INTRODUCTION TO BIORISK MANAGEMENT

BASIC CONCEPTS OF BIORISK MANAGEMENT

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LICENSE

INTRODUCTION

This lecture has been designed and developed in order to introduce you to the **fundamental principles, concepts, terminologies** and practices associated with the management of risks posed by biological agents.

LEARNING OBJECTIVES

The objectives of this lecture are as to introduce you to:

1. **Biosafety** management and **biosecurity** management.
2. The principles of biorisk management.
3. The concept of **containment**.
4. Biological agents.
5. Processes involving biological agents.
6. International guidelines and regulations.

LEARNING OUTCOMES

Upon completion of this module, you should be able to:

1. Differentiate between **biosafety** and **biosecurity** management.
2. Demonstrate an understanding of the overall process of **biorisk management.**
3. Differentiate between primary and secondary **containment**.
4. Demonstrate a basic understanding of **biological agents**.
5. Describe some of the laboratory **processes** that involve biological agents.
6. Demonstrate a knowledge of the international manuals and guidelines.

INTRODUCTION

- Viruses, bacteria and other pathogens have posed a challenge to human civilizations for millennia.
- Pandemics such as the 1918 Pandemic (H1N1 virus) caused global mass global mortalities with more than 50 million deaths.
- The emergence of **new pathogens** with enhanced resistance to antibiotics and other therapeutic agents poses and increasing threat to our existence.
- **Synthetic biology** and **genetic engineering.**
- The added spectre of **bioterrorism** is another challenge.

BIOSAFETY & BIOSECURITY

BIOSAFETY MANAGEMENT

- Biosafety management focuses on the **"unintentional"** release of a biological agent.
- This can be attributed to accidents or incidents which may occur in the laboratory.
- The "intent" is not to cause harm, but rather the result of a lack of oversight and lack of adherence to standard operating procedures.
- However the consequences include a significant impact on the laboratory users as well as the community.
- Key term: **biological agent.**

BIOSAFETY: INCIDENTS

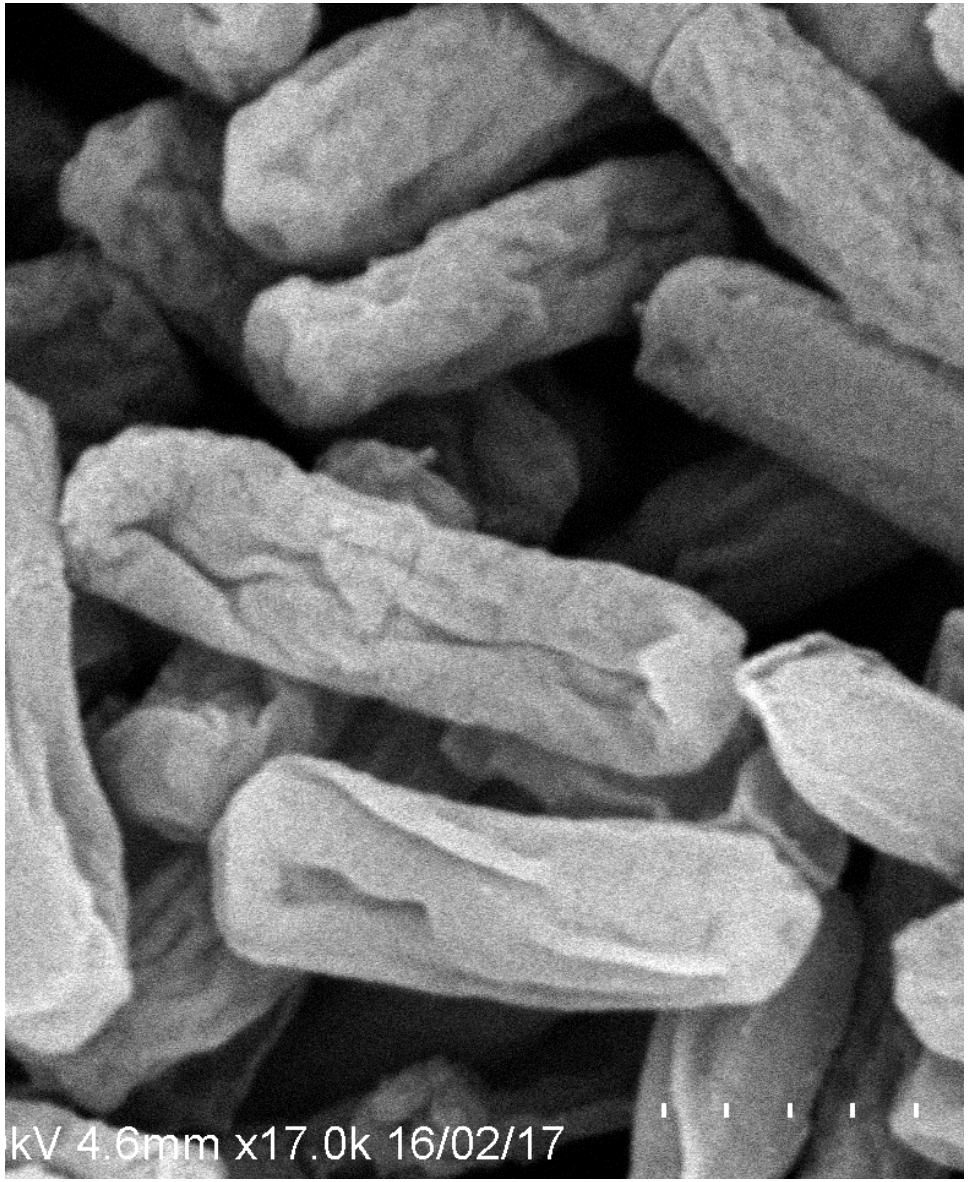
- 2011 Germany ***E. coli* O104:H4** outbreak.
- Foodborne pathogen.
- Secreted Shiga toxin.
- Consumers ingested it via raw vegetables.
- Fatalities: 53

BIOSECURITY MANAGEMENT

- Biosecurity management focuses on the **"intentional"** release of a **biological asset**.
- The **intent** is to cause harm to public health and safety.
- The **intent** can also be to create a sense of fear in society.
- Biosecurity management involves the application of appropriate biosecurity protocols or measure to prevent the intentional release of **biological assets**.
- Key terms: **biological asset**.

BIOSECURITY: INCIDENTS

- 2011 Anthrax attacks.
- Amerithrax (FBI).
- *Bacillus anthracis*.
- Pathogen found is soil.
- Ability to form spores.
- Fatalities (5).



BIORISK MANAGEMENT

MANAGING BIORISK

- Biological agents in themselves do not pose a risk to society.
- **Processes** involving biological agents pose a risk to laboratory users and to society.
- These processes may be **critical** to the development of vaccines, therapeutic agents or diagnostic procedures.
- Biorisk management focuses on **mitigating** the risk posed by biological agents by the application of pertinent **controls**.
- There is always a certain level of risk which is termed as **"residual risk"**.

BIORISK MANAGEMENT: The AMP Model

RISK ASSESSMENT

- What are the possible risks posed by working with the biological agent?
- Are the facilities adequate?
- Are the laboratory personnel suitably trained to address the risk?
- Are the facilities secure?

RISK MITIGATION

- How can I reduce the level of risk?
- How can I apply the pertinent "controls" to mitigate the risk level?
- Should I apply more than one control?
- Should the application be concurrent?

PERFORMANCE ASSESSMENT

- Are the **controls** adequate?
- Has the risk of exposure been **reduced**?
- Have new risks emerged after the application of the controls?
- Have there been and reports of **accidents** or **incidents**?
- How can the biosafety level be improved upon?
- Continuous Quality Improvement (**CQI**).

CONTAINMENT

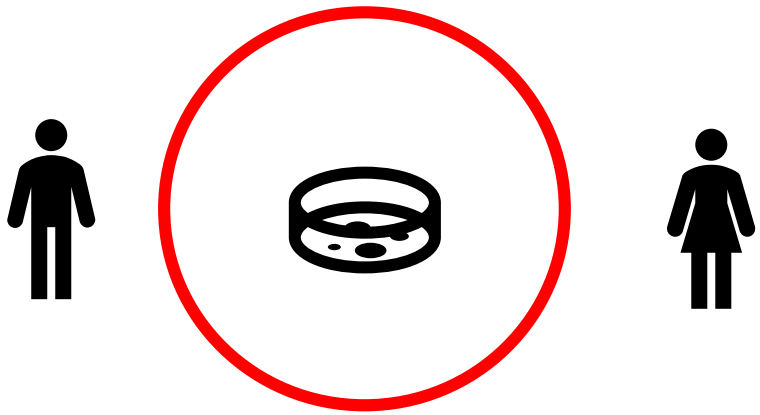
(EN 12128:1998)

CONTAINMENT

- Containment as the terms suggests is "**the action of keeping something harmful under control or within limits**".
- Biosafety management is directed towards keeping the biological agent or biological asset under containment.
- Primary containment
- Secondary containment

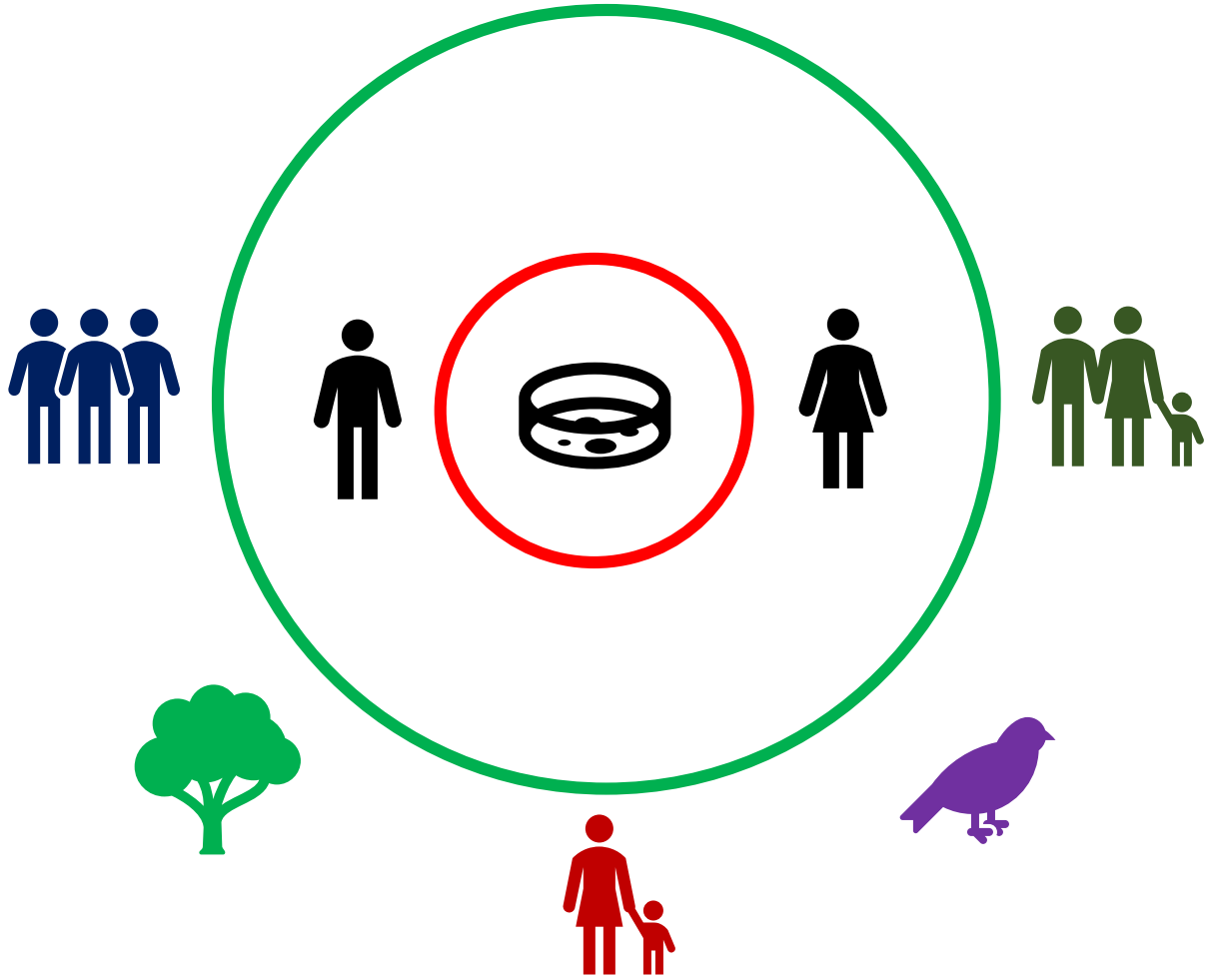
PRIMARY CONTAINMENT

- The
  set of controls which protect th
  e laboratory users from the
  biological agent.
- Personal protective equipment.
- Administrative controls: standar
  d operating procedures.



SECONDARY CONTAINMENT

- The set of controls which protect the environment and the laboratory users from the biological agent.
- Physical containment: containment facility.
- Administrative controls: standard operating procedures.



BREACH OF CONTAINMENT

- A **breach of containment** implies a temporary or permanent loss of the controls which limit the spread of the biological agent.
- This can have **consequences** for the laboratory users as well as the environment.
- Adequate measures must be put in place to mitigate any consequences posed by potential breaches in containment.

BIOLOGICAL AGENTS

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- Viruses
- Bacteria
- Fungi
- Prions
- Genetically Modified Organisms
- Biotoxins

MANUALS & GUIDELINES

MANUALS AND GUIDELINES

- World Health Organization: Laboratory Biosafety Manual.
- Biosafety in Microbiological and Biomedical Laboratories (BMBL): Centers for Disease Control and Prevention.
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.
- CWA 16393: CWA Laboratory biorisk management - Guidelines for the implementation of CWA 15793:2008

SPECIFIC NATIONAL LAWS

- Biosafety laws
- Laws pertaining to genetic engineering.
- Occupational health and safety laws.
- Standards pertaining to biosafety and biorisk management.

SUMMARY OF LECTURE 1

- Biosafety and biosecurity.
- The principle of biorisk management.
- Containment.
- Biological agents
- Manuals and guidelines.

THANK YOU