Biosafety Principles & Microbiological Risk group

2018

Principle of Biosafety

- Biosafety Levels 1-4 describe combinations of:
  - Laboratory Practices and Techniques
  - Safety Equipment including PPE (Primary Barriers)
  - Laboratory Facilities (Secondary Barriers)

- Biosafety Levels 1-4 Provide
  - Increasing levels of personnel and environmental protection
  - Guidelines for working safely in laboratories using biological agents

Principle of containment

- Used to describe safe methods for managing infectious agent in the laboratory environment where they are being handle or maintained.

Elements of containment

- Primary containment

  - Protection of personnel and the immediate laboratory environment
  - Use of laboratory practices, technique, safety equipment

- Secondary containment

  - Protection of environment external to immediate laboratory

Selection of containment measures (the biosafety level)

- Knowledge of containment mechanisms(the laboratory)

  - understanding of the mechanisms of containment and measures used to control the potential for escape, transmission and exposure

- Match containment to risk
- Source of assistance

  - National/ international guidelines and professional biosafety personnel

Biosafety Level 1 (BSL-1)

- Suitable for work involving well-characterized agents not known to consistently cause disease in immuno competent adult humans
- Minimal potential hazard to laboratory personnel and the environment
- Laboratories are not necessarily separated from the general traffic patterns in the building

e. g biological lab in secondary school or college working with e coli

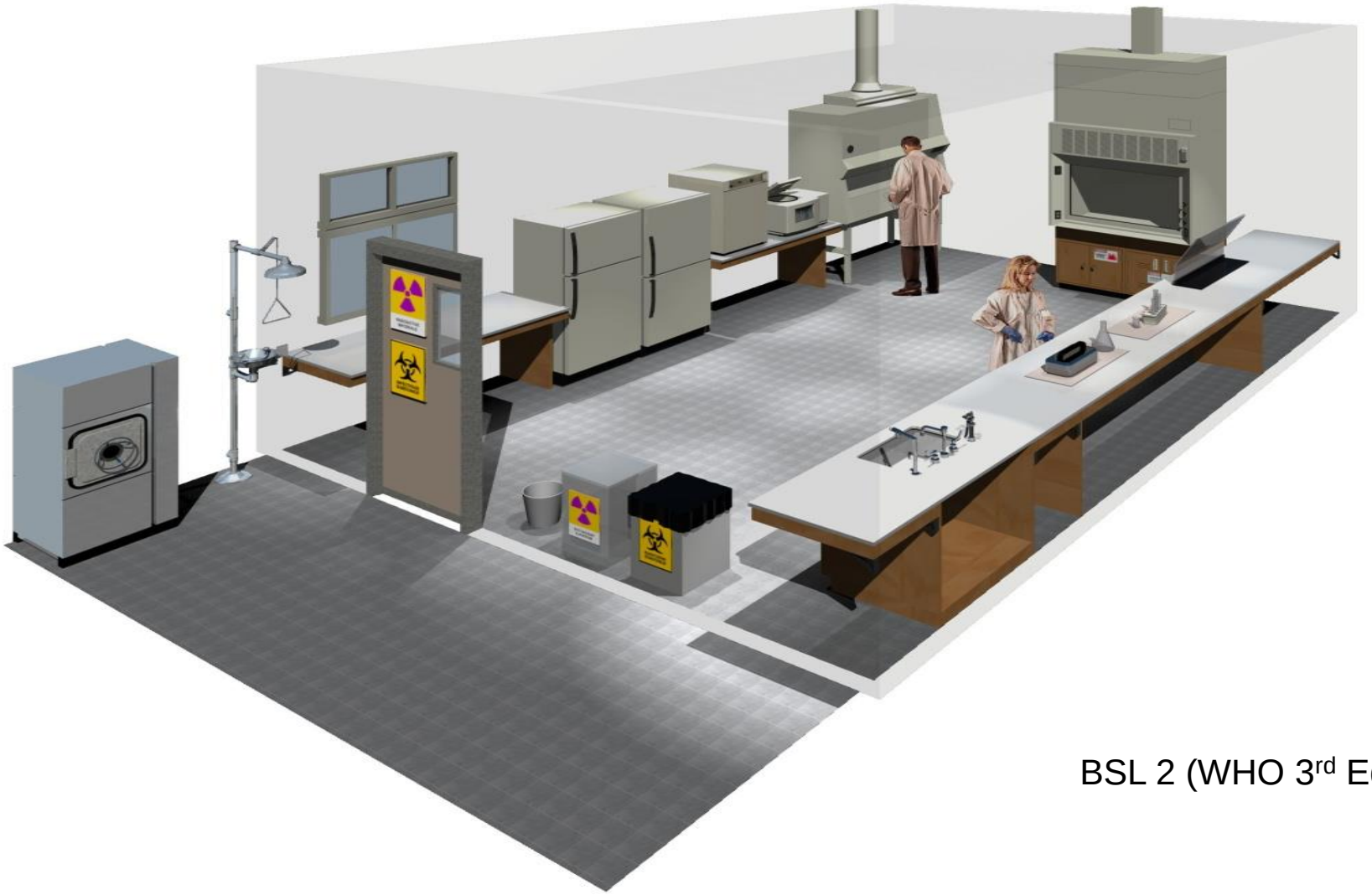
Biosafety Level 2 (BSL-2)

- Builds upon BSL-1
- BSL-2 is suitable for working involving agents that pose moderate hazards to personnel and the environment
- Laboratory personnel have specific training in handling pathogenic agents
- Personnel are supervised by scientists competent in handling infectious agents an associated procedures
- Access to the laboratory is restricted when work is being conducted

Biosafety Level 2 (BSL-2)

- All procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets (BSCs) or other physical containment equipment

- Mandatory warning Sign
  - Designate Biosafety Level
  - Special Entry Procedures
  - Immunizations
  - PPE
  - Contact Information
- E. g Hospital Lab, Universities working with Streptococci



BSL 2 (WHO 3rd Ed)

Biosafety Level 3 (BSL-3)

- Is applicable to clinical, diagnostic, teaching, research or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through inhalation route exposure.

- Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents

- Must be supervised by scientists competent in handling infectious agents and associated procedures

Biosafety Level 3 (BSL-3)

- Biosafety Level-2 plus all procedures involving the manipulation of infectious materials must be conducted within BSCs, or other physical

- Personnel wear additional appropriate personal protection equipment including respiratory protection as determined by risk assessment

- A BSL-3 laboratory has special engineering and design features

    - Directional air flow

Figure 4. ***A typical Biosafety Level 3 laboratory***
(graphics kindly provided by CUH2A, Princeton, NJ, USA). The laboratory is separated from general traffic flow and accessed through an anteroom (double door entry or basic laboratory – Biosafety Level 2) or an airlock. An autoclave is available within the facility for decontamination of wastes prior to disposal. A sink with hands-free operation is available. Inward directional airflow is established and all work with infectious materials is conducted within a biological safety cabinet.

Biosafety Level 4 (BSL-4)

- Required for working with dangerous and exotic agents that pose a high individual risk of life-threatening disease, aerosol transmission, or related agent with unknown risk of transmission

- Agents with a close or identical antigenic relationship to agents requiring BSL-4 containment must be handled at this level until sufficient data are obtained either to confirm continued work at this level, or re-designate the level

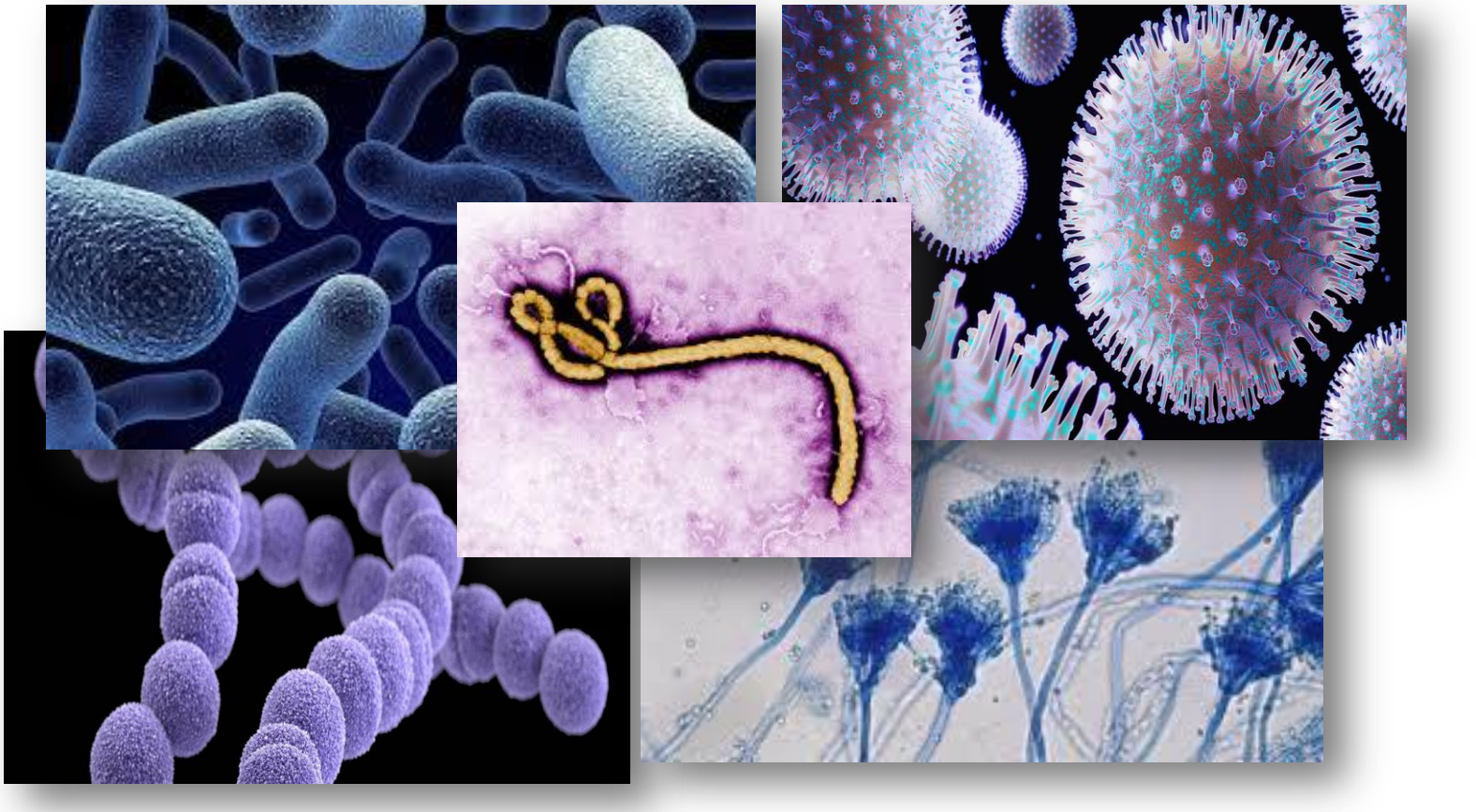
- Laboratory staff must have specific and thorough training in handling extremely hazardous

Biosafety Level 4 (BSL-4)

- Laboratory staff must understand the primary and secondary containment functions of standard and special practices, containment equipment and laboratory design characteristics
- All laboratory staff and supervisors must be competent in handling agents and procedures requiring BSL-4 containment
- Access to the laboratory is controlled by the laboratory supervisors in accordance with institutional policies
- Two types of laboratory providing absolute separation of the worker from the infectious agents (suit Laboratory & cabinet laboratory)

Biosafety Level 4 (BSL-4)

Microbiological Practices
Classification of Risk Group Agent



WHO Classification of infective microorganisms by risk group

- Risk Group 1 (no or low individual and community risk)
- Risk Group 2 (moderate individual risk, low community risk)
- Risk Group 3 (high individual risk, low community risk)
- Risk Group 4 (high individual and community risk)

Risk Group 1

- No or low individual and community risk

- A microorganism that is unlikely to cause human diseases or animal disease

e.g. *E.coli K12*

Bacillus subtilis,

Staphylococcus epidermidis

Risk Group 2

- Moderate individual risk, low community risk
- Pathogen causes human or animal disease but it unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment
- May cause serious infection but effective treatments and preventive measures are available
- Risk of spread it limited

e.g. Herpes viruses , VSV ……

Escherichia coli

Staphylococcus aureus

Risk Group 3

- High individual risk, low community risk
- Pathogen usually cause serious human or animal disease but does not ordinarily spread to others
- Effective treatment and preventive measures are available

E.g *Mycobacterium tuberculosis,*

Burkholderia pseudomallei

Rickettsia spp.

Risk Group 4

- High individual and community risk
- A pathogen cause serious human or animal disease; readily transmitted from one individual to another
- Effective treatment and preventive measures are usually not available
  - Eg: *Ebola, Marburg,* and *Nipah viruses*

Risk groups & biosafety levels

BSL	Laboratory type	Laboratory practices	Safety equipment
1	Basic teaching, research	Good microbiological techniques	None Open bench work
2	Primary health services; diagnostic services, research	Good microbiological techniques, protective clothing, biohazard sign	Open bench PLUS biological safety cabinet for potential aerosols
3	Special diagnostic services, research	As BSL 2 PLUS special clothing, controlled access, directional airflow	Biological safety cabinet and/or other primary devices for all activities
4	Dangerous pathogen units	As BSL 3 PLUS airlock entry, shower exit, special waste	Class III biological safety cabinet, positive pressure suits, double ended autoclave (through the wall), filtered air

Risk groups

HIV	**2 or 3?**
Burkholderia pseudomallei	2 or 3?
Mycobacterium tuberculosis	2 or 3?
Hantavirus	2 or 3?
Rabies virus	2 or 3?
SARS virus	3 or 4?

Factors to consider in Classification

- Pathogenicity of the agent
- Modes of transmission and host range of organism
- Local availability of preventive measures
- Local availability of effective treatment

In summary

- There is no internationally accepted list of microorganisms classified according to risk groups
  - Different microorganisms may pose different risks in different countries.
- WHO recommends each country (region) to draw up a national (region) classification of microorganisms by risk group
- The choice of biosafety level and practices should be the result of a comprehensive risk assessment

Thank you for your attention