

**PATHOLOGY AND LABORATORY MEDICINE SERVICE BIOSECURITY AND  
BIOSAFETY PROCEDURES**

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Handbook provides general security and additional safety procedures for clinical laboratory in the possession, handling, and shipment of biological materials identified as potential agents of terrorism within Department of Veterans Affairs (VA) facilities.
- 2. SUMMARY OF CONTENTS:** This Handbook provides supplemental implementation instructions for VHA Directive 1106 with specific procedures defined for the possession, use, and transfer of select agents and toxins within the clinical and anatomic pathology laboratories in VA facilities or in contract facilities managed by VA.
- 3. RELATED ISSUES:** VHA Directive 1106, and VHA Handbook 1106.1.
- 4. RESPONSIBLE OFFICE:** The Office of Patient Care Services, Diagnostic Services Strategic Health Care Group (SHG), is responsible for the contents of this Handbook. Questions may be referred to 202-273-8332.
- 5. RESCISSIONS:** None.
- 6. RECERTIFICATION:** This VHA Handbook is scheduled for recertification on or before the last working day of May 2009.

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## PATHOLOGY AND LABORATORY MEDICINE SERVICE PROCEDURES

### 1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides general security and additional safety procedures for any Department of Veterans Affairs (VA) clinical laboratory in the possession, handling, and shipment of biological materials identified as potential agents of terrorism within facilities; it further defines requirements unique to VA.

### 2. BACKGROUND

a. Pathology and Laboratory Medicine Service (P&LMS) provides the principal medical diagnostic laboratory testing and transfusion functions in all VA medical centers and sets the standards for quality, test methods, and procedures for laboratory testing for patient care in medical centers and supported clinics.

b. In 2002, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188, June 12, 2002). This act requires institutions that possess certain pathogens or toxins identified as “select agents” by the U.S. Department of Health and Human Services (HHS) and certain animal and plant pathogens or toxins as identified by the U.S. Department of Agriculture (USDA), to implement special notification and handling procedures for these select agents.

c. Regulatory guidance for implementation of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 was then published by HHS under Title 42 Code of Federal Regulations (CFR) Parts 73 and 1003.

d. The regulations for the Possession, Use, and Transfer of Select Agents and Toxins, 42 CFR 73, have been and will continue to be modified over time. Rather than revisiting and publishing VA regulations so that they are equal to 42 CFR 73, this Handbook substitutes 42 CFR 73 for VA regulations except in those areas that are specifically addressed, or in which this Handbook may be more stringent than the published Federal regulations.

### 3. SCOPE

a. All VA laboratories that test patients for the diagnosis, treatment, and prevention of disease must meet the applicable clinical laboratory requirements for handling select agents defined in 42 CFR 73 and 1003. **NOTE:** *These requirements are generally defined under subsec73.6 of 42 CFR 73.*

b. Where applicable, the laboratories must meet any requirements for handling select agents; any security measures; hazardous materials and waste management measures; and emergency management procedures as defined by the following organizations: Joint Commission on Accreditation of Healthcare Organizations (JCAHO), College of American Pathologists (CAP), American Association of Blood Banks (AABB), Commission on Office Laboratory

Accreditation (COLA), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), Department of Transportation (DOT), HHS Centers for Disease Control and Prevention (CDC), and Nuclear Regulatory Commission (NRC).

c. In accordance with guidance previously published in VHA Directive 1106 and VHA Handbook 1106.1, all clinical laboratory testing sites, regardless of location, must undergo an on-site inspection by an accrediting agency approved by the Centers for Medicare and Medicaid Services (CMS) and VA.

d. All applicable clinical laboratory requirements of 42 CFR 73 and 1003, and appropriate accreditation standards, must be met for any laboratory services offered within VA medical facilities and outreach clinics, regardless of the physical relationship to the main P&LMS, or the administrative service assigned to direct the personnel, research, or technical aspects of the test site.

e. Unless otherwise annotated, each Chief, P&LMS, is responsible for ensuring that all laboratories under their direction are in compliance with the policy and regulatory requirements detailed in this Handbook.

#### 4. CLINICAL LABORATORY STANDARDS

a. **Laboratory Biosafety Level (BSL).** CDC defines a biohazard as: "An agent of biological origin that has the capacity to produce deleterious effects on humans, i.e., microorganisms, toxins, and allergens derived from those organisms; and allergens and toxins derived from higher plants and animals." The four basic classifications for these biohazards are:

- (1) **BSL-1.** Agents not known to cause disease.
- (2) **BSL-2.** Agents associated with human disease.
- (3) **BSL-3.** Indigenous and/or exotic agents associated with human disease and with potential for aerosol transmission.
- (4) **BSL-4.** Dangerous and/or exotic agents of a life threatening nature.

b. **Biological Safety Cabinets.** Class I, Class II, and Class III biological safety cabinets are designed to protect laboratory personnel from aerosols created in handling and manipulating biological agents. The cabinets afford increasing protection as the class of the cabinet increases and the required class of the cabinet is selected based upon: the hazard of the agent, the need for protection of personnel, and the extent to which aerosols may be produced. *NOTE: For most microbiological organisms encountered in clinical laboratories, a Class I or Class II cabinet is more than adequate.*

(1) Since control of any aerosols produced depends upon proper biological safety cabinet performance, certification is necessary at initial installation and annually; after moving a cabinet; and after replacing a high efficiency particulate air (HEPA) filter.

(2) The certification procedure should include: a halogen leak test to ensure the air flow plenums are gas tight; measuring the air inflow velocity; measuring the airflow within the cabinet (uniform and unidirectional); and a leak test of the HEPA filter to ensure that it is properly installed and leak-free.

(3) Under no circumstances should a biological safety cabinet ever be moved or the filter changed without the cabinet and ductwork being properly decontaminated.

(4) A biological safety cabinet should also never be placed back into service unless it has been properly certified.

c. **Requirements and Personnel Standards.** The laboratory requirements and personnel standards are defined for each of the four basic classifications and are increasingly stringent for the laboratories from BSL-1 through BSL-4. *NOTE: A combination of administrative controls, engineering controls, and personal protective equipment may be used to minimize employee exposure to bio-hazardous materials in a laboratory setting.* An applicable reference that defines the specific laboratory requirements for each BSL is the fourth edition of the CDC and National Institutes of Health (NIH) Biosafety in Microbiological and Biomedical Laboratories (CDC&NIH Manual).

d. **Modified BSL-3 Practices**

(1) The CDC&NIH Manual defines some modified practices for laboratories that may not have all of the facility features recommended for BSL-3 (i.e., double-door access zone and sealed penetrations). For example, diagnostic procedures involving the propagation of an agent for identification, typing, and susceptibility may be done in a BSL-2 facility if:

- (a) The exhaust air from the laboratory room is discharged to the outdoors.
- (b) The ventilation to the laboratory is balanced to provide directional airflow into the room.
- (c) Access to the laboratory is restricted when work is in progress.

(2) The recommended Standard Microbiological Practices, Special Practices, and Safety Equipment for Biosafety Level 3 must be rigorously followed.

(3) Under no circumstances should any laboratory that does not meet the minimal or modified BSL-3 requirements, as defined in the CDC&NIH Manual, continue to culture or even retain cultures of *Mycobacterium tuberculosis*.

e. **Acceptable Use of Modified BSL-3 Practices.** Modified BSL-3 practices are considered to be temporary measures to be used only until the necessary permanent facility modifications are completed in order for the sites to meet the full BSL-3 requirements. Over 5 years ago, all sites were surveyed and those not meeting full BSL-3 requirements were requested to submit any necessary facility modifications to bring them up to standards in order to continue

culturing organisms like *Mycobacterium tuberculosis*. It was recently found that many sites did not follow through with the necessary modifications. Therefore, the following policy changes now apply.

(1) If a site is using BSL-3 modified practices, they must have submitted a facility request for full BSL-3 compliance within 6 months of beginning the modified practices and have a maximum of 24 months to be fully compliant. In no instance will a VA laboratory continue these modified practices beyond 24 months.

(2) All existing VA laboratories performing diagnostic procedures involving the propagation of an agent that calls for BSL-3 practices for identification, typing, and susceptibility must be fully BSL-3 compliant by March 15, 2006, or must cease such operations.

(3) All new laboratory sites implementing identification and testing procedures that require BSL-3 practices will not implement such procedures until the facility meets the full BSL-3 requirements.

f. **General Laboratory Procedures for Culturing Patient Specimens.** Any clinical laboratory routinely culturing patient specimens for microbiological organisms must meet, at a minimum, the BSL-2 facility and personnel training requirements defined in the CDC&NIH Manual.

g. **Laboratory Procedures for Performing Acid Fast Stains.** As only BSL-2 practices and procedures are required for non-aerosol-producing manipulations of clinical specimens such as preparation of acid-fast (AFB) smears on *Mycobacterium tuberculosis*, it is acceptable to carry out direct AFB smear staining procedures (concentrated AFB smears should only be performed in a properly certified BSL-3 laboratory) in a BSL-2 laboratory. Due to the risk of aerosols, any AFB smears performed in a BSL-2 laboratory must, however, be limited to direct AFB smears.

h. **Laboratory Procedures Associated With Aerosol Transmission.** BSL-3 organisms as defined by the CDC, such as *Histoplasma*, *Coccidioides*, *Blastomyces*, and *Mycobacterium tuberculosis*, are potentially infectious to laboratory workers and staff, visitors, and patients by virtue of aerosol dissemination. Employee screening, engineering controls, and personal protective equipment, as described in the following, can minimize the dangers.

(1) At low-exposure facilities (those that isolate and identify cultures of any BSL-3 organisms from six or fewer patients per year), laboratory employees who are potentially exposed to *Mycobacterium tuberculosis* must be tested for exposure to this organism every year.

(2) At high-exposure facilities (those that isolate and identify cultures of any BSL-3 organisms from more than six patients per year), laboratory employees who are potentially exposed to *Mycobacterium tuberculosis* must be tested for exposure to this organism every 6 months.

(3) In laboratories that routinely work with bacterial agents such as *Mycobacterium tuberculosis* in culture or with cultures that yield *Histoplasma capsulatum*, *Coccidioides*

*immitis*, *Blastomyces dermatitidis*, or other BSL-3 agents, both the design and operation of the facility must adhere to the full BSL-3 facility requirements detailed in the CDC&NIH Manual.

## 5. SITE REQUIREMENTS FOR HANDLING SELECT AGENTS

a. **Select Agents Potentially Encountered in Clinical Laboratories.** In 42 CFR 73, a number of select agents and toxins are identified; however, the majority of these agents and toxins would not be routinely encountered in most clinical laboratories. The agents of most relevance to clinical laboratories are the six pathogens designated by the CDC as “Category A” diseases or agents. These are the organisms or toxins that are believed to pose the most risk to national security as they may be easily cultured or acquired and could result in high mortality rates or cause public panic. These Category A agents include *Bacillus anthracis*, *Clostridium botulinum* toxin, *Brucella species (abortus, melitensis, and suis)*, *Yersina pestis*, smallpox (variola major), *Francisella tularensis*, and the agents causing viral hemorrhagic fevers, i.e., Ebola and Marburg viruses.

b. **Select Agent Handling Requirements.** Special procedures are detailed in 42 CFR 73 and by CDC for culturing and handling these select agents. Those procedures applicable for clinical laboratories are summarized as follows. **NOTE:** *Current additional information can be found on the CDC Select Agent Program website at <http://www.cdc.gov/od/sap/>.*

(1) The clinical laboratory must immediately report to HHS any select agent or toxin identified as a result of diagnosis or verification.

(2) Any reports required under applicable Federal, State, or local laws must also be immediately initiated.

(3) Upon completion of applicable patient and proficiency testing, or the transfer of the select agent to a facility eligible to receive them, the laboratory must:

- (a) Appropriately destroy the culture or toxin;
- (b) Document the steps taken in the destruction process; and
- (c) Have an appropriately instructed individual witness and document the destruction.

(4) The clinical laboratory is required to safely transfer to an outside laboratory or destroy the select agent or toxins used for diagnosis or testing within 7 days after identification unless directed otherwise by Federal or other law enforcement officials. If a stock culture is kept (for isolates that have been transferred to an outside laboratory), this culture must be destroyed within 7 days after the clinical laboratory is notified that a select agent has been positively identified.

(5) Select agents or toxins used for proficiency testing must be transferred or destroyed within 90 days after receipt.

(6) A record of the identification, transfer, or destruction of select agents must be documented on the appropriate CDC form and submitted to HHS within the time specified. Copies of these records must be maintained for a specified period. **NOTE:** *At the time of the publication of this Handbook, CDC Form 0.1318, Report of the Identification of a Select Biological Agent or Toxin in a Clinical or Diagnostic Laboratory, is being used for documentation; 7 days after identification is the time specified for transfer or destruction; and all documents must be retained for a period of 3 years.*

c. **Security Requirements.** By design, clinical laboratories are open and accessible to clinicians and other members of the medical staff. Providers often come into the laboratory to review slides and/or other clinical materials, or to consult with the laboratory staff. While it is important to maintain an appropriate level of access, certain changes must be made in order to ensure that access to select agents is appropriately restricted.

**NOTE:** *Department physical security requirements are codified in VA Directive and Handbook 0730, "Security and Law Enforcement." A memorandum modifying this Handbook to meet the new clinical and research laboratory security requirements was disseminated on July 29, 2002. Until the Handbook is republished, this memorandum serves as the interim guiding document. Specific requirements are found in Appendix B of the Handbook, "Physical Security Requirements and Options." Areas where biohazardous materials, as defined by the CDC, are stored are to be found under the standards K, L, and M of the Appendix B matrix. The facility Director is responsible for general facility security and must ensure that applicable facility modifications and other security measures defined in VA Directive and Handbook 0730, have been implemented.*

(1) Any of the select agent organisms that are not absolutely required for patient care, proficiency testing, or educational purposes must be destroyed and the destruction documented. **NOTE:** *Once cultures of the listed organisms are identified, a clear audit trail must be maintained.*

(2) In general, only select agent organisms that are cultured from VA patients or stock cultures that are necessary for ongoing quality control or proficiency testing purposes need to be retained.

(3) Once patient specimens and cultures have been determined to contain any select agent organisms, they must be secured under lock and key anytime they are not being actively worked-up, or are to be left unattended.

(4) Access to the incubation, refrigeration, freezer, or other storage and work up areas for these select agents must only be accessible to authorized personnel.

(5) Clearly, it would be prudent to restrict access to certain other high-risk areas of the laboratory that contain radioactive, toxic, or infectious materials. While many laboratories are already doing this, it seems reasonable to conduct regular reviews and to revise laboratory specific security plans in conjunction with the facility's overall plan. Each Chief, P&LMS, must

ensure a laboratory-risk assessment is conducted, a security plan is developed, and that local laboratory policies governing personnel and security procedures are well documented.

(6) Procedures for defining an approval process and updated lists for access to specific rooms and areas, and procedures for security during "low-staffing" periods, notification procedures, etc., must be addressed.

(7) Added security measures may be required, particularly at some of the larger sites, to monitor and register personnel entering and leaving the laboratory. In assessing the need for additional security measures, the local VA Chief of Police needs to be consulted in determining the most appropriate method of laboratory access control. Since the use of a contract guard, or other person, controlling access to a specific center can be cost prohibitive, less expensive methods, such as existing access control cards, need to be explored and the most efficient option selected. Added video surveillance may be applicable and may be of value for some clinical laboratories.

## 6. SHIPPING BIOLOGICAL AND INFECTIOUS SUBSTANCES

a. **Regulatory Requirements.** The regulations governing the packaging and shipment of biological, infectious, and hazardous substances are primarily found in 49 CFR parts 100-185 and 397. The parts of 49 CFR specifically dealing with biological and infectious specimens are 107, 171, 172, and 173. While the majority of shipments packaged and processed by the clinical laboratories are classified as diagnostic specimens, all specimens, as well as any select agents and toxins that are identified, must be packed and shipped in accordance with the applicable guidance provided in 49 CFR. *NOTE: In conducting vulnerability assessments related to shipping and receiving products, particular attention needs to be focused on addressing procedures and restrictions applicable to unescorted vendor deliveries.*

b. **Hazardous Materials (Hazmat) and Security Training.** As many biological specimens are now classified as hazmat, any laboratory personnel involved in packing and shipping laboratory specimens are required to have transportation security awareness training; this training must be documented for each laboratory employee. While a number of commercial training programs are available that satisfy this requirement, a free training program is available from the Department of Transportation website at [http://hazmat.dot.gov/hmt\\_security.htm](http://hazmat.dot.gov/hmt_security.htm). It is the responsibility of each Chief, P&LMS, to ensure that all personnel who deal with specimen transportation and shipment receive this training.