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."
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.
For more information, please contact the Select Agent Program

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Questions