



Enhanced BSL-3: Risk Assessment-Based Decision Making

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When is Biosafety Level 3 appropriate?

- clinical, diagnostic, teaching, research, or production facilities
- indigenous or exotic agents that may cause serious or potentially lethal disease
- inhalation route of exposure.

Examples of agents that are worked with at BSL-3 include: SARS CoV; MDR and XDR TB; HPAI

What is Biosafety Level 3?

Summary

Facility Requirements

- Physical separation from access corridors
- Pass through two sets of doors to enter
- Directional inward airflow is established
- Exhaust laboratory air is not recirculated

Procedures and PPE

- All work must be conducted within a Class II Biological safety cabinet or other containment device
- Protective laboratory clothing with a solid-front such as tie-back or wraparound gowns, scrub suits, or coveralls
- Special decontamination and waste handling procedures

When is Biosafety Level 4 appropriate?

- Dangerous or exotic agents posing a high individual risk for aerosol-transmitted laboratory acquired infection
- Life-threatening disease
- No available vaccine or therapy
- Documented cases of severe and frequently fatal naturally occurring human infections
- Agents with a close or identical antigenic relationship
- Examples of agents that are worked with at BSL-4 include: Marburg and Ebola viruses; Congo-Crimean hemorrhagic fever virus, Lassa hemorrhagic fever virus

What is Biosafety Level 4? Summary

Facilities

- equipment and engineering controls are used to isolate the worker from the hazardous agent
- Increasing negative pressure zones
- Suit lab or Cabinet Lab
- Double HEPA-filtered exhaust (in series)
- Liquid effluent treatment and other special waste handling procedures

Procedures and PPE

- All manipulations of infectious agents must be performed within a BSC or other primary barrier system
- Positive pressure suit supplied with breathing air
- Chemical shower
- Personal body showers are required

What is an Enhancement to Biosafety Level 3 for Work with 1918 Influenza and HPAI?

- Facility
 - HEPA filtration on the exhaust
 - Shower facility available at the laboratory
 - Increased security measures
 - Rigorous systems validation
 - NIH Requirements for Certification of BSL-3 Laboratories

What is an Enhancement to Biosafety Level 3 for Work with 1918 Influenza and HPAI?

- Administrative Procedures
 - Procedures for physical separation of agents
 - Requirements for complete clothing change
 - Requirements for showering upon exiting
 - Additional security measures to preclude unauthorized access
 - Training, testing and compliance monitoring
- Personal Protective Equipment
 - Protective suit
 - Wrap-back disposable gown
 - Double gloving
 - Double shoe coverings
 - Powered Air-Purifying Respirator (PAPR)



What is an Enhancement to Biosafety Level 3 for Work with 1918 Influenza and HPAI?

- Agent-Specific Medical Support Services
 - Pre-placement medical evaluations
 - Plan for suspected exposures and symptoms suggestive of laboratory transmission of disease
 - Plan is coordinated with ID specialists, patient transport and hospital services









