

VA MARYLAND HEALTH CARE SYSTEM

BALTIMORE, MD

RESEARCH AND DEVELOPMENT SERVICE SECURITY PLAN

1. PURPOSE:

- a. The Research and Development (R&D) Service Security Plan is designed to ensure that access to VAMHCS research laboratories is restricted to trained, authorized personnel and to visitors escorted by authorized personnel.
- b. The Security Plan establishes procedures for reporting of incidents, alarm activations and security breaches.
- c. The Security Plan includes established standard operating procedures of the Laboratory of Molecular Neurovirology (LMN) (ABSL-3 laboratory) and VAMHCS policies, including applicable Engineering Service polices regarding radiation safety and security.
- d. The Security Plan establishes procedures which are compliant with 42 CFR Parts 72&73, 42 CFR Part 1003, 7 CFR Part 331 and 9 CFR Part 121.

2. POLICY:

- a. Administer a program that applies current knowledge and feasible practices to ensure the protection of all patients, visitors and staff from exposures to hazardous or potentially hazardous chemical, radiological and biological agents.
- b. Establish security procedures to prevent theft or misuse of hazardous agents used in VAMHCS research laboratories.
- c. Routinely evaluate the effectiveness of security measures.
- d. Collect and report data on incidents of security breaches to identify areas for improvement.
- e. It is required that all VA research investigators and staff, regardless of appointment status (compensated, WOC, or fee basis), will comply with all provisions of this policy.

3. RESPONSIBILITIES: The VAMHCS Research and Development Service, the ACOS for R&D and the VAMHCS R&D Committee are responsible for the implementation of this policy

4. ACTIONS:

- a. **Physical Security:** The VAMHCS Research laboratories are controlled by a state of the art Hirsch Access Security System. The system is continuously active (24 hours per day, 7 days per week) and is backed up by emergency power. It is monitored during normal working hours by Research and Development Service staff as well as VA Police Service. During nights, weekends and holidays it is monitored by VA Police Service.

- i. 3rd floor BSL2 laboratories and the Animal Research Facility (ARF): The BVAMC 3rd floor research laboratories and the ARF on level BB are secured with a Hirsch Access Security System which is controlled by the Research Office. The VAMHCS Police Service also monitors this system.
- ii. The ABSL-3 Laboratory area is located inside the ARF and is secured by the Hirsch Access Security System with additional security measures including a motion alarm inside the ABSL-3 for detecting intruders as well as security cameras that monitor both entrances to the area. The VAMHCS Police Service monitors the cameras.

b. Access Control

- i. All authorized staff is provided with key cards to allow and to track access and egress to and from the laboratory areas.
- ii. All visitors including VAMHCS non-laboratory staff, must sign in on a log kept in the Research and Development Service office, obtain and wear a visitor's badge, and be escorted into and through the laboratory areas. Visitors are expected to follow all VAMHCS safety and security policies at all times.
- iii. When research laboratory staff terminate their employment in the research laboratories, they are required to return their keycard to the Research and Development Service. The keycard is then deleted from the electronic access system.
- iv. If a key card is lost or stolen or if a former employee fails to return a key card, the keycard is deactivated in the electronic access system. The ACOS/R&D, or designee, is notified and an incident report is filed with the Police Service.
- v. On a weekly basis, the Deputy ACOS/R&D or designee reviews and signs off on the visitor logs.
- vi. Access privileges for all personnel are reviewed annually.

c. Background and Security Clearances:

- i. All staff, regardless of appointment status (compensated, WOC, or fee basis), are required to complete the SF-85 forms to initiate a background check before access is granted to any of the research laboratories.
- ii. ABSL-3 Staff undergo a security risk assessment by the Attorney General, which must be subsequently approved by the Administrator or the HHS Secretary (or Administrator of APHIS). After recommendations by the R&D Committee, final approval is granted by the VAMHCS Responsible Official (RO) for unescorted access to the ABSL-3. Details are in LMN SOP 1.2.

d. Inventory Control:

- i. The ABSL-3 Laboratory:
 1. All Select Agent materials are strictly controlled and kept in locked freezers inside the A-BSL3 lab. When the material is in use, it is in sight of an approved individual at all times.
 2. Inventory of select agents in freezers is tracked using a password-protected software program. Monthly audits are conducted and

unresolved discrepancies are reported to the Laboratory Director and RO.

3. Agent-infected animals are checked daily for general condition and to confirm that they are present in their cage.
 4. All waste is disposed of according to LMN SOP 2.3 and 3.13 and tracked through logs and contractor manifests.
 5. Any loss or release of select agent or missing select agent samples/infected animals is reported according to LMN SOP 11.1.
 6. Details are available in the LMN Security Plan and LMN SOPs.
- ii. Radioactive material inventory is conducted in accordance with VAMHCS Policy Memorandum 512-138/ENG-026.
- e. Access for Maintenance:**
- i. Engineering and Environmental Management Services staff who routinely require access to the Research BSL-2 laboratories are issued keys/cards that allow access.
 - ii. Housekeeping staff do not enter the ABSL-3 area. ABSL-3 staff perform routine cleaning and maintenance as described in LMN SOPs (2.12, 3.11, 3.14, 3.16).
 - iii. When major maintenance or repairs are necessary, outside contractors must register in the visitors log in the Research and Development Service office (3C138) and obtain a visitors badge. Before entering the ABSL-3 area, they also sign into the ABSL-3 visitors log and wear the proper personnel protection equipment (PPE). They are then accompanied by an authorized ABSL-3 individual at all times while in the facility (LMN SOPs 2.1 and 2.14).
 - iv. All other visitors to the ABSL-3 area must follow the procedures in e.iii above.
 - v. VA Police and VA Engineering Staff are trained in proper procedures for entering the ABSL-3 if an emergency should occur.
- f. Cyber Security:**
- i. Access to the VAMHCS computer network is granted to staff who are paid VA employees as well as WOC staff who require it.
 - ii. Access to the Computerized Patient Record System (CPRS) is only granted to approved staff.
 - iii. Access to the ABSL-3 network requires a VA-assigned user name and password which must be changed every 3 months. Access to the sample-tracking database requires different access codes. In addition, VAMHCS Policy Memorandum 512-ISO-002 (“Background Investigations of Information Technology Employees in Critical-Sensitive Positions”) is followed as applicable.
- g. Education & Training:**
- i. Environmental Services staff, Engineering Service staff, or other VAMHCS staff who enter the research laboratory area for routine maintenance and work orders receive the VAMHCS annual security and safety trainings as well as instructions from laboratory staff.

- ii. All laboratory staff receives orientation to the security measures in the research laboratory areas, required annual VAMHCS trainings, and job-specific training.
- iii. ABSL-3 staff are trained according to LMN SOP 1.2, including:
 - 1. New staff: orientation on BSE, and security measures and more advanced one-on-one technical and safety training.
 - 2. All staff: regular ABSL-3specific trainings and reviews,
 - 3. Required annual VAMHCS security and safety trainings.
- iv. Safety and security training for laboratory staff includes instruction on response to alarms, intruders, suspicious packages, the theft or loss of access key cards; the theft, loss or release of select agents (ABSL-3); the acquisition, use, transfer and destruction of hazardous agents; and other related topics.

h. Evaluation:

- i. The Research and Development Service conducts an annual Vulnerability Assessment which includes involvement of the VAMHCS Safety Office, the Police Service, the R&D Service, and the Executive Office.
- ii. The VAMHCS Safety Office conducts disaster and fire drills throughout the year. Results of these drills are incorporated into the Vulnerability Assessment.
- iii. Corrective action plans are developed and evaluated for any deficiencies discovered through these processes.

5. REFERENCES:

VHA Handbook1200.06: Control of Hazardous Agents in VA Research Laboratories
VHA Handbook1200.08: Safety of Personnel Engaged in Research
VAMHCS Policy Memorandum 512-07B-001 “Police and Security Management Plan”
VAMHCS Policy Memorandum 512-07B-004 “Intrusion/Duress Alarms and Video Surveillance System”
VAMHCS Policy Memorandum 512-138/Eng-026 “Radiation Safety Policy”
VAMHCS Policy Memorandum 512-138/ENG-016 “Emergency Operations Plan”
VAMHCS Policy Memorandum 512-05/HR-016 “Personnel Suitability and Security Program”
Laboratory of Molecular Neurovirology (LMN) Security Plan and applicable LMN SOPs

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