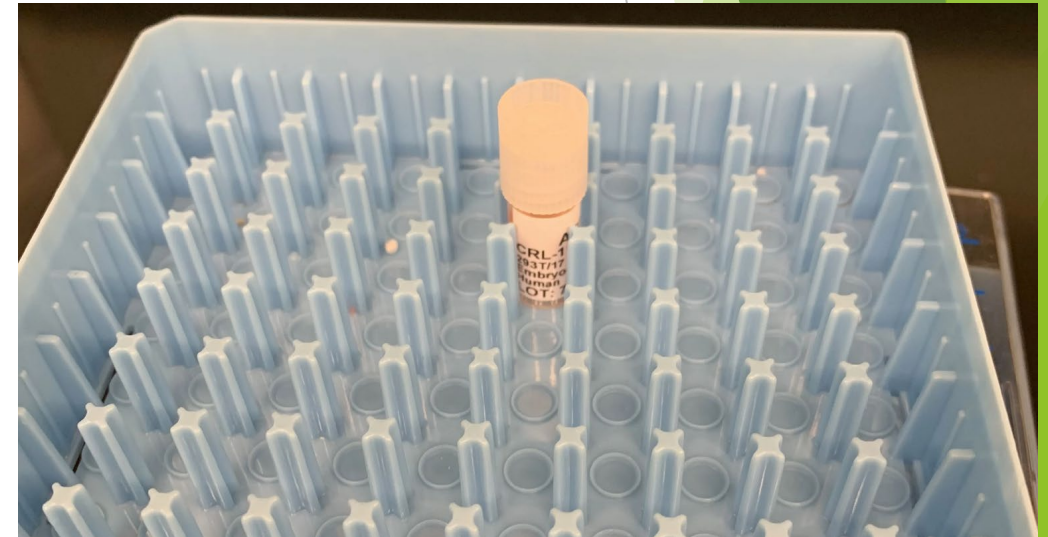
Accountability

All material should have an associated “accountable person” who is ultimately responsible for the material

- ▶ The person in the best position to answer questions about the associated material
- ▶ Ensure that no material is “orphaned”
- ▶ Not someone to blame!



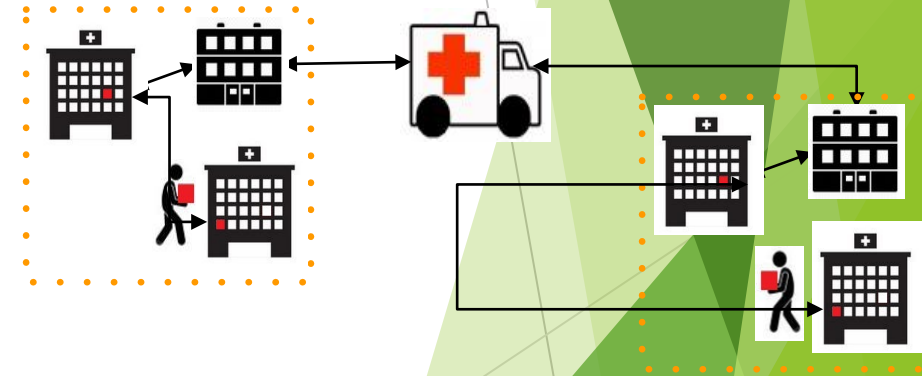
As a student, what do you think is your responsibility in Material Control and Accountability?



Transport Security

Pillar 3: **Transport Security** is the protection of biological materials while they are being transported outside the laboratory

- ▶ **Transport** is the movement of biological material outside of a restricted area
- ▶ **Transport** can occur
 - ❖ Across international borders
 - ❖ Within a country
 - ❖ Within a facility



Question: How is the biosecurity risk different during transportation?

As a student, what do you think is your responsibility in Transport Security?



Information Security

Pillar 4: **Information Security** is the protection of **sensitive** and **valuable** information from theft or diversion.

Information security for laboratories:

- ▶ Includes but is not limited to cyber-security
- ▶ Should be based on risk, known threats, and consequences of the information being released

Common laboratory information security measures include:

- ▶ Restrict methods of communication
- ▶ Implement network and desktop security
- ▶ Label information as restricted
- ▶ Physically secure information
- ▶ Train staff



As a student, what do you think is your responsibility in Information Security?



Personnel Security

Pillar 5: Personnel Security, in the context of biosecurity, is the policies and procedures used to ensure that individuals given access to sensitive biological materials **are authorized** to have that **access**.

- ▶ Determine the trustworthiness of personnel requiring access
- ▶ Procedural and administrative access control requirements
- ▶ Manage authorized personnel access to secure areas and assets
- ▶ Manage visitor access to the facility

Ensure security awareness among personnel



**Personnel Security
is the principal pillar
to mitigate the risk
of insider threat!**



As a student, what do you think is your responsibility in Personnel Biosecurity?

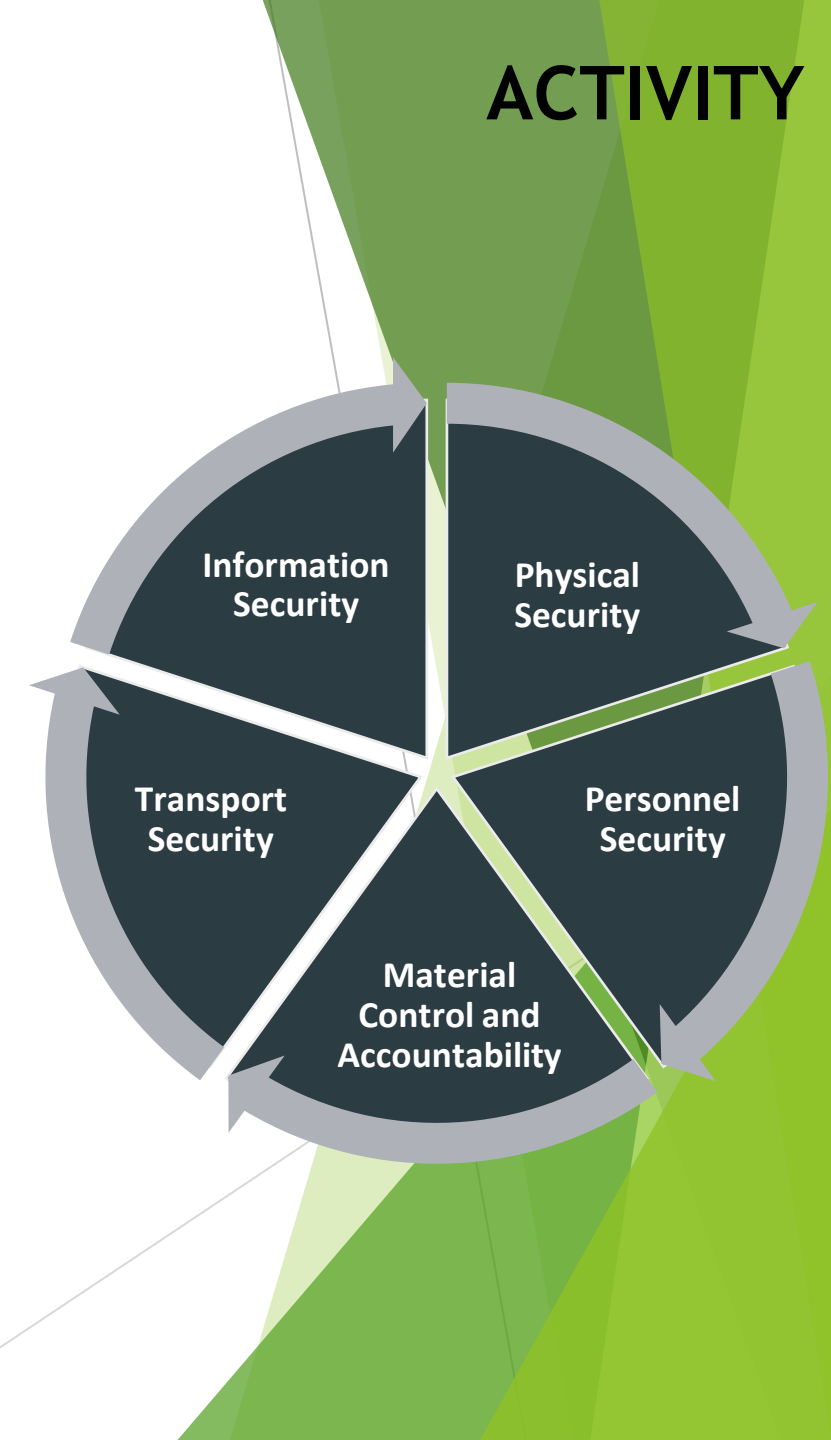


Pillars of Biosecurity

A short reflection on the pillar

Case study:

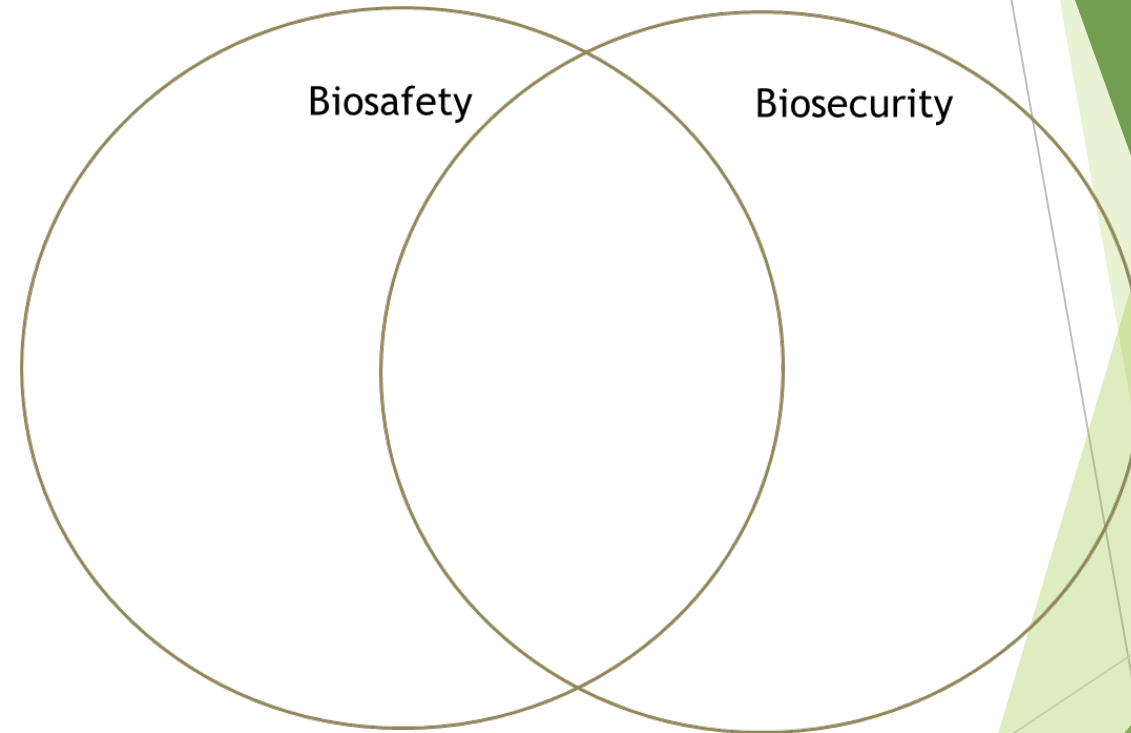
Your junior, without your knowledge, took a vial of your genetically modified virus, placed it in his luggage, flew from KL to Sarawak on the AirAsia Airline, to deliver the vial to his friend who is working on a similar project.



Laboratory Biosafety vs Biosecurity

Activity:

Brainstorm to determine where to place biosafety and biosecurity



Take-home Assignment

Identify the biosecurity control to be installed in your laboratory with respect to each pillar

1 Physical Security	2 Material Control & Accountability	3 Transport Security	4 information Security	5 Personnel Security
Access card system	Designated-80 freezer compartment for keeping samples	SOPs for transportation of VBM out of the laboratory	Each student has a designated login account	Only authorized personnel is allowed to enter specific rooms
	Biological Inventory			



KEY MESSAGES

- ▶ The concept of Biosecurity
- ▶ Biosecurity threat
- ▶ The FIVE pillars of Biosecurity



THANK YOU



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