

National Select Agent Workshop: Biosafety/Biocontainment

Richard Henkel, PhD

Division of Select Agents and Toxins

Charles Divan, PhD

Agriculture Select Agent Program



**Select Agent Program
Workshop Series**



Overview

Biosafety in Select Agent Facilities

42 CFR Part 73 §73.12 Biosafety

9 CFR Part 121 §121.12 Biosafety

7 CFR Part 331 §331.12 Biosafety



**Select Agent Program
Workshop Series**



Biosafety Requirements

- An individual or entity required to register under this part must develop and implement a written biosafety plan
- “commensurate with risks ...given its intended use”
- Must contain sufficient information and documentation to describe biosafety and containment procedures



**Select Agent Program
Workshop Series**



Biosafety Requirements

- Plan must be reviewed annually and revised as necessary
- Drills or exercises must be conducted at least annually



Good Biosafety Plan Characteristics

- **Risk-based:** Smallpox vs Ricin
- **Rehearsed:** Drills and exercises
- **Reviewed:** RO, PI, BSO, others as needed
- **Revised:** Changes in agents, methods, facilities
- **Relevant:** Addresses what is actually being done
- **Reasonable:** Avoids excessive costs, procedures
- **Realistic:** More than two pages.....
- **Written:** All aspects of plans need to be described



**Select Agent Program
Workshop Series**



Biosafety Plan Guidelines

- Plan should consider BMBL recommendations for infectious agents
- OSHA regulations for chemical hygiene plan for toxin use
- NIH Guidelines For Research Involving Recombinant DNA Molecules

Office of Health and Safety
Office of the Director, Office of Health and Safety

is

Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition

NOTE: - Printed booklets, HTML and Spanish versions not yet available

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
and
National Institutes of Health
Fifth Edition, Feb 2007

US Government Printing Office
Washington: 2007

Complete 5th Edition of BMBL (All Sections) 
(PDF - 2.4 MB)

Table of Contents

Title Page and Credits	Biosafety in Microbiological and Biomedical Laboratories, 5th Edition
SECTION I	Introduction
SECTION II	Biological Risk Assessment
SECTION III	Principles of Biosafety
SECTION IV	Laboratory Biosafety Level Criteria
Table 1 (Sect.IV)	Summary of Recommended Biosafety Levels for Infectious Agents
SECTION V	Vertebrate Animal Biosafety Level Criteria, for Vivarium Research Facilities
Table 1 (Sect.V)	Summary of Recommended Biosafety Levels for Activities in Which Experimentally or Naturally Infected Vertebrate Animals Are Used
SECTION VI	Principles of Laboratory Biosecurity
SECTION VII	Occupational Health and Immunoprophylaxis
SECTION VIII	Agent Summary Statements
SECTION VIII-A	Bacterial Agents
SECTION VIII-B	Fungal Agents
SECTION VIII-C	Parasitic Agents
SECTION VIII-D	Rickettsial Agents
SECTION VIII-E	Viral Agents

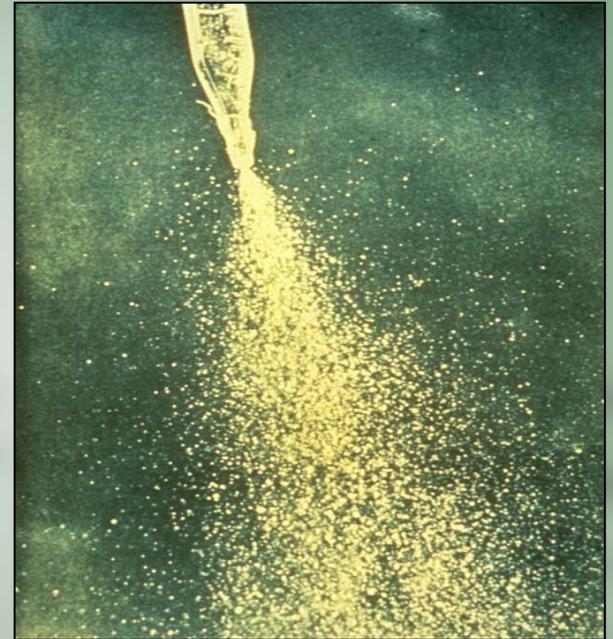


**Select Agent Program
Workshop Series**



Hot Topics

- No BSL-2 + in 5th edition of BMBL
- All procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment at BSL-2



Hot Topics

The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.



**Select Agent Program
Workshop Series**



Hot Topics

The BSL-3 facility design, operational parameters, and procedures must be verified and documented prior to operation.

Facilities must be re-verified and documented at least annually.

Office of Health and Safety
BSL2 Laboratory Safety Validation Checklist

Laboratory Location: _____
 Laboratory Supervisor: _____
 Division/Section: _____

	Y	N	N/A	Comments
Administrative documents, signs and labels				
Laboratory door properly posted for hazards: a) Biosafety Level, b) Point of contact, c) Immunizations required, d) Radiation hazards, e) Chemical hazards, and f) Laser hazards				
Laboratory equipment properly labeled (biohazard, radioactive, toxic, etc.)				
All appliances properly labeled. (microwaves, refrigerators)				
Site specific Biosafety manual available				
Facility				
Proper directional airflow verified				
Visual indicator of directional airflow available				
Sink available for hand-washing				
Vacuum lines protected with HEPA filters				
All doors self closing and properly adjusted				
All shelves secured				
Bench-tops waterproof and resistant to acids, alkali, organic solvents and heat				
Chairs covered with non-porous material				
Adequate illumination provided				
Fire alarm system present				
Sprinkler heads free and unobstructed				
Compressed gas cylinders				
All cylinders properly stored/secured				
Caps on reserve cylinders				
Chemicals				
Chemicals properly labeled and segregated				
Flammables properly labeled and stored				
Corrosives properly labeled and stored				
Spill kit available				
Material Safety Data Sheets available				
Site specific Chemical Hygiene plan available				
LER Refrigerators/freezers/cold rooms				
Current emergency contact information				
Properly secured				
Labeled externally if containing carcinogens, radioactivity and/or biohazards				



Select Agent Program Workshop Series



Hot Topics

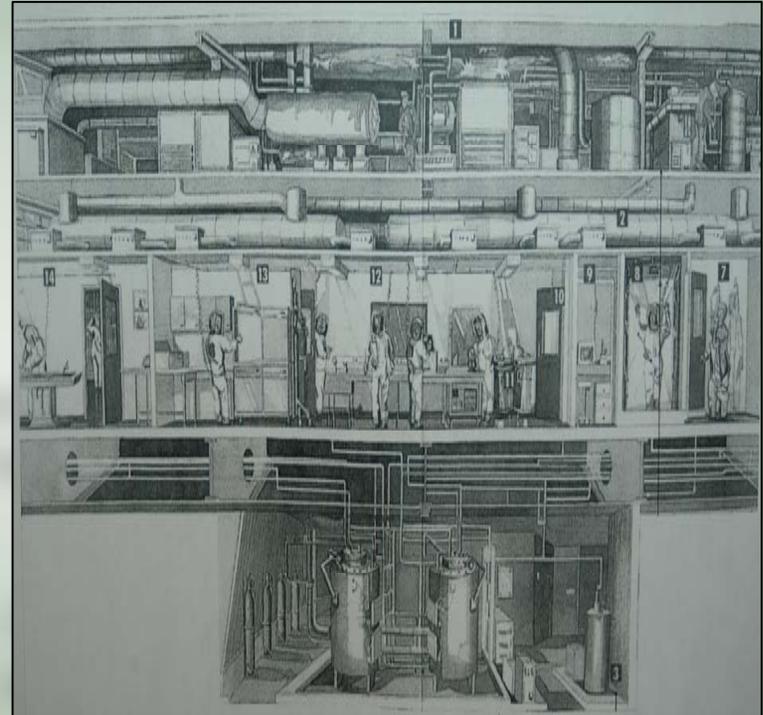
A ducted air ventilation system is required within a BSL-3. This system must provide sustained directional airflow by drawing air into the laboratory from “clean” areas toward “potentially contaminated” areas.

The laboratory shall be designed such that under failure conditions the airflow will not be reversed.



Hot Topics

“Services, plumbing or otherwise that penetrate the BSL-4 laboratory walls, floors, ceiling, plumbing or otherwise, must ensure that no backflow from the laboratory occurs. These penetrations must be fitted with two (in series) backflow prevention devices.



Biocontainment

USDA-APHIS biocontainment response—

- The need for U.S. research of foreign pathogens balanced by the need to protect American agriculture.



**Select Agent Program
Workshop Series**



Biocontainment

- Laboratories
- Growth chambers
- Greenhouses



**Select Agent Program
Workshop Series**



Biocontainment

- Biocontainment Requirements:
 - Are risk-based
 - Depend on the biology of the pathogen
 - Depend on the type of research conducted
 - Independent of authorizing Acts
- There are additional legal, procedural, and security sensitive information (SSI) requirements for Select Agents and Toxins.



**Select Agent Program
Workshop Series**



Biocontainment

APHIS Procedural Policy

- Personnel Quarantine Policy for:
 - Highly pathogenic avian influenza (HPAI)
 - Virulent Newcastle disease virus (vNDV)



**Select Agent Program
Workshop Series**



Biocontainment Greenhouse



**Select Agent Program
Workshop Series**



Biocontainment Greenhouse



**Select Agent Program
Workshop Series**



Failures of Biosafety/Biocontainment

- Failure to comply with 7 CFR 331, 9 CFR 121, or 42 CFR 73
 - To annually review and revise the security plan
 - To annually provide training to personnel concerning biosafety, biocontainment, and security
 - Incident response plans (theft, loss, and release) or emergencies
 - Inventory control (must be accurate and current)
 - Record keeping requirements
 - Security plans are not based on site-specific risk assessment
 - Human or environmental exposures



**Select Agent Program
Workshop Series**



Questions?



**Select Agent Program
Workshop Series**

