

## CONTROL OF HAZARDOUS AGENTS IN VA RESEARCH LABORATORIES

- 1. PURPOSE:** This Veterans Health Administration (VHA) Handbook establishes policy and procedures related to select agents and toxins and the prevention and/or detection of terrorist events occurring in or originating from the Department of Veterans Affairs (VA) research laboratories. *NOTE: The procedures contained in this Handbook apply to all Research and Development (R&D) laboratories located within VA facilities, including leased space, and to space within a VA facility leased to a private entity. VA research laboratories located in approved off-site facilities such as affiliate universities are expected to comply with all VA and other Federal laws and regulations regarding security of both research laboratory facilities and select agents and toxins.*
- 2. SUMMARY OF CHANGES:** This revised VHA Handbook incorporates new Federal regulations and addresses issues related to the security of VHA research laboratories. The changes related to these issues are extensive and are to be found throughout all sections of this Handbook.
- 3. RELATED ISSUES:** VHA Directive 1200 and VHA Handbook 1200.8.
- 4. RESPONSIBLE OFFICE:** The Office of Research and Development (12) is responsible for the contents of this VHA Handbook. Questions may be referred to (202) 254-0183.
- 5. RESCISSIONS:** VHA Handbook 1200.6, Control of Hazardous Agents in VA Research Laboratories, dated June 15, 2004 is rescinded.
- 6. RECERTIFICATION:** This VHA Handbook is scheduled for recertification on or before the last working day of October 2010.

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## CONTROL OF HAZARDOUS AGENTS IN VA RESEARCH LABORATORIES

**1. PURPOSE:** This Veterans Health Administration (VHA) Handbook establishes procedures related to select agents and toxins and the prevention and/or detection of terrorist events occurring in or originating from the Department of Veterans Affairs (VA) research laboratories.

*NOTE: The procedures contained in this Handbook apply to all Research and Development (R&D) laboratories located within VA facilities, including leased space, and to space within a VA facility leased to a private entity. VA research laboratories located in approved off-site facilities, such as affiliate universities, are expected to comply with all VA and other Federal laws and regulations regarding security of both research laboratory facilities and select agents and toxins.*

### 2. BACKGROUND

a. The scope of this Handbook includes the physical and organizational controls for the storage and use of select agents, toxins and other highly dangerous hazardous agents. Applicable physical security requirements apply to all research areas as described in VA Handbook 0730.

b. The availability of human pathogens, their products, chemicals, gases, radioactive materials, and/or radioactive sources for VA research, is essential for advancing medical knowledge to meet and improve the health care needs of the veteran population. In the past decade, biological and chemical terrorist events in the United States (U.S.) and in other countries have become a reality. It is the responsibility of the VA Office of Research and Development (ORD) to develop policies to prevent illegal entry into VA research laboratories and the improper use and/or theft of hazardous agents. The protection of VA personnel, patients, visitors, and the surrounding community from terrorist events demands stringent controls for the use of hazardous agents capable of being misused for terrorism or other acts that may injure persons, the environment, physical structures, or other resources.

c. The VHA R&D Program operates its laboratories in compliance with policies, statutes, and regulations of appropriate Federal agencies including VA, Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Nuclear Regulatory Commission (NRC), Department of Transportation (DOT), Department of Health and Human Services (HHS), United States Department of Agriculture (USDA), and any applicable state or local regulations. All applicable guidelines issued by HHS, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), USDA, United States Postal Service (USPS), and the Animal and Plant Health Inspection Service (APHIS) must be followed. This Handbook specifically addresses security policies that are distinct from those relating to laboratory safety, but requirements may overlap with other policies. Policies, procedures, and responsibilities for VA research laboratory security, personnel identification and training, inventory controls, and the interactions with other VA facility personnel, such as security and law enforcement personnel, are addressed in this Handbook.

d. **Penalties.** Failure to conform to the requirements and standards of this Handbook may result in immediate withdrawal of VA research funding and/or suspension of the research program. Individuals who knowingly fail to follow the provisions of this Handbook are subject to disciplinary action proportionate to the severity of the violation, up to and including termination of VA employment or termination of a contract. Failure to comply with Title 42

Code of Federal Regulations (CFR) Part 73, 7 CFR Part 331, 9 CFR Part 121, and other Federal regulations may also result in criminal or civil penalties.

### 3. DEFINITIONS

For purposes of this Handbook, the following definitions apply.

a. **Approved Individual.** An approved individual is a VA employee appointed on a full-time, part-time, intermittent, fee basis, or without compensation (WOC), that has undergone credentialing and a background check required for appointment to a Title 5, Title 38 position, or as a WOC. An approved individual may also be a contractor who has undergone the required credentialing and background check (see subpar. 4j and subpar. 7c).

b. **Authorized Individual.** An authorized individual is a VA employee appointed on a full-time, part-time, intermittent, fee basis, or WOC, that has undergone credentialing and a background check required for appointment to a Title 5 position, Title 38 position, or as a WOC. In addition, the individual has an approved Security Risk Assessment as required in 42 CFR 73.10, 7 CFR 331.10, or 9 CFR 121.10. An authorized individual may also be a contractor who has undergone the required credentialing and background check as well as having an approved Security Risk Assessment (see subpar. 4j and subpar. 7c).

c. **Excluded Select Agents and Toxins.** Excluded select agents and toxins are attenuated strains of select agents or toxins that have been determined to not pose a severe threat to public health and safety. Once excluded, the agent or toxin is not covered by the select agents and toxins regulations. A list of attenuated strains may be found at [www.CDC.gov/od/sap](http://www.CDC.gov/od/sap) and at [www.aphis.usda.gov/vs/ncie/bta.html](http://www.aphis.usda.gov/vs/ncie/bta.html).

d. **Exempt Quantities.** Exempt quantities are permissible amounts of toxins that an investigator is allowed to store or use that are not subject to regulations found in 42 CFR Part 73 and 9 CFR Part 121. The toxins and the exempt quantities of toxins may be found at <http://www.cdc.gov/od/sap>

e. **Hazardous Agent.** A hazardous agent is biological material including the CDC list of select agents and toxins (42 CFR Part 73), APHIS biological agents (7 CFR Part 331, and 9 CFR Part 121), and products of such biological material, i.e., toxins. For purposes of this Handbook, the term also includes highly-toxic chemicals, exempt quantities of toxins, or gases that have the potential for being used as weapons by terrorists, as well as radioactive materials and/or radioactive sources (see App. A). When additional agents are added to, or deleted from, the hazardous agent list that are not contained in the CDC or APHIS list, the new list is posted on ORD's website and a notice is sent to all facilities. The terms select agents and toxins in this Handbook to refer to both the CDC select agents and toxins and the APHIS biological agents and toxins.

f. **VA Research Laboratories.** VA Research Laboratories are research laboratories under the control of VA. In the context of this VHA Handbook, the VA research laboratory director is the VA investigator responsible for a particular laboratory. VA research laboratories include:

- (1) VA research laboratories located within VA facilities and in leased space;

(2) VA research laboratories located in approved off-site facilities such as affiliate universities; and

(3) Laboratories within the VA medical center in space that is leased to a private entity.

g. **Select Agent.** A select agent is one of a group of agents (viruses, bacteria, rickettsiae, fungi, toxins, and recombinant deoxyribonucleic acid (DNA)) designated by CDC as requiring registration with the CDC Laboratory Registration Program. The regulation of select agents is codified in 42 CFR Part 73, "Possession, Use and Transfer of Select Agents and Toxins; Interim Final Rule." For purposes of this Handbook, select agents and hazardous agents are synonymous, and are to be handled at the same level of security. For the purpose of this Handbook, the terms select agents and toxins also refer to biologic agents and toxins that the Secretary of Agriculture has determined to have the potential to be a severe threat to animal and plant health (7 CFR Part 331, and 9 CFR Part 121). **NOTE:** Refer to Appendix A for a list of hazardous agents, to CDC's website at <http://www.cdc.gov/od/sap> for select agents and toxins, and to the APHIS website ([www.aphis.usda.gov](http://www.aphis.usda.gov)) for a list of regulated biological agents and toxins.

h. **Sensitive Materials.** Sensitive materials include, but are not limited to, any hazardous agents as defined in subparagraph 3d and identified in Appendix A; research equipment and/or supplies used to store, test, destroy, or otherwise handle hazardous agents; and laboratory notebooks or other written or computerized records documenting possession of and/or research using hazardous agents.

i. **Terrorist Event.** A terrorist event is the unauthorized removal or theft, from VA research laboratories or other VA-assigned space (including off-site space), of hazardous agents capable of being used as weapons by those who intend harm to persons, the environment, physical structures; or other resources of mass destruction; and/or the unlawful use of such hazardous agents. It specifically encompasses the illicit and unauthorized use of VA research laboratory facilities (including equipment, supplies, computers, faxes, phones, etc.) for the production, purification, or dissemination of any hazardous agent.

(1) The term also refers to the illegal transfer of agents into or out of VA research laboratories and other research space, such as: animal care facilities, storage areas, offices, etc.

(2) The term may also refer to activities such as dissemination, detonation, and contamination of hazardous agents, select agents, toxins, or sensitive materials within VA research laboratories or the building housing these laboratories.

j. **Toxin.** According to 42 CFR 73.1, a toxin is the toxic material or product of plants, animals, microorganisms (including, but not limited to: bacteria, viruses, fungi, rickettsiae, or protozoa), infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production. It includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer of biological product, homolog, or derivative of such a substance.

k. **USA Patriot Act.** The USA Patriot Act, Public Law 107-56, was passed by Congress on October 26, 2001, in response to the terrorist attacks of September 11, 2001. The purpose of the

Act is to unite and strengthen America by providing appropriate tools to intercept and obstruct terrorist acts. The law includes provisions to deter and punish terrorist acts, enhance law enforcement investigational tools, and other purposes, such as aid to victims of terrorism. The Act prohibits certain restricted persons from possessing biological agents or toxins that are identified as select agents in 42 CFR Part 73. This provision of the Act, codified at Title 18 United States Code (U.S.C.) § 175b, defines a “restricted person” as an individual who:

- (1) Is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;
- (2) Has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;
- (3) Is a fugitive from justice;
- (4) Is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));
- (5) Is an alien illegally or unlawfully in the United States;
- (6) Has been adjudicated as a mental defective or has been committed to any mental institution;
- (7) Is an alien (other than an alien lawfully-admitted for permanent residence) who is a national of a country as to which the Secretary of State ( pursuant to section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App 2450(j)), Section 620A of Chapter 1 of part M of the Foreign Assistance Act of 1961 (22 U.S.C. 2371) , or Section 40(d) of Chapter 3 of the Arms Export Control Act (22 U.S.C. 2780(d)), has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; or *NOTE: The Secretary of State makes such determinations; as of the date of this Handbook, identified countries include Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria.*
- (8) Has been discharged from the U.S. Armed Services under dishonorable conditions.

1. **Weapons of Mass Destruction.** The term “weapon of mass destruction,” as referenced in the USA Patriot Act, is defined in 18 U.S.C. § 2332a. It includes destructive devices (as defined in 18 U.S.C. § 921); weapons designed or intended to cause death or serious bodily injury through the release, dissemination, or impact of toxic or poisonous chemicals or their precursors; weapons involving certain biological agents, toxins or vectors (defined in 18 U.S.C. § 178); or weapons designed to release radiation or radioactivity at a level dangerous to human life. *NOTE: A hazardous agent defined in subparagraph 3e and identified in Appendix A of this handbook, or a combination of these agents, when used in any destructive device or weapons, falls within the definition of a weapon of mass destruction.*

#### **4. HAZARDOUS AGENTS CONTROL PROGRAM AND RESPONSIBILITIES**

a. **Hazardous Agents Control Program.** Each VA facility must ensure the security of VA research laboratories and the security of hazardous agents including select agents, toxins and associated sensitive materials, which are stored in or used by these VA research laboratories through the development of a Hazardous Agents Control Program. Each VA facility Director

must ensure that a VA Research Laboratory Hazardous Agents Control Program is developed. This program is a comprehensive approach to ensuring that:

- (1) VA research laboratories maintain an appropriate level of security.
- (2) All staff listed in subparagraph 7i receive the appropriate training related to:
  - (a) The acquisition, use, transfer, or destruction of hazardous agents and, if used, including select agents, toxins and associated sensitive materials.
  - (b) The safety requirements for working with hazardous agents, including select agents and toxins, are in effect.
  - (c) The security requirements for working with hazardous agents, including select agents and toxins and the associated sensitive materials.
- (3) VA facilities monitor and evaluate their program at least annually.
- (4) VA facilities monitor and evaluate status of appropriate personnel in laboratories to preclude restricted persons from gaining access to areas (see subpar. 4j(3)(b)3 and subpar. 7c(2)(f)).
- (5) All appropriate officials, committees and individuals coordinate efforts to ensure the successful implementation of the program.

b. **Human Resource Management Service (HRMS)**. HRMS is responsible for assisting the research program in issues related to personnel, including new personnel actions, appointment of WOC employees, developing the position risk and sensitivity designation of all research employees, and initiating the appropriate background investigations. HRMS is also responsible for reviewing applications for employment (salaried, WOC, or fee basis) for citizenship and visa status.

c. **Office of Security and Law Enforcement (OSLE)**. OSLE, Security and Investigations Center (SIC), is responsible for implementing the Personnel Suitability and Security Program within VA. SIC, OSLE, is responsible for processing employee and contractor background investigations and making eligibility and security determinations for VA. The Police Service, OSLE, is responsible for assisting with background investigations, the security of research laboratories, emergency response, vulnerability assessments, and assisting research offices with the development and implementation of a Hazardous Agents Control Program.

d. **Chief Research and Development Officer (CRADO), VA Central Office**. The CRADO is responsible for the overall VA research laboratory antiterrorism policy, the planning and coordination of system-wide plans to prevent terrorist events from occurring in VA research laboratories, and maintaining the highest level of laboratory and inventory security for hazardous agents including select agents, toxins, and the associated sensitive materials. The CRADO, in consultation with the Under Secretary for Health, is responsible for identifying specific training requirements for persons working in VA research laboratories and for those persons working with hazardous agents, including select agents and toxins. The training requirements also apply to research administrators responsible for VA research laboratories. These training requirements

include information on safety, containment, and security of hazardous agents including select agents, toxins, and the associated sensitive materials.

e. **Chief, Office of Research Oversight (ORO)**. The Chief, ORO, is responsible for oversight or evaluation of issues related to compliance with this Handbook and other applicable Federal regulations addressing biosecurity.

f. **Veterans Integrated Service Network (VISN) Directors**. VISN Directors are responsible for ensuring:

(1) That each VA research program at facilities under their jurisdiction is in compliance with current policies and guidelines relating to the prevention of terrorist events, the security of VA research laboratories, and the security of hazardous agents, including select agents, toxins and the associated sensitive materials as defined in subparagraph 3g.

(2) The physical security of VA research laboratories, and other specialized research containment areas including biosafety level (BSL) 2, BSL-3 laboratories and animal care facilities throughout their respective VISNs.

g. **Medical Center Director**. The Medical Center Director is the Responsible Official (RO). The term Medical Center Director is synonymous with the Facility Director or Chief Executive Officer of a medical center or health care system. The Medical Center Director may appoint one or more Alternate Responsible Official(s) (ARO) to assist in administering this program. The ARO(s) acting in the absence of the RO may conduct all activities required by the RO related to the facility's Hazardous Agents Program. If the facility uses or stores select agents or toxins the RO and ARO must meet all the qualifications as found in 42 CFR 73.9, 7 CFR 331.9, and 9 CFR 121.9.

(1) The Medical Center Director is responsible for granting requests for authorization for access to research areas (BSL-3 laboratories, other laboratories, or storage areas) in which select agents or toxins are used or stored after reviewing the recommendation of the R&D Committee in compliance with the USA Patriot Act and other applicable criteria, regulations, and policies.

(2) The Medical Center Director is responsible for ensuring that adequate staffing and resources are available to comply with this Handbook.

(3) The Medical Center Director, as RO, may delegate the following responsibilities to the ARO(s), but remains the institutional official responsible for the overall VA research laboratory Hazardous Agents Control Program and compliance with all applicable regulations and policies. The RO is responsible for:

(a) Ensuring that the facility's research program is in compliance with current VA and Federal regulations, with current policies relating to prevention of terrorist events and with the security of hazardous agents, including select agents, toxins and associated sensitive materials as defined in subparagraph 3g.

(b) Delegating authority and responsibility to the ARO(s) to ensure that all applicable regulations and policies are met at the institution in the absence of the RO.



(c) Ensuring that all specifications for personnel, facility security and law enforcement contained in VA Handbook 0730, VHA Handbook 0730/1, and VHA Handbook 0710 are adhered to by facility staff, patients, visitors, and guests.

(d) Ensuring that the facility's policies and standard operating procedures address all requirements in this Handbook.

(e) Ensuring that changes in facility security procedures are made known to the research service, the other appropriate medical center personnel, and ARO(s).

(f) Ensuring that the ARO(s) possess expertise in the areas of physical security of facilities, safety of personnel working in both VA research laboratories and when applicable, working with select agents, toxins and hazardous agents.

h. **RO and ARO(s)**. If select agents or non-exempt quantities of toxins are used or stored for research purposes, the RO and ARO(s) must have an approved Security Risk Assessment as required in 42 CFR 73.7, or if agents or toxins are regulated by APHIS, in compliance with 7 CFR 331.7, or 9 CFR 121.7, as applicable. The RO and ARO(s) must:

(1) Be familiar with all applicable regulations, policies, and guidance and be able to perform all duties required for this position.

(2) Oversee the development, implementation, and evaluation of all components of the VA Research Laboratory Hazardous Agents Control Program as required by this Handbook and applicable VA and Federal regulations. This requires:

(a) Developing and implementing safety, containment, security, and emergency response plans.

(b) Allowing only authorized individuals to have access to select agents or toxins.

(c) Providing appropriate training for safety, containment, security, and emergency response.

(d) Maintaining, using, purchasing, transferring, and destroying select agents or toxins in accordance with applicable regulations and policies, including the regulations and policies of the agencies listed in subparagraph 2c.

(e) Providing timely notice of any theft, loss, or release of a select agent or toxin in accordance with 42 CFR 73.19, 7 CFR 331.19, and 9 CFR 121.19, as applicable.

(f) Maintaining detailed records of information necessary to give a complete accounting of all activities related to select agents or toxins.

(g) Conducting annual inspections of VA research laboratories, including BSL-3 laboratories and laboratories where select agents or toxins are used or stored to ensure compliance with all policies, procedures and protocols including plans for safety, security, and incident response as required in subparagraph 7a(9). The inspections must be conducted at least annually and after each incident. Findings must be documented and any deficiencies corrected.

(h) Conducting drills or exercises, at least annually, to test and evaluate the effectiveness of the safety, security and incidence response plans. The drills or exercises must be documented and any deficiencies corrected.

(i) Completing the annual vulnerability assessment of VA research areas and informing appropriate facility personnel of the assessment results and correcting any deficiency.

(j) Notifying CDC or APHIS when an individual's access to select agents or toxins is terminated and the reason why it was terminated.

(k) Immediately notify CDC or APHIS if a facility using or storing select agents or toxins loses the services of its RO. To continue use of the select agents or toxins, the facility must appoint another person as RO who already has an approved Security Risk Assessment.

*NOTE: In facilities using or storing select agents or toxins the ARO may act as the RO if the RO is unavailable.*

i. **Associate Chief of Staff (ACOS) for R&D.** The ACOS for R&D is responsible for:

(1) All activities in the Research Service, including the implementation of all requirements set forth in this Handbook.

(2) Appointing, or serving as, the designated research point of contact for interacting with facility security personnel, health and safety staff, Medical Center Director-RO, ARO, and oversight committees (e.g., R&D Committee, Subcommittee on Research Safety (SRS), Radiation Safety Committee).

(3) Ensuring the Medical Center Director, or designee, remains informed of all activities involving hazardous agents, select agents, toxins, and other sensitive materials in VA research laboratories.

(4) Ensuring that changes in facility security procedures are made known expeditiously to all staff in the research service.

(5) Ensuring that all non-VA persons (i.e., those that are not appointed as VA employees or VA contractors) working in VA research laboratories, in VA research laboratories in approved off-site locations, leased space, or in VA space leased to another institution, conform to all VA standards for security described in this Handbook.

(6) In conjunction with the RO or alternate RO(s), completing the annual vulnerability assessment of research areas and assisting with the annual drills or exercises for safety, security and incident response.

(7) Informing OSLE of any changes in research affecting the facility's security rating.

(8) Reviewing records of access to the VA research laboratories as required in subparagraph 7d(1)(c) of this Handbook and recording the results of this review. *NOTE: The ACOS for R&D may delegate this responsibility to another appropriate administrator such as the Administrative Officer (AO) for R&D.*

(9) Notifying ORD and ORO if a new BSL-3 research laboratory is planned or a current one is closed. Ensuring that VA Central Office approval has been obtained prior to beginning the construction of a new BSL-3 research laboratory, or beginning major renovations of current BSL-3 research laboratories.

j. **R&D Committee.** The R&D Committee may serve as the primary committee responsible for the following areas or it may delegate them to SRS. The SRS reports to the R&D Committee.

(1) If the responsibilities are delegated to the SRS, the R&D Committee must oversee the functions of the SRS through review of minutes, reports, and/or other appropriate mechanisms.

(2) The R&D Committee may add to the SRS requirements to obtain approval or may disapprove an action approved by the SRS. It may not approve an action that the SRS has disapproved.

(3) Either the R&D Committee or the SRS may, at its discretion, invite individuals with competence in special areas to assist it in fulfilling its responsibilities related to a Hazardous Agents Control Program as defined in this Handbook. **NOTE:** *Handbook 1200.8 contains additional information on the functions and responsibilities of the R&D Committee and SRS.* Actions taken, based on the responsibilities of the R&D Committee and SRS (e.g., reviews, approvals, disapprovals) must be formally documented in minutes or by other means. These responsibilities include, but are not limited to:

(a) Assisting the Medical Center Director in carrying out the responsibilities of the RO.

(b) Controlling access to VA research laboratory areas housing select agents, toxins, other hazardous agents and to BSL-3 research laboratories by:

1. Reviewing and making recommendations to the Medical Center Director for approval or disapproval of requests to grant authorization for access to BSL-3 laboratories and laboratories using or storing select agents or toxins. **NOTE:** *Subparagraph 7c outlines request procedures.* Prior to recommending approval to the Medical Center Director, the R&D Committee must follow guidelines found in subparagraph 7c(2).

2. Reviewing and taking action on requests for employees (compensated, WOC) or contractors to work in BSL-3 research laboratories not containing select agents or toxins.

3. Reviewing the status of personnel granted access to VA research laboratories at least semi-annually (see subpar. 7c(2)(f)). This review includes the need for such personnel based on the research being conducted, the individual's qualifications to hold the position, the visa status, if applicable, appointment status, and if working with select agents and toxins, the individual holds an approved Security Risk Assessment from CDC or APHIS.

(c) Reviewing and approving requests for a CDC or APHIS laboratory registration number and Certificate of Registration prior to the requests being forwarded to ORD, ORO and then to CDC or APHIS. Obtaining a Certificate of Registration will allow VA research laboratories to receive, transfer, or use select agents or toxin.

(d) Approving or disapproving requests to purchase, transfer, use, or destroy select agents or toxins. Approving or disapproving requests to use exempt (excluded) quantities of toxins.

1. Approval for purchase may be granted only if the select agent or toxin is required for a VA-approved research protocol and the purchase is in compliance with all applicable regulations and policies. Approval for use of exempt (excluded) quantities of toxins may be granted only for VA-approved research protocols.

2. Transfer of select agents or toxins may only be approved if the transfer is completed in compliance with this Handbook and is transferred (intra-facility or outside the facility) to another laboratory holding a CDC or APHIS Certificate of Registration and in accordance with all Department of Transportation (DOT) and other applicable regulations.

3. Destruction of a select agent or toxin following requirements in subparagraph 7g(6) of this Handbook must be ensured. **NOTE:** *VHA Handbook 1200.8 contains applicable requirements.*

(e) Conducting inventory of all hazardous agents or reviewing inventory if responsibility is delegated to an individual or individuals.

(4) All R&D Committee and SRS activities need to be documented in meeting minutes or by the use of specific reports.

k. **VA Research Investigators, Laboratory Directors, and Research Staff.** VA research investigators and staff, regardless of appointment status (compensated, WOC, or fee basis), are required to comply with all provisions of this Handbook. **NOTE:** *Those requiring WOC appointments include, but are not limited to, students, fellows, residents, university employees, other non-VA employees working at VA, and visiting scientists who are not compensated by VA for their employment.* All contractors must comply with all requirements of this Handbook. For requirements that differ from those for appointed VA employees (compensated, fee basis, or WOC), the Handbook contains alternate language that is applicable to contractors.

(1) Appropriate authorizations and approvals must be obtained prior to beginning work in VA research laboratories.

(2) All VA research laboratory directors and investigators must ensure that those they supervise have received approval to access laboratories prior to beginning work (see subpar. 7c(1-2)). If it is a laboratory (BSL-3 or non-BSL-3 laboratory) using or storing select agents or toxins, employees must have an authorization to both access these areas and to work within them. If the select agents or toxins are not used or stored in a BSL-3 laboratory, persons working in the BSL-3 laboratory must obtain specific approval from the R&D Committee to do so, but the completion of the Federal Bureau of Investigation (FBI) Form FD-961, Federal Bureau of Investigation Bioterrorism Preparedness Act: Entity/Individual Information, and obtaining a Security Risk Assessment is not required. Laboratory directors and investigators are responsible for:

(a) Identifying the level of security access required for VA research laboratory staff (compensated or WOC) being considered for employment or being approved to work within the

investigator's research laboratory. For those working with select agents and/or toxins, a Security Risk Assessment must be completed by the FBI prior to being authorized to work in the laboratory as required by 42 CFR 73.10, 7 CFR 331.10, or 9 CFR 121.10. The Security Risk Assessment is in addition to the background investigation required by VA Handbook 0710 (see subpar. 7c(2)).

(b) Ensuring that all their staff have received the required training (prior to beginning work in the laboratories and annual training updates), and that staff are familiar with information specific to the hazardous nature of materials they will be using and that security precautions are followed in handling, transferring, or destroying such materials as well as containment procedures.

(c) Regularly reviewing and accounting for inventory of hazardous agents including select agents or toxins (non-exempt and exempt quantities). The review must be documented. *NOTE: The review period may be daily, weekly, or monthly according to the nature of the substance, but may not exceed 6 months.*

(d) Forwarding a copy of the inventory to the ACOS for R&D, the R&D Committee, the RO and to the facility Safety Officer or Radiation Safety Officer as appropriate, or other officials and specialists, as identified by facility policy and determined by the nature of the materials on, at least, a semi-annual basis. If the R&D Committee delegates responsibility for inventory control to the SRS, it must be submitted to the SRS who then forwards the request to the R&D Committee.

(3) Select agents or toxins (non-exempt and exempt quantities) may be used only after receiving appropriate approvals.

(4) VA research laboratory directors and investigators are responsible for all aspects of their research including the supervision of their staff.

(5) All requests for unpublished research information (data, methodology used, etc.) must be forwarded to the facilities Freedom of Information Act Officer (FOIA).

(a) If the researcher believes that the requested records contain information which, if disclosed, may possibly compromise national and/or homeland security, then the researcher needs to communicate this concern to the FOIA Officer responsible for processing the FOIA request.

(b) The researcher should also convey this concern to the ACOS for R&D. If the concern remains after discussing it with the ACOS for R&D, the ACOS for R&D needs to then forward the request to the Chief, Police Service.

1. **Individuals Working in VA Research Facilities.** Each individual must immediately report the following to the RO or ARO(s):

(1) Any loss or compromise of their keys, passwords, combinations, etc.

(2) Any suspicious persons or activities.

(3) Any loss, release or theft of select agents or toxins (non-exempt and exempt quantities).

(4) Any sign that inventory and use of records of select agents or toxins (non-exempt and exempt quantities) have been altered or otherwise compromised.

## **5. INSPECTIONS OF VA RESEARCH LABORATORIES AND RESEARCH FACILITIES**

Officials authorized by VA, the Secretary HHS, the Secretary USDA, Government Accountability Office (GAO), or other authorized Federal agencies, including such entities as the CDC, VA Office of the Inspector General (OIG), ORD, and ORO may conduct inspections of all research laboratories covered by this Handbook. Individuals conducting the inspections must be allowed to inspect the site and inspect and copy any records relating to activities covered by this Handbook, but they may be required to complete facility security procedures (review of credentials, badging, signing security statements, etc.). The inspections may be either announced or unannounced.

## **6. THEFT, LOSS, OR RELEASE OF SELECT AGENTS OR TOXINS**

When the theft, loss, or release of a select agent or toxin is discovered, the VA research laboratory must immediately notify the appropriate supervisor, the ACOS for R&D, the VA Police Service, the RO, ARO(s), appropriate Federal, state and local law enforcement agencies, VA OIG, ORD, ORO, and APHIS or CDC, as applicable, via e-mail, facsimile, or telephone. A report to APHIS or CDC must be followed up with a completed APHIS or CDC Form 3 within 7 calendar days. The facility's Safety Officer and the VISN Safety and/or Industrial Hygiene (IH) Officer must also be notified.

a. The specific procedures for reporting the theft, loss, or release are defined in subparagraph 7h(4)(q). These procedures include specific reporting requirements, the sequence of reporting, the individual responsible for the reporting, the type of notification (oral, written, electronic, etc.), the timeframe for reporting, and the required documentation.

b. All reporting procedures in 42 CFR 73.19, 7 CFR 331.19, or 9 CFR 121.19, whichever is applicable, must be followed immediately upon discovery of the theft, loss or release.

c. Applicable procedures identified in paragraph 24 must be immediately implemented upon detection of theft or loss of select agents or toxins.

d. Thefts or loss must be reported whether the select agents or toxins are subsequently recovered or the responsible party(ies) identified (see 42 CFR 73.19, 7CFR 331.19, and 9 CFR 121.19).

## **7. COMPONENTS OF A HAZARDOUS AGENT/SELECT AGENT CONTROL PROGRAM**

a. **Safety Plan.** The safety (biosafety) plan must include all VA research laboratories, including those in leased space and approved off-site locations. **NOTE:** *The plan must include requirements found VHA Handbook 1200.8.* This safety plan must:

(1) Meet the biosafety standards and requirements for BSL-2, BSL-3, and BSL-4 operations as they pertain to the respective select agents and toxins that are contained in the most recent edition CDC-NIH publication "Biosafety in Microbiological and Biomedical Laboratories." This includes all appendices except Appendix F and all updates on the CDC website.

(2) Meet all applicable OSHA regulations, including, but not limited to: requirements for handling toxins found in 29 CFR 1910.1450, and/or 29 CFR 1910.1200, depending on which one applies. This is in addition to specific provisions for handling toxins found in Appendix I of the CDC-NIH publication "Biosafety in Microbiological and Biomedical Laboratories," or its most recent update.

(3) Be commensurate with the risk of the agents in use, and there must be sufficient information available to describe the biosafety and containment procedures.

(4) Incorporate the NIH "Guidelines for Research Involving Recombinant DNA Molecules" requirements for portions of the safety plan related to genetic elements, recombinant nucleic acids, and recombinant organisms. This includes:

(a) Provisions regarding risk assessment.

(b) Physical containment.

(c) Biological containment.

(d) Local review.

(5) Include applicable sections of the "NIH Guidelines for Research Involving Recombinant DNA Molecules," see the website at: <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

(6) Specifically state that the following experiments may not be conducted unless approved by the HHS Secretary after consultation with experts:

(a) Experiments using recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire that trait naturally, if such acquisition could compromise the use of the drug to control disease agents in human, veterinary medicine, or agriculture (42 CFR Part 73).

(b) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at a LD 50 <100ng/kg, i.e., a dose of less than 100 nanograms per kilogram is lethal to 50 percent to the test animals. (42 CFR 73.13)

(7) Include the mandatory emergency response program, in accordance with 29 CFR 1910.38, and its requirement for drills to test implementation of the plan:

(8) Be reviewed at least annually (see 42 CFR 73.12) and revised as necessary.

(9) Include as mandatory the regular (at least annually) safety inspections and drills or exercises conducted to test and evaluate the effectiveness of the plan.

(10) Identify, record, and correct any deficiencies identified as a result of the inspections.

b. **Security Plan.** A security plan must be developed and implemented by each VA facility housing VA research laboratories, including those that receive, maintain, transfer, or destroy select agents or toxins (non-exempt or exempt quantities). The security plan must be site-specific and provide graded protection commensurate with the risk, including the risk of a select agent or toxin given its intended use. The following are elements that must appear in the written plan. *NOTE: Subparagraphs 7c-7g describe actions that must occur based on the security plan.*

(1) The plan must be based on a systematic approach that:

(a) Defines threats.

(b) Identifies and examines vulnerabilities.

(c) Mitigates risks associated with any identified vulnerabilities using a security systems approach.

(2) The security plan must include the following:

(a) A description of security for:

1. Inventory control.

2. Physical security.

3. Cyber security including information systems control.

4. Access control (keycards, logs, etc.).

5. Background and security clearances.

(b) Provisions for routine cleaning, maintenance, and repairs.

1. For VA research laboratories not containing hazardous agents, procedures describing how personnel from Environmental Management Service, Engineering Service, or others either obtain approval to access VA research laboratories, or are escorted and monitored by an approved individual to complete their duties (see subpar. 3a for the definition of an approved individual).

2. For VA research laboratories in which select agents, toxins or associated sensitive materials are used or stored, procedures describing how personnel from Environmental Management Service, Engineering Service, or others, either obtain authorization to access VA research laboratories or are escorted and monitored by an authorized individual to complete their duties (see subpar. 3b for a definition of an authorized individual).

(c) Minimal education and experience criteria for personnel with access to hazardous agents including select agents or toxins.



- (d) Procedures for training personnel on security requirements (see subpar. 7i).
- (e) Procedures for ensuring that all individuals with access, including personnel and visitors, understand security requirements and are trained and equipped to follow them.
- (f) Actions to be taken when an intrusion alarm is activated.
- (g) Procedures for securing and controlling access to the areas (locks, card access, key pads, or other equivalent or superior mechanisms) 24-hours a day, 7-days a week, including weekends and holidays.
  - 1. Procedures for changing locks, access numbers, or other appropriate mechanisms following changeover in personnel.
  - 2. Actions to be taken if there is loss or compromise (including sharing with others) of keys, passwords, codes, etc., and procedures to prevent such occurrences.
  - 3. Procedures for reviewing changes in personnel, or access control measures after incidents occur.
- (h) Procedures for control of access to:
  - 1. VA research laboratories in which select agents or toxins are not stored or used.
  - 2. VA research laboratories in which select agents or toxins are stored or used.
  - 3. VA BSL-3 research laboratories.
- (i) Procedures for control of access to containers, cabinets, refrigerators, freezers, and other areas where hazardous agents, including select agents and toxins (exempt or non-exempt quantities), are used or stored.
- (j) Procedures for securing the areas that contain hazardous agents, including select agents or toxins, when authorized persons are not present or cannot visually monitor the area.
- (k) Procedures for accepting packages or taking the packages into secure areas (see subpar. 7e(1)(g)).
- (l) Procedures for reviewing access records and egress records if required, on a weekly basis.
- (m) Procedures for escorting any unauthorized person or persons when these persons require access to a secure area.
- (n) Procedures for reporting suspicious persons or activities, reporting loss, theft or release of select agents or toxins (exempt and non-exempt quantities), or reporting alteration of inventory records.
- (o) Procedures for reporting and removing unauthorized persons.

(p) Procedures for acquisition, transfer, or destruction of select agents or toxins.

(q) Procedures for the RO to review and test the performance of the plan through drills or exercises, and to update the security plan annually and after each incident, drill, or exercise.

(r) Requirements for an annual inspection of each laboratory where select agents and toxins are used or stored to determine compliance with all applicable regulations and policies.

c. **Personnel.** All individuals must obtain formal approval prior to beginning work in VA research laboratories and must be appointed as full-time, part-time, or intermittent, as compensated, uncompensated (WOC) employee, or fee basis (see subpar. 3a, subpar. 4j, and subpar. 7c(9) for requirements for contractors).

#### (1) Authorization and Approval

(a) If the individual will be working in a BSL-3 research laboratory that does not house select agents or toxins, the individual must obtain specific approval to work in the BSL-3 research laboratory that will be used.

(b) If the individual will be working in a VA research laboratory using or housing select agents or toxins, a formal authorization as outlined in subparagraph 7c(2), must be obtained prior to beginning work in this laboratory (see subpars.3b and 4j).

(c) No individual may enter a VA research laboratory containing select agents or toxins unless they have obtained authorization to enter unescorted or have obtained approval to enter when escorted and monitored by an authorized individual. *NOTE: VA research laboratories that use agents that have been excluded from the select agents or toxin list or which uses exempt quantities of toxins are considered laboratories that fall under subparagraph 7c(1) (see App. A for more information on exempt quantities and excluded agents).*

#### (2) VA Research Laboratories and BSL-3 Research Laboratories Not Using or Storing Select Agents or Toxins

(a) Prior to beginning work in a VA research laboratory that does not use or store select agents or toxins, HRMS verifies the person's credentials. HRMS and/or the Police Service submit both a Standard Form (SF)-85, Questionnaire for Non-Sensitive Positions, for low-risk level positions (when required or other applicable forms as determined by the individual's position risk and sensitivity level) and fingerprints to the Office of Personnel Management for completion of a background check. HRMS notifies SIC via VA Form 2280, Position Sensitivity Level Designation, and VA Form 0237, Personnel Security Action Request and Certification, when the position sensitivity level is above the low-risk level. SIC transmits the necessary forms to the employee or contractor required to initiate a background investigation.

(b) The VA research laboratory director or ACOS for R&D must verify that this has been done. Once it has been verified that this process has been initiated, the individual is considered approved to enter non-BSL-3 VA research laboratories and BSL-3 VA research laboratories not using select agents and toxins unescorted and begin work. The ACOS for R&D must recheck to verify if the background investigation has been completed and a suitability determination made according to VA and other Federal regulations (see VA Directive and Handbook 0710, and 5

CFR Parts 731 and 736). Employees that will be working in a BSL-3 research laboratory not containing select agents or toxins must obtain approval to do so from the R&D Committee.

**NOTE:** *The verification of credentials and the completion of the SF-85 (or other applicable forms) are required by VA Directive and Handbook 0710, VHA Handbook 1100.19 (applicable to licensed health care practitioners who are allowed by the facility to practice independently), and VA Handbook 5005 for all VA employees, whether compensated or WOC.*

(3) **VA Research Laboratories Using or Storing Select Agents or Toxins.** The following apply to individuals who will work in VA research laboratories using or storing select agents or toxins:

(a) An individual may not have access to laboratories in which select agents or toxins are used or stored unless the individual is both authorized for such access based on an approved Security Risk Assessment and possesses the appropriate education, training, and/or experience to handle or use select agents or toxins. An individual can not have access to select agents or toxins even when escorted until the Security Risk Assessment is completed.

1. According to CDC and APHIS, an individual is deemed to have access to select agents and toxins if the individual has possession of a select agent or toxin or the ability to gain possession of a select agent or toxin. (42 CFR 73.10(b), 7 CFR 331.10(b), 9 CFR 121.10(b)). Such individuals must undergo a Security Risk Assessment by the Attorney General. The Security Risk Assessment may be denied or revoked based on the criteria set forth in 42 CFR 73.10(f), 7 CFR 331.10(f), or 9 CFR 121.10(f), as applicable.

2. Based on this Security Risk Assessment, the HHS Secretary (or Administrator of APHIS) determines whether the individual can have access to a select agent or toxin. HRMS and VA Police Service must initiate a Security Risk Assessment through the Department of Justice, Federal FBI, by submitting FBI Form FD-961 and two sets of fingerprints to the FBI (more information may be found at: <http://www.CDC.gov/od/sap> or <http://www.aphis.usda.gov>).

3. With some limitations, an approval is valid for 5 years (see 42 CFR 73.10(i), 7 CFR 331.10(h), or 9 CFR 121.10(i)). The Security Risk Assessment is in addition to the background investigation required by Handbook 0710. Unlike other background investigations, individuals may not have access to, or work with, select agents until their Security Risk Assessment is approved. **NOTE:** *The USA Patriot Act prohibits certain restricted persons from possessing select agent or toxins (see subpar. 3i which gives further information on restricted persons).* If, while the employee holds an approved Security Risk Assessment, the employee becomes a restricted person as defined in subparagraph 3j, the employee must notify the employee's supervisor and the ACOS for R&D. **NOTE:** *Penalties for failing to make such notifications may be found in subparagraph 2d.*

(b) After completing the Security Risk Assessment process and receiving approval from the HHS Secretary (or USDA Secretary, if applicable), the R&D Committee or SRS recommends final authorization for access to VA research laboratories in which select agents or toxins are used or stored. The Medical Center Director is the person responsible for granting the authorization (see subpars. 4 g and 4j). Prior to making this recommendation, the R&D Committee must:

1. Evaluate any relevant materials, including information and reviews obtained by VA Police Service, HRMS, Department of Justice, the facility's Safety Committee, the Radiation Safety Subcommittee, and Research Service.

2. Ascertain that an authorization is necessary for the person to perform their duties. This needs to be done prior to the initiation of the Security Risk Assessment.

3. Ascertain that the individual has an approved Security Risk Assessment.

4. Ensure that authorization is for a specific VA research laboratory and not one that allows access to all VA research laboratories. If access is required to multiple laboratories, the need for access to each VA research laboratory must be reviewed and approved.

(c) The deliberations and final recommendation of the R&D Committee or SRS must be recorded in the minutes of the meeting at which the request was reviewed.

(d) Facility management, VA Police Service, HRMS, the Research Service, the R&D Committee, the facility Safety Officer and Safety Manager, and the Radiation Safety Officer and/or IH, when appropriate, must:

1. When initiating a VA research Laboratory Hazardous Agents Control Program, coordinate efforts to identify individuals currently granted access to VA research laboratories housing select agents or toxins in order to evaluate the appropriateness of their access into these areas, if this has not been done within the last 6 months. This review includes the need for such personnel based on: the research being conducted; the individual's qualifications to hold the position; the visa status, if applicable; appointment status, and if working with select agents and toxins, the individual must hold an approved Security Risk Assessment from CDC or APHIS.

2. Review and make recommendations to the medical center Director for approval, as appropriate, of future requests for access into these areas or changes in local policy related to access.

3. Coordinate efforts with other services, such as Environmental Management Service and Engineering Service, to allow those services to request authorization for access when a specific individual's duties require that individual to routinely enter a restricted area. Personnel from other services must meet the same requirements as research personnel prior to receiving access. This includes obtaining an approved Security Risk Assessment and appropriate training on safety and security.

(e) VA research laboratory directors must submit a written request to the facility's R&D Committee or SRS to initiate the process for the granting of an authorization or access to VA research laboratories for new employees or employees transferring into the laboratory.

1. The VA research laboratory director's request must specify the individual's legal address, employment status, basis for which access is required, and a description of the sensitive material in the VA research laboratory area in which the individual will work.

2. The appropriate facility managers, the VA research laboratory director, and the individual must be notified of the final status of the request.

(f) The status of personnel granted access to VA research laboratories using or storing select agents or toxins must be reviewed at least semi-annually, or more frequently as needed, by the VA research laboratory director (see subpar. 4j(3)(b)3 for information on reviewing status and subpar. 7c(2)(d)1).

1. The R&D Committee or SRS must be formally notified following the review of the individuals requiring continued access to sensitive laboratory areas. Sufficient explanations must be provided to the R&D Committee or SRS to allow an informed concurrence by them on the continued access.

2. The SRS and R&D Committee must record their concurrence in the minutes of the meeting at which the concurrence was given.

(g) A change in personnel VA appointment status or visa status (e.g., termination, suspension, or change in duties) for which access is no longer required, or is denied, must be reported immediately to the SRS, R&D Committee, VA Police Service, HRMS, Research Service, and the appropriate facility managers.

(h) If an individual's access to select agents or toxins is terminated by the facility, CDC, or APHIS must be notified by the RO of the termination and the reason for the termination.

(4) **HRMS Responsibilities.** HRMS must review applications from non-United States citizens for their current residency status in the United States prior to employment or granting access to VA research laboratory areas.

(a) HRMS is responsible for reviewing, verifying, and tracking citizenship and visa status. Follow-up with appropriate external agencies such as the Immigration and Naturalization Service, may be necessary to clarify or validate a non-citizen's credentials. The research office must verify that this has been done.

(b) The individual's status as a legal alien must be verified annually.

(c) Local facility personnel (HRMS or Police Service) are responsible for initiating the required background checks based on the individual's position risk and sensitivity level. If the position designation is greater than "low-risk, non-sensitive," OSLE (07) is responsible for conducting personnel security background checks for controlled area access as required by VA Handbook 0710 (see VA Directive and Handbook 0710 for further information, and see subparagraphs 7c(1) and 7c(2) for further discussion on background checks and security risk assessments that must be completed). *NOTE: Careful attention to these procedures is required to ensure that inappropriate or illegal non-citizens are not permitted in VA research laboratories. Discrepancies must be reported to the local Federal Marshal through the VA Police Service, and to the VA OIG.*

(5) **Students, Fellows, Residents, Visiting Scientists.** Students, fellows, residents, visiting scientists, and others who may be at the VA for short periods of time may not be granted authorizations to enter laboratories containing select agents or toxins, unless the procedures for granting authorization as defined in this Handbook have been completed and approved by the

Medical Center Director. These individuals may be granted limited approval to access VA research laboratories or storage areas that do not house select agents or toxins if:

- (a) Their credentials have been verified.
- (b) A background check has been completed as required by VA Directive and Handbook 0710.
- (c) Their citizenship status has been verified and they are either citizens or legal aliens.
- (d) A determination has been made that they are in a low-risk category.
- (e) Access is limited to daytime hours when approved or authorized VA employees are present.
- (6) If access is requested to a BSL-3 research laboratory not containing select agents or toxins, the request must be approved by the R&D Committee.
- (7) If a visitor already holds a Security Risk Assessment while working at another facility the visitor may be allowed to work with select agents or toxins if all applicable CDC, or APHIS applicable, requirements are met and the R&D committee authorization is received.
- (8) Individuals leaving VA employment, or no longer working in the VA research laboratory, are expected to comply with the procedures described in subparagraph 7b(2)(g)1, including following all clearance procedures such as turning in identification badges, keycards, other access items, etc. (see subpar. 7d(1)(e)2).
- (9) In the event an individual with access to a VA research laboratory inexplicably disappears, is suspected to have violated procedures, or has committed a security breach, VA Police Service and other security officials, including the VA OIG, must be notified immediately. *NOTE: Law enforcement officials are to take necessary steps to treat the areas affected as potential crime scenes.*
- (10) WOC appointments for those individuals who have been granted approval to enter VA research laboratories must be reviewed annually to determine the appropriateness of their WOC appointment. If this review is done by Research Service personnel or HRMS, the results must be submitted to the SRS or R&D Committee for its concurrence,
  1. The SRS and R&D Committee must record its concurrence in the minutes of the meeting where the issue was reviewed.
  2. The findings must be conveyed to the ACOS for R&D, the VA research laboratory director, and the individual. If the SRS or R&D Committee does not concur, HRMS must also be notified and the individual's WOC appointment and authorization terminated. *NOTE: The individual may continue in the WOC status if the individual qualifies for another position.*
- (11) Personnel are to enter VA research laboratory areas only when required to perform their duties and responsibilities. *NOTE: Restrictions and guidelines for personnel must ensure adequate and sufficient access by the health and safety staff and for authorized inspectors from*

*regulatory agencies and VHA oversight offices. Personnel procedures must not preclude or interfere with employee or worker opportunity to report safety concerns or to participate in other protected activities under 10 CFR Parts 19 and 30, the Civil Service Reform Act of 1978, and the Whistleblower Protection Act of 1989.*

(12) All contractors working in research laboratories, including BSL-3 laboratories that do not contain select agents or toxins, must undergo a background check that is equivalent to that of a VA employee. The contractor's employer is responsible for ensuring this is completed and for supplying verification to VA that this has been done.

(13) For contractors that will be working with select agents or toxins, an approved Security Risk Assessment applicable to the laboratory in which the person will be working must be obtained. The Security Risk Assessment must be coordinated through VA, but the contractor's employer is responsible for all associated fees.

d. **VA Research Laboratory Access.** Access to VA research laboratories must be controlled at all times. VA research laboratories are not be open to the public.

(1) All VA research laboratory areas, including animal housing areas and storage areas, must include a state-of-the-art security system that generates permanent, dated records with identification of persons entering the area and times of entry. For BSL-3 laboratories and laboratories using or storing select agents and toxins, the time persons exit must also be recorded.

(a) Access control must be on a 24-hour, 7-days per week schedule (i.e., must include holidays and weekends).

(b) An intrusion alarm system must be present and either connected to, or otherwise monitored by, the facility VA Police Service.

(c) The ACOS for R&D, or designee, must conduct and document a review of access records on a weekly basis. The written record of each review must be retained by the local Research Service in accordance with guidelines established by the OSLE. Irregularities identified during a review, or in the course of daily activities, must be immediately reported to VA Police Service, the RO, the Research Service, and other appropriate personnel identified by the facility.

(d) Keycards or other control mechanisms must be coded such that they only allow access to areas the person is authorized to enter.

(e) A record of keycard assignments, including a record of the expiration date, must be current at all times.

1. Keycards must only be valid for the length of time the individual is assigned to the area requiring the keycard and the expiration date of the keycard must be consistent with the expiration date of the individual's appointment or contract. If the individual is a non-citizen whose status must be ascertained yearly, then the keycard may only be valid for that period of time.

2. Personnel leaving VA employment, or no longer working in the VA research laboratory, including WOC appointees and contractors, as well as non-citizens, must adhere to full clearance and checkout procedures. This includes turning in all identifications, passes, keys, keycards, and other access items.

3. Returned keycards and all passwords (to include Information Technology passwords and other passwords) must be deactivated within 24 hours.

4. For keycards that are not returned, an immediate assessment must be made regarding the potential for a breach in security. Once it is determined that a keycard was not returned, it must be immediately deactivated.

5. A process for ensuring that personnel do not share with any other person their unique means of entry into the VA research laboratory (e.g., keycards, password, etc.) must be in place.

6. A process for ensuring that the staff challenge persons who attempt to enter the area immediately behind them without using their own cardkey, or who are not authorized or approved to enter the areas must be in place.

7. Appropriate facility staff must immediately update records to reflect the turn-in of all access items; this must be documented and must include the date and reason for termination.

***NOTE:** Restrictions and guidelines for VA research laboratory access must ensure adequate and sufficient access for the health and safety staff and for authorized inspectors from regulatory agencies and VHA oversight offices. VA research laboratory access restrictions must not preclude or interfere with employee or worker opportunity to report safety concerns or to participate in other protected activities under 10 CFR Parts 19 and 30, the Civil Service Reform Act of 1978, and the Whistleblower Protection Act of 1989.*

(2) The following additional security procedures must be implemented. These are procedures to ensure that only individuals approved to do so may enter and work in BSL-3 research laboratories in which select agents or toxins are not used or stored; and procedures to ensure only authorized individuals (those having an approved Security Risk Assessment) have access to research laboratories that do store or use select agents or toxins. Issues that must be considered include:

(a) All medical center personnel (full-time, part-time, WOC, fee basis), contractors, and others engaged in VA-approved research on a short-term basis, such as students, fellows, residents, and visiting scientists, must wear photo identification badges at all times. Photo identification badges must contain clearly visible valid expiration dates.

(b) Individuals engaged in VA-approved research on a short-term basis that does not allow for full authorization procedures to be completed cannot enter BSL-3 laboratories or other areas where select agents or toxins are stored or used, nor can they use or possess select agents or toxins while at VA, or at approved off-site locations (see subpars. 4j and 7c(2) for more information on obtaining authorization).



(c) Individuals engaged in VA-approved research on a short-term basis cannot enter a BSL-3 research laboratory not containing select agents or toxins if the time is insufficient to obtain a specific approval to enter the BSL-3 laboratory.

(d) A record of access must be kept for all visitors entering secure laboratory areas, including: service providers, Environmental Services, Engineering Service, safety personnel that have not obtained approval to access the laboratories, individuals with specific approval to access a BSL-3 research laboratory, or individuals with obtained authorization to access research laboratories containing select agents or toxins. The record must specify their name, affiliation, purpose for visiting, times of arrival and the person who is escorting the visitor.

1. A valid personal identification containing a photograph of the individual must be provided prior to being admitted to VA research laboratory areas. Badges designated by the facility for visitors must be issued by VA Police Service, or other appropriate security personnel. Visitor badges must be worn at all times, be readily distinguishable from VA employee badges, and be surrendered upon leaving the medical center.

2. Visitor access must be limited to hours when approved or authorized (as applicable) VA employees are present.

3. If a visitor already holds a Security Risk Assessment while working at another facility the visitor may be allowed to work with select agents or toxins if all applicable CDC or APHIS applicable, requirements are met and R&D Committee authorization is obtained.

(e) Visitors must be accompanied and monitored at all times by a VA employee approved to enter the VA research laboratory area. The employee must be specifically-approved to enter the BSL-3 research laboratory or authorized to enter research laboratories using or housing select agents or toxins if the visitor is allowed to enter these areas. This employee is responsible for the visitor's activities and conduct, and for ensuring that the escorted visitor exits the area at the appropriate time.

(f) Deliveries may only be made to designated areas or centralized receiving areas within VA. These are not to include areas in close proximity to laboratories where select agents or toxins are used or stored.

(3) VA research laboratories may be exempted from some physical security and access requirements if they are not used to house or test hazardous agents (as defined herein and identified in App. A).

(a) The extent to which an exemption will be granted is based on Security Risk Assessments and procedures for safety and security that have been implemented for specific VA research laboratory areas.

(b) In order to receive such an exemption, a waiver request from the Medical Center Director must be submitted to and approved by the CRADO, VHA Central Office (see App. B for instructions for requesting a waiver).

**NOTE:** Restrictions and guidelines for security procedures must ensure adequate and sufficient access for the health and safety staff and for authorized inspectors from regulatory agencies and VHA oversight offices. Security procedures must not preclude or interfere with employee or worker opportunity to report safety concerns or to participate in other protected activities under 10 CFR Parts 19 and 30, the Civil Service Reform Act of 1978, and the Whistleblower Protection Act of 1989.

e. **Physical Security.** Physical security of all VA research laboratories and other research areas of the facility housing hazardous agents, including select agents or toxins, must meet appropriate standards determined by the OSLE (see VA Directive and Handbook 0730), regulatory agencies, and/or cognizant VA oversight offices. Prior to purchasing or installing security devices or before construction designed to improve security is begun, the facility's VA Police Service must be consulted. As allowed under current regulations, graded levels of security based on site-specific risks, which includes the chemicals, agents, or toxins stored or used, may be appropriate.

(1) **Security for all VA Research Laboratories.** All VA research laboratories security plans must include the following:

(a) Control of access on a 24-hour, 7 days a week schedule, including weekends and holidays.

(b) Access must be by keycard or a system that is equal to, or exceeding, the security of a keycard system. The system must allow for procedures that permit VA Police Service access to the area during an emergency.

(c) Records of access. The control system must maintain records of access, which must be reviewed weekly and the findings documented. Irregularities identified during a review or in the course of daily activities, must be immediately reported to VA Police Service.

(d) Self-closing doors. All entry doors from non-research areas into the research laboratory areas must be self-closing and secured at all times (see subpar. 7d(1)(e) for additional precautions).

(e) Unobstructed views of the exterior entry.

(f) An intrusion alarm system that is either connected to, or otherwise monitored by, the facility VA Police Service. Video surveillance systems may also be used. **NOTE:** *Video surveillance systems are required for areas in which select agents or toxins are used or stored (subpar. 7e(2)(e) addresses this issue for BSL-3 research laboratories).*

(g) Inspection of all suspicious packages upon entry to and exit from the area. Package means a wrapped or boxed object, parcel, or container in which something is packed. Special caution needs to be taken for all unexpected or suspicious packages and these need to be inspected by visual or non-invasive techniques. Guidelines or procedures for suspicious packages developed by VA Police Service or other police services having jurisdiction are to be followed. At minimum, if the package is suspicious or unexpected:

1. The sender must be contacted to verify that it is legitimate.

2. And is seen being removed from the laboratory then the appropriate authority needs to be immediately notified.

3. The United States Postal Service Guidelines for recognizing suspicious packages must be followed as applicable. **NOTE:** *The Guidelines may be found at <http://www.usps.com>.*

(h) An annual review of facility security standards (see subpar. 7b(2)(q)).

(i) The responsibility of the ACOS for R&D for informing the facility's Police Service of any changes in research affecting a facility security rating.

(j) Implementation plans for all requirements in subparagraph 7d that address physical security systems.

**(2) Security for BSL-3 Laboratories and for Select Agents or Toxins.** For VA BSL-3 research laboratories, regardless if they do or do not contain select agents or toxins, and all VA research laboratories containing select agents or toxin, additional security requirements must be implemented; these include:

(a) BSL-3 laboratories or areas containing select agents or toxins must currently have or immediately implement measures to achieve an equivalent or greater level of security than defined in 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121.

(b) Access to these areas must be through the use of cardkey access or another system that is either equivalent to or offers greater security than a cardkey system.

(c) Access codes or cardkeys may only allow access to areas for which the individual staff person has been approved or authorized.

(d) The means of access (cardkey, etc.) used to enter the other research areas must not allow entrance into these areas.

(e) Video surveillance of the entrance to these areas must be in place.

(f) The time of entrance and egress of staff and visitors from BSL-3 research laboratory areas must be recorded and the records reviewed and maintained as stated in subparagraph 7e(1)(c).

(g) Security for all containers, refrigerators, freezers, cabinets or other areas where select agents are stored must be provided to ensure control at all times. Other additional monitoring measures such as video surveillance may also be used (see VA Handbook 0730 for specific requirements for locks).

(h) BSL-3 research laboratories and research laboratories in which select agents and toxins are stored or used must not be in public areas of the facility.

(i) The BSL-3 research laboratories and research laboratories in which select agents and toxins are stored must be marked as restricted, and must conform with all CDC, OSHA or other requirements, such as hazard warning signs.

(j) If outside windows or windows in doors are present they must be sealed and security mesh screening or another method that is equivalent to or exceeds the security offered by mesh screening for windows, must be installed to prevent unauthorized access. Security mesh for outside windows is not necessary if the location of the windows meet the requirements in VA Handbook 0730.

(k) Access into the areas from overhead areas must be prevented. The means to prevent such access must be equivalent or better than that found in VA Handbook 0730.

(l) Doors, door jams and frames and locking mechanisms for these areas must meet or exceed the requirements found in VA Handbook 0730.

(m) Audible alarms must be installed and monitored. These alarms are for both safety (to indicate emergencies, such as: fire, hazardous materials incident, or the need to evacuate) and to indicate an intrusion. Strobe lights may be installed if an audible alarm cannot be either heard or installed. If after consultation with the facility's Police Service, it is determined that the intrusion alarm needs to be a silent alarm, the justification for such a conclusion must be documented. The documentation must include a determination that the silent alarm offers equal or greater security than an audible alarm would offer.

(n) A telephone must be located in each of these areas.

(o) Security for these areas must also ensure the security of sensitive materials as defined in subparagraph 3g.

(3) Security of hazardous agents, including select agents and toxins (exempt and non-exempt quantities), in VA-leased space, in space leased to others, or in approved off-site space must be ensured and be equal to the security in onsite space. New-leased or off-site space must be reviewed and approved by the facility's Police Service.

(4) Security for exempt quantities of toxins and hazardous agents (listed in App. A, subpar. 2c, or on the ORD website at: <http://www.va.gov/resdev>) must prevent unapproved use or theft. Toxins and hazardous agents must be controlled when they are not in use or in the direct view of an approved individual. Other additional monitoring measures such as video surveillance may also be considered.

f. **VA Research Laboratory Certificate of Registration.** Registration with the CDC or APHIS Laboratory Registration Program must occur before select agents or toxins specified in 42 CFR 73.7, 7 CFR 331.7, and 9 CFR 121.7 or superseding lists, are used in research protocols or otherwise stored in VA research laboratories. Those laboratories possessing only overlap agents and toxins as defined in 42 CFR 73.4 and 9 CFR 121.4 or superseding lists, may register with either APHIS or CDC (42 CFR 73.7(d), and 9 CFR 121.7(d)). This includes VA research laboratories at approved off site locations, VA research laboratories in space leased by VA, or VA-space leased to other entities.

(1) All Certificates of Registration must be maintained and renewed when applicable, as required by CDC or APHIS, if they continue to purchase, use, store or transfer select agents or toxins. *NOTE: HHS regulations regarding registration are to be found at 42 CFR 73.7, and*

*USDA regulations are to be found at 7 CFR Part 331 and 9 CFR Part 121* The registration is valid only for one physical location (a room or a group of buildings) where the RO is able to perform the responsibilities required in this part for specific select agents or toxins and other specific activities that may be required.

(2) The following procedure for applying for a VA research laboratory Certificate of Registration must be followed:

(a) The ACOS for R&D must submit a Letter of Intent (LOI) to ORO with a copy to the CRADO, on behalf of the investigator. This LOI must be submitted through the facility Chief of Staff, Medical Center Director, and VISN Director prior to requesting a select agent laboratory registration number from CDC or APHIS.

(b) The LOI must contain a detailed justification for the use of select agents. It must also include a description of measures ensuring physical security of the select agents or toxins, and a list of all personnel who will be granted access to the select agent.

(c) A site inspection of the research laboratory(ies) involved must be scheduled with ORO. The timing of the site visit will be determined by ORO. No select agents or toxins may be brought onsite prior to this inspection. Violations of this requirement may result in suspension of the projects and withholding of the facility's research funds.

(d) Once the CDC or APHIS registration application is completed, it is then submitted through the ACOS for R&D to the appropriate officials and committees. This includes being reviewed and approved by the local SRS, R&D Committee, Chief or Staff, Medical Center Director, and VISN Director prior to being submitted to VA Central Office for approval by ORO.

(e) Once ORO approves the application it may be forwarded to CDC or APHIS for their approval. If CDC or APHIS does not issue a Certificate of Registration, both ORO and ORD must be notified. Prior to issuance of a Certificate of Registration, the RO must promptly notify CDC or APHIS of any changes that are made to the application. (42 CFR 73.7(e), 7 CFR 331.7(e), and 9 CFR 121.7(e)).

(f) Unless terminated sooner, a Certificate of Registration is valid for a maximum of 3 years (see 42 CFR 73.7(k), 7 CFR 331.7(k), and 9 CFR 121.7(k)).

(3) If a VA research laboratory voluntarily stops conducting activities with select agents or toxins, ORD, ORO, and either CDC or APHIS must be notified; and the Certificate of Registration will be terminated.

(4) A Certificate of Registration must be amended if a change occurs in any information submitted in the application for Certificate of Registration or amendments, including modifications to the list of authorized individuals, changes in the activities involving any select agent or toxin including use of select agents and toxins (42 CFR 73.7(h), 7 CFR 331.7(h), and 9 CFR 121.7(h)).

(5) If for any reason CDC or APHIS initiates the termination of the VA research laboratory's Certificate of Registration, ORO and ORD must be notified by the next working day. Notification must be made by phone and fax.

(6) CDC or APHIS may deny, revoke or suspend a certificate of registration under specific circumstances. These circumstances may be found in 42 CFR 73.8, 7 CFR 331.8, and 9 CFR 121.8. If: a certificate of registration is revoked or suspended, all use of select agents or toxins must immediately stop, and immediate steps must be taken to safeguard and secure each select agent or toxin covered by the revocation or suspension order from theft, loss, or release (42 CFR 73.8(b)(1), (2); 7 CFR 331.8(b)(1), (2), and 9 CFR 121.8(b)(1), (2)). The facility must comply with all disposition instructions issues by CDC or APHIS.

g. **Inventory Controls.** Inventory control includes maintaining an up-to-date record of all select agents, toxins, exempt quantities of toxins, and other hazardous agents in VA research laboratories. It also includes following the applicable regulations for the acquisition, transfer, and destruction of these agents. Each VA facility with research laboratories must develop inventory controls for select agents or toxins, as well as hazardous agents as defined in subparagraph 3d, including exempt quantities of toxins, biological, chemical, gaseous materials, and radioactive materials and/or radioactive sources. Normally, the Radiation Safety Officer maintains accountability for radioactive materials and/or radioactive sources. **NOTE:** *These requirements are in addition to those found in VHA Handbook 1200.8.*

(1) **Inventory List.** A current, complete list of select agents, toxins and other hazardous chemicals, as defined by OSHA and EPA, must be maintained for each VA research laboratory and when required, be made available to the Local Emergency Planning Committee (LEPC) as required by the Emergency Planning and Community Right-to-Know Act (SARA Title III).

(a) The inventories must be updated each time a new chemical or agent is introduced into the VA research laboratory or when other inventory changes occur.

(b) A hazard assessment must be conducted prior to the introduction of a new chemical or agent to determine the impact on the facility's Emergency Preparedness Program and on safety and security.

(c) In accordance with VHA Handbook 1200.8, the facility Safety Officer must review and approve inventories.

(d) These inventories may be conducted by VA research laboratory personnel on a daily, weekly, or monthly basis, but the review by the Safety Officer must be documented and done on at least a semi-annual basis. Issues that must be considered in implementing this policy include: acquisition, transfers, and destruction or disposal of the agent (chemical, biological, or toxin).

(e) The VA investigator is responsible for ensuring that the inventory is reported and for informing the ACOS for R&D regarding inventory changes which may affect the security rating.

(2) **Acquisition of Agents.** The acquisition of these agents may only occur when there is an approved protocol that requires their use and storage.

(a) Prior to initiating the procurement process, the Safety Officer, the SRS and the R&D Committee must approve this action (see Handbook 1200.8 for further information on the approval process). The approval may be included in the approval of the protocol(s) that require the agents, or as a separate request. The approval for procurement must be specifically stated in the R&D Committee minutes.

(b) Procurement actions must be conducted according to the Federal Acquisition Regulation (FAR) and the Department of Veterans Affairs Acquisition Regulation (VAAR). The independent purchase, possession, receipt, or use of hazardous laboratory materials without appropriate authorization is prohibited.

(c) Only VA research laboratories holding a CDC or APHIS Certificate of Registration and a registration number may acquire select agents or toxins.

**(3) Inventory Transfers.** Transfers of inventory must be in compliance with DOT, OSHA, NRC, CDC, U.S. Postal Service, and USDA APHIS regulations. Transfer of any hazardous agents, including, but not limited to, those specifically identified as CDC select agents and toxins and USDA APHIS biological agents and toxins, must be documented as to the identity of the receiver of the materials, where it is being transferred, and the date of the transfer. If a select agent or toxin is involved in the transfer, the material may only be transferred in compliance with applicable regulations (see 42 CFR 73.16, 7 CFR 331.16, or 9 CFR 121.16).

(a) If a select agent or toxin is transferred, the requirements in 42 CFR 73.16, 7 CFR 331.16, or 9 CFR 121.16 must be followed, to include:

1. The sender has a Certificate of Registration (CDC or APHIS) that: covers the transfer of the particular select agent or toxin to be transferred; meets the exemption requirements under 42 CFR 73.5, 9 CFR 121.5, and 7 CFR 331.5, for the particular select agent or toxin to be transferred; or covers the transfer of the select agent or toxin from outside the U.S.

2. The recipient (a VA research laboratory, a VA laboratory or a non-VA laboratory) has a Certificate of Registration that includes the particular select agent or toxin to be transferred.

3. The sender requests authorization from CDC or APHIS through the use of APHIS or CDC Form 2.

4. CDC or APHIS has authorized the transfer based on the finding that the recipient has a Certificate of Registration covering the transfer of the select agent or toxin before the transfer can occur.

5. The sender complies with all applicable laws concerning packaging and shipping and maintains adequate records to show chain of custody for the select agents or toxin.

6. The RO of the recipient institution submits APHIS or CDC Form 2 within 2 business days of receipt of the select agent or toxin.

7. The recipient immediately reports to CDC or APHIS as appropriate, if the select agent or toxin has not been received within 48 hours after the expected delivery time, or if the package

received containing select agents or toxins has been leaking, was otherwise damaged, or if it is suspected a release of the select agent or toxin may have occurred.

8. The authorization for transfer is valid for 30 calendar days, but becomes immediately null and void if any facts supporting the authorization change.

9. If the transfer is within the facility when the sender and the recipient are covered by the same Certificate of Registration, regulations found in subparagraph 7g(3)(a) do not apply. The transfer must occur under the supervision of an individual with an approved Security Risk Assessment and there must be documentation of the chain-of-custody for the select agent or toxin.

(b) The SRS or the R&D Committee, if it acts as the SRS, must approve all transfers of hazardous agents, including select agents, toxins, and exempt quantities of toxins.

(c) If there are extreme time constraints and there is an appropriate justification for the transfer prior to the next R&D Committee meeting, the Chairperson of the R&D Committee or the SRS may approve the transfer. The full SRS and R&D Committee must be notified of the action at their next meeting.

(d) Transfers of radioactive materials and/or radioactive sources, as well as transfers of select agents, toxins, and other hazardous agents, must be reported to the ACOS for R&D prior to transfer.

(4) **Delivery.** Procedures for delivery and the handling of highly-sensitive materials must be adhered to and must be documented. Packages containing specimens, bacterial or virus isolates, or toxins are to be opened in a safety cabinet or other appropriate containment device.

(5) **Hazardous Agents, Including Select Agents, Toxins and Exempt Quantities of Toxins, not Currently in Use.** Agents not currently in use on approved protocols and for which there are no immediate plans for use, must be transferred to another laboratory, destroyed, or disposed of by methods approved in applicable regulations. Upon termination of the use, a select agent or toxin must be:

(a) Securely stored in accordance with the requirements of this Handbook,

(b) Transferred to another registered laboratory (VA or non-VA) in accordance with regulations regarding transfer of agents as found in 42 CFR 73.16, or 7 CFR 331.16, and 9 CFR 121.16. *NOTE: This does not apply to exempt quantities of toxins.*

(c) Destroyed onsite by autoclaving, incineration, or another recognized sterilization or neutralization process. The destruction must be in compliance with the procedures in subparagraph 7g(6) and with all applicable Federal regulations. Chemicals designated for disposal must be reviewed by the facility IH to determine appropriate disposal method.

(6) **Destruction of Select Agents and Toxins Including Exempt Quantities.** Procedures for implementing this destruction at the local level must be established and implemented. These procedures do not apply if during the select agent's use in the research the characteristics of a select agent or toxin are altered so that it no longer meets the criteria for a select agent or toxin,



or if the select agent is destroyed or consumed during and because of the research. This paragraph applies to destruction of those agents no longer required for the research.

(a) Prior to the destruction of hazardous agents, including select agents, toxins, or exempt quantities of toxins, permission must be obtained from the VISN Safety Office through the Medical Center Director, the Facility Safety Manager, the ACOS for R&D, the R&D Committee, and SRS.

(b) Destruction of select agents or toxins must be carried out in accordance with all applicable regulations, including 42 CFR 73.7(h), 7 CFR 131.7(h), and 9 CFR 121.7(h). These regulations require that the Certificate of Registration is to be amended to reflect changes in circumstances including any addition or removal of select agents or toxins. *NOTE: This does not apply to exempt quantities of toxins.*

(c) The destruction of select agents, toxins, exempt quantities of toxins, or highly-sensitive materials must be witnessed and documented by a scientist, or other professionally-qualified individual, not directly associated with the investigator's laboratory, and who has sufficient skills and knowledge to verify that the sensitive materials are destroyed or inactivated.

(d) The process must be carried out to ensure that the material cannot be cultured or a part of it removed without the knowledge of the witness.

(e) The documentation must include the date and means of destruction or inactivation, and must be signed by the VA investigator, by the personnel actually destroying the material, by one witness not directly associated with the investigator's laboratory, and by at least one person from the local research office (i.e., the ACOS for R&D, or designee).

(f) Following destruction of the material, the signed and dated documentation must be forwarded to the local Research Service, the R&D Committee, and the facility Safety Officer.

(g) Destruction of hazardous agents other than select agents and toxins (non-exempt or exempt quantities) must follow requirements found in subparagraphs 7g(6)(c)-7g(6)(e). The facility's Safety Officer, IH, or VISN IH need to be consulted to ensure the appropriate method of destruction.

h. **Emergency Preparedness and Incident Response.** Each VA facility with research laboratories must develop and implement an emergency preparedness and response plan. This plan must be reviewed and updated annually, and must address research laboratories at approved off-site locations, VA research laboratories in leased space or space leased to others.

(1) The plan must include all elements required by OSHA in 29 CFR 1910.120, 29 CFR 1910.38, 29 CFR 1910.39, and by VHA in the VHA Emergency Management Program Guidebook, and VHA Handbook 1200.8.

(2) The Research Service emergency preparedness and incident response plan must be coordinated with the facility's plan.

(3) The plan must address:

- (a) All types of threats or emergencies. These may include fires; explosions; spills; release of chemicals, biological agents, toxins or radioactive material; bomb threats; severe weather (i.e., hurricanes, floods); and other natural disasters or emergencies.
- (b) Planning and coordination with outside parties such as first responders. If the laboratory is in an approved off-site location or in leased space, the plan must be coordinated with the plan for the building where the laboratory is located.
- (c) Emergency recognition and prevention.
- (d) Personnel roles, lines of authority, training, procedures for accounting for all employees, and communication.
- (e) Hazards associated with the use of hazardous agents, including select agents or toxins and those identified by OSHA (see 29 CFR 1910.1450).
- (f) Hazards associated with response actions that could lead to a spread of the hazardous agent, including a select agent or toxin.
- (g) Special procedures needed to address the hazards of special agents.
- (h) Emergency alerting and response procedures.
- (i) Safe distances and places of refuge.
- (j) Site security and control for both research laboratories on the VA campus and for off-site locations, as well as security of all hazardous agents including select agents and toxins.
- (k) Evacuation routes and procedures.
- (l) Emergency evacuation plans for all facilities with consideration of the impact on the evacuation route of agents and materials used in VA research laboratories.
- (m) Emergency medical treatment and first aid.
- (n) Personal protective and emergency equipment.
- (o) Decontamination.
- (p) Actions to be taken in the event of an intentional release of chemical or biological material to the atmosphere, wastewater system, or immediate environment.
- (q) Critique of response and follow-up.
- (r) Procedures for reporting of theft, loss, or release of select agents or toxins, including: the sequence of reporting; the individual responsible for the reporting; the type of notification (oral, written, electronic, etc.); the timeframe for reporting, and the required documentation. **NOTE:** *APHIS or CDC must be immediately notified by facsimile, e-mail, or telephone and an APHIS or*

*CDC Form 3 must be completed within 7 calendar days if the theft, loss or release involves a select agent or toxin.* The documentation requirements include, but are not limited to:

1. Description of the event.
2. Notification (who was notified, by what means and when).
3. Outcome of the event.
4. Results of the post-incident vulnerability assessment, including findings and corrective actions that must be or have been implemented.

5. If the release of a select agent or toxin causes an occupational exposure or a release outside the primary barriers of the biocontainment area CDC or APHIS must be immediately notified.

(s) Procedures for notification of the VISN Director, ORD, ORO, and the Assistant Deputy Under Secretary for Health.

(4) Other issues to include in the plan are:

(a) A provision for providing a listing of all Hazardous Agents in VA research laboratories to the LEPC and participating with their emergency drills and activities.

(b) A Spill Prevention Control and Counter Measures (SPCC) plan specifically addressing VA research laboratories.

(c) A description of the facility response to an intrusion alert, including provisions for nonstandard duty hours, nights, and holidays.

(d) A facility designee who can be contacted at all times.

(e) A designee from the Research Service that can be contacted at all times.

(f) A response cascade with contact names, phone numbers, and other contact information listed.

(g) Procedures for ensuring protection of sensitive materials and equipment during an illegal intrusion or activity. **NOTE:** *These procedures are to include the role of police and research personnel.*

(h) Lock down procedures of the facility to:

1. Protect patients, visitors, and personnel; and
2. Prevent theft or destruction of sensitive materials or equipment.

(i) Emergency preparedness drills to be conducted annually.

(j) Initial and annual vulnerability assessments of all facility research laboratories by a multidisciplinary team consisting of local research personnel, a representative from VA Police Service, the facility Safety Officer, Safety Manager, Radiation Safety Officer, and/or IH. Vulnerability assessments must also be conducted after any incident. This assessment is to identify high-risk areas, sensitive materials, and physical security issues.

1. Assessments must include, but are not limited to: physical security (doors, windows, wall openings, ceilings, partitions); access security (keys, badges, keycards, codes, etc.); utility system security (electricity, ventilation, water, wastewater); security of hazardous agents; and information security (information technology (cyber) or hard copies).

2. The results of the assessment must be provided to the local SRS, the R&D Committee, and the RO.

3. All vulnerabilities identified during the assessment must be eliminated and the steps taken to eliminate the vulnerabilities documented.

4. Training of facility personnel must reflect the assessment by addressing all aspects of responding to intrusions and/or terrorist events, including security awareness training, and emergency procedures to detect and safely respond to unauthorized individual(s) in research laboratory areas.

(5) The plan must be reviewed at least annually and revised as appropriately.

(6) Drills or exercises to test and evaluate the effectiveness of the plan must be held at least annually. The plan must be revised when the results of the drill or exercise indicates such a need.

i. **Training Requirements.** All individuals (VA employees appointed as full-time, part-time or intermittent paid employees, WOC, and fee basis employees, as well as contractors) working in VA research laboratories, those working with hazardous agents including select agents or toxins, those working within BSL-2, BSL-3, or BSL-4 laboratories, and all individuals directly administering these VA research laboratories must be appropriately trained to ensure both safety and security within research laboratories and the safe handling of, and the security of, select agents, toxins, or other hazardous agents. The training must include training on the Laboratory's Emergency Preparedness and Response Plan. Information and training on safety and security must be provided to individuals visiting areas where select agents and toxins are handled or stored.

(1) ORD, in consultation with the Under Secretary for Health, identifies specific training requirements; these training requirements must include:

(a) General information on safety and security within VA research laboratories, as well as safety, security, containment, and transferring of hazardous agents, including select agents or toxins.

(b) Specific information related to the laboratory in which they will work and to the agents with which they will work.

(c) Training requirements set forth by OSHA, CDC, other applicable Federal agencies and other VA policies.

(2) The RO must ensure that all required personnel complete such training and its completion must be documented.

(3) All new research staff and new administrators (e.g., ACOS for R&D, AO R&D, supervisors, managers) responsible for VA research laboratories, including those using or storing hazardous agents (including select agents or toxins), must complete the required training prior to assuming their duties.

(4) All individuals must receive additional training prior to assignments with new exposure situations or when security systems and procedures are changed.

(5) All unauthorized (without an approved Security Risk Assessment from the Secretary HHS or USDA) individuals requiring escort and monitoring to enter areas containing select agents or toxins must be provided information and training on safety and security to ensure they understand the hazard the agents represent and do not cause a security breach. These individuals may be either visitors or personnel who must enter the area to complete their duties, e.g., employees of Environmental Management Service and Engineering Service.

(6) All individuals who are required to obtain initial training or have been certified by the RO as having the appropriate knowledge to work in VA research laboratories must obtain refresher training annually.

(7) The RO or ARO(s) must maintain training records for both the initial training and all annual refresher training. This includes the identity of the individual, the date of training, and the means used to verify that the employee understood the training. A notation must be made in the training log regarding individuals that were certified by the RO under subparagraph 7i(4). The written certification for these individuals must also be maintained on file.

j. **Record Keeping**. The RO or ARO(s) must complete records relating to the activities covered by this Handbook.

(1) Records must include:

(a) An up-to-date, accurate list of all individuals approved to work within or enter VA research laboratories unescorted, and all individuals authorized to enter or work in laboratories using or storing select agents or toxins. The record needs to specifically identify individuals with approved security risk assessments under 42 CFR 73.10, 7 CFR 331.10, or 9 CFR 121.10 for access to select agents or toxins.

(b) An accurate, current inventory of all hazardous agents, including select agents, toxins, and exempt quantities of toxins within the facility. These records must be secured from unauthorized access, but must be available during an emergency. For select agents or toxins, the inventory must include:

1. Name, characteristics, source data, purpose or use, and location of storage.

2. The quantity held on the date of the first inventory (for toxins only).
3. The quantity acquired, the source, the date of acquisition, and the total held.
4. The quantity, volume, or mass-destroyed, or otherwise disposed of; the mechanism of disposal; the date of each such action; and the name of the witness to the destruction.
5. The quantity used and date(s) of the use (for toxins only).
6. The quantity transferred, the date of transfer, and individual to whom it was transferred. This includes transfers to other persons or other laboratories (VA or non-VA) within the facility. This must be recorded even when the sender and receiver are covered by the same Certificate of Registration.
7. The current quantity held (toxins only).
8. Any select agent or toxin lost, stolen, or otherwise unaccounted for.
9. A written explanation of any discrepancies.

(c) Information on access to each select agents or toxins must include the:

1. Name of each individual who has accessed any select agent or toxin.
2. Select agent or toxin used.
3. Date when the select agent or toxin was removed, if removed from long-term storage or holdings for stock cultures.
4. Quantity removed (toxins only).
5. Date the select agent or toxin was returned to the long-term storage, or holdings, or holdings for stock cultures.
6. Quantity returned (toxins only).

(d) Information on access to the areas where select agents or toxins are used or stored. This must include the:

1. Name of each individual who has access to the area.
2. Date and time the individual entered the area.
3. Date and time the individual left the area.
4. The name of the authorized individual approved under 42 CFR 73.7, who accompanied the unapproved individual (for individuals not approved under 42 CFR 73.7). **NOTE:** *Persons having a Security Risk Assessment approved under 42 CFR 73.10 must also be authorized by the Medical Center Director (see subpar. 4g(1)).*

(e) Training Records.

(f) Safety and Security Incident Reports. Safety and Security Incident Reports including:

1. All safety and health Notices issued by OSHA; the VISN; and the facility safety, health, fire protection, security, and infection control staff.

2. All incidents reported to the VISN and VA Central Office.

(2) A mechanism must be implemented to ensure that all records (written, computer databases, spreadsheets, etc.) are accurate and one which allows for the authenticity of these records being verified.

(3) A record must be kept of all inspections of the VA research laboratories covered by this Handbook, including:

(a) Inspections by authorized entities such as CDC, VA OIG, USDA, GAO, ORD, ORO, the VA facility, and VISN Safety and Health officials.

(b) All inspections of the VA research laboratories required by subparagraph 4h(2)(g) and subparagraph 7a(7).

(4) A record of all findings, deficiencies and corrective action based on the inspections listed in subparagraph 7j(3) must be maintained.

(5) All safety, security, and emergency response plans (including a record of when last reviewed, the mechanism used to disseminate the plan, and new changes to the affected research staff) must be maintained and available for inspections.

(6) Transfer documents (APHIS and CDC Form 2) and permits.

(7) Records of distribution of keycards, passwords, etc., including the date distributed, the person receiving it, and the date of termination or return of it.

(8) Access and, if applicable, egress records and the results of the weekly review of the records.

(9) Records related to any review of visa status for employees that are not U. S. citizens.

(10) Copies of applicable current policies and procedures.

(11) Records must be maintained for a minimum of 5 years.

## **8. ANNUAL REVIEW OF PROGRAM COMPONENTS OR ACTIONS**

The following components need to be reviewed on an annual basis.

a. Training records and requirements (see subpar. 7i(8)).

b. Inspection of laboratories as required under subparagraph 4h(2)(g) and 7a(9).

- c. The safety (Biosafety) plan (see subpar. 4h(2)(h) and subpar. 7a(6)).
- d. Safety (Biosafety) inspection (see subpar. 7a(9)).
- e. Security plan (see subpar. 7b(2)(p)). *NOTE: The security plan must also be reviewed after each incident.*
- f. Vulnerability assessment and results (see subpar. 4h(2)(i) and subpar. 7h(5)(j)).
- g. Emergency response plan (see subpar. 7h).
- h. Emergency preparedness and response drill (see subpar. 7h(5)(i)).
- i. Visa status of non-citizens (see subpar. 7c(3)(b)).
- j. Status of WOCs (see subpar. 7c(7)).

## 9. REQUIRED SEMI-ANNUAL REVIEW

A semi-annual review is required regarding the:

- a. Inventory of Hazardous Agents, including select agents and toxins (see subpar. 4k(2)(c), 4k(2)(d), and 7g(1)(d)).
- b. Status of those persons approved to enter VA research laboratories and those holding authorizations to enter areas where select agents or toxins are stored or used (see subpar. 4j(3)(b)3 and subpar. 7c(2)(f)).

## 10. REFERENCES

- a. Public Law 107-188, Public Health Security and Bioterrorism Preparedness and Response Act of 2002.
- b. Title 18 U.S.C. § 175b.
- c. Title 5 CFR Parts 731 and 736.
- d. Title 7 CFR Part 331.
- e. Title 9 CFR Part 121.
- f. Title 10 CFR Parts 19 and 30, the Civil Service Reform Act of 1978, and the Whistleblower Protection Act of 1989.
- g. Title 29 CFR Parts 1910.38, 1910.120, 1910.1450 and 1960.
- h. Title 39 CFR Part 111, incorporating by reference the Domestic Mail Manual (DMM), CO24 – Hazardous Materials.
- i. Title 42 CFR Parts 72 and 73.



- j. Title 49 CFR Parts 171-178.
- k. CDC-NIH. "Bio-safety in Microbiological and Biomedical Laboratories," 4<sup>th</sup> edition.
- l. NIH Guidelines: "Recombinant DNA and Gene Transfer," April 2002.
- m. VA Directive and Handbook 0710.
- n. VA Directive and Handbook 0730.
- o. VA Handbook 5005.
- p. VHA Handbook 1100.19.
- q. VHA Handbook 1200.7.
- r. VHA Handbook 1200.8.
- s. VHA Handbook 7701.1.

(Date)

## HAZARDOUS BIOLOGICAL AND CHEMICAL AGENTS

1. The Centers for Disease Control and Prevention (CDC) has identified certain biological, chemical and radioactive materials or agents as having potential for use as weapons by terrorists. Improper use and/or containment of these materials or agents pose a risk to national security because of their:

- a. Ease of dissemination or transmittal between individuals;
- b. Potential for high mortality rates and major public health impact;
- c. Potential for causing public panic and social disruption; and
- d. Risk for public health preparedness.

2. Storage and/or use of these materials or agents in any quantity in a Department of Veterans Affairs (VA) research laboratory requires special consideration for physical security, personnel access, inventory control, and emergency preparedness. These include:

a. **Select Agents and Toxins.** A current list of select agents and toxins may be found at <http://www.CDC.gov/od/sap>. This site also includes agents and toxins that are included on the United States Department of Agriculture (USDA) list of biological agents and toxins that overlap with the CDC list. This website contains:

(1) A list of toxin amounts (exempt quantities) permissible for an investigator to store or use without requiring compliance with Title 42 Code of Federal Regulations (CFR) 73; and

(2) A list of agents and toxins that have been excluded from the list of select biological agents and toxins.

b. **List of USDA Biologic Agents and Toxins.** A list of USDA biologic agents and toxins may be found at: <http://www.aphis.usda.gov/>.

c. **Chemical Agents Considered to be Hazardous Agents.** The following chemicals are **considered** hazardous agents. *NOTE: This list may be updated in the future and updates will be found on the Office of Research and Developments website: <http://vaww1.va.gov/resdev/>.*

- (1) 3-quinuclidinyl benzilate (BZ);
- (2) Chlorine gas;
- (3) Cyanogen chloride (CK);
- (4) Cyclosarin (GF);
- (5) Diphosgene (DP);
- (6) Hydrogen cyanide (AC);

(7) Lewisite (L); *NOTE: There are three individual chemicals included in this category, L-1, L-2, and L-3.*

(8) Lysergic acid diethylamide (LSD);

(9) Nitrogen mustard (HN-1, HN-2, or HN-3);

(10) Phosgene (CG), also known as carbonyl chloride;

(11) Phosgene oxime (CX);

(12) Sarin (GB);

(13) Soman (GD);

(14) Sulfur mustard (H, HD, or HT), also called mustard gas or mustard agents;

(15) Tabun (GA); and

(16) VX (VX is both the name and symbol).

d. **Radioactive Materials and/or Radiation Sources**

(1) The special considerations required for radioactive materials and/or radiation sources need to be based on the specific radionuclide, the half-life, and the quantity present.

(a) For a “radiation high-risk” situation, more restrictive security measures need to be followed. “Radiation high-risk” is a single location or room where the total activity of a single radionuclide with a half-life of more than 3 days is greater than one Curie, and the radionuclide is received, store, or used.

(b) For a “radiation low-risk” situation, basic security measures need to be followed. “Radiation low-risk” is any location other than a “radiation high-risk” location and where radioactive materials and/or radiation sources are received, stored, or used.

(2) Security measures for radioactive materials and radiation sources must be commensurate with possible risks from unauthorized use or removal from VA custody and ensure compliance with applicable regulations, policies, and guidelines. *NOTE: Applicable regulations, policies, and guidelines include 10 CFR Parts 19 and 20, VHA Handbook 0730, and VHA Handbook 1105.1*

(3) Security measures must be a joint effort among the VA Police Service, the local Radiation Safety Committee, the Radiation Safety Officer, and research staff. The National Radiation Safety Committee and National Health Physics Program have oversight for the use of radioactive materials and/or radiation sources.

e. **Changes in biological and chemical agents considered to be Hazardous Agents**

(1) As additional agents or materials are identified by the CDC, those agents or materials will be considered by VA as hazardous agents, and will be subject to the same security requirements as those agents or materials identified in preceding subparagraph 2c.

(2) As additional materials are identified by the Veterans Health Administration (VHA) as Hazardous Agents the list on the VHA R&D website (<http://vaww.va.gov/resdev/>) will be updated and all applicable requirements for Hazardous Agents as defined in this Handbook apply.

**INSTRUCTIONS FOR PREPARATION AND SUBMISSION OF REQUESTS FOR  
EXEMPTION TO SPECIAL SECURITY CONSIDERATIONS FOR VA RESEARCH  
LABORATORIES**

The Department of Veterans Affairs (VA) research laboratories may be exempted from some physical security requirements per paragraph 7d(3) of this Handbook. The following paragraphs contain information on how to request a waiver from the Chief Research and Development Officer.

**1. Format.** Applications need to consist of single-spaced typed pages. Use only letter-quality print. The font size should be at least eleven point, with no more than fifteen characters per inch and no more than six lines per inch.

**2. Content.** Each application should consist of the following materials:

a. A cover sheet listing the following information in the order specified:

(1) Laboratory Security Waiver Request.

(2) VA medical center name and address.

(3) Location of laboratory(ies) for which waiver is requested, including:

(a) Laboratory location (VA medical center, VA-leased space, or off-site).

(b) Building and room number.

(4) VA Laboratory Director (name and degree of investigator).

(5) Does the facility have a Biosafety Level (BSL)-3 laboratory? If so, identify the BSL-3 location. Describe the proximity of the BSL-3 laboratory to the research laboratory for which the waiver is requested.

(6) Are any hazardous agents, including select agents and toxins (as identified in App. A), housed in any laboratory within the facility? If so, identify the agent(s) or material(s), investigator(s) using the agent(s) or material(s), and identify laboratory location and proximity to the laboratory for which the waiver is requested.

(7) Name, title, and signature of the Associate Chief of Staff for Research and Development.

(8) The following statement, followed by the name, title, and signature of the Medical Center Director: "I certify that the information contained in this request for exemption to special security considerations for VA research laboratories is accurate and complete."

b. A narrative describing the following:

- (1) The requirement(s) for which the waiver is being requested and the specific laboratory(ies) for which it is being requested. Specifically reference the requirement by paragraph and subparagraph in this Handbook.
- (2) A brief description of research conducted in the laboratory. Include general overview, specific biological or chemical agents, or radioactive materials and/or radiation sources used.
- (3) A discussion of security accommodations and procedures for the overall VA medical center or other facility and those for the research area of the building. Include a description of access control procedures, screening of personnel, and emergency preparedness.
- (4) A discussion of the proximity of the laboratory area(s) in relation to patient care facilities. What security measures are in place to ensure that wandering patients and/or visitors do not inadvertently enter laboratory areas? Would increased laboratory security measures adversely affect patient care?
- (5) A discussion of any specialized security accommodations and procedures for the laboratories within the facility that house hazardous agents (as identified in App. A). Include a description of special access control procedures, screening of personnel, and emergency preparedness. If no hazardous agents (as identified in App. A) are used at the facility, so state.
- (6) Discussion of the financial, staffing, and other logistical ramifications for the facility if the request for waiver is denied.
  - c. A floor plan on 8.5" x 11" paper with the location of the laboratory(ies) for which an exemption is requested.

3. **Due Dates.** Requests may be submitted at any time. VA medical centers are encouraged to submit consolidated requests rather than separate requests for individual laboratories.

4. **Mailing Address.** Applications are to be mailed to the following address:

Department of Veterans Affairs  
Office of Research and Development (12)  
810 Vermont Ave., NW  
Washington, DC 20420