

VA MARYLAND HEALTH CARE SYSTEM

BALTIMORE, MD

RESEARCH AND DEVELOPMENT SERVICE SAFETY PLAN

- 1. PURPOSE:** To establish a safety program within the Research and Development (R&D) Service of the VAMHCS that ensures that every employee is aware of the inherent hazards associated with the research environment, including biohazards, chemical hazards, and physical hazards (as defined in VHA handbook 1200.08) and employs appropriate measures to safely conduct research in this environment.
- 2. POLICY:** The R&D Service strives to eliminate accidents and injuries within the Service and the facility through the activities of the Subcommittee on Research Safety, by defining the responsibilities of management and employees, providing training, monitoring performance, providing protective equipment, inspecting all research areas, investigating and following up on every accident, and evaluating performance. The VAMHCS Research Program operates research laboratories in compliance with policies and regulations of appropriate Federal agencies including policies of the Baltimore VA Medical Center, VA Central office (including the Office of Research and Development (ORD) and The Office of Research Oversight (ORO)), the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), VA National Health Physics Program (NHPP), and any applicable state and local requirements. In addition, all applicable National Institutes of Health (NIH) and/or Centers for Disease Control and Prevention (CDC) and the United States Department of Agriculture (USDA) guidelines must be followed. The ABSL-3 laboratory maintains its own safety program specifically covering the ABSL-3 and the use of select agents when applicable.
- 3. RESPONSIBILITIES:** The Medical Center Director, the Associate Chief of Staff (ACOS) for Research and Development, the VAMHCS R&D Committee, the Subcommittee on Research Safety (SRS), and individual Principal Investigators/Laboratory Directors are responsible for the implementation of this policy.

Medical Center Director is responsible for:

- a. Ensuring that the research safety program is staffed adequately and that resources are available to maintain full compliance with all applicable regulations and standards of safety.
- b. Ensuring that all Research personnel are included in the facility Occupational Safety and Health program and that research space is included in annual workplace inspections.

NOTE: *Research personnel must be covered by all other facility safety programs (e.g., the Respiratory Protection program, the Fire Safety program, etc.)*

- c. Ensuring the resolution of any facilities-related deficiencies identified in inspections.

- d. Providing engineering support in conducting ventilation maintenance and validation of required specifications.
- e. Providing the technical assistance of facility safety and health professionals as needed.
- f. The Associate Chief of Staff (ACOS) for R&D will ensure that measures for the security of the research laboratories and surrounding space is developed.
- g. Providing adequate administrative support for SRS, including:
 - (1) Space sufficient to provide privacy for conducting sensitive duties related to biosafety,
 - (2) The personnel to support the review and record-keeping functions of SRS, and
 - (3) Support for the timely preparation of investigator correspondence and other documents.

ACOS for R&D is responsible for:

- a. Ensuring that safety related communications from the Chief Research and Development Officer (CRADO) are disseminated to appropriate personnel on time after receipt.
- b. Ensuring the responses to safety “holds.”
- c. Ensuring that research activity ceases until a particular “hold” is lifted.
- d. Ensuring continuous development and evaluation of performance standards of the Research Safety program.

R&D Committee is responsible for:

- (1) Reviewing all R&D submissions.
- (2) Ensuring the SRS review of those protocols and submissions for funding that involve safety hazards to personnel and the environment.
- (3) Prior to review of a proposal, ensuring that a complete list of chemicals designated or identified by OSHA or EPA as “hazardous” has been reviewed and approved by the Safety Officer.

NOTE: *This chemical inventory is reviewed and maintained locally; and it is not submitted along with the research proposal submitted to Office of Research and Development (ORD) for funding consideration.*

- (4) Acting upon SRS recommendations for approval or non-approval of reviewed proposals submitted to ORD for funding consideration.

- (5) Reviewing and acting upon SRS minutes.
- (6) Appointing a Research Safety Coordinator who is responsible for supervising and operating the Research Safety Program. Specific responsibilities for this position must be specified in the written local policy of the Research Safety Program.
- (7) Appointing a Biological Safety Officer, if research is conducted at the facility involving:
 - (a) The use of recombinant DNA at BSL 3 or 4, or
 - (b) Large scale (greater than 10 liters of culture) research or production activities involving viable organisms containing recombinant DNA molecules *In all cases this committee or subcommittee must report to the R&D Committee following review of protocols involving recombinant DNA that are covered by NIH Guidelines for Research Involving Recombinant DNA.*
- (8) Ensuring the development and implementation of the laboratory Chemical Hygiene Plan.
- (9) Appointing a Chemical Hygiene Officer to provide technical guidance on the implementation of the Plan. The Chemical Hygiene Officer should be a standing member of the SRS.
- (10) Overseeing compliance with this plan by Principal Investigators (PIs) conducting research at this facility.
- (11) Ensuring the development and implementation of safety protocols by the PI for individual research projects as needed.
- (12) Ensuring that the Research Office provides support to the SRS to assist in their functions.
- (13) Ensuring that the minutes of SRS meetings are documented correctly (see App. D 1200.08), and maintained by the Research Office.
- (14) Provides the ACOS for R&D, the facility, or Veterans Integrated Service Network (VISN) safety officials with adequate information to evaluate the performance of the R&D safety program.
- (15) Ensuring coordination with other regulatory programs or committees such as the Radiation Safety Officer or Radiation Safety Committee.
- (16) Reviewing accident and injury trends reported by SRS. Recommending and ensuring the implementation of corrective action.

(17) Reviewing all citations issued by regulatory agencies and ensuring that appropriate committee members and PIs take prompt corrective actions, and coordinating the necessary responses to regulatory agencies.

SRS is responsible for:

a. Reviewing all research activities involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines prior to submission for R&D approval. This includes a review of all research applications for funding that will be conducted at the VA facility or by VA personnel with VA funding located off-site.

(1) The review of VA Form 10-0398, Research Protocol Safety Survey (RPSS), must include a risk assessment of the facilities, level of containment, laboratory procedures, practices, training and expertise of personnel involved in the specific research conducted including recombinant DNA research.

(2) All research projects involving biological, chemical, physical, and radiation hazards must be approved by SRS and then by the R&D Committee prior to commencement. SRS must review proposed research at convened meetings at which a quorum (majority of voting members) is present.

b. Providing written notification of the results of SRS review to the R&D Committee, the Research Office, and the PI.

c. Reviewing annually all active research protocols involving biological, chemical, physical, and radiation hazards, regardless of funding status or source. The date of continuing review will be based on the date of SRS approval. Research protocol changes not included in the original application must be documented on an amended RPSS and must be approved by the SRS and the RDC prior to the implementation of the changes.

d. Ensuring that a complete list of chemicals has been submitted to the Industrial Hygienist for review and approval.

e. Coordinating all safety-related activities in research laboratories including mandatory and non-mandatory training, safety inspections, accident reporting, and liaison activities with all facility safety committees and officials to include:

(1) Coordinating follow-up evaluations to ensure that deficiencies cited during inspections are permanently and effectively abated, and

(2) Reporting follow-up results to the R&D Committee.

f. Reporting operational problems or violations of directives to the Research Office within 30 days of occurrence or detection, unless SRS determines that a report has been previously filed by the PI.

- g. Identifying the need for health surveillance of personnel involved in individual research projects; and if appropriate, advising the R&D Committee and Employee Health Practitioner on the need for such surveillance.
- h. Maintaining adequate documentation of all the SRS or equivalent subcommittee activities.
- i. Forwarding minutes of SRS to the R&D Committee.
- j. Ensuring that all laboratory personnel receive annual research specific safety training.
- k. Holding SRS meetings at least quarterly.
- l. Ensuring coordination with other regulatory programs, personnel, or committees such as the Radiation Safety Officer or Radiation Safety Committee.
- m. Ensuring the collection of appropriate personnel samples to make employee exposure determinations whenever the proposed use of laboratory chemicals may potentially exceed OSHA Permissible Exposure Limits or Action Levels.
- n. Evaluating annually the effectiveness of the laboratory's Chemical Hygiene Plan and making necessary revisions.
- o. Ensuring the review of investigation reports of all lost-time injuries and all significant adverse environmental events.
- p. Ensuring the proper reporting of injury and illness trends to the R&D Committee, as appropriate.
- q. Requesting, when appropriate, the appointment of an ad hoc committee (consisting of members with appropriate expertise) to investigate and report on occupational injuries, illnesses, and adverse environmental events.
- r. Ensuring the development of a policy for the preservation of employee medical and OSHA exposure records and environmental records (i.e., hazardous waste, air monitoring).
- s. Cooperating with appropriate medical center personnel to review the quantity and type of hazardous waste generated by each PI annually.
- t. Providing technical assistance, where appropriate, in recycling programs and reduction of the quantity of waste.

The PI or Laboratory Director is responsible for research activities conducted in assigned space, including:

a. Submitting a completed VA Form 10-0398 to the medical center Research Office along with each research proposal regardless of funding status or source.

(1) The “Work Proposed” section of the research proposal must accompany the survey.

(3) A complete list of chemicals to be used must be submitted with each research proposal.

NOTE: *This chemical inventory is reviewed and maintained locally by the Laboratory Director.*

b. Ensuring that active protocols and new pilot projects have been reviewed by SRS, regardless of funding status or source.

c. Identifying laboratory specific hazards, and:

(1) Ensuring that all personnel receive training specific to the hazard(s).

(2) Advising laboratory personnel of any potential risk to themselves or the research environment.

(3) Establishing and enforcing standards of practice which minimize employee exposures to biological, chemical, physical, and radiation hazards.

d. Supervising the performance of the laboratory staff to ensure the correct use of required safety practices and techniques (including personal protective equipment).

e. Ensuring that Biological Safety Cabinets are certified annually. **NOTE:** In research settings involving airborne pathogens, certification must be performed on a semi-annual basis.

f. Reporting problems and concerns about operation and containment practices and procedures to the Research Safety Coordinator, facility Safety Officer, Veterinary Medical Officer (VMO), Radiation Safety Officer (if applicable), and other appropriate authorities.

g. Ensuring that all accidents are reported to the Employee Health Office and the facility safety office using appropriate VHA forms.

h. Securing approval of the R&D Committee through the SRS for any significant changes made in the original research plan.

i. Coordinating with appropriate safety staff such as the Radiation Safety Officer for removal or disposal of all chemicals, biological agents, radioisotopes, and waste generated by these materials.

j. Notifying all pertinent personnel prior to departure/relocating the research laboratory space, (see SOP for procedure for decommissioning laboratories).

k. Ensuring that a copy of the laboratory's Chemical Hygiene Plan is readily available to all employees in their work area, that employees have been trained in the contents of the Plan, and that all provisions of the Plan are implemented in all laboratories under the PI's supervision.

l. Maintaining employee exposure to hazardous chemicals in laboratory activities at the lowest possible levels. At no time may employee exposures to chemicals exceed the Permissible Exposure Limits established by OSHA (see subpar. 6e(3)).

m. Maintaining an up-to-date inventory of all hazardous chemicals located in the laboratory.

(1) Ensuring that all laboratory personnel know the location of this inventory.

(2) Providing this inventory to the Industrial Hygienist.

n. Managing all biological and chemical waste in accordance with Federal, State, and local regulations and all VA, VHA, and facility policies.

(1) Seeking technical assistance when needed to ensure proper waste management.

(2) Implementing waste reduction techniques, where appropriate.

o. Investigating the deficiencies cited during all inspections of work areas. Submitting a written abatement plan for all deficiencies cited during inspections to the person who performed the inspection within the specified time limits.

All Supervisors:

(1) Will provide employees with training on safe work practices, policies, and procedures annually, and document its occurrence. This training will include:

(a) Fire Safety

(b) Emergency Management and Disaster Planning

(c) Hazardous Materials Handling, Hazard Communication

(d) General Safety

(e) Job Specific Training

(2) Will determine the presence of physical hazards and unsafe practices in the work area through quarterly inspections. Inspections will be documented on the Supervisor's Safety Inspection Checklist.

(3) Will report all unsafe conditions or hazards and initiate steps to secure correction after assuring temporary safeguards are in place.

(4) Will provide initial laboratory specific orientation to new employees.

(5) Will investigate accidents, whether injury producing or not, prepare required reports, analyze conditions, and institute or recommend measures to preclude repetition within the supervisor's area of responsibility.

- (6) Will provide personal protective equipment as needed and assure that employees are trained in the use and maintenance of personal protective equipment. Assure that employees use personal protective equipment when required.
- (7) Will review employees' performance of safety responsibilities as part of their annual evaluations.
- (8) Will maintain a listing of all hazardous materials and their Material Safety Data Sheets (MSDS) in their work areas of responsibility. This list will be updated on an annual basis and be accessible to all employees.
- (9) Will identify hazardous wastes produced by work operations. If necessary, contact the Safety Office for technical guidance prior to disposal, so that compliance with local, state, and federal standards is maintained.
- (10) Will participate in all pre planned fire drills and disaster drills.
- (11) Have an up to date cascade call back list.

4. ACTIONS:

a. The SRS addresses all biosafety issues within the Research Service and functions as detailed in the SRS SOP.

b. The Research and Development Service must develop a service-wide safety manual. It shall include a description of biohazard controls (e.g., engineering, procedures and personal protective equipment), guidelines on risk of exposure to bloodborne pathogens, emergency procedures, physical hazards, and an emergency cascade phone list specific to the facility. This document must be updated, reviewed, and approved annually by the SRS and forwarded to the R&D Committee for approval.

c. All research must meet the biosafety standards and requirements found in the CDC-NIH publication "Biosafety in Microbiological and Biomedical Labs". This includes all appendices and all updates on the CDC website.

d. All labs wishing to use toxins or select agents must follow all regulations as required in the Code of Federal Regulations (CFR) 42 Part 73, CFR 7 Part 331 and CFR 9 Part 121 (<http://www.selectagents.gov/resources/>) as well as Maryland Department of Health and Mental Hygiene Title 10 Chapter 11. Additional information is found in VHA Handbook 1200.06 "Control of Hazardous Agents in VA Laboratories". Laboratory personnel follow safety procedures that apply to all activities within the ABSL-3 facility which are described in the ABSL-3 Standard Operating Procedures manual.

e. Hazard analysis and laboratory inspections are conducted annually to review all potential hazards, to minimize risk, to ensure regulatory compliance, and to evaluate the effectiveness of the safety plan. Deficiencies that are noted during an inspection are corrected in a timely manner in accordance with requirements of the inspectors.

f. Employees must read and sign the R&D Service Laboratory Safety Manual. Employees will also be familiar with the R&D Chemical Hygiene Plan, R&D Infection Control Policy, Utilities Failure Management Plan for Research and Development, Research Laboratory

Biohazardous Waste Management Policy, R&D Policy for use of peroxide forming chemicals and Perchloric Acid, Emergency Preparedness Plan, VAMHCS Bloodborne Pathogen Exposure Control Plan, and the Hospital Radiation Safety Plan and, if research involves animals, the Emergency Protocol for the Animal Facility.

g. Radiation Safety is covered by a comprehensive program administered by the VAMHCS Radiation Safety Officer (RSO) in accordance with regulations and guidelines from the VHA National Health Physics Program as well as the VAMHCS Radiation Safety Manual (512-138/ENG-026) which provides radiation safety guidelines for VAMHCS staff.

h. All Research that involves recombinant DNA molecules must follow the "NIH Guidelines for Research Involving Recombinant DNA Molecules" found on the website <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>. All protocols must be approved by the University of Maryland Baltimore (UMB), Institutional Biosafety Committee (IBC), (a subcommittee of the VAMHCS SRS) SRS and the R&D committee before studies involving recombinant DNA can begin. The R&D Committee will make recommendations regarding risk assessment, physical containment, and biological containment.

i. The following experiments may not be conducted unless approved by the NIH Director after consultation with experts:

1. Experiments using recombinant DNA that involve the deliberate transfer of a drug resistance trait 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 (NIH guidelines).

2. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of 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. (NIH guidelines).

j. In case of an emergency, the Research Service Emergency Preparedness Plan will be followed. Staff working in the ABSL-3 is trained in emergency response at least annually or after an incident by the Biosafety Officer for the ABSL-3.

k. This plan will be reviewed and updated annually.

5. REFERENCES:

"Biosafety in Microbiological and Biomedical Laboratories"
<http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf>, (CDC, and NIH)
VAMHCS Emergency Operations Plan Memorandum 512-138/ENG-016
VAMHCS Safety Management Plan 512-138/ENG-003
VAMHCS Hazardous Materials and Wastes Management Plan 512-138/ENG-017
VAMHCS Safety, Occupational Health and Fire Protection Plan 512-138/ENG-001
VAMHCS Radiation Safety Plan 512-138/ENG-026

VAMHCS Research and Development Committee SOP
VAMHCS Subcommittee on Research Safety SOP
VAMHCS Exposure Control Plan 512-11/COS-IC-002
VAMHCS Emergency Plan for Animal Facility
VAMHCS Bloodborne Pathogen Exposure Control Plan
VHA Handbook 1200.06: Control of Hazardous Agents in VA Research Laboratories
VHA Handbook 1200.08: Safety of Personnel Engaged in Research

Research Policies:

- a. Research Service Laboratory Safety Manual
- b. Research Service Infection Control Policy
- c. Research and Development Chemical Hygiene Plan
- d. Utilities Failure Management Plan for R&D
- e. Research Laboratory Biohazardous Waste Management Policy
- f. Emergency Protocol for the Animal Facility
- g. Emergency Facilities Management Plan for the ABSL-3 Facility
- h. R&D Policy for use of Ethyl Ether
- i. R&D Policy for use of Perchloric Acid
- j. Research and Development Emergency Preparedness Plan

6. RESPONSIBLE OFFICE: The Associate Chief of Staff for Research and Development (151/RD) is responsible for the contents of this memorandum.

7. RECISSION: None

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ACOS for R&D

Date: September 30, 2011