

# **BMBL 6th Edition How Changes Affect Inspections**

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# FSAP Authority



# FSAP Authority

- **Code of Federal Regulations (CFR)**
  - 9 CFR Part 121
  - 42 CFR Part 73
- **Entities are required to develop and implement a biosafety plan**
  - Section 12(a) and 12(b)
- **In developing a biosafety plan, an individual or entity should consider:**
  - The CDC/NIH Publication *Biosafety in Microbiological and Biomedical Laboratories*
  - Section 12(c)



# Project Overview



# Project Overview

- **FSAP reviewed all FSAP biosafety checklist line items that reference the BMBL**
- **Each line item was compared to the BMBL 6<sup>th</sup> edition text**
- **Over 200 modifications to the checklist were made to include:**
  - Text modifications to meet 6<sup>th</sup> edition standards
  - Correction of typos
  - Removal of standards
  - Addition of standards
  - Reorganization of agent-specific checklist
- **Most changes were minor text changes that did not affect implementation of the standard**
- **BSL3-Ag checklist contained the most revisions**



# Project Overview

- **Guidance for FSAP inspectors is built into the system to standardize how inspectors assess each standard**
  - This information was also reviewed/revised as part of the project
- **Checklist updates were posted to Federal Select Agent website on May 19, 2021 for review by regulated community prior to implementation**



# **BMBL 6<sup>th</sup> Edition Changes**



# Agent Special Requirements

- **Removed individual agent-specific checklists**
  - Many items are “should” statements or recommended practices
    - Not enforceable by FSAP
    - But are considered when reviewing a facility
- **Created one checklist for agents with special requirements**
  - Severe Acute Respiratory Syndrome coronavirus (SARS-CoV)
  - Arboviruses (Venezuelan Equine Encephalitis [VEE], Rift Valley Fever Virus [RVFV])
  - Variola major virus (Smallpox virus)
  - Reconstructed 1918 Influenza Virus





# Agent Special Requirements

- **Agent special requirements checklists**
  - Focuses on the requirements specific to the agent
    - Occupational health program for SARS-CoV work
    - Routine vaccination for work with smallpox
    - HEPA filtration for work with VEE
    - Several standards for 1918 influenza added



# Agent Special Requirements

- **1918 influenza standards added**

- At a minimum, BSL-3 and ABSL-3 practices, procedures, and facilities must be utilized.
- Animals, including non-human primates, should be housed in primary barrier systems in ABSL-3 facilities.
- Use of negative pressure, high efficiency particulate (HEPA)-filtered respirators, or powered air-purifying respirators (PAPRs).
- Personnel rigorously adhere to respiratory protection and clothing change protocols.
- Following work, personnel shower prior to exiting the laboratory.



# Removals

- **All standards still assessed**
- **Removal of duplicated or similar line items**



# Modification to Standard

BMBL 5	BMBL 6
Two self-closing doors	Two <b>consecutive</b> self-closing doors
HEPA filtration on laboratory exhaust is required for RVF.	HEPA filtration on laboratory exhaust is <b>recommended</b> for RVF.
Not Present	<b>If caging is actively ventilated, the system is alarmed to indicate operational failure.</b>
Laboratory airflow does not reverse under failure conditions.	Laboratory airflow does not <b>reverse at the containment barrier</b> under failure conditions.
Downdraft tables or other physical containment device(s) operate according to manufacturer's specifications, when applicable.	Downdraft tables or other physical containment devices operate according to manufacturer's specifications and <b>exhaust air through HEPA filtration (or equivalent) before being discharged into the animal facility. HEPA filters are tested annually and replaced as needed.</b>



# **BMBL 6th Edition Changes and the Impact on Inspections: A/BSL-3 Ag**



# Main Changes Affecting A/BSL-3Ag Spaces

- **Entrance and exit of the facility**
- **Waste handling procedures**
- **HVAC system**
- **Primary containment barrier**



# Main Changes Affecting A/BSL-3Ag Spaces

- **Entrance and exit of the facility**
  - Security of access points
  - Barriers of protection at containment boundary
  - Decontamination



# Entrance into the Facility

- **Authorized personnel and locks or electronic access systems on all entry and exit points.**

## BMBL 5th Edition

Access doors are self closing and lockable.

## BMBL 6th Edition Update

External facility doors are self-closing and self-locking. Access to containment areas should be restricted to authorized personnel. **All entry and exit points should be secured with locks or equivalent electronic access systems** and protected by alarms that will alert authorities of unauthorized movement into or out of the facility.





# Entrance into the Facility

- **Barriers and/or procedures that provide separation between containment and non-containment.**

## **BMBL 5th Edition**

The facility is arranged so that personnel ingress and egress are only through a series of rooms.

## **BMBL 6th Edition Update**

Entrance into the facility is through a **series of barriers and/or with procedures that provide a distinct separation between containment and non-containment areas.**

Provisions include removing, disinfecting, and/or disposing of contaminated PPE, footwear, uniforms, and/or equipment.



# Entrance into the Facility

- **Entry through double door vestibule.**
- **Air pressure resistant door opening to non-containment space.**

## BMBL 5th Edition

Entry into the BSL3Ag laboratory must be through an airlock fitted with airtight doors. These airlock doors must be located at the exit leading from the laboratory into the inner (dirty) change area and at the exit leading from the inner (dirty) change room into the personal body shower and must function as a primary containment barrier. Additional airtight doors may be located at other locations including the exit from the outer (clean) change room or between different zones within the containment space.

## BMBL 6th Edition Update

The entrance to the ABSL-3Ag containment facility should have a **double door vestibule** that separates containment areas from non-containment areas; the doors should be mechanically interlocked to prevent simultaneous opening.

When two doors are interlocked, **at least one of the doors must meet APR** specifications, preferably the door that opens into non-containment space (i.e., the door from the facility shower to non-containment space).



# Entrance into the Facility

- **APR doors equipped with pneumatic or mechanical compression seals.**
- **Verified airtight.**

## BMBL 5th Edition

New for the 6<sup>th</sup> edition BMBL.

## BMBL 6th Edition Update

APR doors must be equipped with **either pneumatic or mechanical compression seals**. Mechanical compression seals should **be checked and adjusted at regular intervals** to ensure full contact when the seal is engaged. Pneumatic lines that inflate the gaskets on APR doors should be equipped with HEPA filters and check valves.

New for the 6<sup>th</sup> edition BMBL.

Integral features of all APR doors (e.g., hinges, latches, knobs, locking mechanisms, viewing panels) must be sealed **and verified airtight through pressure decay testing**.



# Exit from the Facility

- **Two transition zones and a personal shower at the containment-non-containment boundary.**

## BMBL 5th Edition

The facility is arranged so that personnel egress from the laboratory containment area(s) into non-containment space is achieved through a series of rooms arranged to ensure sequential passage from the laboratory through an inner (dirty) change area, a personal shower, and then by passage into an outer (clean) change room. Exit from the clean change room completes the egress process.

## BMBL 6th Edition Update

Decontamination of personnel exiting the containment zone should **involve two separate transitions** to ensure maximum environmental protection: the first transition involves exiting the animal room and entering the change room, and the second transition involves exiting the change room and then the containment zone or facility. From a design perspective, ABSL-3Ag facilities must have a **personal shower** at the containment-non-containment boundary even if **alternate exit strategies are implemented that do not always require a second shower by personnel.**



# Main Changes Affecting A/BSL-3Ag Spaces

- **Waste handling procedures**
  - Site-specific risk assessment
  - Validations and verifications
  - Liquid effluent



# Waste Handling Procedures

- **Based on site-specific risk assessment. A two-step process may be indicated (i.e., autoclave and then incineration).**

## BMBL 5th Edition

Disposable materials must be decontaminated through autoclaving or other verifiable decontamination method followed by incineration or other approved means.

## BMBL 6th Edition Update

Waste handling procedures must adhere to the results of a **site-specific risk assessment**, applicable regulations, and local policies and procedures. In some cases, **a two-step waste process may be indicated**. For example, waste can first be autoclaved for removal from the facility and then destroyed through incineration (i.e., locally at the facility or through a commercial service). Regulations pertaining to the transport of potentially infected waste must be considered in this process.



# Waste Handling Procedures

- **Validation with biological indicator (BI), culture of treated waste, or the equivalent.**
- **Operating parameters validated and periodically verified.**

## BMBL 5th Edition

New for the 6<sup>th</sup> edition BMBL.

## BMBL 6th Edition Update

Decontamination systems and procedures must be **validated using biological indicators, culture of treated waste, or another equivalent process** to ensure the selected cycle and operating parameters are appropriate for the agents as well as the types and volumes of waste generated. **Operating parameters should be validated for each load type that is treated and periodically verified** using an appropriate method.



# Waste Handling Procedures

- **Liquid effluent decontamination based on risk assessment.**

## BMBL 5th Edition

Liquid effluents from BSL-3Ag areas must be collected and decontaminated in a central liquid waste sterilization system before disposal into the sanitary sewers. Typically, a heat decontamination system is utilized in these facilities and equipment must be provided to process, heat and hold the contaminated liquid effluents to temperatures, pressures and times sufficient to inactivate all biohazardous materials.

## BMBL 6th Edition Update

Liquid effluents from ABSL-3Ag containment areas must be collected and decontaminated before disposal into a sanitary sewer. **Collection and decontamination methods should be selected after a site-specific risk assessment.** Installation of a central liquid effluent waste collection and decontamination system is the preferred method. Heat decontamination systems must be designed so that the contaminated effluent can be held at specified temperatures, pressures, and times to ensure complete inactivation of all hazardous materials. Systems should operate at a range of temperatures and holding times to economically and efficiently process a wide range of effluents.





# Waste Handling Procedures

- **Laboratory sink, biological safety cabinet (BSC), and floor drain effluent should be decontaminated prior to discharge.**
- **Risk assessment for effluent from autoclaves, showers, and toilets.**

## BMBL 5th Edition

Liquid wastes from shower rooms and toilets must be decontaminated prior to discharge to a public sewer system.

## BMBL 6th Edition Update

At minimum, effluents from laboratory sinks, BSCs, and floor drains should be directed into the waste collection system for decontamination before discharge. A site-specific **risk assessment** should be performed to **(1) determine if effluent from autoclave chambers, shower rooms, and toilets should be collected and decontaminated**, and **(2) identify the optimal decontamination method** that is required (i.e., validated chemical treatment system or heat liquid waste decontamination system).



# Waste Handling Procedures

- **Filtration or decontamination of condensate or exhaust from equipment.**

## BMBL 5th Edition

For destruction of large amounts of biomass (animal carcasses), a terminal destruction method must be adjacent to the BSL-3Ag space (e.g., incinerator, digester, render etc.). The procedures must have been demonstrated to be efficacious for the pathogens being studied.

## BMBL 6th Edition Update

Decontamination systems used in ABSL-3Ag include autoclaves, tissue digesters, incinerators, renderers, gaseous decontamination chambers, liquid disinfectant dunk tanks, and similar equipment. Autoclaves, tissue digesters, renderers, and incinerators, should be designed or programmed to prevent opening of the outer door until the decontamination cycle is completed and verified to have met program parameters. **A site-specific risk assessment** should be performed to determine the need for **filtration or decontamination of the condensate and/or exhaust from decontamination equipment (e.g., autoclaves).**



# Main Changes Affecting A/BSL-3Ag Spaces

- **HVAC system**
  - Site-specific risk assessment
  - Visual and audible indicators
  - Supply air ductwork



# HVAC System

- HVAC pressure differentials based on a site-specific risk assessment to protect against sustained reversal of airflow.

## BMBL 5th Edition

The directional airflow within the containment spaces moves from areas of least hazard potential towards areas of greatest hazard potential.

## BMBL 6th Edition Update

HVAC pressure differentials should be designed after a **site-specific risk assessment** to incorporate engineering features that protect against sustained reversal of directional airflow in the event of a breach of containment (e.g., opening doors).



# HVAC System

- Audible or visual alarms inside and outside containment.
- Visual indicators with real-time pressure differentials.

## BMBL 5th Edition

An alarm system should be considered to notify personnel of ventilation and HVAC system failure. Audible alarms are acceptable as long as they are not installed within the animal rooms. A visual indicator inside the animal rooms that is tied into the alarm system should be considered. All alarm devices must register/report to a central monitoring station, or similar remote location.

## BMBL 6th Edition Update

**Audible or visual alarms** are needed that can be **heard and/or seen both inside and outside of the containment space** to alert staff when pressure differentials are outside the pre-set range. The alarm system should be compatible with worker safety and animal welfare (i.e., audible without being so loud that animals are startled or stressed, or just visual). Intercom systems should limit the type and number of overhead announcements that can be disruptive and contribute to excessive noise levels.

**A visual indicator that displays real-time pressure differentials should be available outside** the containment facility to confirm personnel can enter safely.



# HVAC System

- **Supply air ductwork with HEPA filter and/or a fast-acting bioseal.**
- **Preventative maintenance program with annual validations.**

## BMBL 5th Edition

Supply air to the BSL3 Ag laboratory, including the inner (dirty) change room, must pass through a HEPA filter. All exhaust air from the laboratory, shower and fumigation or decontamination chambers must pass through two HEPA filters, in series before discharge to the outside. The exhaust air discharge must be located away from occupied spaces and air intakes.

## BMBL 6th Edition Update

Supply air must pass through ductwork with **either a HEPA filter and/or a fast-acting bioseal (i.e., bubble tight) damper that fails in the closed position** to prevent the reverse flow of contaminated air through supply ducts into other containment zones or non-containment areas outside the facility. In the absence of a supply HEPA filter(s), **a robust preventative maintenance program that includes an annual validation process** must be implemented to ensure the fast-acting bioseal damper operates as designed to prevent reversal.



# Main Changes Affecting A/BSL-3Ag Spaces

- **Primary containment barrier**
  - USDA ARS Facilities Design Standards
  - Pressure decay testing



# Primary Containment Barrier

- **Each primary containment unit verified airtight.**

## BMBL 5th Edition

Each BSL-3Ag containment space shall have its interior surfaces (walls, floors, and ceilings) and penetrations sealed to create a functional area capable of passing a pressure decay test and being certified as airtight.

## BMBL 6th Edition Update

All penetrations in the floor, walls, and ceilings must be sealed and **verified to be airtight** to prevent cross-contamination and to allow gaseous or vapor phase fumigation within the containment facility without affecting adjacent non-containment space (see specifications in the USDA ARS Facilities Design Standards 242.1M-ARS). This includes openings around ductwork; plumbing fixtures; doorframes; door hardware and gaskets; electrical boxes; and vents.

The room envelope must meet the minimum criteria for a primary containment barrier that is equivalent to performance standards established for secondary barriers in ABSL-3 spaces. **Each ABSL-3Ag primary containment unit (i.e., room, suite) must be verified to be airtight.**





# Rollout Plan



# Rollout Plan

**Publish  
Checklists:**  
FSAP Website  
[www.selectagents.gov](http://www.selectagents.gov)

**Training:**  
RO Webinar  
Series  
May 26, 2021

**Questions to  
POC:**  
Implementation  
Scenarios

**FSAP SMEs  
Review and  
Respond to  
Entity**

**Checklists  
Effective:**  
90 Days Post-  
Publication



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