



Occupational Health Program Guidance

(42 CFR Part 73, 7 CFR Part 331, and 9 CFR
Part 121)

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Centers for Disease Control and Prevention (CDC)
Division of Select Agents and Toxins
Animal and Plant Health Inspection Service (APHIS)
Agriculture Select Agent Program

Table of Contents

Change/Highlight Section	3
Introduction	3
OHP Requirements	4
Risk Assessment.....	5
Tier 1 BSAT Precautions.....	6
Respiratory Protection	6
Visitor Policy	6
Medical Assessment and Surveillance.....	7
Emergency Examinations	7
Post-Exposure Medical Surveillance.....	7
Post Exposure Management	9
Risk Assessment after Exposure	9
Enhanced OHP Elements	9
Policies for Agents without Treatment Options	9
Hazard Communication	10
Reporting and Analyzing Occupational Exposure.....	10
Records Management and Retention	10
Vaccine Information	11
Appendix 1: List of Tier 1 BSAT	13
Appendix 2: Minimum Requirements for an Occupational Health Program for Tier 1 BSAT	14
Appendix 3: Vaccine Resources for Tier 1 BSAT	16
References	17

Change/Highlight Section

This is a living document subject to ongoing improvement. Feedback or suggestions for improvement from registered Select Agent entities or the public are welcomed. Please submit comments directly to the Federal Select Agent Program (FSAP) at:

CDC: LRSAT@cdc.gov

APHIS: AgSAS@aphis.usda.gov

Revision History:

October 12, 2012: Initial posting

July 5, 2013 (Revision 1): The revisions are primarily changes to correct editorial errors from previous version.

May 2016 (Revision 2): The revisions are primarily changes to the organization to improve usability from previous version.

Introduction

Section 12(d) of the select agent regulations ([42 CFR §73.12](#), [7 CFR §331.12](#), and [9 CFR §121.12](#)) requires that individuals with access to Tier 1 biological select agents and toxins (Tier 1 BSAT) must be enrolled in an Occupational Health Program (OHP). This requirement is intended to ensure the availability of professional medical evaluations and treatment.

The guidance provided in this document is intended to assist entities develop and implement an OHP to protect workers with access to Tier 1 BSAT. Entities should develop and implement OHPs that address the site-specific health hazards identified by each institution's assessments, based on the individual circumstances of each entity. Entities should also include provisions in their plans that address other recognized occupational health risks not specifically related to Tier 1 BSAT (e.g., hearing protection and chemical hygiene). There will be differences in the scope and complexity of OHPs developed by different organizations due to the individual circumstances at each entity.

OHP Requirements

A successful occupational health program is designed to reduce the risk of infection and complications in employees with access to Tier 1 BSAT in the event of exposure. Employees with access to Tier 1 BSAT should be introduced to the OHP before being granted access to such select agents and toxins. The key elements of an effective OHP include:

- Risk assessment
- Medical assessment and surveillance
- Access to clinical health services and management
- Hazard communication

Though the RO is ultimately responsible for ensuring that the requirements for an OHP are met, the OHP is a living document that should undergo regular review by subject matter experts for updates to ensure that it is effective in preventing infection and reducing complications due to exposure to Tier 1 BSAT. Many elements of an OHP may already exist in the biosafety, security, and incident response plans. While regulation does not require that the OHP is consolidated into one document, FSAP recommends doing so to ensure ease of comprehension and training for laboratory workers.

Risk Assessment

Consider the inherent risk of the select agent or toxin in question and the conditions of the laboratory. This type of risk assessment may be performed as a part of the biosafety plan. Perform a risk assessment based on the following criteria:

- Route of exposure
- Incubation period
- Infectious dose
- Agent virulence
- Environmental stability
- Communicability of the select agent or toxin
- Genetic modification
- Inherent risk
- Available resources for pre- and post-exposure prophylaxis
- Available vaccine options
- Use of personal protective equipment
- Biocontainment issues

Use the information identified in the risk assessment as a guide for the selection of appropriate medical preventions and countermeasures. The risk assessment should specifically identify:

- Hazardous characteristics of a known infectious or potentially infectious agent or material
- Activities that can result in a person's exposure to an agent
- Likelihood that such exposure will cause a laboratory acquired infection (LAI)
- Probable consequences of such an infection

An entity with Tier 1 BSAT should consider providing workers with access to Tier 1 BSAT a card that lists:

- All select agents and toxins that he/she works with
- Emergency phone numbers for:
 - Personal contacts
 - Primary care physicians
 - Occupational health physicians
 - Preferred or designated hospital
 - Entity's Responsible Official

This information may be necessary when no occupational support is available (e.g., a trip to the emergency room).

Tier 1 BSAT Precautions

There are several types of precautions that may need to be taken based on the complexity and the type of agents at the in the registered area.

Respiratory Protection

Entities should develop and implement a respiratory protection program for workers with access to Tier 1 BSAT.

Visitor Policy

Entities should have policies and provisions in place for at-risk visitors to provide access to their occupational health service on a risk-based approach.

Medical Assessment and Surveillance

Workers who may be exposed to a Tier 1 BSAT should receive a thorough medical evaluation prior to initiation of work or contact with these agents. In order to determine an individual's medical fitness to perform the duties of a specific position, the healthcare provider should review each employee's:

- Previous and ongoing medical problems
- Current medications
- Allergies
- Prior immunizations
- Necessary medical services to permit the individual to safely assume the duties of the position

Establish criteria for fitness for duty based on the occupational health hazards identified from the site-specific comprehensive risk assessment.

Healthcare providers should be aware of potential hazards via a written description of the potential health hazards present in the work environment.

Periodic medical evaluations targeted to job requirements may be appropriate for workers with substantial risk of exposure to infectious agents or other circumstances such as clearance for respirator use or work in a pressurized suit.

Medical support for occupational illnesses should also be provided for workers with access to Tier 1 BSAT. Workers should be encouraged to seek medical evaluation for symptoms that they suspect may be related to infectious agents in their work area. A high index of suspicion for potential occupational exposures should be maintained during any unexplained illness among workers or visitors to worksites containing Tier 1 BSAT. The healthcare provider should have a working understanding of the biohazards present in the workplace and remain alert for evidence of infection and atypical presentations. All exposures to Tier 1 BSAT should be reported to the medical support services provider. Strategies for responding to biohazard exposures should be formulated in advance.

Emergency Examinations

Prompt medical evaluation may be necessary in instances including:

- All potential exposures, including both direct exposures and proximity exposures
- Potential human disease
- When there is a potential impact on public health and safety

The plan should cover contingencies during work and after hours. OHPs should contain measures for infection control.

Post-Exposure Medical Surveillance

Proper post-exposure response is facilitated by exposure-specific protocols that define:

- Appropriate first aid

- Potential post-exposure prophylaxis options
- Recommended diagnostic tests
- Sources of expert medical evaluation

These protocols should address how exposures or reports of potential LAIs that occur at work outside of regular work hours are handled and these protocols should be distributed to potential healthcare providers (e.g., local hospital emergency departments).

Post Exposure Management

Risk Assessment after Exposure

Conduct a risk assessment after potential occupational exposures to any Tier 1 BSAT. Assessment of the potential exposure risk should cover the following circumstances:

- All breaches in the established safety practices while working with Tier 1 BSAT
- All injuries incurred inside laboratory when handling Tier 1 BSAT
- Unexplained acute illness or febrile disease in a Tier 1 BSAT worker
- All incidents covered under section 19(b) of the section agent regulations including:
 - Occupational exposures
 - Release of a select agent or toxin outside of the primary containment barriers

For additional information, please see the [FSAP guidance for reporting theft, loss, or release \(Form 3\)](#).

The exposure risk assessment should identify all potentially exposed individuals. Consider the following factors when assessing exposure risk after an incident:

- Agent or toxin information
- The nature of the mishap and associated circumstances
- The specific personal protective equipment worn at the time of the incident
- First aid procedures performed in response to the incident
- Personal health issues that may make an individual more susceptible to infection

Enhanced OHP Elements

For personnel working with Ebola virus, Marburg virus, Variola major virus, Variola minor virus, and Yersinia pestis, isolation provisions and protocols must be considered for inclusion in the OHP.

These agents may be relatively easy to transmit from person-to-person and therefore may pose a significant public health risk. To limit the potential exposure of the general public, consider isolation of patients with confirmed or suspected illness caused by these agents.

Policies for Agents without Treatment Options

Since there is no pre- or post-exposure prophylaxis, nor well established treatment options at the present time available for several of the Tier 1 BSAT, entities in possession of these agents should develop plans for providing post exposure care and support for workers.

Hazard Communication

All personnel approved for access to Tier 1 BSAT should be provided with the following information:

- The risk and health hazards associated working with the Tier 1 BSAT
- Typical signs and symptoms of the diseases associated with the select agent or toxin with which they work
- The available pre- and post-exposure resources for treatment
- Whom to contact and what to do in an emergency
- Policies for immediately reporting and documenting all potential occupational exposures

The Responsible Official is required by federal regulation to immediately notify the Federal Select Agent Program regarding all occupational exposures to Tier 1 BSAT by telephone, facsimile, or e-mail (form3@cdc.gov) or (AgSAS@aphis.usda.gov), and submit a completed [APHIS/CDC Form 3 \(Report of Theft, Loss, or Release of Select Agents and Toxins\)](#) within seven calendar days.

Reporting and Analyzing Occupational Exposure

Evaluate all potential occupational exposures to identify factors that contributed to the incident. Identify and document all corrective actions taken to mitigate the risk of recurrence.

Records Management and Retention

Maintain all Tier 1 BSAT personnel occupational health related documents and records including copies of the Form 3 for at least three years.

Vaccine Information

Commercial vaccines should be made available to workers to provide protection against infectious agents to which they may be occupationally exposed. Provide current, applicable vaccine information statements whenever a vaccine is administered. Each worker's immunization history should be evaluated for completeness and currency at the time of employment and re-evaluated when the individual is assigned job responsibilities with a new biohazard.

At present time, the following vaccines are available for Tier 1 BSAT:

- *Francisella tularensis*
- Variola major virus
- Variola minor virus
- *Bacillus anthracis*

The vaccines for smallpox (vaccinia vaccine) and anthrax are FDA licensed. The vaccines for tularemia are available through U.S. Food and Drug Administration (FDA) investigational new drug (IND) protocols. Immunization with IND vaccines should be optional. If indicated by risk assessment, the IND vaccines may be made available on a voluntary basis under FDA research protocols with informed consent.

The Anthrax vaccine is recommended by the U. S. Department of Health and Human Services' (HHS) Advisory Committee for Immunization Practices (ACIP) for groups at risk for repeated exposures to B. anthracis spores. Five groups at risk for repeated exposure include:

- Laboratory personnel handling environmental specimens (especially powders) and performing confirmatory testing for B. anthracis in the U.S. Laboratory Response Network (LRN).
- Workers who will be making repeated entries into known B. anthracis-spore-contaminated areas.
- Workers in other settings in which repeated exposure to aerosolized B. anthracis spores might occur.

Laboratory workers using standard Biosafety Level 2 practices in the routine processing of clinical samples or environmental swabs are not considered by ACIP to be at increased risk for exposure to B. anthracis spores. (For persons not at risk for repeated exposures to aerosolized B. anthracis spores through their occupation, pre-exposure vaccination against anthrax is not recommended).

Currently no vaccine is available for immunization of laboratory personnel working with botulinum toxin or cultures of botulinum neurotoxin producing species of *Clostridium*. Although administered under an FDA IND since 1965, CDC discontinued distribution of the Pentavalent (ABCDE) Botulinum Toxoid vaccine in 2011 due to decline in potency and CDC observed increase in moderate local reactions. An equine-based heptavalent (A, B, C, D, E, F, and G) antitoxin is available through a CDC-sponsored FDA IND for treatment of individuals with symptoms consistent with botulism. Health-care providers for exposed laboratory personnel should consult their state health department epidemiologist to determine if use of HBAT is warranted.

When occupational exposure to highly pathogenic agents is possible and no commercial vaccine is

available, it may be appropriate to immunize workers using vaccines or immune serum preparations that are investigational, or for which the specific indication constitutes an off-label use. Use of investigational products, or of licensed products for off-label indications must be accompanied by adequate informed consent outlining the limited availability of information on safety and efficacy. Use of investigational products should occur through IND protocols providing safety oversight by both the FDA and appropriate institutional human subjects research protection committees. Recommendation of investigational products, as well as commercial vaccines that are less efficacious, associated with high rates of local or systemic reactions, or that produce increasingly severe reactions with repeated use, should be considered carefully.

The healthcare provider should design medical support services in consultation with representatives from the entity's institutional environmental health and safety program and the principal investigators. Workers should be fully informed of the available medical support services and encouraged to utilize them.

Appendix 1: List of Tier 1 BSAT

Agents	Disease	Category	Recommended Biosafety Level2
Ebola virus	Ebola hemorrhagic fever	HHS	4
<i>Francisella tularensis</i>	Tularemia	HHS	2 or 3
Marburg virus	Marburg hemorrhagic fever	HHS	4
Variola major virus	Smallpox	HHS	4
Variola minor virus	Smallpox	HHS	4
<i>Yersinia pestis</i>	Plague	HHS	2 or 3
Botulinum neurotoxin	Botulism	HHS	2
Botulinum neurotoxin producing species of <i>Clostridium</i>	Botulism	HHS	2
<i>Bacillus anthracis</i>	Anthrax	Overlap	2 or 3
<i>Burkholderia mallei</i>	Glanders	Overlap	2 or 3
<i>Burkholderia pseudomallei</i>	Melioidosis	Overlap	2 or 3
Foot and Mouth Disease virus	FMDV	USDA	3
<i>Rinderpest virus</i>	Cattle plague	USDA	3

Appendix 2: Minimum Requirements for an Occupational Health Program for Tier 1 BSAT

Agents	Minimum Requirements
Ebola virus	Pre-placement Examinations Respiratory Protection Program Emergency Medical Evaluation Post-exposure Management Isolation Protocols
<i>Francisella tularensis</i>	Pre-placement Examinations Risk-based Respiratory Protection Program Emergency Medical Evaluation Post-exposure Management
Marburg virus	Pre-placement Examinations Respiratory Protection Program Emergency Medical Evaluation Post-exposure Management Isolation Protocols
Variola major virus	Pre-placement Examinations Vaccinia immunization Respiratory Protection Program Emergency Medical Evaluation Post-exposure Management Isolation Protocols
Variola minor virus	Pre-placement Examinations Vaccinia immunization Respiratory Protection Program Emergency Medical Evaluation Post-exposure Management Isolation Protocols
<i>Yersinia pestis</i>	Pre-placement Examinations Risk-based Respiratory Protection Program Emergency Medical Evaluation Post-exposure Management
Botulinum neurotoxin	Pre-placement Examinations Emergency Medical Evaluation Post-exposure Management
Botulinum neurotoxin producing species of <i>Clostridium</i>	Pre-placement Examinations Emergency Medical Evaluation Post-exposure Management
<i>Bacillus anthracis</i>	Pre-placement Examinations Risk-based anthrax vaccine Risk-based Respiratory Protection Program Emergency Medical Evaluation Post-exposure Management

<i>Burkholderia mallei</i>	Pre-placement Examinations Risk-based Respiratory Protection Program Emergency Medical Evaluation Post-exposure Management
Agents	Minimum Requirements ^(1,2,6)
<i>Burkholderia pseudomallei</i>	Pre-placement Examinations Risk-based Respiratory Protection Program Emergency Medical Evaluation Post-exposure Management
Foot and Mouth Disease virus	Pre-placement Examinations Risk-based Respiratory Protection Program Emergency Medical Evaluation Post-exposure Management
Rinderpest virus	Pre-placement Examinations Risk-based Respiratory Protection Program Emergency Medical Evaluation Post-exposure Management

Appendix 3: Vaccine Resources for Tier 1 BSAT

Agent	Disease	Availability of vaccine	Type of vaccine	Source
Ebola virus	Ebola hemorrhagic fever	NA	NA	NA
<i>Francisella tularensis</i>	Tularemia	IND	Live attenuated bacteria vaccine	USAMRIID ^a
Marburg virus	Marburg hemorrhagic fever	NA	NA	NA
Variola major virus/ Variola minor virus	Smallpox	FDA licensed ⁴	Live vaccine virus	CDC ^b
<i>Yersinia pestis</i>	Plague	NA	NA	NA
Botulinum neurotoxin/ Botulinum neurotoxin producing species of <i>Clostridium</i>	Botulism	NA	NA	NA ^c
<i>Bacillus anthracis</i>	Anthrax	FDA licensed ⁵	Inactivated	Commercially available
<i>Burkholderia mallei</i>	Glanders	NA	NA	NA
<i>Burkholderia pseudomallei</i>	Melioidosis	NA	NA	NA

Notes:

- **IND** – the vaccine is available under an Investigational New Drug protocol and is available for limited use.
- **NA** – not available.
- **USAMRIID** – The United States Army Medical Research Institute for Infectious Diseases (USAMRIID).
- Tularemia vaccine is available through USAMRIID special immunization program.
- Smallpox Vaccine: CDC is the only source of vaccinia vaccine and VIG for civilians. Vaccine will be shipped to the responsible physician. Requests for vaccine and VIG, including the reason for the request, should be referred to:

Centers for Disease Control and Prevention
 Drug Services, National Center for Infectious Diseases
 Mailstop D-09
 Atlanta, GA 30333
 Telephone: (404) 639-3670
 Facsimile: (404) 639-3717

- In 2011, CDC discontinued the distribution of Pentavalent (ABCDE) Botulinum Toxoid vaccine which was available under a CDC-sponsored FDA IND since 1965.

References

1. The October 2011 revisions of the guidelines for research involving recombinant DNA molecules (NIH Guidelines). <http://oba.od.nih.gov/oba/rac/Guidelines/NIHGuidelines.htm>.
2. Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition. HHS Publication No. (CDC) 21-1112, Revised December 2009.
3. Coppee GH. Occupational Health Services and Practice. <http://www.ilo.org/safeworkbookshelf/english?content&nd=857170174>.
4. Vaccinia (Smallpox) Vaccine Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2001. MMWR. 50(RR10): 1-25, 2001.
5. CDC. Use of anthrax vaccine in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2000. 49(No. RR-15), 2000.
6. 29 C.F.R. § 1910.134 (Respiratory Protection).
8. CDC. Notice of CDC's discontinuation of investigational pentavalent (ABCDE) botulinum toxoid vaccine for workers at risk for occupational exposure to botulinum toxins. 2011. MMWR. 60 (42): 1454-1455.
9. CDC. Investigational heptavalent botulinum antitoxin (HBAT) to replace licensed botulinum antitoxin AB and investigational botulinum antitoxin E. 2010. MMWR 59 (100: 299).