SECURITY AND CONTROL OF HAZARDOUS AGENTS IN RESEARCH LABORATORIES

1. PURPOSE: To establish policy regarding the security and control of hazardous agents in the laboratories of Research & Development Service.

2. **POLICY:** Research laboratories will be secured in keeping with the intent and scope of VHA Handbook 1200.6, which outlines prevention and/or detection of terrorist events and policy for housing select agents and toxins in VA research laboratories. The policy applies to all individuals entering the secured area, to include VA employees, without compensation (WOC) employees, contract employees, oversight entities, vendors, employees from other VA services, and visitors.

3. RESPONSIBILITIES:

- a. The **Medical Center Director**, or designee, is responsible for:
 - (1) Granting requests for authorization for access to research areas; and
 - (2) Ensuring adequate staffing and resources are available to comply with this MCM.

b. The Associate Chief of Staff for Research (ACOS/R), by and through the Administrative Officer for Research (AO/R), is responsible for:

(1) Developing and implementing appropriate security policies; and

(2) Ensuring that the Director remains informed of all activities involving hazardous agents, select agents, toxins and other sensitive materials in VA research laboratories.

c. The **Human Resource Management Service** is responsible for:

(1) 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;

(2) Initiating the appropriate background investigations;

(3) Reviewing applications for employment for citizenship and visa status; and

(4) Communicating the results of background checks to the AO/R in a timely manner.

- d. The **Police Service** is responsible for:
 - (1) Assisting with security of research laboratories;
 - (2) Providing emergency response;
 - (3) Conducting an annual security vulnerability assessment;

(4) Acting as a resource to the R&D Service in the creation and monitoring of security policies; and

(5) Monitoring security compliance by walking through the secured area once per day during normal working hours.

e. The **Subcommittee for Research Safety**, which reports to the **Research & Development Committee**, is responsible for:

(1) Reviewing and making recommendations to the Director for approval or disapproval of requests to grant authorization for access to laboratories, including laboratories using or storing select agents or toxins;

(2) Reviewing the status of personnel granted access to VA research laboratories at least semi-annually;

(3) Reviewing and approving requests for a CDC or APHIS laboratory registration number; and

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

f. VA Investigators, Laboratory Directors, Research Investigators and

Research Staff, regardless of appointment status, are responsible for:

(1) Complying with all provisions of this policy;

(2) Obtaining appropriate authorizations and approvals prior to beginning work in VA research laboratories;

(3) Ensuring that those individuals they supervise have received approval to access laboratories prior to beginning work;

(4) Ensuring that their staff have received required training;

(5) Complying with information specific to the hazardous nature of materials they will be using and the security precautions to be followed in handling, transferring or destroying such materials, as well as containment procedures;

(6) Reviewing and accounting for inventory of hazardous agents including select agents or toxins on a semi-annual basis and forwarding to the R&D Committee through the Subcommittee on Research Safety; and

(7) Reporting theft, loss or release of select agents or toxins as outlined in VHA Handbook 1200.6.

4. **PROCEDURES**:

a. **Definitions:**

(1) **Approved Individual:** A VA employee appointed on a full time, parttime, intermittent, fee basis, or without compensation (WOC), that has undergone credentialing and a background check required for appointment to a Title 5 or Title 38 position, or as a WOC. An approved individual may also be a contractor who has undergone the required credentialing and background check. (2) **Authorized Individual:** A VA employee appointed on a full-time, parttime, intermittent, fee basis, or WOC, that has undergone credentialing and a background check required for appointment to a Title 5 or Title 38 position or as a WOC. In addition, the individual has an approved security risk assessment as required in 42 CFR 73.8, 7 CFR 331.10, or 9 CFR121.11. 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.

(3) **Compensated Work Therapy (CWT) Individual:** A patient who is participating in the Compensated Work Therapy (CWT) Program (offered by the Mental Health Division) as an employee of the Medical Center as part of his/her therapy. The credentialing and background check requirements for these individuals are currently under development. VHA Directive 0710 provides the opportunity for station level exemption of individuals provided the employment is consistent with the interests of national security. Specifically, these individuals may not have access to Patient, Employee, or Fiscal data without having the appropriate level of background check. Employment of these individuals will be only in the Veterinary Medical Unit where this level of control and oversight can be achieved.

(4) **Exempt Quantities:** 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 <u>http://www.cdc.gov/od/sap/</u>.

(5) **Hazardous Agent:** A biological material including the CDC list of select agents and toxins (Download CDC Select Agent Regulations (42 CFR Part 73)), APHIS biological agents (Download APHIS Select Agent Regulations (7 CFR Part 331)), (Download APHIS Select Agent Regulations (9 CFR Part 121)), and products of such biological material, i.e. toxins. Hazardous agents also includes highly toxic chemicals, exempt quantities of toxins, or gases that have the potential for being used as weapons of mass destruction, as well as radioactive materials and/or radioactive sources (Attachment 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 will be posted on the ORD's website. A notice will be sent to all facilities when agents have been added to or deleted from the list. The terms select agents and toxins refer to both the CDC select agents and toxins and the APHIS biological agents and toxins.

(6) **Minor:** Any individual under the age of 18. In order to be considered for a particular position or placed on a without compensation appointment, applicants must be

- (a) at least 18 years old, or
- (b) at least 16 years old and

i. Have graduated from high school or been awarded a certificate equivalent to graduating from high school; or

ii. Have completed a formal vocational training program; oriii. Have received a statement from school authorities agreeing with their preference for employment rather than continuing their

education; or iv. Be currently enrolled in a secondary school and either work only during school vacation periods or work part-time during the school year under a formal student employment program.

(c) Minors may be employed for unlimited hours in any occupation other than one declared to be hazardous by the Secretary of Labor. Positions declared to be hazardous are any occupations involving exposure to radioactive substances and to ionizing radiation (ionizing radiations shall mean any alpha and beta particles, electrons, protons, neutrons, gamma, and X-ray and all other radiations which produce ionizations directly or indirectly, but does not include electromagnetic radiations other than gamma and X-ray). The following occupations are prohibited:

i. Any work in any workroom in which (workroom includes the entire area bounded by walls of solid material and extending from floor to ceiling):

 radium is stored or used in the manufacture of selfluminous compound (self-luminous compound means any mixture of phosphorescent material and radium, mesothorium, or other radioactive element);

- self-luminous compound is made, processed, or packaged;
- self-luminous compound is stored, used or worked upon;
- incandescent mantles are made from fabric and solutions containing thorium salts, or are processed or packaged;
- ii. Any other work which involves exposure to ionizing radiations in excess of 0.5 rem per year.

(7) **VA Research Laboratories:** Research laboratories under the control of VA. In the context of VHA Handbook 1200.6, the VA research laboratory director is the VA investigator responsible for a particular laboratory. VA research laboratories include:

(a) VA research laboratories located within VA facilities, or in leased space;

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

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

(8) **Select Agent:** One of a group of agents (viruses, bacteria, rickettsiae, fungi, toxins, and recombinant deoxyribonucleic acid (DNA)) designated by the 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." Select agents and hazardous agents are synonymous, and are to be handled at the same level of security. The terms select agents and toxins also refers 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). Refer to:

(a) Attachment A for a list of hazardous agents;

(b) CDC's website (<u>http://www.cdc.gov/od/sap/</u>) for select agents and toxins; and

(c) APHIS website (<u>http://www.aphis.usda.gov/</u>) for a list of regulated biological agents and toxins.

(9) **Sensitive Materials** include, but are not limited to, any hazardous agents as identified in Attachment A, as well as 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.

(10) **Terrorist Event:** The unauthorized removal or theft of hazardous agents capable of being used as weapons of mass destruction from VA research laboratories, or other VA-assigned space including off-site space) 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. 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. The term may also refer to activities such as dissemination, detonation, and contamination of hazardous

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agents, select agents, toxins or sensitive materials within VA research laboratories or the building housing these laboratories.

(11) **Toxin**: The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and 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 (refer to 42 CFR 73.1).

(12) **USA Patriot Act:** Public Law 107-56, 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 also 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:

(a) Is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;

(b) Has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;

(c) Is a fugitive from justice;

(d) Is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802);

(e) Is an alien illegally or unlawfully in the United States;

(f) Has been adjudicated as a mental defective or has been committed to any mental institution;

(g) 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;* and/or

(h) Has been discharged from the Armed Services of the United States under dishonorable conditions.

(13) **Weapons of Mass Destruction** include any of the classes of hazardous agents as defined in subparagraph 3d and identified in Appendix A, or combinations of these agents that are capable of inflicting morbidity and mortality on a widespread basis.

b. Inventory Control:

(1) VA Investigators are responsible for maintaining continuous updated inventory of hazardous agents in their research laboratories.

(2) The Subcommittee for Research Safety is responsible for a semi-annual review of these inventories and reports this information to the R&D Committee semi-annually.

c. **Physical Security:**

(1) Access to research laboratories is controlled and limited to authorized individuals. No research laboratories will be open to the public. All laboratory areas, including the VMU and storage areas, include a state-of-the-art electronic Personal Identity Verification (PIV) card that generates permanent, dated records with identification of persons entering the area and times of entry. Entry is controlled on a 24-hour/7-day per week schedule.

(2) PIV cards are issued by the Research & Development Service to allow entry of authorized personnel into the secured areas.

(3) A record of PIV card assignments is current at all times. Personnel leaving employment or no longer working in the research laboratory must adhere to full clearance and checkout procedures to include turning in all identifications, keys, PIV cards and other access items.

(4) Authorized health and safety inspectors, emergency response staff, Police Service, inspectors from regulatory agencies, and personnel from VHA oversight offices will have access to the secured area. The nature of that access will be determined on a case-by-case basis, based upon the frequency of access needs, the potential urgency of access needs, and the potential for after-hours access needs.

(5) CWT employees may be provided with a PIV card provided that the access is limited to the Veterinary Medical Unit (VMU) facility located on the 6th floor of Building 101. Limiting access to this facility prevents unsupervised access to expanded hospital and laboratory space where access to sensitive patient, employee, or fiscal data may be stored.

d. Cyber Security

(1) All individuals who request access to the VA computer system must become an either a paid or non-paid (without compensation, WOC) employee of the PVAMC.

(2) Once this status has been obtained, Human Resource Management Service notifies Technology and Information Management Service which provides appropriate level of computer access.

(3) CWT employees will not be provided with access to the VA computer system.

e. Access Control

(1) The Research Service, as a designee of the Subcommittee for Research Safety, will grant authorized access to secured research laboratory areas.

(2) The process of obtaining authorization to enter the secured area begins with the Principal Investigator (PI). The PI or designee must accompany the new staff member to the Research & D Service administrative office.

(3) Depending upon type of employment, i.e. VA, non-profit corporation, university affiliate, or volunteer, each individual requiring access to the secured area must complete the required paperwork as outlined at http://www.visn20.med.va.gov/portland/research/p-i-services/hiring/appointment-requirements.htm#checklists.

(4) Criteria and elements to be considered when granting approval: acceptable and work-related need to be in secured area; certification that individual is not prohibited person; Application and PI Request completed; copy of photo ID (drivers license preferred); statement of U.S. citizenship OR copy of current and legal permission to be in U.S.; positive results from criminal record check; age of the individual requesting access; and verification that required training has been completed.

(5) The Subcommittee on Research Safety must review the continued status of staff access annually. The Subcommittee for Research Safety must approve renewal of staff access to laboratories housing hazardous materials semi-annually with concurrence/approval required by the R&D Committee. Factors that will be considered when addressing requested renewal include:

- (a) the number and nature of security exceptions by the individual;
- (b) whether required training is current; and

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(c) security-related information deemed pertinent to the Subcommittee for Research Safety.

f. Background and Security Clearances:

(1) 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. In addition, 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 using or housing select agents or toxins, a formal authorization must be obtained prior to beginning work in this laboratory. 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.

(2)Prior to beginning work in a VA research laboratory, Human Resources Management Service will verify the person's credentials. HRMS will 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 for all paid and nonpaid VA employees who work in R&D Service. HRMS will submit both a Standard Form (SF)-83 and fingerprints to the Office of Personnel Management for all employees who will have access to the P-3 Facility. HRMS will notify Security Investigation Center (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. The VA research laboratory director or ACOS for Research 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 unescorted and begin work. The ACOS for Research must recheck to see if the background investigation has been completed and a suitability determination made according to VA and other Federal regulations. 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.

(3) CWT patients are exempted from the background check in accordance with VHA Directive 0710.01. Screening of these patients will be performed by Mental Health Services in accordance with VHA Handbook 1103.01. The

Veterinary Medical Officer or ACOS for Research must verify that this has been done.

g. Requirements after Entry has been Authorized:

(1) All authorized individuals must wear their VA identification badge at all times.

(2) Personnel may enter the secured area only to perform required duties.

(3) Unauthorized persons entering the secured area will be reported to Police Service.

- (4) It is the responsibility of each authorized individual to:
 - (a) Use their PIV card only for personal entrance into the secured area.
 - (b) Not allow any individual to follow them through the door.
 - (c) Report any security violations, including unauthorized individuals

(d) Turn in their PIV card immediately when laboratory access is no longer necessary.

(5) Prohibited persons will be not granted access to the Biosafety Level Three (BSL3) laboratory, the VMU or the cesium source irradiator. Prohibited persons may be granted access to the general secured area on a case-by-case basis, as approved by the Subcommittee for Research Safety with concurrence of the R&D Committee.

(6) Each individual must receive training in: Security Policies & Procedures; Emergency Procedures; and Lab Safety Procedures. Research Administration will maintain verification of training.

h. Administration:

(1) The Subcommittee for Research Safety will make recommendations to the R&D Committee in relation to approval of secured area access. The R&D Committee makes final approval in regard to access approval. The Subcommittee for Research Safety may grant conditional access to the secured area if the individual has met all of the requirements of authorized personnel.

(2) Irregularities in security access will be reported to the Police Service and the Subcommittee for Research Safety, who will make recommendations for action to the R&D Committee and/or the Director.

(3) In the event an individual with secured access inexplicably disappears, is suspected to have violated procedures, or committed a security breach Police

Service must be notified immediately. The VA Police in consultation with the ACOS for Research will determine whether further action is necessary.

(4) The ACOS Research, or designee, will conduct a review of access records on a monthly basis. Each month a random sample will be pulled reviewed, and maintained for review and trending of results. Irregularities will be reported to Police Service.

(5) Police Service will conduct an annual vulnerability assessment of the Research Laboratory area. The AO/R&D is responsible for informing Police Service of any issues affecting security.

(6) **Safety Standards:** All individuals given authorized access to the laboratory area must abide by all safety standards as mandated by Occupational Safety and Health Administration, Veterans Health Administration, and PVAMC.

(7) **Emergency Preparedness Standards:** All individuals given authorized access to the laboratory area must be knowledgeable of the R&D Emergency Preparedness Plan, as outlined in the PVAMC Emergency Management Plan.

i. **Penalties:** Failure to conform to the requirements may result in immediate withdrawal of VA research funding, suspension from the research program, and/or denied access of the secured area. Individuals who knowingly fail to follow the provisions of this policy are subject to disciplinary action proportionate to the severity of the violation, up to and including termination of VA employment or without compensation (WOC) status and criminal prosecution.

5. **REFERENCES:**

- a. <u>42 CFR 73</u>, CDC Select Agent Regulations.
- b. <u>7 CFR 331</u>., APHIS Select Agent Regulations.
- c. <u>9 CFR 121</u>, Possession, Use, and Transfer of Select Agents and Toxins.
- d. <u>VHA Directive 1200.6</u>, Control of Hazardous Agents in VA Research Laboratories.
- e. <u>VHA Directive 0710</u>, Personnel Security and Suitability Program.
- f. <u>VHA Handbook 0710.01</u>, Position Risk and Sensitivity Designations for VHA Positions and Medical Center Policy.
- g. <u>VA Handbook 0730</u>, Security and Law Enforcement.

- h. <u>VHA Handbook 1103.01</u>, Mental Health and Behavioral Sciences Service Procedures Handbook for Specific Programs.
- i. <u>VHA Handbook 1200.08</u>, Safety of Personnel Engaged in Research.
- j. VA Handbook 5005, Part II, Chapter 2, Para. 4 (for Title 5) and Part II, Chapter 3, Section G, Para. 7 (for Title 38), Without Compensation Appointments. (<u>http://vaww1.va.gov/vapubs/viewPublication.asp?Pub_ID=175&FType=2</u>).
- k. <u>MCM 05-10</u>, Personal Identity Verification.
- 1. <u>MCM 138-09</u>, Control of Proximity Cards.
- m. <u>MCM 00-08</u>, Facility Information Security Plan.

6. CONCURRENCES:

- a. R&D Committee (R&D)
- b. Chief of Security, (P4POL)
- c. Deputy Director for Administration and Finance (P4DD-A&F)
- d. Deputy Director for Primary Care Services (P4PCS)
- d. Director, Quality and Performance (P4Q&P)
- e. Chief of Staff (P3CCE)
- f. Chief, HRMS (P4HRMS)
- 7. **RESCISSION:** MCM 151-02 October 3, 2005

8. FOLLOW-UP RESPONSIBILITY: Acting Chief of Staff for Research and Development Service

9. **REVIEW DATE:**

MICHAEL W. FISHER Acting Director

Distribution: A

Attachment (1)

Attachment A

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 of mass destruction. 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 <u>http://www.cdc.gov/od/sap/.</u> 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 <u>amounts (exempt quantities</u>) 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.** As of the date of publication of this Handbook, the following chemicals are considered hazardous agents. 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.

- (8) Lysergic acid diethylamide (LSD);
- (9) Nitrogen mustard (FIN-i, HN-2, or I{N-3};

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- (10) Phosgene (CG), also known as carbonyl chloride;
- (11) Phosgene oxime (CX);
- (12) Sarin (GB);
- (13) Soman (GD);

(14) Sulfur mustard (H, or 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. For a "radiation high-risk" situation, more restrictive security measures need to be followed. For a "radiation low-risk" situation, basic security measures need to be followed.

(2) "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. "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.

(3) 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.