Meeting the Challenges of BSL-2+

When to Use it and How to Adapt it to Your Facility

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What Do You Call It?

BSL-2+

BSL-2 Enhanced

BSL-2 with Conditions

What is BSL-2+ ?

- The use of selected BSL-3 practices/procedures in a BSL-2 laboratory facility.
- It is not:
  - A recognized containment level, but may be appropriate for certain research projects.
  - To be used for any Risk Group 3 (RG3) pathogens that are infectious via inhalation.

Introduction

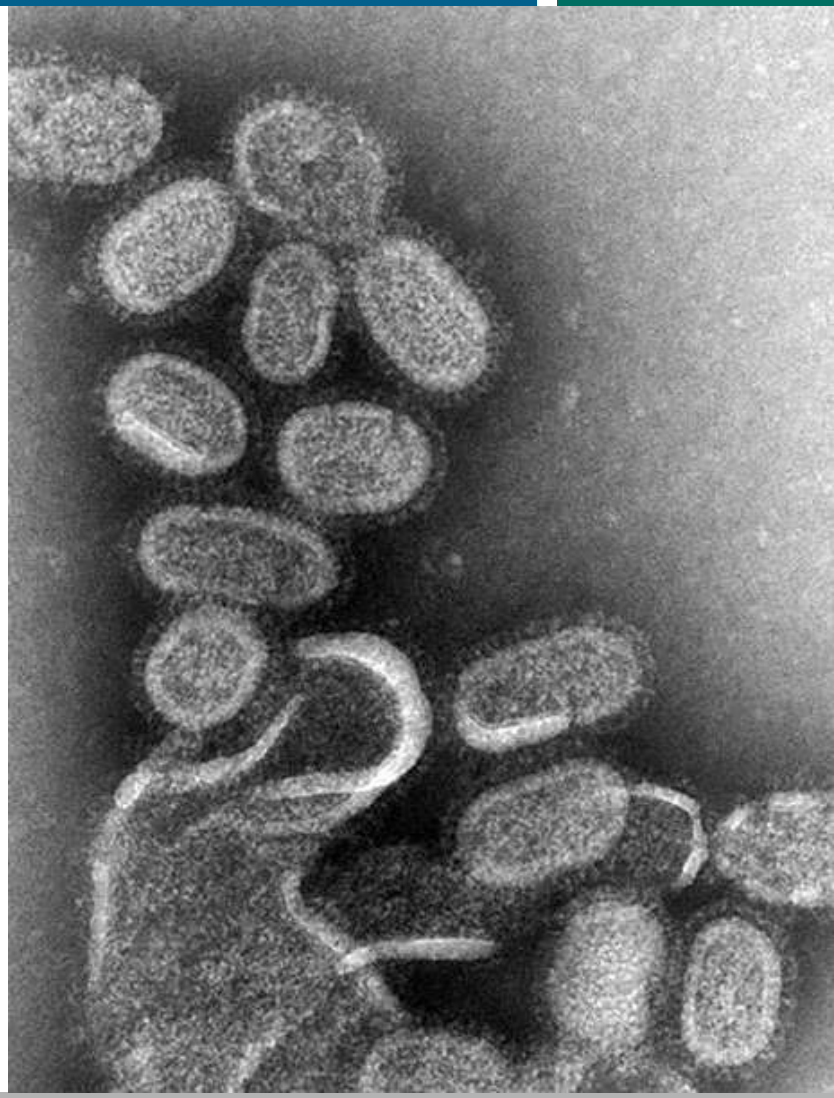
- EH&E conducted a survey in 2012 of academic, biotech, and healthcare institutions to gain an understanding of the challenges that institutions face when implementing BSL-2+
- The 3 areas rated most challenging were:
  - Determining what projects require BSL-3 practices
  - Ensuring that researchers are properly trained
  - Ensuring that the PI (or his/her designee) develops a project-specific SOP

How Does One Arrive at BSL-2+ ?

- The risk assessment process must drive the decision to use BSL-2+.
- Engage in discussions with the Principal Investigator (PI).
- The Institutional Biosafety Committee (IBC) or other safety committee in conjunction with a biosafety officer should review and approve.

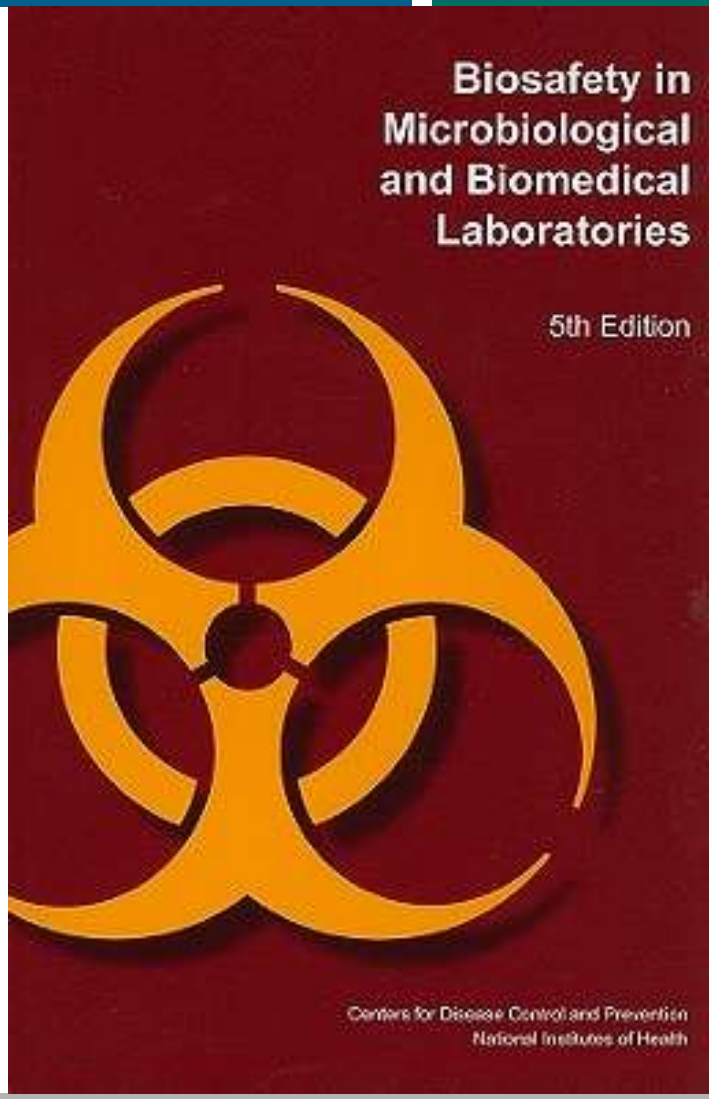
Examples

- Lentiviral vector with an oncogene or gene of unknown function
- HIV, low titer, small volumes
- *Neisseria meningitidis*, serogroup B



Risk Assessment

- The BMBL details the steps involved in the risk assessment process, and states that after determination of the appropriate biosafety level it is important to select additional precautions as indicated by the risk assessment.
- “One Size Fits All” BSL-2+ is not recommended.



Project Review Process

1. Project registration document serves to detail the risk assessment. Project purpose and steps to be conducted with biohazardous material are detailed.
2. PI submits document to BSO.
3. Review and discussion of the project take place with the PI, BSO and perhaps selected members of the IBC (or equivalent).

Project Review Process

4. Appropriate lab space is identified.
5. PI develops project-specific SOP with BSO's assistance.
6. IBC review and consensus.
7. Risk communication and training are conducted:
   - Lab personnel plus others
   - Written SOP is used as a training tool

BSL-3 Practices

- Are we talking about ALL BSL-3 practices from the BMBL? Not necessarily!
- Select the BSL-3 practices that enhance the safety of the work.

BSL-2 Facility

- Selection of lab facility is based on many factors:
  - Separation from non-BSL-2+ work
  - Ability to accommodate equipment (BSCs, centrifuge, incubator, fax machine, etc.)

BSL-2 Facility

- A BSL-2 “tissue culture” room may be ideal. Provides limited access.
- Consider beneficial features when renovating or new construction:
  - Anteroom
  - Hands-free sinks

“What If” Scenarios

- What if a BSL-2 project needs to be conducted concurrently in the BSL-2+ lab?
- Consider:
  - Defaulting to BSL-3 practices for all projects in the lab
  - Training the non-BSL-2+ project staff

“What If” Scenarios

- What if the BSL-2+ project occurs infrequently and lab space is at a premium?
- Consider:
  - Signage, BSL-2+ to BSL-2 and vice versa
  - SOP detailing switch
  - Decontamination

Case Study

- *Neisseria meningitidis*, serogroup B strain, RG2 agent
- No vaccine available, infectious dose unknown
- Infectious via injection, ingestion and droplet exposure to mucous membranes
- April 2012 death in California of a lab worker
- MMWR September 5, 2014 / 63(35);770-772
  - *"CDC recommends the use of enhanced biosafety level two (BSL-2) containment practices, where BSL-2 requirements are met and some BSL-3 practices also are adopted"*

Summary

- BSL-2+ is a viable option for research projects that require enhanced practices and procedures for safe work.
- The risk assessment process is key to establishing BSL-2+.
- Select the BSL-3 practices and procedures that enhance the safety of the project.

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For more information:
http://www.eheinc.com/strat_biosafety.htm