



# Occupational Health Program Requirements for Tier 1 BSAT and SARS-CoV

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# New Select Agent Biosafety Plan Requirements

## 42 CFR Part 73, section 12(d):

"The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program."



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42 CFR Part 73  
Possession, Use, and Transfer of Select Agents and Toxins; Biennial  
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# Purpose of the Regulation's Change

- Intended to ensure availability of professional medical evaluations and treatment.
- Requires planning and preparation to adequately address unique hazards presented by Tier 1 Biological Select Agents and Toxins (BSAT) in the workplace.
- Goal is to promptly detect and treat laboratory acquired infections (LAIs) to reduce any adverse impact to worker safety and public health.



# Key Elements of Occupational Health Programs (OHPs)

- 1) Risk assessment
- 2) Medical surveillance
- 3) Access to clinical occupational health services and management
- 4) Hazard communication



# Initial Risk Assessment Considerations

- Route of exposure, incubation period, infectious dose, agent virulence, environmental stability, communicability, genetic modification, available resources for pre- and post-exposure prophylaxis, available vaccine options, use of personal protective equipment, and biocontainment requirements.
- The information identified in the risk assessment will provide a guide for the selection of appropriate medical preventions and countermeasures.
- This information must be communicated effectively with health care providers during program development.



# Initial Risk Assessment Considerations

## (Continued)

The risk assessment should specifically identify:

- The hazardous characteristics of a known infectious or potentially infectious agent or material,
- activities that may result in a person's exposure to an agent,
- likelihood that such exposure will cause a LAI, and
- the probable consequences of such an infection.



# Post-Exposure Risk Assessments

A risk assessment should be conducted after all 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.
- An unexplained acute illness or febrile disease in a Tier 1 BSAT worker.
- All incidents covered under section 19(b) of the select agent regulations including occupational exposures or any release of a select agent or toxin outside of the primary containment barriers.



# Medical Surveillance

## (Planning and Preparation)

- 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.
- The healthcare provider should review any previous and ongoing medical problems, current medications, allergies, and prior immunizations to determine an individual's medical fitness to perform the duties of a specific position.
- Criteria of fitness for duty should be established based upon occupational health hazards identified from the site-specific risk assessment.
- Healthcare providers should be cognizant of potential hazards via a written description of the potential health hazards present in the work environment.
- Medical assessment should consider personal immunization status and personal health status.



# Medical Surveillance

## (Emergency Examinations)

- Prompt medical evaluation may be necessary in instances including:
  - Potential exposures, including both direct and proximity exposures,
  - cases of suspected human disease caused by Tier 1 BSAT, and
  - instances where there is a potential impact on public health and safety.
- The plan should cover contingencies during work and after hours, including:
  - Medical alert card
  - Emergency contact information
- OHPs should contain measures for infection control.



# Access to Occupational Health Services

## (Post-Exposure Response)

- 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.



# Access to Occupational Health Services

## (Post-Exposure Response)

- 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.
- 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



# Access to Occupational Health Services

## (Medical Support)

- Protocols should address how exposures or reports of potential LAIs that occur at work outside of regular work hours are handled.
- Protocols should be distributed to potential healthcare providers (e.g., local hospital emergency departments).
- Medical support services should be developed with input from the entity's institutional environmental health and safety program.
- Workers should be fully informed of the available medical support services and encouraged to utilize these services.
- Isolation provisions and protocols should be considered for personnel working with Ebola virus, Marburg virus, Variola virus and *Yersinia pestis*, inclusion in the OHP.



# Access to Occupational Health Services

## (Vaccination)

- Commercial vaccines should be made available to workers.
- Vaccine information statements must be provided 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*, (IND)
  - Variola major virus,
  - Variola minor virus, and
  - *Bacillus anthracis*.



# 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
- The available pre- and post-exposure resources for treatment;
- Whom to contact and what to do in an emergency, and
- Policies for immediate reporting and documenting all potential occupational exposures.



# 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.



# Other Considerations

- **Reporting and Analyzing Occupational Exposure**
  - All potential occupational exposures should be evaluated to identify factors that contributed to the incident.
  - Corrective actions to mitigate the risk of recurrence should be identified.
- **Records Management and Retention**
  - All Tier 1 BSAT personnel occupational health related documents and records must be maintained for three years.



# Occupational Health Considerations for SARS CoV

- Institutions performing work with the SARS-CoV or handling specimens likely to contain the agent should develop and implement a **specific** occupational medical plan with respect to this agent.
- At a minimum, the plan should contain procedures for managing the following:
  - identifiable breaks in laboratory procedures;
  - exposed workers without symptoms;
  - exposed workers who develop symptoms within ten days of an exposure;
  - symptomatic laboratory workers with no recognized exposure.



# Occupational Health Considerations for SARS CoV (Continued)

## SARS-CoV OHPs should:

- Require storage of a baseline serum sample from individuals who work with the virus or virus-containing specimens.
- Require personnel trained regarding the symptoms of SARS-CoV infection and counseled to report any fever or respiratory symptoms to their supervisor immediately.
- Require post-exposure evaluation and monitoring for fever or lower respiratory symptoms, sore throat, rhinorrhea, chills, rigors, myalgia, headache, and diarrhea.



# Occupational Health Considerations for SARS CoV (Continued)

- Laboratory workers who are believed to have had a laboratory exposure should be evaluated and counseled about the risk of SARS-CoV transmission to others.
- Local and/or state public health departments should be promptly notified of laboratory exposures and illness in exposed laboratory workers.
- CDC/DSAT should be notified immediately of occupational exposures or any release of SARS-CoV outside of primary containment barriers.



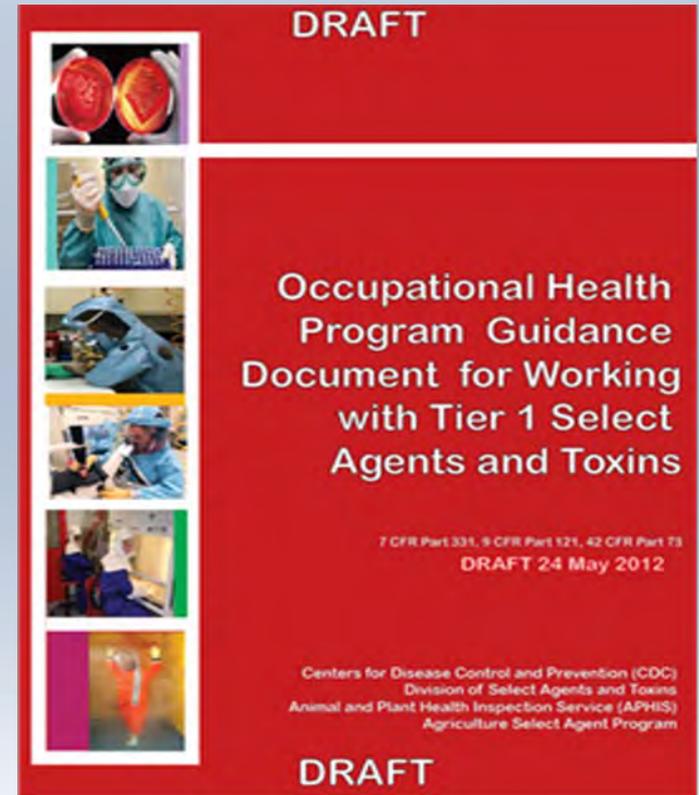
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# Questions

