

# Research Safety Manual

Research Emergency Response and Disaster Plan (Attachment 1) and the Durham Research and Development Service Hazardous Agents Control Program (Research Security Plan) (Attachment 22)

Research & Development Service (558/151)  
Department of Veterans Affairs Medical Center  
Durham, NC 27705

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## Preface

The Durham Veterans Affairs Medical Center (DVAMC) Research and Development (R&D) Service is committed to providing a safe environment for all research personnel. Safety is everyone's responsibility. Research personnel should be familiar with their safety responsibilities, strive to follow those safety practices at all times, act proactively to prevent accidents and injuries, communicate hazards to the appropriate safety division, and be prepared for emergencies that may occur in the workplace.

This manual is intended to be used for general guidance for research laboratory safety practices and to serve as an adjunct to the DVAMC safety policies and procedures. The DVAMC safety policies and procedures can be found in the DVAMC Medical Center Memoranda on the VISN 6 Intranet.

This manual contains the Research Emergency Response and Disaster Plan (Attachment 1) and the Durham Research and Development Service Hazardous Agents Control Program (Research Security Plan) (Attachment 22). As a whole, this manual will be reviewed, revised as needed and approved annually by the Subcommittee for Research Safety and the R&D committee. All laboratory staff will also review this manual annually.



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## **Medical Center Memoranda**

All DVAMC Research employees have access to the MCM folder, located on the **S:\Drive**. From this location, the MCMs can only be reviewed; you will not have the ability to print, copy or save. If you need to print an MCM, please follow the normal process of accessing the web-based files to do so.

The folder can be found at: **S:\All Employees\MCM**

The MCMs are listed separately by the Service that is accountable for the MCM. If you know the Service where the MCM resides you can easily find it.

Durham MCM's can be found on VA computers at <http://vaww.visn6.va.gov/default.aspx?id=32&fac=2> under "Forms-Pubs-MCM's"

### **A quick reference has been added for the MCMs below:**

- Formaldehyde Program MCM 558-11-138.16
- Fetal Protection Policy 558-11-11.17
- Occupational Health Program 558-11-11C.2
- Anesthetic Gases Program 558-11-138.21
- Comprehensive Emergency Management Program 558-11-00.2
- Fire Response Plan 558-11-138.5
- Exposure Control Plan for Bloodborne Pathogens 558-10-111.15
- Environmental Heat Stress Management Program 558-11-138.28
- Infectious Waste Disposal 558-11-137.1
- Laboratory Chemical Hygiene Program 558-11-138.23
- Hazardous Chemical Waste Management Program 558-11-138.8
- Hearing Conservation Program 558-11-138.12
- Personal Protective Equipment (PPE) 558-11-138.25
- Research and Development (R&D) Committee 558-09-151.2
- Reporting Unsafe and Unhealthy Working Conditions 558-11-138.20
- Reporting Of Accidents, Incidents, Injuries, Occupational Illnesses and Fires 558-11-138.26
- Safe Handling of Potentially Hazardous Drugs 558-11-119.12
- Response to Active Threats on Facility Grounds 558-11-07b.14
- Respiratory Protection Program 558-11-138.17
- Safe Use of Electrically Operated Equipment 558-08-138.7
- Severe Weather Plan 558-10-001.4
- Research and Development Chemical Hygiene Plan (CHP) 558-12-138.23

### **Formaldehyde Program MCM 558-11-138.16**

- **PURPOSE:** To establish policy and procedures to minimize exposure of patients, visitors and employees to Formaldehyde and ensure compliance with Occupational Safety and Health Administration (OSHA) as well as environmental regulations.
- **POLICY:** It is the policy of this Medical Center to minimize the risk of exposure to Formaldehyde during storage, use, handling and disposal through the implementation of engineering and administrative control

measures, safe work practices, training, exposure monitoring, personal protective equipment (PPE), signage, container labeling, emergency response procedures and medical surveillance.

#### **Fetal Protection Policy 558-11-11.17**

- **PURPOSE:** To provide a policy for the protection of the fetus/embryo of the pregnant employee occupationally exposed to ionizing radiation.
- **POLICY:** Radiation exposure should be kept to a minimum, particularly during pregnancy. Pregnant employees may be reassigned, as appropriate, to avoid radiation exposure.
- **ACTION:** Female employees will be informed that special radiation protection is available to all employees who become pregnant, and that they must declare their pregnancy in writing to the Medical Center Radiation Safety Officer in order to obtain the protection under this policy. This information will be presented during employee safety orientation and annual mandatory training.

#### **Occupational Health Program 558-11-11C.2**

- **PURPOSE:** To define the methods of implementation and scope of the Occupational Health Program. Program services include, but are not limited to, pre-placement examinations; employee physical examinations; evaluation and treatment of occupational injuries; emergency treatment of illnesses that are potentially work-related (to be defined by the Department of Labor), and unrelated causally to work (sick call); appropriate immunizations; surveillance of employees with exposure or potential exposure to hazardous substances; and any other medical surveillance or examination program required by the Department of Veterans Affairs or other government regulatory agencies.
- **POLICY:** It is the policy of the Veterans Health Administration (VHA) to provide occupational health services for all VHA employees (with or without compensation), volunteers and others as stated in VHA Handbook 5019, Occupational Health Services.

#### **Anesthetic Gases Program 558-11-138.21**

- **PURPOSE:** To establish policy and procedures to minimize exposure of patients, visitors and employees to uncontrolled releases of anesthetic gases and ensure compliance with Occupational Safety and Health Administration (OSHA) and environmental regulations as well as Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards.
- **POLICY:** It is the policy of this Medical Center to minimize risk of exposure to uncontrolled releases of anesthetic and waste anesthetic gases during storage, use, handling, administration, disposal through implementation of engineering and administrative control measures, safe work practices, training, exposure monitoring, personal protective equipment (PPE), container labeling and medical surveillance. It is the intent of this Medical Center to implement a program for the safe use of anesthetic gases that meets or exceeds OSHA requirements, JCAHO standards, and in the absence of specific OSHA requirements, the recommendations of occupational health advisory agencies (e.g., the National Institute for Occupational Safety and Health (NIOSH), American Conference of Governmental Industrial Hygienists (ACGIH) and the American Society of Anesthesiologists (ASA).

#### **Comprehensive Emergency Management Program 558-11-00.2**

- **PURPOSE:** This Memorandum establishes the Comprehensive Emergency Management Program to ensure that the Medical Center develops and maintains appropriate goals, objectives and strategies to provide effective planning for and response to emergency incidents, disasters, catastrophes and events affecting the environment of care. Emergency procedures to be followed by all personnel and programs at this Medical Center are attached by reference as an Emergency Operations Plan.

**Fire Response Plan 558-11-138.5**

- PURPOSE: To establish the Fire Response Plan for the Durham Veterans Affairs (VA) Medical Center.
- POLICY: To provide a hazard free environment, reduce risk of human injury, protect patients, visitors, employees and property from fire and products of combustion and provide for safe use of buildings and grounds.
- ACTION: A copy of these regulations will be kept available by all supervisory personnel. Supervisors must acquaint their employees with these regulations, provide annual refresher Fire Safety Training and ensure regulations are enforced.

**Exposure Control Plan for Bloodborne Pathogens 558-10-111.15**

- PURPOSE: This Medical Center Memorandum establishes the Exposure Control Plan required by 29 CFR 1910.1030, Occupational Exposure to Bloodborne Pathogens; Final Rule.
- POLICY: The Medical Center will minimize occupational exposure to blood or other potentially infectious material through a combination of engineering controls, work practice controls, personal protective equipment (PPE), housekeeping practices, universal precautions, medical surveillance, vaccination if indicated and training.

**Environmental Heat Stress Management Program 558-11-138.28**

- PURPOSE: To establish guidelines, policy, procedures and controls to avoid exposing employees to dangerous levels of heat stress. The scope of this program is limited to heat stress as an occupational health risk.

**Infectious Waste Disposal 558-11-137.1**

- PURPOSE: To provide a system for defining, collecting and disposing of infectious waste material in a manner which will ensure the safety of patients, staff and the community, and be in compliance with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), North Carolina Solid Waste Management Rules, Occupational Safety and Health Administration (OSHA) and Medical Center Infection Control Guidelines.
- POLICY: To dispose of infectious waste as prescribed by federal, state, and local regulations and in such a manner that minimizes the threat to the general public.

**Laboratory Chemical Hygiene Program 558-11-138.23**

- PURPOSE: To establish policy and procedures for the implementation of a Chemical Hygiene Plan to minimize exposure of patients, visitors and employees to chemical hazards posed by operations in both clinical and research laboratories at this Medical Center. The Chemical Hygiene Plan is intended to ensure compliance with the Occupational Safety and Health Administration (OSHA) Laboratory Standard and only applies to clinical and research laboratory activities.

**Hazardous Chemical Waste Management Program 558-11-138.8**

- PURPOSE: To establish a program for management of hazardous chemical waste generated within the Medical Center. Hazardous chemical waste is identified based on criteria set forth by the Resource Conservation and Recovery Act (RCRA) and subject to environmental regulations governing hazardous waste disposal.
- POLICY: It is the policy of this Medical Center to manage hazardous chemical waste in a safe and environmentally sound manner, which complies with federal, state and local laws and regulations.

**Hearing Conservation Program 558-11-138.12**

- **PURPOSE:** The purpose of the Hearing Conservation Program is to prevent hearing impairment or loss as a result of exposure to excessive noise in the work environment in accordance with Occupational Safety and Health Administration (OSHA) requirements.

#### **Personal Protective Equipment (PPE) 558-11-138.25**

- **PURPOSE:** The purpose of this Medical Center Memorandum (MCM) is to describe the Medical Center's Personal Protective Equipment Program. This MCM does not supersede the requirements of Medical Center Memorandums, Respirator Program and Chemical Hygiene Plan.
- **POLICY:** As needed, PPE for eyes, face, head and extremities will be provided at no cost to employees. This equipment will be used and maintained in a sanitary and reliable condition wherever it is necessary by reason of hazard of processes or environment, chemical hazards, radiological hazards or mechanical irritants encountered in a manner capable of causing injury or impairment in the function of any part of the body through absorption, inhalation or physical contact.

#### **Research and Development (R&D) Committee 558-09-151.2**

- **PURPOSE:** The research mission of the Department of Veterans Affairs (VA) is conducted within individual VA medical centers according to the highest ethical standards with accountability to all involved stakeholders. Responsibility for oversight and maintaining high standards is assigned to the R&D Committee.
- **POLICY:** All R&D activities within the facility, whether funded or unfunded, are within the Research and Development Committee's purview.

#### **Reporting Unsafe and Unhealthful Working Conditions 558-11-138.20**

- **PURPOSE:** To establish a procedure whereby employees and representatives of employees are encouraged to report unsafe and unhealthful working conditions or other safety issues without the fear of reprisal from management.
- **POLICY:** The Medical Center will ensure a safe environment is maintained, including prompt analysis and response to employee reports of unsafe and unhealthful working conditions and/or a request for a safety and health inspection of specific work areas, practices or conditions. Appropriate corrective actions will be implemented by the Medical Center in a timely fashion. All employees have a right and an obligation to fulfill their responsibilities in reporting any unsafe or unhealthful working condition they believe exists without the fear of reprisal. Reprisal against employees who exercise their rights to report unsafe and unhealthful working conditions or request an inspection will not be tolerated. This policy is not intended to interfere in any way with the prior, simultaneous or subsequent use by the employee of the grievance procedures established by the Federal Labor-Management Relations Program or collective bargaining agreement as a means of requesting correction of alleged unsafe or unhealthful working conditions.

#### **Reporting Of Accidents, Incidents, Injuries, Occupational Illnesses and Fires 558-11-138.26**

- **PURPOSE:** To establish a program for the reporting of accidents, incidents, injuries, occupational illnesses and fires at this Medical Center and Community Based Outpatient Clinics (CBOC's).
- **POLICY:** All reports on accidents, incidents, injuries, occupational illnesses and fires will be submitted to Engineering Service within three workdays.

#### **Safe Handling of Potentially Hazardous Drugs 558-11-119.12**

- **PURPOSE:** To establish policies and procedures for the safe handling of potentially hazardous injectable, topical and oral drugs and items associated with their use including preparation, administration and disposal. Antineoplastic drugs are known to be potentially harmful to workers handling them. There may be long-term carcinogenic or teratogenic effects on exposed workers. Topical and oral medications which are identified as potentially hazardous include antiviral medications, hormones, antineoplastics and other therapies.

#### **Response to Active Threats on Facility Grounds 558-11-07b.14**

- **PURPOSE:** To establish immediate reaction procedures to the response of an Active Threat on VA controlled property.
- **POLICY:** It is the policy of this VA Medical Center to establish standards that promote an environment in which employees, visitors, and patients are afforded reasonable protection from harm that may result from the introduction and use of weapons on facility property.

#### **Respiratory Protection Program 558-11-138.17**

- **PURPOSE:** To establish policy and procedures for the implementation of a Respiratory Protection Program to protect employees from airborne contaminants, including but not limited to infectious agents, e.g., tuberculosis (TB), severe acute respiratory syndrome (SARS) and smallpox, as well as contaminants encountered by Decontamination Team members while decontaminating victims received by the Medical Center from external incidents involving hazardous materials.

#### **Safe Use of Electrically Operated Equipment 558-08-138.7**

- **PURPOSE:** To provide a safe electrical environment for patients, visitors and staff in the Medical Center. This policy reflects the multidisciplinary approach to safety in the environment of care by involving all users with responsibilities for electrical safety.

#### **Severe Weather Plan 558-10-001.4**

- **PURPOSE:** To define and communicate Medical Center policy concerning the continuation of critical functions during snow and/or other severe weather conditions.
- **POLICY:** The Medical Center will remain open and continue to provide health care services during the period of adverse weather.
- **ACTION:** The Director has sole responsibility for declaration of adverse weather emergencies and for activation of all or part of this Plan. Employees are encouraged to watch or listen to local news media (WTVD News Channel 11, WPTF News Channel 28, WGDR – FM 94.7, WQDK - FM, 97.5, WDCG, G105.1 FM and WZZU, 93.9 FM) to be notified of the situation and proceed accordingly. News media announcements must specifically say Durham Veterans Affairs (VA) Medical Center or the announcement does not apply.

#### **Research and Development Chemical Hygiene Plan (CHP) 558-12-138.23**

- **PURPOSE:** to establish policy and procedures for the implementation of a Chemical Hygiene Plan (CHP) to minimize exposure of visitors and employees to chemical hazards posed by operations in research laboratories at this Medical Center. The Chemical Hygiene Plan is intended to ensure compliance with the Occupational Safety and Health Administration (OSHA) Laboratory Standard and only applies to research laboratory activities.
- **POLICY:** It is the policy of this Medical Center to provide a safe and healthful work environment for all employees who work in and around hazardous chemicals. The Medical Center will keep employee exposure limits below permissible limits through measures such as engineering and administrative controls. Full

compliance with applicable federal, state and local regulations to protect applicable personnel, visitors, property and the environment is the goal of the Medical Center.

➤ **The CHP is intended to:**

1. Inform laboratory employees of the potential health and safety hazards present in their workplace.
2. Inform laboratory employees of the precautions and preventative measures that have been established by the DVAMC to protect employees from a workplace injury or illness.
3. Inform laboratory employees of the required safety rules and procedures established by the DVAMC to meet the requirements of 29 CFR 1910.1450 and 29 CFR 1910.1200.

**OSHA Laboratory Standards (This list is not all-inclusive):**

All OSHA Standards can be found online at OSHA website: <http://www.osha.gov/index.html>

9 CFR 1910 Occupational Health and Safety Standard

29 CFR 1910.1030 Bloodborne Pathogens Standard

29 CFR 1910.1450 Occupational Exposure to Hazardous Chemicals in Laboratories

29 CFR 1910.1200 Hazard Communication Standard

29 CFR 1910.132 Personal Protective Equipment (PPE) Standard

29 CFR 1910.138 Hand Protection Standard

29 CFR 1910.133 Eye and Face Protection Standard

29 CFR 1910.134 Respiratory Protection Standard

29 CFR 1910.147 Control of Hazardous Energy Standard

29 CFR 1910.1048 Formaldehyde Standard

29 CFR 1910.1000 Air Contaminants Standard

29 CFR 1910.1047 Ethylene Oxide Standard

\*The Occupational Exposure to Hazardous Chemicals in Laboratories and the Bloodborne Pathogens Standards are contained in this manual as attachments.

## Introduction to the Research Laboratory Safety Program

The Veterans Affairs Medical Center (VAMC) and Research & Development (R&D) Institutional Biosafety and Subcommittee on Research Safety

**Supervisors, Principal Investigators and Managers have the primary responsibility for maintaining laboratories under their supervision as safe, healthy places to work and for ensuring that applicable health, safety and environmental regulations are followed.**

The VAMC and the R&D Service have an obligation to provide a safe and healthy work environment. Therefore, a safety committee [Subcommittee for Research Safety (SRS)] functions within the Research Service to provide help with research laboratory safety. The purposes of the committee are outlined on the following pages. When the committee sends out new safety information memos, each laboratory should file the memos in their copy of the research laboratory safety manual for ready reference. In addition, the names of the current members of the committee are listed below in Table 1. The appropriate representative can be contacted if one has questions about safety issues in the laboratory or anywhere else.

**Table 1:**

**Research & Development Service Biosafety and Subcommittee on Research Safety Committee**

Chairperson Investigator, Immunology & Geriatrics	X7740
Safety Specialist	X7554
Chemical Hygiene Officer Industrial Hygienist, Research	X7807
Radiation Safety Officer	X7909
Investigator, Neurobiology	X3661
Clinical Psychologist	
Investigator, Neurobiology	X3660
Investigator, Neurobiology	X3664
Infectious Diseases, Medical Microbiology	X6681
Microbiology, Chief	X5785 or 6529
Union Representative	X6534
Community Representative	N/A
Community Representative	N/A
Veterinary Medical Officer	X5182
Administrative Officer (AO) for Research	X7632
Associate Chief of Staff (ACOS) for Research and Research Safety Coordinator (RSC)	X6540

## **A. Research Safety Coordinator (RSC)**

### **(A.1)**

The R&D Committee has designated the ACOS for R&D as the RSC at the Durham VAMC.

As required in VHA Handbook 1200.8 “Safety of Personnel Engaged in Research”, the Research & Development (R&D) Committee is required to designate a Research Safety Coordinator (RSC) who is responsible for supervising and operating the Research Safety Program. RSC responsibilities include ensuring the implementation of all research safety requirements, communication with the facility Director on research safety related matters and activities, ensuring the safety and security of research laboratories and facilities, ensuring the conduct of annual vulnerability assessments, ensuring the conduct of annual research laboratory safety audits, as well as ensuring other aspects of the research safety program are competently managed.

### **(A.2)**

#### **Subcommittee for Research Safety (SRS) Purpose:**

The SRS reviews, approves and maintains a record of all research activities that involve hazardous biological agents, toxins, human cell lines, and recombinant DNA molecules, agents infectious to humans, animals or plants, and other genetically altered organisms and agents. The SRS ensures that all activities involving these materials and the facilities used to conduct such research are in compliance with current external regulations and applicable Durham VA Medical Center policies.

The SRS advises and recommends policies to guide principal investigators (PIs) in carrying out good biological safety practice emphasizing protection of personnel, the general public and the environment. The SRS functions to discharge obligations and responsibilities as outlined in current governmental requirements, including those described in:

- The NIH Guidelines For Research Involving Recombinant DNA Molecules
- The CDC/NIH Biosafety in Microbiological and Biomedical Laboratories
- Occupational Safety & Health Administration (OSHA)
- Institutional Animal Care and Use Committee (IACUC)

As well as other requirements that overlap with or are reviewed by other committees [e.g., Institutional Review Board (IRB) and R&D].

### **(A.3)**

#### **Institutional Biosafety Committee (IBC)**

The SRS is registered as the Institutional Biosafety Committee (IBC) with the NIH Office of Biotechnology Activities (OBA).

### **(A.4)**

#### **Subcommittee for Research Safety (SRS) Responsibilities:**

Review 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 funding. 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.

**(A.5)**

**Research Protocol Safety Survey (RPSS)** (see **VA Form 10-0398, App. G**) 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.

**(A.6)**

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.

**(A.7)**

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

**(A.8)**

Annually reviewing 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 (see VA Form 10-0398, App. G) and must be submitted to and reviewed by SRS prior to the implementation of the changes.

**(A.9)**

Ensuring that a complete list of all products containing chemicals designated or identified by the Occupational, Safety and Health Administration (OSHA) and/or Environmental Protection Agency (EPA) as “hazardous” has been submitted to the Research Industrial Hygienist (RIH) for review and approval prior to the submission of a protocol for local review.

**(A.10)**

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:

**(A.11)**

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

**(A.12)**

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

**(A.13)**

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

**(A.14)**

Identifying the need for health surveillance of personnel involved in individual research projects; and if appropriate, advising R&D Committee and Employee Health Practitioner on the need for such surveillance.

**(A.15)**

Maintaining adequate documentation of all SRS or equivalent subcommittee activities.

**(A.16)**

Forwarding minutes to the Research Office.

**(A.17)**

Ensuring that all laboratory personnel receive annual research specific safety training.

**(A.18)**

Holding SRS meetings at least quarterly (currently meeting monthly).

**(A.19)**

Ensuring coordination with other regulatory programs, personnel, or committees, such as the Radiation Safety Officer (RSO) and/or Radiation Safety Committee.

**(A.20)**

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.

**(A.21)**

Annually evaluating the effectiveness of the research laboratory's Chemical Hygiene Plan, Hazardous Agents Control Program, and Safety Manual, along with making necessary revisions.

**(A.22)**

Ensuring the review of investigation reports of all lost-time injuries and all significant adverse environmental events.

**(A.23)**

Ensuring the proper reporting of injury and illness trends to the R&D Committee, as appropriate.

**(A.24)**

When appropriate, requesting 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.

**(A.25)**

Ensuring the development of a policy for the preservation of employee medical and OSHA exposure records.

**(A.26)**

Cooperating with appropriate medical center personnel to review the quantity and type of hazardous waste generated by each PI annually.

**(A.27)**

Providing technical assistance in the reduction of the quantity of waste and/or recycling programs, where appropriate.

**(A.28)****Research Compliance Reporting Requirements**

**As required in VHA Handbook 1058.01 “Research Compliance Reporting Requirements:** The SRS will review all noncompliance, safety, and security-related incidents as required by VHA Handbook 1058.01. As part of that review, a determination will be made on whether the event requires a report to the Office of Research Oversight (ORO).

Human Deaths. VA personnel, including Without Compensation (WOC) and Intergovernmental Personnel Act (IPA) appointees, must ensure oral notification of the SRS immediately upon becoming aware of any human death that may be the result of work (or other activity) in a research laboratory or dedicated research area (e.g., research specimen storage area).

(1) The SRS must alert ORO by e-mail or telephone within 2 business days after receiving such notification. The VA facility Director and the ACOS/R&D must receive concurrent notification.

(2) VA personnel, including WOC and IPA appointees, must ensure written notification of the SRS within 5 business days of becoming aware of the death.

Human Accident, Injury, Illness, or Exposure. VA personnel, including WOC and (IPA) appointees, must ensure written notification of the SRS within 5 business days after becoming aware of any serious accident, injury, illness, or exposure (other than those that result in death) that may be the result of work (or other activity) in a research laboratory or dedicated research area (e.g., research specimen storage area).

Reportable Incidents Under Applicable Federal Standards. VA personnel, including WOC and IPA appointees, must ensure written notification of the SRS within 5 business days after becoming aware of any incident related to research safety that is reportable under relevant VHA Handbooks or applicable Federal requirements, including Occupational Safety and Health Administration (OSHA) requirements.

SRS Review of Reported Incidents. The SRS must review any report of an incident described above at its next convened meeting.

(1) Incidents that involve a human death or present a significant risk to the safety of research personnel or the environment call for immediate attention and require the SRS to convene an emergency session prior to the next scheduled meeting.

- (2) The SRS must notify the MCD and the ACOS/R&D within 5 business days after any determination that a reportable incident has occurred. No individual or committee may reverse or overrule the SRS's decision that a reportable incident has occurred.
- (3) The MCD must report the incident or event to ORO within 5 business days after receiving the SRS notification.
- (4) The SRS must **also** notify the MCD and the ACOS/R&D within 5 business days after any determination that an incident brought to its attention, based on the required reporting events listed above, was **not reportable**.

Time Period for Required SRS determinations. If the SRS is unable to make a determination within 60 calendar days after receiving notification of the relevant event, it must immediately notify the MCD who, within 5 business days after receiving the SRS's notification, must provide ORO with an acceptable justification for the delay and an acceptable completion timeline.

Additional Review of Reported Incidents. The MCD and others acting within their areas of responsibility may also investigate such incidents and make separate determinations as to reporting, but cannot reverse or overrule a determination by the SRS that a reportable incident has occurred.

- (1) The MCD must be notified within 5 business days after any such separate determination that a reportable incident has occurred.
- (2) The MCD must report to ORO within 5 business days after making or receiving any separate determination that a reportable incident has occurred, and the SRS must receive a concurrent copy of the report.

Memoranda of Understanding (MOU). New or substantially revised MOUs related to research safety must be reported to ORO within 5 business days after the final concurrence/signature. ORO strongly encourages contacting ORO early in the development of new or revised MOUs.

Laboratory Decommissions and Re-assignments. The investigator or laboratory director must obtain authorization (i.e., permission) from the SRS and the ACOS/R&D prior to decommissioning or reassigning existing laboratory space (including modifying, vacating, or converting to non-laboratory use) that requires identification and disposal of hazardous materials, infectious agents, or equipment between uses.

- (1) The request for authorization to decommission or reassign laboratory space must be made in writing to the SRS and the ACOS/R&D at least 1 month prior to implementation.
- (2) Upon receiving such a request the SRS, in collaboration with the ACOS/R&D, must evaluate the space and determine if there are any specific hazards that require remediation.
- (3) The ACOS/R&D must notify the Safety Officer to ensure coordination of efforts in the inventory and efficient removal of hazardous materials, infectious agents, or equipment.
- (4) The ACOS/R&D must notify the MCD and the Safety Officer of any unauthorized decommissioning or re-assignment of laboratory space within 5 business days after becoming aware of the unauthorized decommissioning or re-assignment.
- (5) The MCD must report any unauthorized decommissioning or re-assignment of laboratory space to ORO within 5 business days after being notified.

**(A.29)****Recombinant DNA**

Recombinant DNA (rDNA) in the laboratory requires specific approval prior to use. A form outlining the experimental protocol and biosafety level (BL) class **must** be completed and approved by the Institutional Biosafety Committee (IBC) and Subcommittee on Research Safety (SRS) before any work with the agent can begin. The SRS Chairman can be contacted for specific questions regarding the use of rDNA. Guidelines for working with rDNA are available from the National Institute of Health website. If it is determined that the work is classified as Biosafety level 3, the laboratory personnel working with the recombinant DNA must undergo specialized training, orientation, and further background investigation for authorization to use a BSL3 facility.

**(A.30)**

**There is no active BSL3 environment available at the Durham VA as of 2009**

**B. The VAMC R&D Laboratory Safety Representatives Committee****(B.1)**

The Laboratory Safety Representatives committee is a network of peers for the research laboratories. The purpose of the committee is to standardize research laboratory safety practices and to assure research is carried out in a way that:

- Prevents accidents and minimizes exposure to hazardous agents and conditions
- Prevents degradation of the environment through responsible waste management and active waste reduction
- Conserves resources and minimizes losses
- Achieves regulatory compliance

**(B.2)**

The committee, with the support of laboratory Principal Investigators, is charged with the following objectives:

- To conduct a safety self-inspection of their representative labs once per year
- To keep laboratory staff informed regarding good workplace safety practices
- To maintain an as needed up to date hazardous materials inventory
- To dispose of un-used and/or outdated chemicals
- To comply with regulatory standards
- Laboratory Safety Reviews and Inspections

**(B.3)****Inspections**

At times, various individuals may inspect research areas for safety and security purposes. These may include, but are not limited to:

- Medical center administrative teams (Environment of Care)
- Accrediting and investigative bodies (JCAHO, ORO, AAALAC, OIG, etc)
- Service level teams (Subcommittee for Research Safety, Semi-Annual Program Review)
- Medical center employees (Industrial Hygienist and Safety Office Personnel)

**(B.4)**

**Laboratory personnel should ask to see identification of individuals who are unfamiliar and are seeking access to research areas.**

**(B.5)**

All research laboratories undergo an inspection/safety review on a regular basis, but no less than four times per year. The research industrial hygienist and/or safety officer will schedule inspections/reviews with the principal investigator and/or the Laboratory Safety Representative semi-annually to include toxins, building security, and chemical and material safety data sheet compliance. Each laboratory will complete a Research Laboratory Self-Assessment Form (**Attachment 16**) annually. The completed, signed and dated self-assessment form will be returned to the research safety & occupational health specialist for the SRS committee members to use during their annual research laboratory inspection/safety review.

**C. DVAMC Training and Education Plan for Research Staff****VHA Handbook 1200.08****Safety of Personnel Engaged in Research****8. Responsibilities of the Principal Investigator or Laboratory Director****C. Identifying Laboratory Specific Hazards, And:****(1) Ensuring That All Personnel Receive Training Specific to the Hazard(S)****(C.1)**

The Principal Investigator will ensure that all required personnel complete such training and its completion is documented.

**(C.2)**

Without Compensation (WOC), part-time, temporary, and contract employees and students must adhere to the same safety training requirements as a full-time employee for the job being performed. It is the responsibility of the Principal Investigator employing the WOC, part-time, temporary, or contract employee or student to enforce the safety training guidelines to these special category employees.

**(C.3)**

Prior to starting work, all individuals (VA employees appointed as full-time, part-time or intermittent paid employees, and WOC employees) will receive a New Research Staff Checklist from the Research Administration Secretary. New staff are required to return all completed items on the checklist prior to starting work.

**(C.4)**

**Prior to starting work, all staff are required to check-in with the Research Safety Office to receive A New Employee Safety Packet that includes:**

- New Employee Orientation (Research or Administrative)
- New Employee Job Specific Activities Questioner
- New Employee Required Training Checklist

- The Required Training Checklist is a comprehensive task specific questioner that gives staff the location, frequency and contact information for the required training.
- New Employee Training on Laboratory Hazards and Personal Protective Equipment
- Required Training for All Personnel

**(C.5)**

The New Employee Safety Packet is returned to the Research Safety Office, along with the employees Training History

**(C.6)**

New Animal Research Staff are required to check-in with the Animal Protocol Office prior working in a lab or the Animal Facility to ensure all paperwork and training is complete.

**(C.7)****Training is available in the following ways:**

- VAMC Orientation Program
- Talent Management System (TMS) Training Program on the VISN 6 Intranet
- Specialty Training Programs presented by the Research/Facility Industrial Hygienist
- Specialty Training Programs presented by Research/Facility Safety
- Principal Investigator Protocol Specific Training
- Computer based Modules
- Training provided by the Laboratory Safety Representatives
- CITI Program

**(C.8)****Subcommittee on Research Safety Committee (SRS)**

All active research protocols involving biological, chemical, physical, and radiation hazards, are reviewed initially and then annually. Each Protocol must include a Research Protocol Safety Survey (VA Form 10-0398) that explains laboratory procedures, materials used and practices. Protocols must also include Standard Operating Procedures (SOP) and the training of personnel involved.

**(C.9)**

Comparable safety training received through the Duke University Safety Training Program may be substituted for many of the DVAMC Research Laboratory Safety requirements, such as:

- Bloodborne Pathogens Training
- Biological Safety for Physicians
- Biosafety Level 2 and BBP for Lab Workers
- Chemical Safety - General
- Formaldehyde Exposure Awareness
- Laboratory Safety – General
- Laser Safety - Non Clinical Use

(C.10)

**Table 2:****Safety Training Requirements for DUKE Research Laboratory Personnel that is accepted by the Durham VA Research Safety Department**

<b>Safety Training Requirements for Research Laboratory Personnel Requirement</b>	<i>Orientation</i>	<i>Update</i>	<i>Who</i>
Tuberculosis (TB)	At the time of hire or before working in an area of exposure potential	Annually (365 days)	Those with potential exposure to TB
Fire/Life Safety	At the time of hire	Annually (365 days); also covered in Laboratory Safety - General	All employees
Formaldehyde Exposure Awareness	At the time of hire or before working with formaldehyde or paraformaldehyde	Taken once if working at the VA	Employees who will be working with formaldehyde or paraformaldehyde
Laboratory Safety - General	At the time of hire	Annually (365 days)	Employees who work in wet laboratories; also covers general chemical safety training for lab staff
Shipping Biological Materials	At the time of hire	Every two years (730 days)	Employees who will be shipping biological materials
Laser Safety Clinical Use (Non-embedded)	Prior to using a laser	Annually if working at the VA	Employees who work with class 3b or 4 lasers.
Laser Safety for Non-Clinical Use (Non-embedded)	Prior to using a laser	Annually if working at the VA	All research employees who work with class 3b or 4 laser systems
BSL-2 and BBP (Bloodborne pathogens)	Prior to working in a BSL2 laboratory	Annually (365 days)	Lab employees who work with BSL2 agents
<b>Note:</b> This list is not all-inclusive. Other training may be required based on the hazardous materials being used in the laboratory.			

(C.11)

**Table 3:****Required Training for All Research Lab Personnel**

	<b>Course Name</b>	<b>Course Location</b>	<b>Take at</b>	<b>Valid For</b>
<b>1</b>	Durham VA New Employee Laboratory Orientation	<b>Location:</b> Research Safety Office <b>Form:</b> RSF-001 <b>Questions Contact:</b> Research Safety (x 7341)	VA Only	Taken Once
<b>2</b>	Privacy and HIPAA Training	<b>Location:</b> Talent Management System (TMS) <b>Course Number:</b> 10203 <b>Questions Contact:</b> Research Admin (x 6926)	TMS Only	1 Year
<b>3</b>	VHA CO Compliance and Business Integrity (CBI) Awareness Training	<b>Location:</b> Talent Management System (TMS) <b>Course Number:</b> 7318 <b>Questions Contact:</b> Research Admin (x 6926)	TMS Only	1 Year
<b>4</b>	VA Privacy and Information Security Awareness & Rules of Behavior	<b>Location:</b> Talent Management System (TMS) <b>Course Number:</b> 10176 <b>Questions Contact:</b> Research Admin (x 6926)	TMS Only	1 Year
<b>5</b>	Fire/Life Safety	<b>Location:</b> Talent Management System (TMS) <b>Course Number:</b> VA 1341082 <b>Questions Contact:</b> Research Safety (x 7341)	Duke or TMS	1 Year
<b>6</b>	Emergency Preparedness Management Program-V06	<b>Location:</b> Talent Management System (TMS) <b>Course Number:</b> 1341136 <b>Questions Contact:</b> EMC (x 5975)	TMS Only	1 Year
<b>7</b>	Radiation Safety Basics-V06	<b>Location:</b> Talent Management System (TMS) <b>Course Number:</b> VA 1358297 <b>Questions Contact:</b> Radiation Safety (x 7909)	TMS Only	1 Year
<b>8</b>	DVAMC Research Hazardous Agents Control Program (Research Security Plan)	<b>Location:</b> Research Safety Office <b>Course Name:</b> Research Hazardous Agents Control Program (Research Security Plan) <b>Delivery Method:</b> Power Point / Test	VA Only	Taken Once

(C.12)  
Table 4:

**New Employee Required Training Checklist**

Item	Please answer each question	Circle Answer		Required Training if answered "YES" to corresponding question
1	Will you be performing any activities in a lab while at Durham VAMC?	YES	NO	<b>Location / Tracked By:</b> TMS or Duke <b>Course Name:</b> General Lab Safety Training <b>TMS Course Number:</b> 1345291 <b>Delivery Method:</b> Web/Computer Based <b>Questions Contact:</b> Research Safety (x 7341)
1A	If answered "YES" to question 1; this training is also required			<b>Location / Tracked By:</b> <a href="https://citiprogram.org">https://citiprogram.org</a> <b>Course Name:</b> Biosecurity <b>Course Number:</b> N/A <b>Delivery Method:</b> Web/Computer Based <b>Questions Contact:</b> Research Safety (x 7341)
2	Will you be working in a laboratory conducting research on/with <b>humans</b> while a Durham VAMC? (Working with VA IACUC)	YES	NO	<b>Location / Tracked By:</b> <a href="https://citiprogram.org">https://citiprogram.org</a> <b>Course Name:</b> Human Subjects Courses <b>Course Number:</b> N/A <b>Delivery Method:</b> Web/Computer Based <b>Questions Contact:</b> Protocol Office (x 5170)
3	Will you be working in a laboratory conducting research on/with <b>animals</b> while at Durham VAMC?	YES	NO	<b>Location / Tracked By:</b> <a href="https://citiprogram.org">https://citiprogram.org</a> <b>Course Name:</b> Animal Care and Use <b>Course Number:</b> N/A <b>Delivery Method:</b> Web/Computer Based <b>Questions Contact:</b> Protocol Office (x 6548)
4	Will you be performing <b>only</b> administrative duties while in an active lab while at Durham VAMC? (Your workstation is in a lab)	YES	NO	<b>Location / Tracked By:</b> TMS <b>Course Name:</b> Hazard Communication <b>TMS Course Number:</b> 1278997 <b>Delivery Method:</b> Web/Computer Based <b>Questions Contact:</b> Research IH (x 7807)
5	Will you at any time while at Durham VAMC, be involved in activities where you will be required to use a respirator?	YES	NO	<b>Location / Tracked By:</b> Research Industrial Hygienist <b>Course Name:</b> Respirator Training <b>Course Number:</b> N/A <b>Delivery Method:</b> Live Presentation <b>Questions Contact:</b> Research IH (x 7807)
6	Will you at any time at Durham VAMC, encounter or may possibly encounter human blood, tissue, cell lines or any other potentially infectious materials?	YES	NO	<b>Location / Tracked By:</b> TMS or Duke <b>Course Name:</b> Bloodborne Pathogen Awareness <b>TMS Course Number:</b> 1345291 <b>Delivery Method:</b> Web/Computer Based <b>Questions Contact:</b> Research Safety (x 7341)

(C.12)  
Table 4:

**New Employee Required Training Checklist**  
*(Continued)*

7	Will you be handling chemicals at any time while at Durham VAMC?	YES	NO	<b>Location / Tracked By:</b> TMS <b>Course Name:</b> Chemical Hygiene Plan Training <b>TMS Course Number:</b> DUR VA 1345226 <b>Delivery Method:</b> Web/Computer Based  <b>Questions Contact:</b> Research IH (x 7807)
7A	If answered "YES" to question 7; this training is also required			<b>Location / Tracked By:</b> Research Safety Office <b>Course Name:</b> Hazardous Waste <b>Delivery Method:</b> Power Point/Test  <b>Questions Contact:</b> Research Safety (x 7341)
7B	If answered "YES" to question 7; this training also required			<b>Location / Tracked By:</b> Research Safety Office <b>Course Name:</b> Research Chemical Spill Response <b>Location:</b> This Research Safety Packet <b>Delivery Method:</b> Power Point / Test  <b>Questions Contact:</b> Research Safety (x 7341)
7C	If answered "YES" to question 7; this training also required			<b>Location / Tracked By:</b> Research Safety Office <b>Course Name:</b> Emergency Eyewash / Shower Training <b>Location:</b> This Research Safety Packet <b>Delivery Method:</b> Power Point / Test  <b>Questions Contact:</b> Research Safety (x 7341)
8	Will you use lasers or be in the approximately of lasers at any time while a Durham VAMC? <b>(Not embedded lasers)</b>	YES	NO	<b>Location / Tracked By:</b> TMS or Duke <b>Course Name:</b> Laser Safety Training - SAH0449 <b>TMS Course Number:</b> 27250 <b>Delivery Method:</b> Web/Computer Based  <b>Questions Contact:</b> Radiation Safety (x 7909)
9	Will you at any time be working in Building 14 (Animal Housing Facility) while at Durham VAMC ?	YES	NO	<b>Location / Tracked By:</b> Facility Safety Manager <b>Course Name:</b> Fire Extinguisher Training <b>Course Number:</b> N/A <b>Delivery Method:</b> Live Presentation  <b>Questions Contact:</b> Facility Safety (x 7554)

(C.12)  
Table 4:

**New Employee Required Training Checklist**  
(Continued)

10	Will you work in Building 14 as Animal Housing Facility <b>STAFF</b> while at Durham VAMC?	YES	NO	<b>Location / Tracked By:</b> TMS or Duke <b>Course Name:</b> Hearing Conservation / Heat Stress <b>TMS Course Number:</b> 1370650 <b>Delivery Method:</b> Web/Computer Based
				<b>Questions Contact:</b> Research IH (x 7807)
10A	If answered "YES" to question 9; this training is also required			<b>Location / Tracked By:</b> Research Industrial Hygienist <b>Course Name:</b> Respirator Training <b>Course Number:</b> N/A <b>Delivery Method:</b> Live Presentation
				<b>Questions Contact:</b> Research IH (x 7807)
10B	If answered "YES" to question 9; this training is also required			<b>Location / Tracked By:</b> TMS <b>Course Name:</b> Hazard Communication <b>TMS Course Number:</b> 1278997 <b>Delivery Method:</b> Web/Computer Based
				<b>Questions Contact:</b> Research IH (x 7807)
11	Will you package; label packages; load, unload or prepare paperwork for the shipment (mailing) of potentially infectious materials or dry ice?	YES	NO	<b>Location / Tracked By:</b> <a href="https://citiprogram.org">https://citiprogram.org</a> / Duke <b>Course Name:</b> Shipping Biohazardous Specimens <b>Course Number:</b> N/A <b>Delivery Method:</b> Web/Computer Based
				<b>Questions Contact:</b> Research Safety (x 7341)
12	Will you have any potential exposure to Tuberculosis (TB) at any time while at the Durham VAMC?	YES	NO	<b>Location / Tracked By:</b> TMS or Duke <b>Course Name:</b> TB-Tuberculosis V06 <b>TMS Course Number:</b> 1367513 <b>Delivery Method:</b> Web/Computer Based
				<b>Questions Contact:</b> Research IH (x 7807)
12A	If answered "YES" to question 12; this training also required			<b>Location / Tracked By:</b> Research Industrial Hygienist <b>Course Name:</b> Respirator Training <b>Course Number:</b> N/A <b>Delivery Method:</b> Live Presentation
				<b>Questions Contact:</b> Research IH (x 7807)
13	Will you use / handle controlled drugs at any time while at the Durham VAMC?	YES	NO	<b>Location / Tracked By:</b> GEMS <b>Course Name:</b> Pharmaceutical Waste Management <b>Course Number:</b> N/A <b>Delivery Method:</b> Live Presentation / Train-the-Trainer
				<b>Questions Contact:</b> GEMS (x 6470)

(C.12)

**Table 4:**

**New Employee Required Training Checklist**  
(Continued)

14	Will you use or be in the approximately of anesthetic gases at any time while at the Durham VAMC?	YES	NO	<b>Location / Tracked By:</b> Research Industrial Hygienist <b>Course Name:</b> Use of Anesthetic Gases <b>Course Number:</b> N/A <b>Delivery Method:</b> Live Presentation  <b>Questions Contact:</b> Research IH (x 7807)
14A	If answered "YES" to question 14; this training also required			<b>Location / Tracked By:</b> Research Industrial Hygienist <b>Course Name:</b> Use of an F/Air Canister <b>Course Number:</b> N/A <b>Delivery Method:</b> Live Presentation  <b>Questions Contact:</b> Research IH (x 7807)
15	Will you use or be in the approximately of Formaldehyde, Para Formaldehyde or Formalin at any time while at the Durham VAMC?	YES	NO	<b>Location / Tracked By:</b> TMS or Duke <b>Course Name:</b> Formaldehyde Awareness Training <b>TMS Course Number:</b> 1345523 <b>Delivery Method:</b> Web/Computer Based  <b>Questions Contact:</b> Research IH (x 7807)
16	Will you use radioactive material at any time while at the Durham VAMC?	YES	NO	<b>Location / Tracked By:</b> Radiation Safety Officer <b>Course Name:</b> Durham VAMC Radiation Safety <b>Course Number:</b> N/A <b>Delivery Method:</b> Live Presentation  <b>Questions Contact:</b> Radiation Safety (x 7909)
17	Will you use time sensitive or peroxide-forming chemicals at any time while at the Durham VAMC?	YES	NO	<b>Location / Tracked By:</b> Research IH <b>Course Name:</b> Peroxide Formers Training <b>Course Number:</b> N/A <b>Delivery Method:</b> Power Point / Test  <b>Questions Contact:</b> Research IH (x 7807)
18	Will you use compressed gas cylinders or gas regulators any time while at the Durham VAMC?	YES	NO	<b>Location / Tracked By:</b> Research Safety Office <b>Course Name:</b> Gas Cylinder/Regulator Training <b>Delivery Method:</b> Power Point / Test  <b>Questions Contact:</b> Research Safety (x 7341)
19	Will you use liquid nitrogen at any time while at the Durham VAMC?	YES	NO	<b>Location / Tracked By:</b> Research Safety Office <b>Course Name:</b> Liquid Nitrogen Safety <b>Delivery Method:</b> Power Point / Test  <b>Questions Contact:</b> Research Safety (x 7341)
20	Will you be using needles on <b>Humans</b> to draw blood, perform injections or use IVs at any time while a Durham VAMC?	YES	NO	<b>Tracked By:</b> Research Safety Office <b>Training:</b> Competencies in the use of sharps engineering controls must be demonstrated and recorded. <b>Contact:</b> Research Safety (x 7341)

## **D. GENERAL LABORATORY PRACTICES**

### **(D.1)**

Access to the laboratories is limited or restricted in compliance with regulatory and security requirements. All employees are responsible for following the rules on the use of the key card access system in all research areas. All doors to labs and offices must be locked after working hours when not occupied by authorized employees. Medical Center Security will report the incidence of unlocked doors.

### **(D.2)**

The Animal Research Facility (Building 14) is locked at all times. A magnetic key card (VAMC Photo Identification Badge coded for admittance) is required to gain entry through the exterior doors. A key card may be obtained after completing the relevant paperwork in the Research Office. Documentation of animal handlers training and occupational health assessment is required prior to admittance into Building 14.

### **(D.3)**

Always be careful to assess possible hazards of working alone in certain laboratory situations. Such situations include work with highly toxic substances, high-pressure or high-vacuum systems, cryogenics, high-energy electrical systems, flammable liquids, or work in confined areas with difficult egress. Do not work alone in a walk-in freezer or cold room.

### **(D.4)**

Laboratory areas are to be designated as clean or potentially contaminated and appropriate signs and labels must be in place. Contaminated areas require the practice of Universal Precautions. Phones, counter tops, computers and other equipment must be disinfected in contaminated work areas at the end of each shift and when gross contamination occurs, with a 1:10, or 1:100 diluted bleach, or other approved tuberculocidal disinfectant. **If diluted bleach is used, it must be dated and discarded after one week.**

### **(D.5)**

Potentially contaminated lab coats, gloves and other personal protective equipment (PPE) must not be worn in clean areas. **Any PPE worn in a laboratory setting is considered potentially contaminated.** Place soiled laundry, including lab coats worn as PPE, directly in the laundry bags (red plastic biohazard labeled bags or standard laundry bags supplied by the Hospital laundry service). Identify laundry bags (plastic or cloth) with Laundry issued labels. For laundry sent to an outside service, the bags must be labeled with a biohazard label or color-coded (orange or red) to communicate the potential biohazard.

### **(D.6)**

Eating, drinking, handling contact lenses and applying cosmetics are prohibited in technical work areas and clerical work areas located within an open laboratory.

### **(D.7)**

**Food is prohibited** in refrigerators where reagents or specimens are stored and refrigerators used for food and drink must be clearly labeled.

**(D.8)**

**Smoking is prohibited** inside all VA medical center buildings. Smoking is allowed in designated smoking area only. (MCM 558-13-001.3)

**Smoking is prohibited:**

- In the elevated walkway between the Medical Center and the parking garage.
- Within 35 feet of entrances to VHA leased buildings.
- In any government vehicle.

**(D.9)**

Smokers will deposit debris and cigarette butts in a proper receptacle. Individuals who are smoking in prohibited areas will first be educated about the policy, followed by restrictive or disciplinary action for repeat offenses. Research and Development Service will ensure that research protocols involving smoking within the Medical Center meet the requirements stated above.

**(D.10)**

**Mouth pipetting is prohibited. Mechanical pipetting devices must be made available in the work area.**

**(D.11)**

If splash and/or splatter is anticipated while working with hazardous substances, all personnel must wear safety goggles and a mask or use a face shield. Employees are strongly advised not to wear contact lenses in the laboratory. If contact lenses are worn, personnel protective equipment must be used to protect the eyes when working with hazardous substances. Personnel wearing contact lenses should be aware that they offer no protection from splash and may concentrate caustic or biohazardous materials against the cornea or prevent tears from washing the eye.

**(D.11)**

Hands must be washed with soap and water before and after contact with subjects (human and animal), before eating or smoking, drinking, handling contact lenses and applying cosmetics, after removing gloves and before leaving the laboratory. In areas with no hand washing sink, alcohol based waterless hand rub may be used until the employee can get to a hand washing sink. ***Never leave a "dirty area" to go out into the general public environment without removing your PPE and washing your hands with soap and water.*** To avoid recontamination, use a paper towel to turn water off after hands are washed and dried. A good alternative method uses knee, foot or automatic controlled faucets where available. Additionally, hand to face contact should be avoided. Gloves should be removed and hands washed prior to touching your face.

**(D.12)**

The standard isolation and precaution policies of the hospital should be observed when indicated. Consult MCM 111.15. Doors to the laboratory should be kept closed. Exits and corridors must not be blocked, bolted or obstructed in any way to block egress.

**(D.13)**

Equipment, supplies or trash are not permitted in exit routes (hallways).

**(D.14)**

Do not allow trash to accumulate in any area.

**(D.15)**

Do not store personal belongings in the technical work area.

**(D.16)****Laboratory personnel must adhere to the following dress code requirements:**

- Hair must be secured to prevent contact with contaminated materials or surfaces. Personnel with beards must observe the same precautions.
- Appropriate personal protective equipment for the protocol in process.
- Laboratory personnel should wear sturdy shoes with non-slip soles that cover the entire foot. Shoe covers must be worn whenever gross contamination due to splash or spill is anticipated. Sandals are not allowed at any time in the laboratory.
- Shorts and miniskirts are not to be worn while working in a laboratory. Exception would be if worn under a long laboratory coat or apron.

**(D.17)**

Laboratory personnel shall comply with **waste minimization guidelines**, as set forth in the facility Green Environmental Management System (**GEMS**) Policy (MCM 138.10), to reduce the volume of both non-hazardous (non-regulated) and regulated hazardous waste generated in the laboratory to include:

**(D.18)**

Recycle of paper, plastic and chemical products

**(D.19)**

Redistribution of supplies and reagents

**(E.20)**

Reduction of biological specimens and reagent requirements through process changes

**(D.21)**

Operating on an “as needed” inventory

**(D.22)**

Elimination of disposing of non-hazardous waste in the biological and chemical waste disposal containers.

**(D.23)****Laser Safety**

Laser Safety Program participation for preventing and controlling occupational exposures is required for employees using Class 3b and 4 lasers. Contact the facility Laser Safety Officer at X6952 for further information.

## **E. WARNING SIGNS AND LABELS**

Warning signs and labels are the primary resource in identifying potential hazards and safety equipment to the employee in the laboratory. For the employee's personal safety, there should be signs located at the safety shower, eye wash stations and other safety equipment. There should also be warnings at areas of machinery where special and unusual hazards exist. Additionally, some general considerations for Chemical, Biological and Radiation signs and labels are presented below.

### **(E.1)**

#### **Chemical Labels and Warnings**

Occupational Safety and Health Administration (OSHA) standards require that manufacturers and distributors of hazardous chemicals label all containers with the identity of the chemical, the appropriate hazard warnings and the name and address of a responsible party from whom additional chemical information may be obtained. The label should also include first aid directions. Further information concerning Hazards/Safety issues can be found in the Material Safety Data Sheets (MSDS) which manufacturers are required by law to provide. A copy of MSDS published by the manufacturer of each chemical used in the lab must be available in the lab for employees. If the reagent is made in the laboratory, the label should include the chemical name, date prepared, technologist's initials and expiration date (if applicable). The manufacturer's label **MUST** be left on the container; however, intralab labels may be added to warn the employees of potential hazards, (i.e. "Strong Acid", "Potential Carcinogen").

### **(E.2)**

#### **Biohazard Warning Labels**

OSHA requires biohazard labels or other appropriate forms of warning be provided on containers of regulated medical waste, on refrigerators or freezers that are used to store blood or potentially infectious materials (PIMS), on other containers used to store or transport blood, or other PIMS or materials contaminated with blood or PIMS (i.e., laundry) and any contaminated equipment. The only exception would be the substitution of red bags or red containers with the biohazard symbol for infectious waste. CDC/NIH Guidelines require the entrance to laboratories be posted with a biohazard sign. The sign should include the universal biohazard symbol, the word "Biohazard", the appropriate biosafety containment level (i.e. BSL-2 or BSL-3), the responsible person's name and contact number, the text "Authorized Personnel Only", and any special requirements for entry (i.e. personal protective equipment or vaccination requirements). At a minimum, the sign must include the universal biohazard symbol and the word "Biohazard". The other guideline requirements for a biohazard sign can be enforced depending on the laboratory biosafety containment level and location.

### **(E.3)**

#### **Radiation Labels and Warnings**

If radioactive materials are used, they should be placed in separate, labeled containers. The radioactivity use area must be labeled, and the door to the laboratory must have a radiation sign posted. The sign must include the universal radiation symbol and the words "Radioactive Materials" or "Radiation Area" as appropriate. There should also be an appropriate waste container for radioactive waste. This should be labeled with the name of the laboratory, the isotope used, and its concentration.

## **F. Biological Specimen Transport (By Foot)**

Laboratory specimens should be transported so that the integrity of the specimen and safety of the personnel and the transport system are maintained.

**(F.1)**

Observe universal precautions and wear personal protective equipment (PPE) when handling and transporting specimens.

**(F.2)**

Biohazard labels must be placed on all specimens.

**(G.3)**

Do not transport specimens in a syringe or other container bearing a needle.

**(F.4)**

Transport reusable sharps in a leak proof, puncture-resistant container.

### **G. Biological Specimen Shipping (By Mail)**

**(G.1)**

Package specimens properly to protect them in transit as well as to protect the personnel handling them. Never mail a specimen in Petri plates.

**(G.2)**

Never enclose dry ice in airtight (hermetically sealed) containers.

**(G.3)**

Specimens shall be packed, packaged and labeled in full accordance with the Department of Transportation (DOT) and the International Air Transportation Association (IATA) requirements.

**(G.4)**

All shipments originating from Durham VAMC Research & Development must comply with the Dangerous Goods Regulations (DGR).

**(G.5)**

“Proper Shipment of Biological Materials” training is required by staff who package biological materials for land or air transport. **Training must be renewed at least every two years.**

**(G.6)**

**The required training can be found at:**

- <http://www.safety.duke.edu>
- <http://www.citiprogram.org>

\*See Attachment 3 of this document for packaging guidelines.

### **H. Biological Safety and Infection Control**

**(H.1)**

Handle all specimens potentially contaminated with a pathogenic fungi or mycobacteria (TB) in a biological safety cabinet (BSC). If a BSC is not available, then personnel processing these specimens must be fitted for and wear an N95 respirator mask. Other personnel in the room when these specimens are processed must also wear an N95 respirator mask for which they have been fitted or leave the room.

**(H.2)**

All tissue known or suspected of being infected with TB must be frozen by immersing the tissues in Freon. Under no circumstances should any type of spray be used for freezing tissue. Universal/Standard Precautions will be practiced at all times when handling fresh human tissue.

**(H.3)**

Use screw-capped cups in specimen processing centrifuges. Use stoppered tubes (double containment) when centrifuging samples. Do not operate centrifuges in biological safety cabinets. In labs handling pathogenic fungi or mycobacteria, the safety cups must be opened in a BSC.

**(H.4)**

Sterilize bacteriological needles and loops so as not to cause aerosols. Allow the tip to cool to avoid aerosols caused by searing the surface of the media.

**(H.5)**

Document annual BSC certification. Document filter changes. Establish policies for routine disinfecting and methods to handle spills in the biological safety cabinet.

**(H.6)**

Female and male workers who are contemplating having children, or pregnant women who work in research laboratories may discuss with Employee Occupational Health occupational reproductive concerns they may have.

**(H.7)**

**The TB skin test is available through Employee Occupational Health bi-annually for the microbiology laboratory staff and annually for the staff in all other research laboratories.**

**(H.8)**

Modify procedures to reduce or eliminate splashing, splattering, aerosolization, spills or other contamination. Include a safety section for each procedure in the procedure manual to address any special hazards. When potential exposures cannot be eliminated, perform work behind a splash shield or in a biological safety cabinet if available. If neither are available, wear appropriate personal protective equipment defined in the task assessment program (i.e., face shield, goggles, mask or respirator caps, etc.). Wear gloves during specimen and culture processing. Dispose of contaminated gloves in biohazard waste receptacles. Wash hands after removal and disposal of gloves.

**(H.9)**

All employees are required to comply with the medical center Bloodborne Pathogen Exposure Control plan, MCM 111.15, as required by OSHA's Standard 29 CFR 1910.1030, Bloodborne Pathogens

(See Attachment 6).

**(H.10)**

**It is mandatory that employees follow the SRS-SOP-201 “Research Using Human Blood, Tissue, or Cell Lines” (See Attachment 4) when in contact with and when handling all human biological specimens.**

**(H.11)**

All laboratory employees with anticipated exposure to blood or body fluids are offered the Hepatitis B vaccine and are encouraged to receive it. Care must also be taken to minimize exposure to potential pathogens through aerosolization, ingestion, direct inoculation, and mucous membrane contact of solutions possibly containing infectious agents. Arthropod vectors may also serve as a source of infection; therefore the environment must be kept free of infestations. Warning signs incorporating the universal biohazard symbol must be posted at all locations where there is a risk for occupational exposure to blood, other body fluids, and infectious agents and laboratories should limit access to authorized persons who have been advised of the potential biohazard and who comply with Universal Precautions.

**(H.12)**

Personal protective equipment (PPE), sharps collection devices and disposal containers are evaluated and approved by the medical center Infectious Disease Committee. Medical center staff personnel participate in the evaluation and implementation process.

**(H.13)**

**Table 4:**

**Infectious Disease Staff Contact Numbers**

Infectious Diseases Fellow	Contact hospital operator for pager #
Chief, Infectious Diseases	Pager 970-PLAG (7524)
Infectious Diseases Attending	Contact hospital operator for pager #
Infection Control Nurses	Extension 6028 or 7307, pager 287 or 278 (contact hospital operator after administrative hours)

**(H.14)**

**Universal/Standard Blood and Body Fluid Precautions**

The following are the key elements of the plan to control occupational exposures to bloodborne pathogens. Healthcare workers must consider all blood, body fluids and other human specimens as potentially infectious and use appropriate protective measures to prevent exposures. Additional comments are made to specifically address hazards in the laboratories in the 29 CFR 1910.1030 the Bloodborne Pathogens Standard (See Attachment 6).

**(H.15)**

**Hand Hygiene**

- Fingernails must be maintained in a clean condition and well groomed.

- If direct subject contact (example phlebotomy) is required in order to perform a task then:
- Artificial fingernails or extenders cannot be worn
- The length of the nail should not exceed 1/4 inch beyond the tip of the finger
- Fingernails must be free of chipped or peeling nail polish.
- Wash hands with soap and water or an approved waterless hand cleaning agent when gloves are removed, between subject contact, whenever they become contaminated and after completing laboratory activities.
- Locate hand wash and eyewash stations as close to the work area as is feasible and where absent, provide a substitute technique.
- Hand cream (tube or dispenser) is not considered a "cosmetic", and its use in the work area to prevent chapping and help maintain skin integrity is encouraged following hand washing.

**NOTE:** *Use of the hand lotion supplied by the facility is recommended.*

- Cover all skin defects (dermatitis, exudative lesions, scratches, paper cuts, damaged cuticles) with water-impermeable, occlusive bandages (Op Site, Tegaderm), if indicated, and gloves prior to direct subject contact or to handling materials containing potentially infectious agents or clinical specimens. If the area cannot be covered, refrain from such contact.

#### **(H.16)**

##### **Personal Protective Equipment for Anticipated Blood or Body Fluid Contact**

- Remove all personal protective equipment and perform hand washing prior to exiting the work area and entering designated public access areas (e.g., lunchrooms, elevators, break rooms, restrooms, etc.).
- Laboratory Principal Investigators must provide personal protective equipment and training and must also be responsible for its proper use, cleaning, maintenance and disposal.
- Laboratory Principal Investigators must choose personal protective equipment as part of their task assessments. For example, provide face shield, goggles, caps, shoe covers and fluid resistant gowns for work situations where significant gross contamination can be anticipated.
- Laboratories must provide employees of other departments (internal or external) with the same personal protective equipment required by laboratory workers.

#### **(H.17)**

##### **Gloves**

- Wear gloves when working with blood, body fluids, mucous membranes or non-intact skin of patients.
- Wear gloves when handling items or surfaces soiled with blood or body fluids.
- Wear gloves when performing vascular access procedures (e.g. phlebotomy).
- Gloves should be changed and hands washed between each patient procedure.
- Wear gloves when processing specimens (e.g. removing tops from vacuum tubes).
- Remove gloves if they become visibly contaminated with blood; if physical damage occurs; before handling the telephone, laboratory equipment, door knobs, etc. in areas designated "clean" (without biohazard sign); and after processing specimens.
- Replace gloves as soon as is practical after contamination.
- Have protective gloves of appropriate sizes available and address special needs, such as allergies to powder or latex.

#### **(H.18)**

##### **Latex Sensitivity / Allergy**

Laboratory personnel follow the medical center guidelines for the selection of protective gloves. The medical center prescribes a latex-safe environment that includes the use of powder-free latex and non-latex gloves. The medical center Employee Occupational Health provides consultation, evaluation, and treatment for employees in the event of an allergic reaction. (Latex Sensitivity / Allergy MCM 558-12-11C.18)

**(H.19)****Laboratory coats, gowns, aprons, etc.**

- Wear appropriate gowns or aprons when splashes or soiling of skin or clothing with blood or body fluids is likely.
- Laboratory coats used as personal protective equipment must be at least 3/4 length, buttoned or closed in front and long-sleeved (not worn with sleeves rolled above gloves). These may be standard stock, disposable plastic, or the operating room gown type of garment.
- Laboratory management must provide personal protective equipment that is laundered and repaired at no cost to the employee.
- Do not take laboratory coats home for cleaning.
- Remove and replace laboratory coats when penetrated by blood and other potentially infectious materials.
- Change laboratory coats at appropriate intervals to ensure cleanliness.
- Wear a laboratory coat when working with blood and body fluids.
- Lab coats used as PPE must not be worn out of the work area (i.e., cafeteria or library).

**(H.20)****Masks, goggles, shields, etc.**

- Use facial barrier protection (masks, goggles, face shield) during procedures likely to generate splashes of blood or body fluids into the mouth, nose or eye.
- Use one of the following as appropriate for the situation:
- Use a gauze pad to cover the rubber stopper or snap-cap while removing it from a specimen container.
- Use a plastic splash shield under which tubes are opened.
- Use a surgical mask to protect the nose and mouth and wrap-around safety glasses or goggles with a plastic cushion seal to provide adequate eye protection. Ordinary prescription glasses are not adequate.
- Use a full face plastic shield for complete protection of the face and neck.
- Use a Class I or II Biological Safety Cabinet when risk of substantial splatter or major aerosolization is present. Such activities include blending, sonicating and vigorous mixing
- Use mechanical pipetting devices when manipulating all liquids. Do not mouth pipette. Dispose of contaminated pipettes in a puncture resistant container. Once filled, the container is to be discarded as biohazard waste.
- Protect against aerosols when handling solutions that may contain concentrated or high titers of infectious agents. Such activities include removing stoppers or plugs from sample tubes, dropping solutions onto hard surfaces, centrifuging unstoppered tubes and heating liquids too rapidly (including microbiological inoculating loops).

**I. Needles and Other Sharps**

**(I.1)**

Use safety needle/sharps devices to reduce percutaneous injuries where applicable (See Note.). This includes the use of the "Safety-Butterfly" (winged steel needle) system, the "Interlink" blood collection system, the "Eclipse" vacutainer and hypodermic needle, the blood transfer device for syringe transfer, the retractable lancet, the plastic coated capillary tube, and the blood gas covered system.

**(I.2)**

**DO NOT recap, bend, cut, break, remove from disposable syringes or otherwise manipulate used needles. When resheathing of needles is required, use the "one-handed scoop" technique or a recapping device. Use sharps including needles, skin lancets and scalpel blades only when absolutely necessary.**

**(I.3)**

Never touch or unscrew any needle from the collection sleeve after collecting a blood specimen. Discard both the sleeve and needle as a unit into the needle box after use.

**(I.4)**

Discard contaminated scalpels, needles, capillary pipettes, slides, coverslips and other sharp-edged disposable items into designated "sharps" containers (properly labeled and puncture-resistant).

**(I.5)**

Sharps container should be located near blood or other potentially infectious material.

**(I.6)**

Sharps container must be secured to prevent it from tipping over.

**(I.7)**

Use a mechanical device (e.g. forceps or dustpan and broom) to place contaminated, broken glassware into a "sharps" container. Do not attempt to pick this material up by hand.

**(I.8)****Sharps Decision Form**

Along with drawing blood, administering injections, or inserting IVs, BSL-2 (laboratories working with human blood, body fluids, and/or cell lines) and ABSL-2 (laboratories working with animals and using agents associated with human disease) must use the safest available devices. If the safest engineered sharps device cannot be used with a process/protocol, the laboratory must complete the "Sharps Decision Form" (See Attachment 17.) and attach to the VA Form 10-0398 (Research Protocol Safety Survey (RPSS) for submission to the SRS/IBC committee. This form will be used to document exceptions to the sharps devices guidelines as stated in the "OSHA Occupational Exposure to Bloodborne Pathogens" standard and the VA MCM 111.15.

**J. Exposures to Blood or Body Fluid via Needle Sticks, Mucous Membrane or Broken Skin Contact**

**(J.1)**

- Wash affected skin sites immediately with soap and water or rinse eyes at eye wash station. Use large quantities of water to wash contaminated mucosal and conjunctival sites.
- Apply first-aid as indicated.
- Immediately report to the Employee Occupational Health office during normal business hours and to the Emergency Department during other times.

**\*Always get medical attention first and then worry about the paper work.**

**(J.2)**

Report all accidents (needle stick, cut with a contaminated instrument, or blood or body fluid into an open skin lesion or mucous membrane) to the supervisor immediately.

**(J.3)**

The supervisor completes the VA Form 2162 and CA-1 and/or CA-2.

**(J.4)**

The Employee completes the Form CA-1 and/or CA-2 and goes to Employee Occupational Health office for evaluation and follow-up of blood or body fluid, percutaneous, non-intact skin and/or mucous membrane exposures.

**(J.5)**

All pertinent instructions for hepatitis B vaccination and post-exposure follow-up are listed in the Employee Health Post-Exposure Evaluation and Follow-Up.

**K. Environmental Controls****(K.1)****General Housekeeping**

- Maintain your work area in a clean and sanitary condition.
- Decontaminate work surfaces and equipment immediately after a spill of blood or other body fluids, using the recommended spill clean-up protocol (SEE Section “O”, page 44).
- Decontaminate work surfaces and equipment at the end of each shift. If work surfaces and machines are used intermittently (i.e., once or twice per week), these surfaces should be cleaned after each day/shift of use.
- Disinfect work surfaces with 1:10 dilution of sodium hypochlorite (bleach) or other tuberculocidal solutions.
- Decontaminate drains at least at the end of each shift when blood/body fluids or other potentially infectious materials are siphoned or directly drained to a floor drain or sink.
- Cans, bins or pails containing regulated waste which are intended for reuse must be inspected and cleaned on a regular basis. A waste bin lined with a disposable bag which leaks may contaminate the outside of successive bags. Cleaning is required after such contamination.
- Specify the type of disinfectant [i.e., 1:10 or 1:100 diluted sodium hypochlorite (bleach), phenolics, or other compounds] for each work area.
- Disinfectants must be tuberculocidal, and thus effective on HBV.

- Diluted sodium hypochlorite (bleach) solutions at a pH 8.0 should be remade at least **once a week** when stored at room temperature in closed plastic containers. Therefore, **diluted bleach containers must be labeled with the expiration date**.
- Laboratories should be aware of the corrosive aspects of sodium hypochlorite (bleach).
- Discard phenolic disinfectants by pouring down the drain with running water to dilute the solution.

**Note: Bleach solutions used for spill clean-up should be freshly-made.**

**(K.2)**

Each laboratory must have a regular schedule to evaluate whether repair or replacement of engineering controls is required. Documentation of review and repair is suggested. Examples include regular checks of splash shields, hoods, hand washing and eyewash facilities, etc. Check sharps containers regularly to assure replacement at sufficiently frequent intervals to prevent overfilling.

**(K.3)**

**Clean and Dirty Areas**

Laboratories must designate telephones, computer terminals and other generally accessible equipment and surfaces as "clean". These designated "clean" items should not be used by personnel wearing gloves. When equipment must be used by personnel wearing gloves, the equipment will be considered contaminated, and must be labeled with the biohazard symbol.

**(K.4)**

If equipment and surfaces are not labeled "biohazard" or "dirty" then they are understood to be "clean".

**(K.5)**

Decontaminate biohazard labeled equipment and surfaces immediately after gross contamination and routinely at the end of each shift.

**(K.6)**

Computer keyboard covers should be used on keyboards in "dirty" work areas to allow proper surface decontamination.

**(K.7)**

Clean items are stored so that they cannot be contaminated and soiled items are stored so they cannot contaminate their environment. Do not store items directly on the floor as mopping and cleaning may lead to contamination and growth of infectious organisms.

## **L. Research / Medical Wastes**

**(L.1)**

Place contaminated, disposable items (gloves, dressings, etc.) in sturdy, plastic bags and tightly close for transport.

**(L.2)**

Dispose of body fluids such as urine, vomitus, feces, (etc) down the sanitary sewer (commode). These fluids should not be drained into a sink that is used for hand washing, unless the sink is immediately decontaminated after fluid disposal by rinsing sink with 1:10 bleach.

**(L.3)**

Carefully place body fluids contained in pleurevacs, blood bags, suction liners (large volumes) in a "biohazard" box.

**(L.4)**

Specimens and sharps containers including pipette boxes are discarded in biohazard bags and picked up by Environmental Management Services.

**(L.5)**

Discard general specimens, cultures, used media and other disposable material in a container lined with a labeled biohazard bag. The bag should be clearly labeled as to the hazards within it. Double bagging is recommended to prevent leakage. Bags will be picked up by environmental management service (EMS) staff for incineration or autoclaving and disposal.

**(L.5)**

It is recommended that Biosafety level 2 or greater organisms be autoclaved by the lab staff prior to pick up by the EMS.

**(L.6)**

Used media may also be collected and decontaminated with at least 15 % bleach for at least one hour prior to disposal down the sink.

**(L.7)**

Place reusable materials and instruments in stainless steel containers in a 1:10 solution of sodium hypochlorite (bleach) or other tuberculocidal disinfectant until autoclaving, cleaning and sterilization can be done.

**\*Refer to MCM 137.1 “Infectious Waste Disposal”**

## **M. Laundry**

**(M.1)**

Consider all used linen as potentially infectious.

**(M.2)**

Handle soiled linen as little as possible.

**(M.3)**

Place laundry directly in the laundry bags (red plastic biohazard labeled trash bags or standard laundry bags supplied by the Hospital laundry service). Identify laundry bags (plastic or cloth) with Laundry issued labels. For laundry sent to an outside service, the bags must be labeled with a biohazard label color-coded to communicate the potential risk of handling soiled linen.

**(M.4)**

Employees having direct contact with contaminated laundry must wear protective gloves and other personal protective equipment as necessary.

### **N. Special Precautions for Preventing the Transmission of Tuberculosis (TB) for Personnel**

#### **(N.1)**

In addition to Universal Precautions, specific precautions are taken with subjects (both human and animal) having known or suspected pulmonary or laryngeal tuberculosis. The subject is placed in a designated isolation room. Air from these rooms is exhausted to the outside and the rooms are maintained under negative air pressure. The hall door remains closed and entry is made through the anteroom only. A “Special Respiratory Isolation” sign is located on both room doors.

#### **(N.2)**

In areas that cannot meet these requirements use an adjunct ventilation measure such as a portable HEPA filter is used.

#### **(N.3)**

The approved respirator mask is worn at all times by anyone entering the subject’s room. Personnel routinely working with known or suspected TB subjects must be enrolled in the Respiratory Protection Program and be fitted for a respirator.

#### **(N.4)**

**Note: In addition to TB precautions, all other isolation precautions should be followed.**

### **O. Microbiological Spills & Accidents**

#### **(O.1)**

##### **Blood or Body Fluid Spills**

Decontaminate work surfaces as follows:

- 1) Wear gloves and gown.
- 2) Absorb the fluids with disposable towels.
- 3) Clean the spill site of all visible fluids with a detergent solution.
- 4) Decontaminate the area with a **freshly-made** 1:10 dilution of household bleach if the surface is porous. If the surface is hard, smooth and readily cleanable, use a 1:100 dilution.
- 5) Place all disposable materials used in cleanup into a plastic, leak proof bag.

\*Decontaminate a large spill of cultured or concentrated infectious agents by first flooding the spill with a 1:5 solution of bleach. Allow the bleach to stand for several minutes and then proceed as described.

#### **(O.2)**

##### **Accidents and Spills of Cultures**

Liquid or dry spills of Biosafety Level 3 organisms (TB, level 3 fungi):

- 1) Evacuate the area at once. Contact supervisor and director.
- 2) Do not enter area for at least one hour. Restrict entry to person responsible for spill response.

3) Wearing gowns, gloves, N95 respirator and shoe covers (if needed), clean up liquid or dry spills as indicated below for Biosafety Level 2 organisms.

**NOTE:** The Durham VAMC do not currently have a Biosafety Level 3 laboratory. All level 3 work is conducted at the university affiliate, Duke University.

**(O.3)**

**Spills of Biosafety Level 2 organisms (organisms that can cause disease in healthy adults)**

\*Wear appropriate personal protective equipment (gloves, gown, shoe covers).

**(O.4)**

**Liquid spills of organisms:**

- 1) Cover spill with absorbent material to avoid splashes.
- 2) Flood area with disinfectant (1:5 solution of bleach).
- 3) Allow solution to stand for 20 minutes and then proceed as with blood fluid spill (page 34).
- 4) Dispose of the absorbent and contaminated material in biohazard bag or a sealed container for pick up.

**(O.5)**

**Dry "Spills":**

- 1) Flood area with disinfectant (1:5 solution of bleach).
- 2) Soak up disinfectant and contaminated media with absorbent material and dispose of in autoclavable bags.
- 3) Dispose of the absorbent and contaminated material in biohazard bag or a sealed container for pick up.

**(O.6)**

**Centrifuge accidents:**

- 1) Wear protective clothing, gloves and if level 3 organisms are present, use an appropriately fitted N95 or PAPR respirator to clean up the area.
- 2) Mechanical devices (forceps, tongs, hemostats) are used to remove any broken glassware.
- 3) If liquids are present, soak up in an absorbent material and handle as above. If not, clean the instrument and clean the room thoroughly before resuming work.

**(O.7)**

**Spills in incubators, or other closed areas:**

- 1) Wearing appropriate protective equipment, soak up liquids with an absorbent material and dispose of in a biohazard bag or a sealed container for pick up. Decontaminate the unit with an appropriate disinfectant.
- 2) If routine decontamination is not possible, the unit may have to be decontaminated by means of a sterilizing gas such as formaldehyde and left overnight (must be done by a person or contractor trained in such decontamination procedures). Call X7341 for assistance.
- 3) Thoroughly wash the unit (if possible) after decontamination.

**(O.8)**

**Document major accidents in detail to include the following:**

- a. Cause of accident
- b. Type of contamination or hazard
- c. List of personnel possibly exposed

- d. Decontamination procedures
- e. Actions taken to prevent recurrence
- f. Disposal of Contaminated Material

**(O.9)**

Recombinant DNA waste should be treated the same as medical or infectious waste before disposal. Organisms must be rendered enviable before disposal.

**P. CHEMICAL SAFETY**

Each research laboratory is required to keep an updated inventory of chemicals on hand. Laboratory chemical inventories must be updated whenever a new chemical is brought into the lab. An MSDS must be readily available for each chemical in the laboratory. An updated chemical inventory must be provided to the Research Industrial Hygienist (RIH) semi-annually. Guidelines for safe use of chemicals can be found in the Research Chemical Hygiene Plan (CHP) [VAMC Memorandum [138.23](#), Attachment I (Copy located in this manual)].

Specific regulations have been established by OSHA regarding the handling of compounds designated as carcinogens and reproductive toxins. Substances considered by OSHA to be known carcinogens and reproductive toxins are listed in the Research Chemical Hygiene Plan.

Laboratories contain many corrosive, flammable, reactive and toxic materials. Instructions for handling chemicals can be found within the standard operations procedure for the material located in the CHP. The CHP is based on the provisions described in the OSHA regulation entitled the "Occupational Exposure to Hazardous Chemicals in Laboratories Standard" (See Attachment 7). The plan outlines the responsibilities of laboratory workers for: 1) information and training, 2) standard operating procedures, 3) methods to control exposure and 4) emergency response.

Laboratories working with hazardous chemicals must conform to OSHA regulations. The RIH is responsible for a site-specific Chemical Hygiene Plan (CHP) and for informing employees of the dangers inherent in working with hazardous chemicals. The Material Safety Data Sheets (MSDS) which display the characteristics of hazardous chemicals must be readily available to laboratory personnel in an easily accessible location within the laboratory.

**\*The site-specific CHP must be reviewed, evaluated for effectiveness, and modified as necessary annually.**

## P.1

### Corrosive Chemicals:

This refers to a substance that causes visible destruction or irreversible alterations in human tissue at the site of contact.

#### (P.1.a)

##### Handling

- Proper protective garments must be worn.
- Chemicals which produce corrosive vapors, mists or fumes, must be handled in a fume hood.
- Dilution: Use great care and add reagent slowly. Always add acid to water, never water to acid. Allow acid to run down the side of the container and mix slowly by gentle rotation
- Do not smell or taste chemicals
- Do not pipette by mouth

#### (P.1.b)

##### Storage

- Store corrosives near the floor to minimize the danger of spills and breakage.
- Store in a secondary pan container.
- Large amounts should be stored in a corrosive safety cabinet.
- Store acids and bases in separate secondary containers.
- **Store Nitric acid separate from other acids.**

#### (P.2)

### Reactive Chemicals:

A reactive and unstable substance which readily undergoes violent chemical change. Explosive decomposition may occur at normal temperatures and pressure.

**(P.2.a)****Handling**

Use of these chemicals should be minimized.

**(P.2.b)****Storage**

- Care should be taken not to store incompatible chemicals in the same area. For example organic acids should be stored separately from strong oxidizers.
- Explosive chemicals should be stored in cool temperatures and in secured cabinets.

**(P.3)****Flammable:**

This term refers to any chemical that can burn. The term includes both combustible and flammable materials.

**(P.3.a)****Handling**

- The working supplies of flammable and combustible liquids should be minimal.
- While working with these chemicals keep away from open flames and hot plates.
- Follow fire safety requirements defined in the MCM 138.5 "Fire Response Plan".

**(P.3.b)****Storage**

- Flammable and combustible liquids should be stored in an approved container whenever possible.
- The location of the storage depot should be such as to avoid open flames and other sources of heat.
- Flammables must be stored in a fire retardant Safety Cabinet and the total capacity of all approved storage cabinets in a laboratory shall not exceed 60 gallons per 5000 square ft. The total capacity of flammable or combustible liquids outside of approved storage cabinets shall not exceed 10 gallons per 5000 square ft.
- If cold storage is required, flammables must be stored in a refrigerator specifically designed for that purpose.

**(P.4)****Health Hazards****(P.4.a)****Particularly Hazardous Substances (PHS)**

These substances include carcinogens (chemical or agent known to produce or incite cancer), highly toxic chemicals and reproductive toxins. Because of the hazards associated with overexposure, special controls should be practiced. The list of these chemicals is continually changing as new studies are performed and

documented. The most current listing and the most current regulatory and compliance information can be found in the Chemical Hygiene Plan (CHP), Appendices B and C. If the chemical in question is not referenced in the CHP, consult the RIH for assistance.

**(P.4.a.1)**

**Establish a Standard Operating Procedure (SOP) to include the following:**

- Wear personal protective equipment, i.e. lab coat and gloves.
- Use a chemical fume hood. The use of a chemical fume hood or appropriate respiratory equipment is required when working with carcinogens, reproductive toxins, and highly toxic chemicals.
- Use decontamination procedures.
- Establish a designated work area.
- Transport and storage requirements.
- Waste disposal procedures.

**(P.4.a.2)**

**Additional PHS Work Practices:**

- Minimize all chemical exposures. Skin contact with chemicals should be avoided.
- Avoid underestimation of risk. One should assume that any mixture will be more toxic than its most toxic component. Any substance of unknown toxicity should be considered toxic.
- The work area should be kept clean and uncluttered.

**(P.4.a.3)**

**Storage of PHS**

- Store as to prevent leakage, breakage or environmental exposure.
- Store minimal amounts.
- Inventory of substances must be maintained.
- Don't store on bench tops and in fume hoods.
- Avoid heat and direct sunlight.
- Dispose of unneeded PHS chemicals.

**(P.5)**

**Reproductive Warnings**

Female and male workers who are contemplating having children, or pregnant women who work in research laboratories may discuss with Employee Occupational Health occupational reproductive concerns they may have.

**(P.6)**

**Chemical Spill**

In case of a chemical spill, contact the RIH at X7807 or pager 613 and the Research Environmental Safety Technician at X7341 or pager 587. Spill kits are located in the hallway corridors adjacent to every lab. When a spill poses a threat to those who may breathe the vapors, evacuation and the use of a self-contained breathing apparatus may be required. Following a major release of a chemical, evacuate the laboratory and phone x6099 immediately to report.

**(P.6.a)**

A specific spill kit should be made available for labs using a PHS for chemotherapy in the event of a spill of the chemotherapy agent. Procedures to clean such a spill should follow those outlined in the specific SOP for the agent.

**(P.6.b)**

**Spill Kits**

Spill kits are designed for use with small or minor spills of solvents, acids, bases, or other hazardous chemicals. If the spill is major, evacuate and call x6099 to report. A good inventory should be maintained in each kit to include nitrite gloves, universal absorbent material, acid/base absorbent material, and waste containment bags. Call Engineering at x7555 for replacement supplies.

**(P.7)**

**Chemical Accident Response**

In the event of a chemical accident adequate emergency shower and eyewash must be available.

**(P.7.a)**

**Eye contact:** Promptly flush eyes with water for prolonged period (15 min.) and seek medical attention.

**(P.7.b)**

**Ingestion:** Contact Employee Health and the Poison Control Center (1-800-848-6946).

**(P.7.c)**

**Skin contact:** Promptly flush the affected area with water and remove any contaminated clothing. If symptoms persist, seek medical attention.

**(P.7.d)**

**Inhalation:** Leave the area and seek immediate medical attention at the Emergency Department.

**(P.7.e)**

Contact supervisor and complete the appropriate VAMC forms.

**(P.8)**

**Labeling of Chemicals**

The OSHA Hazardous communications standard (29 CFR 1910.1200) requires the primary (incoming) chemical containers to have labels on them that are not removed or defaced. Labels on primary containers must include the following information: product identifier, signal word, hazard statement, pictogram, precautionary statement and name, address, and phone number of the chemical manufacturer, or other responsible party.

**(P.8.a)**

When a chemical product is transferred to another container, the secondary container must be labeled, tagged, or marked with the chemical identity and appropriate pictograms. Physical and health hazard information may be presented in a number of different formats, including but not limited to the National Fire Protection Association (NFPA) diamonds, Hazardous Materials Information System (HMIS) ratings, and the Uniform Laboratory Hazard Signage (ULHS) system. The labels may be preprinted or handwritten. The NFPA rating itself is not required, as long as the hazards are represented in some other way. If at all possible, first aid information should be available on or nearby the secondary container to aid employees in the event accidental contact occurs.

**(P. 8.b)**

In addition to the above, reagents may need to be labeled with the following:

- content and quantity, concentration, or titer
- storage requirements
- date prepared or reconstituted by laboratory
- expiration date

**(P. 8.c)**

If separate boxes or vials of these control substances are maintained in the original, fully labeled primary container, they do not have to be individually labeled with all elements. Alternately, a reagent/solution log file may be used to track materials put into use if it is not practical to fully label small containers, and so long as unique identifiers are applied.

**(P.9)****Initiation of a New Hazardous Chemical**

Prior to purchasing or bringing a new particularly hazardous substance (PHS) (carcinogen, reproductive toxin, or chemical causing acute toxicity) into a VA research laboratory, lab staff must consult with and obtain approval from the Industrial Hygienist (IH) for Research. **(See Attachment 19)**

**(P.9.a)**

The IH will assist in developing Standard Operating Procedures, evaluating potential health hazards, and recommending controls to reduce chemical exposures. Prior to bringing a PHS into a VA research laboratory, lab staff must receive information on the chemical's hazards and training which covers proper handling and storage procedures.

**(P.9.b)**

When receiving or bringing a new chemical into a VA research laboratory, an MSDS must be obtained and made available to all lab staff.

**(P.9.c)**

The chemical inventory must be updated to include the new chemical.

**(P.10)****New/ Proprietary/ Unknown Substances**

The use of substances for which an SDS sheets is not available, due to the fact that the substance is new, proprietary, or not well-characterized must be reviewed and approved by the SRS before they can be used in a protocol.

**(P.10.a)**

The use of the substance will be reviewed on a case-by-case basis, with the potential hazards to research staff carefully considered.

**(P.10.b)**

In most cases, the principal investigator will be required to present a toxicological profile from a reliable source that applies to the substance under consideration. If this is not available, the PI may present other evidence applying to the potential hazards surrounding the substance.

**(P.10.c)**

Substances lacking toxicological or hazardous information must be handled as a particularly hazardous substance.

**(P.10.d)**

The PI should also describe in detail, most appropriately in the form of a Standard Operating Procedure, all precautions that will be taken when using this substance.

**(P.10.e)**

The SRS will carefully weigh the documentation submitted for this material in making a decision as to whether the substance may be used in research at the Durham VA Medical Center.

**(P.11)****Dating Chemicals**

It is good laboratory practice (GLP) to label chemicals with the date received, and date opened. If the expiration date changes once the chemical has been opened the new expiration date must be recorded on the label.

**(P.11.a)**

It is mandatory to label all “time-sensitive” chemicals with a date of receipt, date opened, and expiration date. “Time-sensitive” chemicals are those chemicals that when stored for prolonged periods or under improper storage conditions can develop hazards that were not present in the original chemical. There are four general categories of “time-sensitive” chemicals:

- peroxide formers (e.g., tetrahydrofuran)
- peroxide formers that can undergo hazardous polymerization (e.g., butadiene)
- materials that become shock or friction sensitive upon the evaporation of a stabilizer (e.g., picric acid)
- materials that generate significant additional hazards by undergoing slow chemical reactions (e.g., chloroform).

**(P.11.b)**

It should be noted that “time-sensitive” chemicals can be pure reagents or they can be commercial mixtures; therefore, it is imperative that one read the product material data sheet and evaluate all components of a mixture.

**(P.11.c)**

Table 5 lists the more common “time-sensitive” chemicals with storage limits after opening or receipt date.

**(P.11.d)****Table 5:****Time Sensitive Chemicals Storage Limits**

<b>3 months</b>	<b>6 months</b>	<b>1 year</b>		
Diisopropyl ether	Diethyl ether	Acetaldehyde	Isoamyl ether	Acetal
Divinyl acetylene	Dimethyl ether	Acrylonitrile	Methyl acetylene	Anhydrous Hydrogen fluoride & bromide
Isopropyl ether	Ether	Benzyl alcohol	3-Methyl-1-butanol	Acrylic acid

			(isoamyl alcohol)	
Potassium metal	Picryl chloride (when dry)	2-Butanol	Methyl isobutyl ketone	Calcium carbide
Sodium amide	Tetrafluoroethylene	Butadiene	2-Pentanol	Formic acid
Vinylidene chloride		Chloroform	2-Propanol (isopropanol)	Furan
		Cyclohexanol	Styrene	Liquid Hydrogen Cyanide
		Chloroprene	Tetrahydrofuran	1-pentyne
		Cumene (isopropyl benzene)	Vinyl acetate	<b>Picric Acid</b>
		Diethylene glycol dimethyl ether	Vinyl acetylene	Picrylsulfonic acid (when dry)
		Dioxanes	Vinyl chloride	Sec-butyl alcohol
		4-Heptanol	Vinyl ethers	

- **Note: For 70% Isopropanol used on a protocol, which doesn't involve heating or distillation, will be exempt from the time sensitive tracking requirements.**

**(P.11.e)**

Once a chemical has been determined to be “*time-sensitive*”, it must be inspected periodically and if any change is observed in the chemical, it should be disposed of immediately as a hazardous waste. Notify the GEMS coordinator immediately that a “*time-sensitive*” chemical needs to be picked up from the laboratory. The “Time Sensitive Chemical Tracking” form (See Attachment 18) must be used to track the inspection of all chemicals that require close monitoring because of their unique hazards or properties.

**(P.11.f)**

**NOTE!** Sodium azide is a noteworthy hazardous chemical because it becomes explosive on contact with metals. **Never allow sodium azide to come in contact with a metal.**

**(P.12)****Chemical Management and Disposal Management**

A Chemical Management Program in the laboratory should consist of pre-purchase considerations, inventory control, volume reduction, storage, process-change, recycle and recovery investigation as well as disposal procedures. The Green Environmental Management System (GEMS) has staff available to assist laboratories in this process (See Hazardous Chemical Waste Management Program and MCM 558-11-138.8).

**(P.12.a)****Storage**

- Store or segregate chemicals by class or compatibility.
- Liquid hazardous chemicals must not be stored above eye level.
- Store chemicals in containers which are in good condition.
- Do not store chemicals in a fume hood, on a countertop, or on the floor.
- Pay attention to applicable special storage conditions.

**(P.12.b)****Disposal of Chemical Waste**

**Note 1: Never pour chemical waste down the drain.**

**Note 2: Use the flowchart (Attachment 8) to determine whether a chemical is a waste and is hazardous.**

- 1) GEMS coordinate a waste disposal program for the medical center. The waste disposal program specifies how waste is to be collected, segregated, stored and transported.
- 2) Define a secondary container to be used to house chemical waste until it can be picked up.
- 3) All waste material must be labeled as to content using a special waste label and a “Hazardous Waste Disposal” form (See Attachment 19) completed.
- 4) **Note: Do not complete the “date line” on the waste label.** Dating is completed by the GEMS coordinator or designee when the waste is picked up.
- 5) Notify the GEMS coordinator (X6470) for pick up.
- 6) The GEMS coordinator will arrange for pick-up of the material and disposal in compliance with local and regional regulations for environmental protection.
- 7) Hoods and sinks must not be used as a means of disposal for volatile/hazardous chemicals.
- 8) Flasks/containers used for waste collection must be a closed system when not in use. The aspiration tubing must be clamped off or sealed.

**(P.12.c)****Disposal of Biological and Chemical Waste Mixtures**

- 1) If the mixture is biological and an aldehyde
  - A. Remove the biological material and dispose of as biological waste.
  - B. Pool the aldehyde and follow the neutralization procedure Attachment 9.
- 2) If the mixture is biological and another chemical other than an aldehyde,
  - A. Remove the biological material and dispose of as biological waste.
  - B. Follow the Disposal of Chemical Waste

**(P.13)****Controlled Substances**

All investigators who have been authorized to use controlled substances (schedule II-IV drugs) in their laboratories must comply with all requirements for handling, storing, and securing controlled substance and provide access and support for all assigned inspectors. Inspectors will visit areas unannounced on a monthly basis. A laboratory designee must be available to the inspector and accompany the inspector throughout the inspection.

(P.13a)

**The authorized investigator and staff must comply with the following:**

- Check each green sheet and shipment received from pharmacy to validate accuracy or order and to confirm the amount received is written in red.
- Keep all substances under double lock.
- Document receipt, usage, wastage, and return of substance on green sheet.
- Wastage must be documented on green sheet with two signatures, person responsible for and a witness to the wastage.
- Returned expired and/or empty vials of substances with the appropriate green sheet to the pharmacy vault within 72 hours of expiration and/or emptying of vial.
- Maintain a copy of all green sheets returned to the pharmacy.
- Train all staff in the proper handling, storage, and securing of controlled substances.
- Failure to comply with the above can result in discrepancies being reported to the pharmacy by the inspectors.

**\*Discrepancies can result in revoke of authorization.**

**Q. Fire Prevention and Control**

(Q.1)

**In Case of a Fire Use R.A.C.E.:**

1. **REMOVE** (ALL PERSONS IN IMMEDIATE DANGER TO SAFETY)  
Patients, visitors and employees.
2. ALWAYS **ACTIVATE** PULL ALARM AND DIAL EMERGENCY RESPONSE NUMBER: X6099  
  
Give the exact location, Building, Floor, Area:
3. **CLOSE** (ALL DOORS AND WINDOWS) to prevent the spread of fire and smoke.
4. **EXTINGUISH** OR CONTROL A FIRE BY USING A FIRE EXTINGUISHER

(Q.2)

**To use extinguisher remember P.A.S.S.**

**Do not attempt to use a fire extinguisher unless you have been trained to do so.**

**P** - Pull the pin.

**A** - Aim the nozzle at the base of the fire.

**S** - Squeeze the handle to discharge the extinguishing agent.

**S** - Sweep the fire from side to side.

(Q.3)

**When reporting a fire, AVOID PANIC. Do not alarm others by excited motions. Move calmly and with assurance. When calling the Emergency Response number report the fire as “Fire in...”, and give the location.**

**(Q.4)**

**Fire Alarm System:**

The code red message designates a fire alarm message followed by the building number, floor, wing, zone or area. Example, if the fire alarm system is activated in Bldg. 1, 6<sup>th</sup> Floor, A-Wing, you will hear the following:

The sound of five chimes

Attention . . . . Attention . . . . Code Red . . . . Building 1 . . . . 6<sup>th</sup> Floor . . . . A-Wing

Attention . . . . Attention . . . . Code Red . . . . Building 1 . . . . 6<sup>th</sup> Floor . . . . A-Wing

Attention . . . . Attention . . . . Code Red . . . . Building 1 . . . . 6<sup>th</sup> Floor . . . . A-Wing

**(Q.5)**

Any questions concerning this transition should be directed to the Facility Safety Manager, at extension 7554.

**(Q.6)**

**Evacuation**

**NOTE:** An evacuation route must be defined for any location a staff member might be in when evacuation is required. A safe meeting place must be determined. Each staff member must be accounted for at the safe meeting place. If a staff member cannot be accounted for, emergency staff must be notified immediately by calling 6099.

**(Q.7)**

**Internal Plan of Evacuation**

The extent of the fire and measures taken to control it will enable the fire department officials and hospital administration to determine the plan of evacuation. Should the fire be confined to a floor, and under good control, it may be necessary only to evacuate to a "safe" area. This "safe" area may be on the same floor. "Safe" areas may also be on other floors in the hospital. When evacuating to other floors, movement will generally be to a lower level. Outlying buildings will respond to the audible alarm by general evacuation procedures.

**(Q.8)**

**General Evacuation**

If a general evacuation is ordered, all persons - patients, visitors, and employees - must evacuate the building. Such circumstances would be an extreme emergency and ordered by the Hospital Administration. Persons should be evacuated to the outside of the building by using stairs designated as EXITS. When a **“General Evacuation”** has been announced, General Evacuation procedures should occur. Outlying buildings will respond to the audible alarm bell by general evacuation procedures.

(Q.9)

**Physically/Medically Challenged Employees**

Laboratories that employ physically/medically challenged individuals should develop an Evacuation Policy for these special needs employees. Procedures should be developed to ensure safe evacuation for each person to include an emergency notification plan to contact the appropriate persons in the event evacuation is required.

(Q.10)

**Fire Extinguishers**

**Class A:** Fires involving ordinary combustible materials such as wood, paper, trash, cloth. Extinguishing these fires with water is desirable; however, any extinguisher (carbon dioxide (CO<sub>2</sub>), Dry Chemical, Halotron) can be used.

**Class B:** Any fire involving flammable liquids. Extinguish these fires with CO<sub>2</sub>, Dry Chemical or Halon. Removing the oxygen will extinguish the fire. Caution: Flammable liquids may flashback and re-ignite after extinguishment. Never use water on a flammable liquid fire.

**Class C:** Any fire involving electricity. Use “BC” or “C” rated CO<sub>2</sub> or Dry Chemical or Halon extinguishers. Never use water on electrical fires.

(Q.11)

**Type of Fire Extinguisher available in the facility:**

**DRY CHEMICAL FIRE EXTINGUISHER:** The ABC dry chemical fire extinguisher is a red extinguisher located throughout the Medical Center. Dry chemical is compressed nitrogen that works chemically to stop the combustion process. The extinguisher weighs approximately 10 lbs. The dry chemical extinguisher is rated to extinguish Class A (wood, paper, trash, and cloth), Class B (flammable liquids) and Class C (electrical fires). Use of a dry chemical extinguisher will leave a residue which should be cleaned up as soon as conditions permit.

(Q.12)

**Fire Drill Procedures**

Fire drills are required by law. They are held, not only to comply with this law, but also to protect patients, visitors and employees in the buildings. It is your responsibility to know what to do in the event of a fire. The drills may be conducted at any time. All areas of the hospital, health system and Medical Center are subject to fire drills.

(Q.13)

**Area Drills**

The notification of a fire drill will be passed to an employee by a representative from the facility Safety Officer or designee. A note will be handed to the employee stating:

THIS IS A FIRE DRILL.

THERE IS A FIRE IN \_\_\_\_\_.

CARRY OUT FIRE DRILL PROCEDURES.

**(Q.14)**

**Upon notification of the fire drill, the employee must:**

1. Notify other personnel working in the area. Remove all persons in immediate danger.
2. Activate the fire alarm and report to the police at X6099. Report it as a "Fire Drill".
3. All persons will close doors and windows making sure all staff members are aware of the drill.
4. Locate and retrieve a fire extinguisher to take to the location of the alarm.
5. The facility safety officer or designee will document participation of employees and analyze the drill response.
6. Call X6099 to conclude the drill.

**(Q.15)**

**Stand-By Drills**

The notification of a fire drill in another area of the medical center will be by the hearing of the voice alarm. Upon notification of the fire drill, the employee must:

1. Confirm the alarm is in an adjacent area. If not, no action is necessary. If the alarm is in an adjacent area then
2. Close doors and windows to protect these areas from the spread of fire and smoke making sure all staff are aware of the drill.
3. Locate and retrieve a fire extinguisher.
4. Meet at the location indicated by the alarm and offer assistance.
5. The facility safety officer or designee will document participation of employees and critique the drill response.

**(Q.16)**

**Fire Prevention**

Flammable liquids give off vapors which can burn or explode. Store flammable liquids in safety cabinets. Keep only small quantities in the work area. Return unused material to the safety cabinet as soon as possible.

**(Q.17)**

Do not use flammable liquids near sources of ignition. Do not store flammable liquids near open flames or heat sources. Be aware of possible sources of ignition in the area. Open flames, heating sources, or electrical connections (motors, light switches, friction and static) may ignite fumes. SMOKING is not permitted in the Medical Center.

**(Q.18)**

Quantities greater than ONE GALLON are to be stored in safety cans unless purity of substance will be compromised.

**(Q.19)**

Small quantities "in use" should be kept in chemical hoods or other well ventilated areas.

**(Q.20)**

Bulk storage must be kept in a safety cabinet.

**(Q.21)**

DO NOT STORE ETHER IN REFRIGERATORS OR COLD ROOMS.

**(Q.22)**

Do not store flammable liquids in areas exposed to direct sunlight.

**(Q.23)**

Avoid the use of gas burners in a BSC. If burners must be used, the BSC must be equipped with an external cut-off valve which must be clearly marked.

**(Q.24)**

Avoid panic. Never shout "fire". Do not alarm others by excited motions. Move calmly and with assurance. When calling 6099 report the fire as "Fire in...", and give the location.

**(Q.25)**

Each laboratory should be familiar with the MCM 138.5. The laboratory must comply with the "Evacuation Policy for the Physically/Medically Challenged General Guidelines" should they employ a physically or medically challenged individual.

**(Q.26)**

The Emergency Response and Incident Reporting Guide should be posted in every lab and common areas of Research (Attachment 15, page 147).

**(Q.27)**

**Fire Extinguishers:**

Fire Extinguishers must be checked monthly. Checks and documentation of the Fire Extinguisher maintenance is done by the facility Safety Manager.

(Q.28)

**Fire Detectors and Emergency Lighting:**

Fire detectors and emergency lighting must be checked periodically by laboratories in locations that are not connected to the Medical Center fire alarm and emergency lighting systems. Labs connected to the Medical Center fire alarm and emergency lighting systems are monitored and maintained by Engineering.

**R. Radiation Safety**

(R.1)

**Radiation Safety Program**

The Medical Radioisotope and Radiation Control Committee (MRRCC) has been established by the Medical Center as an administration organization for radiation safety. Radionuclides are used under a permit issued by the VHA National Health Physics Program, which holds a Master Materials License issued by the Nuclear Regulatory Commission.

(R.2)

A Principal Investigator must apply to the MRRCC and be approved in order to become an Authorized User (AU) for radionuclides. Application forms are available from the Radiation Safety Officer (RSO).

(R.3)

Radiation Safety Office approval is required for any purchase of radioactive materials. Likewise, transfer of radioisotopes to or from other institutions requires approval of the RSO. The RSO issues film badges to employees involved with radioisotopes when the situation warrants individual exposure data.

(R.4)

**Table 6:**

**Radiation Protection Personnel**

<b>Radiation Safety Officer (RSO), VAMC</b>	<b>Radiation Safety Coordinator, VAMC</b>
Office: X6952	Office: X6952

(R.5)

All employees working with radioisotopes have the following responsibilities: to keep exposure as low as reasonably achievable, to wear a film badge at all times in laboratories if one has been issued, to follow all established radiation safety procedures, to notify the RSO of any radiation incident or violation of NRC regulations, to secure all radioisotopes from theft, and to obtain orientation and annual refresher training.

(R.6)

The hospital's RSO (X7909) must be informed of any spill or accidental release of radioactive materials. For additional information, refer to the Radiation Safety manual.

(R.7)

Radiation safety regulations are designed to ensure the use of radioactive materials in accordance with applicable regulations and accepted standards to protect health and minimize hazards. Users of radioactive materials comply with the policies and procedures as described in the medical center Radiation Safety Manual.

**(R.8)**

**Precautions**

**The following precautions are required for all procedures using radioactive materials.**

- Warning signs indicating the presence of radioactive materials should be placed in storage, work and waste areas.
- Pipetting aids must be used at all times. **Do not mouth pipette.**
- No smoking, drinking or eating in areas where radioactive materials are used.
- Wash hands thoroughly after handling radioactive materials. Disposable gloves must always be worn.
- Wear a lab coat or other appropriate protection.
- Store radioactive materials in specifically designated posted areas.
- Secure radioactive materials from unauthorized entry and removal.
- Perform all work with radioactive materials in authorized areas.
- Prior to disposal of the empty, uncontaminated packages to unrestricted areas remove the radioactive materials labels or clearly indicate that the containers no longer contain radioactive material.
- Cover workbench areas with disposable protective covering, which aids in clean up. These should be changed once a week or sooner if needed.
- Follow procedures in the Radiation Safety Manual for spills and dispose of the contaminated materials in the radioactive waste container.

**(R.9)**

**Note: ALL RADIOACTIVE SHARPS MUST BE DISPOSED OF IN THE APPROPRIATELY MARKED RADIOACTIVE WASTE SHARPS CONTAINERS.**

**(R.10)**

**Radioactive Waste Disposal**

Radioactive waste must be stored as per the instructions of the Radiation Safety Officer (RSO). Be aware that housekeeping employees must not collect *anything* marked "radioactive". All radioactive waste must be separated by physical form and half-life of the radionuclide(s), and stored in containers provided by Radiation Safety. More detailed information is available in the Radiation Safety Manual.

**(R.11)**

**Reproductive Safety**

The Medical Center has a Fetal Protection Policy, which lowers the Maximum Permissible Dose to one-tenth the normal level for women who declare, in writing, that they are pregnant. Forms are available from the RSO in F-3248.

**(R.12)**

## **Radiation Safety Training**

All personnel working at the Durham VAMC are required to complete “Radiation Safety for Lab Workers” on Talent Management System (TMS) course number: VA 1345306

## **S. Ergonomics**

### **(S.1)**

The Ergonomics Program (See MCM 138.27) is designed to ensure a safe working environment where ergonomic risk factors are minimized, eliminated or controlled through engineering or administrative controls to assure employees are kept healthy, productive, and free of discomfort.

### **(S.2)**

Through the support of the medical center Ergonomic Advisory Board and Engineering Service, the following services are available to laboratory workers to prevent the occurrence of work-related musculoskeletal disorders (MSD):

### **(S.3)**

#### **Training and Education**

Training courses are designed for the laboratory environment and provide information on how to promote neutral body postures and identify risk factors that decrease the risk of developing an injury or illness while working with lab equipment such as fume hoods, microscopes, and pipettes. The Industrial Hygienist (x7555) can also create specialized in-service training to address specific concerns.

### **(S.4)**

#### **Worksite Assessments**

Back, shoulder, neck, wrist and hand pain or discomfort can be minimized or prevented through ergonomic modification of workstations. The Industrial Hygienist will assist in identifying mismatches between worker and workplace and risk factors for developing MSD's and recommend simple and low cost interventions to reduce these risks.

### **(S.5)**

#### **Product Selection**

Recommended laboratory specific products can be obtained from the Industrial Hygienist who can also assist with selection of new products and/or modification of existing products or equipment.

### **(S.6)**

The laboratory safety representative should periodically assess the laboratory for ergonomic risk factors (repetitive motion, awkward postures, contact stress, excessive force, vibration and excessive cold) and risk factors. If risk factors that may lead to an MSD are identified, corrective action should be implemented to reduce or eliminate the risk.

## **T. Noise**

### **(T.1)**

The Hearing Conservation Program (See MCM 138.2) is designed to prevent hearing impairment or loss as a result of exposure to excessive noise in the work environment. Risk of exposure to elevated noise levels is minimized through the implementation of engineering and administrative control measures, safe work practices, training, exposure monitoring, personal protective equipment, signage and medical surveillance as appropriate.

Through the support of the medical center Hearing Conservation Program and Engineering Service, the following services are available to laboratory workers to prevent the occurrence of work-related hearing loss:

**(T.2)**

**Training and Education**

Training courses are provided for the laboratory employees to provide information on selection and use of appropriate hearing protection devices. The training includes proper initial fitting of hearing protection devices. The Industrial Hygienist for Research (x7807) can also create specialized in-service training to address specific concerns.

**(T.3)**

**Worksite Assessment**

Noise evaluation surveys are performed to identify areas where elevated noise levels occur. A list of identified areas and associated noise levels are maintained. Surveys are updated annually or as conditions warrant.

**(T.4)**

**Monitoring**

Exposure monitoring using personal dosimeters is conducted to determine the actual exposure levels and thereby identifying employees for inclusion in the Hearing Conservation Program as appropriate. Employees whose exposures are determined to be equal to or in excess of an 8-hour time weighted average (TWA) of 85 decibels measured on the A scale or an equivalent dose of 50 percent, the OSHA action level, will be included in the Hearing Conservation Program.

**(T.5)**

**Engineering Controls**

Engineering Service will install and maintain feasible engineering controls to reduce noise generated by equipment or to shield noise in order to maintain employee noise exposure levels below OSHA permissible limits. Engineering will also post the appropriate signage.

The laboratory safety representative should periodically assess the laboratory for noise risk factors. A simple rule of thumb is that if you are required to shout to hold a conversation when you are standing within three feet of a person, then it is too noisy and the noise level should be measured to ascertain what action should be taken. Call the IH for Research immediately and request a noise assessment.

## **U. Electrical Safety**

**(U.1)**

The Electrical Safety Procedure is designed to ensure a safe working environment free from exposure to electrical hazards; to ensure compliance with the medical center engineering service.

(U.2)

**Building Electrical Safety**

Document approval from the medical center engineering for all electrical installations.

(U.3)

Report all building electrical systems (switches, outlets, circuit boxes) needing repairs to the medical center engineering via a work order. **Do not attempt to repair them yourself.**

(U.4)

**Equipment**

Develop laboratory policies and document annual safety instruction programs concerning the use of high voltage apparatus such as high voltage electrophoresis apparatus.

(U.5)

When working in hazardous atmospheres, use electrical equipment that has been designed and approved for use in those areas. Hazardous atmospheres are defined in the National Electrical Code (NEC) as those in which flammable gases or vapors are or may be present in the air in quantities sufficient to produce explosive or ignitable mixtures (i.e. recycling solvent stills).

(U.6)

Engineering inspects/tests all electrical equipment identified as clinical equipment (equipment involved in the diagnosis, treatment, and care of patients regardless of ownership) (1) when placed into service, (2) when relocated, and (3) after repair.

(U.7)

Engineering documents all equipment, instrument and electrical checks and submits a report.

(U.8)

Install ground fault circuit interrupters in wet locations, including areas within six feet of sinks.

(U.9)

**Do not use extension cords**; however, if temporary use is necessary, get an approved extension cord from the Engineering.

(U.10)

**Do not use cube caps** to expand the capacity of a duplex outlet.

(U.11)

When you need more outlets than you have, power strips with multi-plugs may be used; however, installation of additional outlets is recommended. **In the event a power strip is used the following must be adhered to:**

- Power strip must contain an internal circuit breaker.
- Power strip must be over-current tested; i.e., UL 1363, 1449, or 46D0 approved.

- Power strip should have a plastic external case.
- The power strip cord must be less than six feet in length and have a three-prong grounded plug.
- There shall be only one power strip plugged into a single duplex electrical outlet.
- Do not connect power strips together in a daisy-chain or piggy-back.
- Do not staple, tack, or tape a power strip.
- Visually inspect power strips regularly and out of service if they are damaged, pinched, crushed, frayed or abused in any way.

**(U.12)**

Do not use three-wire to two-wire ground adapters. If you discover an ungrounded outlet, contact Engineering.

**(U.13)**

Report all shocks (including small ones) immediately by calling the Engineering Office.

**(U.14)**

Do not work on or attempt to repair any equipment. Qualified personnel must perform all repairs.

**(U.15)**

Prior to calibrating instruments that requires adjustments in an operational phase, dry hands thoroughly and remove all jewelry. Proceed with caution according to standard operating procedures for instrument calibration.

**(U.16)**

Do not block electrical panels.

**(U.17)**

Report any missing switch and receptacles faceplates to Engineering.

**V. COMPRESSED GASES**

Precautions must be taken to protect employees, patients and property against hazards associated with the use, handling and storage of compressed gas cylinders. Compressed gases constitute several hazards. Any gas cylinder with a broken valve head or an improperly mounted regulator may become a missile. Specific gases may be toxic and/or flammable. Heating of cylinders may result in explosion.

**(V.1) Pressure Regulators and Needle Valves**

Needle valves and regulators are designed specifically for different families of gases. Use only the properly designated fittings.

**(V.2)**

Threads and fittings must be clean and tightly fitted. Valves must not be lubricated.

**(V.3)**

Tighten regulators and valves only with the proper size wrench.

**(V.4)**

The diaphragm control knob should be opened completely so there is no pressure on the diaphragm before the control valve is opened.

**(V.5)**

All valves should be opened slowly. Personnel should stand to the side of the gauges. Valves that stick should not be forced.

**(V.6)**

Valve handles must be left attached to the cylinders.

**(V.7)**

Valves should be closed when the cylinder is not in use. This releases the pressure on the diaphragm.

**(V.8)**

Leak Testing: Cylinders and connections should be tested by "snoop" or soap solution. The cylinders should be tested before and after regulator attachment.

**(V.9)****Retrieval, Storage, and Use of Compressed Gases****(V.10)**

Cylinders must be secured in an upright position at all times double- chained to wall mounts so they cannot fall.

**(V.11)**

Valve safety covers should be left on until pressure regulators are attached.

Containers must be marked clearly with the name of the contents. Cylinders should be separated according to gas compatibility. Full and empty cylinders should be segregated within a storage area.

**(V.12)**

Cylinders shall not be stored at temperatures above 125 degrees F., (e.g. in direct sunlight) or subjected to artificially created low temperatures.

**(V.13)**

Use hand trucks or dollies to transport cylinders. Cylinders should have a protective valve cap installed (hand-tightened) during transport.

**(V.14)**

Do not attempt to repair damaged cylinders or to force frozen cylinder valves.

**(V.15)**

Cylinders should be protected against tampering and damage.

**(V.16)**

Only gas cylinders connected to laboratory apparatus should be present in the lab.

**(V.17)**

The storage of more than twelve “E” cylinders or more than two “H” cylinders inside of a building requires special precautions such as a one hour separation door closure to the storage room and other special requirements.

**(V.18)**

Manifolding of compressed gas cylinders is permitted.

**(V.19)**

**Empty Compressed Gases Cylinders**

- Empty cylinders must be marked as empty, remain in an upright position and be secured by approved devices during storage or transport.
- Empty or unused cylinders must be returned promptly to manufacturer.
- Cylinders shall not be refilled by anyone other than the owner.

**(V.20)**

**Delivery and Disposal**

Gas cylinders are ordered through the Research Office and are delivered to the individual research laboratory. Laboratory personnel should ensure that non-disposable cylinders are collected when the full tanks are delivered.

**W. Cryogenic Materials**

Cryogenic materials can be defined as liquefied or solidified gases at low temperatures. Examples of cryogenics are **liquid nitrogen**, helium, oxygen, and **dry ice** (solidified carbon dioxide). The primary risks associated with the use of these materials are the physical injuries caused by exposure of tissue to extreme cold (severe frostbite), oxygen displacement (asphyxiation) and pressure build-up (potential for fire and/or explosion).

**(W.1)**

**Handling and Use**

**(W.2)**

Use cryogenics in a well-ventilated area.

**(W.3)**

Wear loose fitting cryogenic handling gloves and apron when handling cryogenics.

**(W.4)**

Wear a face-shield or safety glasses when decanting or entering an open container of cryogenic material.

**(W.5)**

Long sleeves and long non-cuffed pants are recommended.

**(W.6)**

Use special vacuum jacket containers with loose fitting lids when handling small quantities.

**(W.7)**

Avoid splashing. Transfer very slowly from one vessel to another. Introduction of a substance which is at normal room temperature into liquid nitrogen is always somewhat hazardous. There is a violent evolution of gas, and there is likely to be considerable splashing.

**(W.8)**

If any of the liquid contacts skin or eyes, immediately flood that area of the body with large quantities of unheated water and apply cold compresses. Get the victim to an Emergency Care Area (F1293, X6304) as soon as possible.

**(W.9)**

**Storage**

Cryogenics should be stored in a well-ventilated area. Avoid closets or enclosed space where there is no ventilation supply to the area.

**(W.10)**

**Transport**

Transport cryogenics in an approved container (Dewar or vacuum flask/bottle).

**(W.11)**

Only containers with tight fitting certified leak-proof caps can be used to transport via an elevator.

**(W.12)**

Ensure containers do not become over pressurized by expanding gases during transport. Heed the pressure gauge.

**(W.13)**

**Disposal**

Do not dispose of cryogenic liquids down the drain.

**(W.14)**

Let cryogenics liquids evaporate in a fume hood.

**X. Anesthetic Gases**

Isoflurane, Halothane, Desflurane, Methoxyflurane, Enflurane, and Sevoflurane are common halogenated gases used in animal research. Halogenated anesthetics are typically clear, colorless, highly volatile liquids at ordinary temperature and pressure. Research laboratory workers can be exposed to halogenated anesthetic gases during surgical and euthanasia procedures. These gases and vapors are known as waste anesthetic gases (WAGs). Effects of exposure to WAGs include dizziness, feelings of light headedness, nausea, fatigue, irritability, and depression. Serious effects can also include sterility, miscarriage, birth defects, cancer, and liver and kidney disease in exposed workers.

**(X.1)**

The National Institute for Occupational Safety and Health's (NIOSH) recommended exposure limit is 2 ppm averaged over any 1 hour period for Halothane. However, given the similarity of all halogenated anesthetic gases, the 2 ppm limit will apply to all halogenated anesthetic gases used by Durham VA Medical Research Laboratories.

**(X.2)**

**Research laboratory workers can be exposed in a variety of ways:**

- WAGs may escape during the initial hooking up and checking of the anesthesia system or the scavenging system.
- WAGs can escape from around the anesthetic mask.
- Leaks in the anesthesia delivery system.
- Turning on flow meters or inhalants before attaching the breathing system to the subject.
- During the filling of the vaporizer using a non-closed system.
- Opening and closing induction box outside of a chemical fume hood or using an active scavenging system.
- Anesthetic agent spills.

**(X.3)**

Protecting personnel from exposure to WAGs can be accomplished by through the use of scavenging systems, use of effective general ventilation systems, and attention to equipment maintenance and leak detection.

**(X.4)**

**Durham VA Medical Center Research laboratories should follow these best practices to eliminate or reduce personnel exposure to WAGs:**

- Restrict access to the work area.
- Turn on flow meters and vaporizers only when needed, and turn them off when finished.
- Use the lowest flow of fresh gas as is safely possible for the subject.
- Ensure a tight seal around the muzzle of animal subjects when using an anesthetic mask.
- Maintain a reasonable distance between yourself and the source of the inhalant.
- Control exposure during filling of vaporizer:
  - Use a bottle adapter with a spout to prevent excessive spillage.
  - Fill vaporizers at the end of the workday as personnel are leaving to reduce exposure to WAGs.
  - Take care to avoid spilling liquid agent when filling the vaporizer.
  - When possible, fill vaporizer inside of a chemical fume hood.
- Use of induction boxes:
  - Use induction boxes with tight seals that slide open rather than flip open.
  - Use induction boxes inside of a chemical fume hood or provide an active scavenging system to the box (i.e. attach a vacuum line to remove WAG).
  - Use of bell jars inside a chemical fume hood.
- Perform surgery in a well-ventilated room with a minimum of 15 air changes per hour.
- When using F/Air canisters for anesthetic waste scavenging follow SRS-SOP-203, Gas Anesthetic Waste Scavenging.
- Visually check anesthesia tubing and hoses for loose connections, kink, leaks and cracks before using equipment.

**(X.5)**

**For clean-up of anesthetic agent spills follow these guidelines:**

- Alert people in the area.
- For a large spill (one or more bottles of anesthetic agent), evacuate area, close laboratory door, and call 6099.
- For a small spill, don gloves and use absorbent material from Research spill kit to absorb material. Place the saturated absorbent into a plastic bag. Seal and label the bag with a hazardous waste tag, than contact GEMS Coordinator for hazardous waste pick-up at ext. 6470.
- Contact EMS to clean up the spill surface with water.
- Contact Facility IH to replenish the spill kit at ext. 7555 or 5287.

**(X.6)****REFERENCES**

*Anesthetic Gases: Guidelines for Workplace Exposures*, OSHA, 2000

*NIOSH Publication No. 2007-151: Waste Anesthetic Gases - Occupational Hazards in Hospitals*

MCM 138.21 Anesthetic Gas Program

**Y. EQUIPMENT and DEVICES**

Precautions must be taken to protect employees, service engineers, and couriers when performing maintenance, service, and/or transport for/on laboratory equipment.

**(Y.1)****General Laboratory Equipment:**

Equipment should be routinely cleaned with a 1:10 bleach solution. Equipment which may become contaminated with blood or other potentially infectious material must be examined prior to use, service, or shipping and must be decontaminated as necessary.

**(Y.2)****Autoclaves:**

Autoclaves are sometimes used in clinical and medical laboratories for sterilization of glassware and media, and for biohazard decontamination of waste. To insure proper use of an autoclave the following precautions should be practiced:

- Check the time and temperature settings before use.
- Never place chemicals or large tissues in the autoclave.
- Always crack the door to allow steam to slowly escape.
- Check the performance of the autoclave with biological indicators.
- Wear utility gloves when handling hot items.
- Contact maintenance with operating questions.

**(Y.3)****Phlebotomy Collection Devices:**

Contaminated vacutainer sleeves as well as tourniquets must be discarded in biohazardous trash. Vacutainer sleeves cannot be reused. They must be discarded with the needle attached as one unit in a sharps container.

Tourniquets are to be used for one day or until visibly soiled and then discarded. Latex-free tourniquets should be used in latex-free locations and with patients who are allergenic sensitive.

**(Y.4)**

**Emergency Eyewash and Shower Equipment:**

The policy on eyewashes and showers can be referenced in the MCM 8.37. **Safety showers** are provided in laboratories for emergencies in which water is needed for flushing away chemicals, or extinguishing burning clothing. Laboratory personnel shall NOT obstruct the space below the shower with furniture, cabinets, refrigerators, etc. Engineering personnel test these emergency showers on a regular basis. Notify the Research Office (x6926) if there is a shower problem in your laboratory.

**(Y.5)**

**The laboratory staff must check eye washes weekly for the following:**

- Check to ensure the apparatus is not obstructed, and will pull out far enough from the sink to act as a shower.
- Check to ensure that when the apparatus is engaged water flow will flush with adequate pressure to bring water above the head of the apparatus allowing the eyes to be totally emerged in the water.
- Engage the flush for five minutes and then check to ensure the water is clean and the temperature is not uncomfortable to the touch.
- Replace the cap on the apparatus head securely.
- Record results on the maintenance sheet.
- Call maintenance if any problems exist.

**(Y.6)**

**Ultraviolet lights:**

UV is light rays beyond the violet end of the spectrum with wavelengths between 1800 and 3900 angstroms. These lights are used in biological safety cabinets (BSC) as a biocidal to protect the user from exposure and the materials from contamination. Laboratory employees should practice those procedures outlined below when working in areas in which UV light is used.

- The PI shall ensure all personnel are adequately trained in the use of UV lights.
- The UV lamp in a biological safety cabinet (BSC) must be turned off when the cabinet is in use.
- Caution should be used with hand held UV lights to avoid exposures to the skin and eyes.
- Personal protective equipment must be readily available and used by employees when direct work with UV light is required.
- UV lamps in BSC shall be checked for appropriate intensity during the cabinet's periodic certification.
- Problems or concerns with UV lights must be referred to the RSO or Engineering.
- Overexposures resulting in lacrimation (tearing) or painful inflammation of the eyes or reddening of the skin must be reported to Employee Occupational Health.

**(Y.7)**

Continued exposure to UV radiation accelerates skin aging and may cause skin cancer, cataracts, conjunctivitis, and other conditions. Persons with fair skin should avoid prolonged exposure. Protective clothing, gloves and

face shields or glasses (rated for UV wavelengths) should be worn when there is danger of exposure to UV radiation.

**(Y.8)**

**Centrifuges:**

If a tabletop model is used, make certain it is securely anchored. Locate the centrifuge where vibration will not cause bottles or equipment to fall off shelves. Always close the lid when operating the centrifuge. If excessive noise or vibration occurs, the instrument must be turned off immediately because the rotor is not balanced, the shaft is bent, or the bearings are worn, presenting considerable hazard when high speeds are reached. Swinging buckets must be symmetrically arranged and correctly supported, and maximum rotor speed must not be exceeded. Always take proper precautions when centrifuging radioactive or infectious materials to avoid contaminating the room with aerosolized particles. A flammable must not be centrifuged without positive exhaust ventilation. (See page 37 for biological clean up.)

**(Y.9)**

**Cold Rooms:**

Cold rooms are not suitable for flammable liquids. The sparking devices in the room can set off an explosion. Sodium azide solution, even with sodium hydroxide present, has an appreciable vapor pressure of hydrazoic acid over its surface. Such solutions must not be stored in refrigerators with exposed copper parts, since in the presence of azide and moisture, copper is capable of forming copper azides, which are sensitive explosives. Various other volatile liquids can condense on the refrigerator coils. Certain acids (hydrochloric, acetic acid), even when stored in a "closed" container, give off corrosive fumes that can damage refrigerator coils, switches, and other electrical devices in the vicinity.

**(Y.10)**

**Fume Hood:**

Fume hoods protect laboratory workers from chemical exposure if used and maintained properly. Users should always follow these recommendations:

- Work with hazardous chemicals in a fume hood
- Work 6 inches back from the sash of the fume hood
- Work with fume hood sash as low as possible
- Keep sash closed when not working in the fume hood
- Never work in a malfunctioning fume hood
- Tag a malfunctioning fume hood as "out of order"
- Certify fume hood at minimum annually.

**(Y.11)**

**Biological Safety Cabinet (BSC):**

BSCs are intended to contain and minimize exposure when working with biohazardous materials; to protect laboratory personnel against exposure during procedures; to protect materials from contamination; to manipulate human and animal blood and body fluids that may contain high concentrations of infectious agents; and maintain sterile cell and tissue cultures. BSCs must be routinely inspected (at installation, when HEPA filters is changed, when moved, and annually) for proper airflow and filter integrity. The users must:

- Disinfect the work area after each use
- Never block the front intake or rear exhaust grilles
- Limit the use of an open flame in the cabinet
- Aspirate to an overflow collection flask containing a disinfectant
- Never use the BSC as a storage area.

**(Y.12)**

**Heating Devices:**

Most laboratories use at least one type of heating device, such sterilizers, dry ovens, hot plates, heating mantles, baths, Bunsen burners, alcohol burners, Cinerators, and hot air heaters.

**(Y.13)**

Burns and other injuries can occur when heating devices are not used properly. General precautions need to be taken when working with heating devices in the laboratory to prevent personal injury and burns from hot surfaces, liquids, vapors, or flames.

- Always use a device as intended.
- Never leave a heating device unattended.
- Never heat a sealed container.
- Electrical heating devices should have an automatic shut off.
- All heating devices (apart from steam baths) must be kept away from flammable material.
- Worn or damaged devices should never be used.
- Never use open flame devices under a biological safety cabinet.
- Use thermal gloves or tongs to remove items from heating units.
- Use protective eyewear when using heating devices.
- Minimize the use of open flames.

**(Y.14)**

**Microwave Ovens:**

Microwave ovens used in the laboratory may pose several different types of hazards.

**(Y.15)**

As with most electrical apparatus, there is the risk of generating sparks that can ignite flammable vapors.

**(Y.16)**

Metals placed inside the microwave oven may produce an arc that can ignite flammable materials.

**(Y.17)**

Materials placed inside the oven may overheat and ignite.

**(Y.18)**

Sealed containers, even if loosely sealed, can build pressure upon expansion during heating, creating a risk of container rupture.

**(Y.19)**

**To minimize the risk of these hazards:**

- Never operate microwave ovens with doors open in order to avoid exposure to microwave radiation.
- Do not place wires and other objects between the sealing surface and the door on the oven's front face. The sealing surfaces must be kept absolutely clean.
- Never use a microwave oven for both laboratory use and food preparation.
- Electrically ground the microwave. If use of an extension cord is necessary, only a three-wire cord with a rating equal to or greater than that for the oven should be used.
- Do not use metal containers and metal-containing objects (e.g., stir bars) in the microwave. They can cause arcing.
- Do not heat sealed containers in the microwave oven. Even heating a container with a loosened cap or lid poses a significant risk since microwave ovens can heat material so quickly that the lid can seat upward against the threads and containers can explode.
- Remove screw caps from containers being microwaved. If the sterility of the contents must be preserved, use cotton or foam plugs. Otherwise, plug the container with kimwipes to reduce splash potential.

# Attachments

# **2016 Research Emergency Response and Disaster Plan**

(A.1)

## **The Research Disaster Plan**

The Research Service keeps a telephone contact plan (cascade alert system) on file in the Research Office (located in Building 8, Room 101). Revised periodically, the plan lists the telephone numbers of research employees to be contacted in the event of an emergency or disaster. In the event of an emergency or disaster, the Research Service is expected to activate the Research cascade alert system and report available personnel to the Command Center (located in the Medical Center Director's Suite) for reassignment. See Attachment 9 for a service contact cascade.

(A.2)

## **Emergency Action Procedures**

Research Service falls under the medical center-wide Comprehensive Emergency Management Plan (VAMC Memorandum 00.2). Specific emergency procedures are included in this section of the Research Safety Manual. Emergency phone numbers are listed in Table A.

(A.3)

**Table A: Emergency Phone Numbers**

General Emergency, Code or Fire	X6099
Occupational Health Service (F1177)	X6300
Emergency Care Area (F1293)	X6304
Police (non-emergency)	X7830
Police (emergency)	X7888
Radiation Protection Officer	X7909
Research Industrial Hygienist	X7807
Industrial Hygienist	X7555
Safety Manager	X7554
Safety Technician	X7805
Emergency Management Coordinator	X5975
Chemical Waste Management Coordinator (GEMS)	X6470
Research Safety Chairperson	X7740
Research Administrative Officer	X7632
Occupational Health & Safety Specialist	X7341

(A.4)

## **Fire/Explosion**

The medical center-wide Fire Response Plan is published in VAMC Memorandum 8.4.

(A.5)

**Remember the acronyms:**

**\*RACE: Rescue, Alarm, Contain, and Extinguish**

&

**\*PASS: Pull, Aim, Squeeze, and Sweep**

(A.6)

**Fire Plan**

**In the event of a fire, the ultimate priority is human safety!**

1. As the alarm is being turned in, all patients should be transferred out of the endangered area before any other action is taken; then visitors and employees should be evacuated.
2. To report the fire's location and size, as well as any casualties, activate a fire alarm box **AND** dial extension 6099 and give the exact location (Building, floor, and room).
3. Close adjacent doors to confine the fire and smoke.
4. If the fire is on an employee's floor, he/she might report to the scene with a fire extinguisher. The hospital and research buildings have ABC type extinguishers, which are rated for use on all types of fires (flammable liquids, electrical, and paper/wood/cloth).
5. Attempt to fight a fire yourself only if it is reasonably small and you are confident of your ability to do so.

(A.7)

**Fire Alarm System**

The code red message designates a fire alarm message followed by the building number, floor, wing, zone or area. Example, if the fire alarm system is activated in Bldg. 1, 6<sup>th</sup> Floor, A-Wing, you will hear the following:

The sound of five chimes

Attention . . . . Attention . . . . Code Red . . . . Building 1 . . . . 6<sup>th</sup> Floor . . . . A-Wing

Attention . . . . Attention . . . . Code Red . . . . Building 1 . . . . 6<sup>th</sup> Floor . . . . A-Wing

Attention . . . . Attention . . . . Code Red . . . . Building 1 . . . . 6<sup>th</sup> Floor . . . . A-Wing

**Any questions concerning this should be directed to the Facility Safety Manager, at extension 7554**

**(A.8)**

**Fire Drills**

Fire Drills are required by law. They are held not only to comply with this law, but also to protect patients, visitors, and employees in buildings. Drills are conducted quarterly in patient care buildings and annually in all other buildings. The Fire Drill Procedure is published in VAMC MCM 138.11.

**(A.9)**

**Interim Life Safety Measures**

Interim Life Safety Measures will be established to ensure that the level of life safety is not diminished throughout any occupied area or grounds with construction and/or renovation work and throughout buildings with existing Life Safety Code deficiencies. Refer to VAMC Memorandum 138.24.

**(A.10)**

**Tornado Procedure**

**(A.11)**

**TORNADO WATCH:**

- 1. When the weather conditions appear conducive to the development of a tornado,** the Safety Specialist and VA Police will monitor a radio receiver unit for the latest storm bulletins in order to keep abreast of the most precise weather information.
- 2. As soon as a tornado watch is announced for this geographical area,** the Safety Specialist will advise the Chief, Engineering Service; Chief, Police Service; Associate Medical Center Director; and the Director.
- 3. The Director's Office will notify all Service Chiefs and the Chief of Staff.** The Chief of Staff will be responsible for notifying the Research Office. The Research Office will notify all research areas.
- 4. The Chief, Police Service (or the Police Supervisor on duty during non-administrative hours)** will dispatch the patrol vehicle to check the Medical Center grounds, advising all persons to return indoors.

**(A.12)**

**TORNADO WARNING:**

**A tornado warning means that a tornado has been sighted.**

When this condition is announced for the Durham area, the Safety Specialist will notify the Director and will, upon the Director's direction, instruct the switchboard operator to call the Boiler Plant Operator on duty to activate the air horn for a 30-second blast. At the same time, the switchboard operator will activate the disaster signal over the voice alarm system.

**Upon the sounding of these signals, all patients, employees, volunteers and visitors should, insofar as practical:**

1. Move all patients and staff away from windows to interior hallways as far from the windows as possible. Patients in beds who cannot be quickly moved out of the room to a hallway should be moved to the side of the room that is as far from the window as possible. Loose items should be removed from the windowsill. Blankets or sheets can be used as a shield to protect from flying glass.
2. Avoid corridors with glass exposure.
3. Should you be caught in an area where there may be flying glass and other debris, shield yourself and patients with a blanket, coat, or similar item. Place your head between your knees with your arms and hands covering your head.
4. Persons caught out of doors should go to the nearest building to take cover. If this is not possible, they should take cover in ditches or culverts, lying face down, covering head and face with arms.
5. Occupants of Building 5 and the outside smoking shelter should evacuate to the main hospital as quickly as possible. Staff in other outbuildings should take cover in place.
6. If you have a radio, turn it on so you can keep informed of latest reports.

**(A.13)**

**ALL CLEAR:**

When the threat of a tornado no longer exists, the Safety Specialist will advise the Director's Office, who will instruct the switchboard operator to have the "ALL CLEAR" signal sounded. This signal will be a voice stating "ALL CLEAR".

**(A.14)**

**AFTER HOURS PROCEDURES:**

During other than normal duty hours, the senior Police Officer on duty will assume the role of the Safety Officer in implementing tornado watch and warning procedures. The Administrative Officer of the Day will assume the role of the Director and will notify the Medical Officer of the Day, the Nursing Coordinator, the Telephone Operator and the Boiler Plant. Police Officers are to keep informed of weather conditions and be responsible for placing warning procedures in effect.

**(A.15)**

**Police**

Hospital police officers should be notified in an emergency situation because they have radios, keys, and quick access to emergency aid. The police station is located in room A1013, and the officers on duty can be reached at x6230, or by calling the hospital operator (dial 0).

**(A.16)**

## Animal Evacuation

**In the case of an immediate life-threatening disaster, follow the Emergency/Disaster Plan: call in an alarm, evacuate people, wait outside for the Fire Department (in case of fire) or seek shelter as appropriate. Do not evacuate animals.**

### (A.17)

If there is not an immediate threat to life, but the situation poses a *potential* threat [e.g., approaching toxic fumes, fire in the main hospital, possibility of smoke/other damage spreading to the Animal Research Facility (ARF)], seek authorization from the individual in charge - Fire Chief, Veterinary Medical Officer, Research AO - to evacuate the animals as outlined in the Animal Facility Disaster Plan to appropriate housing in labs and outbuildings to be arranged for by the Veterinary Medical Officer at this time, **or** to the Duke University Vivarium - call extension 6926 or 7632 to have the Research Office make the necessary arrangements at this time.

### (A.18)

**After hours, the Veterinary Medical Officer should be contacted: See Table 5 Below**

### (A.19)

If the situation poses no threat to human life, remain with relocated animals; otherwise, be advised by the Veterinary Medical Officer (x5182). Following the disaster, return animals to the Animal Facility or move them to a location specified by the Veterinary Medical Officer or her/his designated representative and continue care.

### (A.20)

**Table B:                    Emergency Contact Numbers for ARF Utility Failure**

VAMC Boiler Plant	x5951
Jemine Scott-Emuakpor Veterinary Medical Officer	x5182 Page: 919-970-4492
James Maxstadt Animal Facility Supervisor	x2699 Pager: 919-970-2058
Bradley Olson Administrative Officer for Research	x7632 Home: 919-528-3176

### (A.21)

#### Utility Failure Plan

**If a utility failure occurs during normal administrative working hours (Mon-Friday, 8:00 AM - 4:30 PM), notify the Research Office (x6926). Research Office personnel will notify Engineering Service (x6483) if necessary. Utility failure at any other time should be reported to the Boiler Plant (x5951).**

### (A.22)

If the utility failure creates a hazardous situation, immediate action to secure the area will be taken by the individuals in the area prior to contacting the Research Office. Upon notifying the Research Office, the individual will report the nature and extent of the hazardous situation. The Research Office will relay this information to the Industrial Hygienist, Safety Specialist and/or Engineering Service as appropriate.

**(A.23)**

**Utility Failure in the Animal Research Facility (ARF)**

In the event of a utility failure in the Animal Research Facility (ARF), the Veterinary Medical Officer or the Administrative Officer for Research will be immediately notified at the numbers listed in table 5. These individuals will make determination if emergency procedures need to be implemented to assure the safety and well being of all animals. Such emergency actions may consist of arranging for water delivery, temporary heating and lighting, or relocation of animals if a prolonged loss of heating/ventilation/air-conditioning (HVAC) should occur. Phone numbers for contact are listed in Table 5. When the lost utility returns to normal functioning, personnel will make a check of all affected equipment to assure proper operation. Problems will be reported immediately to the Research Office (x6926), who will notify Engineering Service, if necessary.

**(A.25)**

**Electrical Failure**

Fume hoods/biohazard hoods will not be used during an electrical outage. If there are hazardous materials in use at the time of the electrical failure, action will be taken to contain the hazardous substances or organisms to prevent potential exposure to any personnel in the area. Biohazardous materials can be secured simply by closing/sealing any bottle or vessel containing them. In the case of volatile chemical fumes, it may be necessary to close fume hood sash and evacuate the room. Do not leave doors to exterior corridors open as this will spread the fumes to the rest of the building! Secure the area and call the Research Office (x6926) for assistance.

**(A.26)**

**Engineering Service may be asked to provide temporary power to critical areas by gasoline-powered generators or electrical extension cords, depending on duration of outage and urgency. Research employees may be able to rent generators from local rental businesses.**

**(A.27)**

Electrical failure can lead to unlighted stairwells and corridors. These corridors should have battery-operated lights that come on automatically when power fails. Note that a power failure may be associated with another emergency, such as a fire, where safe egress is essential and corridors may be totally dark.

**(A.28)**

**Freezers Failure**

Freezers will hold temperature for several hours. If it is determined that the outage will be prolonged, the contents may have to be relocated, or dry ice may have to be obtained to preserve critical perishable items in the freezers. The emergency alarm contact information for equipment that is monitored by Police Service and Temp Trak is located in room A1005. Feel free to stop by anytime to review the emergency

information for your equipment. Let the Research Safety Office know if you need your contact information modified.

For freezer emergencies Price's Scientific Service can be contacted 24/7 and will deliver freezers that are at temperature.

### **Price's Scientific Service**

5839 Wilkins Dr  
Durham, NC 27705  
(919)433-4080  
(919)493-1436 - fax

(A.29)

#### **Incubator Failure**

Incubators will hold temperatures for only short periods of time. Items may have to be relocated to other areas where emergency power is available if the utility failure will be prolonged.

(A.30)

#### **Steam Failure**

Generally, the loss of steam will not create problems for R&D Service personnel. Autoclaves are available throughout the VA and Duke University campus for use in emergency situations. If there is a possibility of water pipes freezing and breaking, in the case of an outage when outside temperatures are at or below freezing, Engineering Service or the Boiler Plant will be called to provide temporary heat, possibly by renting electrical heaters.

(A.31)

#### **Communication Equipment Failure**

The loss of telephone service would not adversely affect research operations in the short term (i.e., less than 24-48 hours).

(A.31)

#### **Gas Failure**

If the natural gas supply is temporarily interrupted, Bunsen burners should be turned off to prevent a gas leak when the natural gas is restored. If you enter an area and can smell gas, get out immediately! Do **not** turn on any lights, do **not** use a phone in that area to report the leak, as this may cause the gas to ignite and explode. Report the leak from a safe place (dial x6099) and warn other personnel of the danger until the VA police can secure the area.

(A.32)

#### **Water Failure**

**A water failure is hazardous when a water-cooled condenser is being used to condense a flammable vapor as in a distillation or reflux operation. If the water supply fails, the heater on this device must be immediately turned off. Recognize that in a water failure, the eyewash fountains and safety showers are not functional.**

(A.33)

**Vacuum Failure**

If a line vacuum is part of a system to trap hazardous substances or organisms, the operation must be ended when the vacuum fails.

(A.34)

**Heating/Ventilation/Air Conditioning (HVAC) Failure**

The loss of HVAC is critical if it occurs within the ARF (Building 14). Refer to part ‘a’ above. All other areas of R&D Service will not suffer during short-term losses of HVAC, but prolonged high or low air temperature may adversely affect experiments and equipment. If a utility failure occurs during normal administrative working hours (Mon-Fri, 8:00 AM- 4:30 PM), notify the Research Office (x6926). Research Office personnel will notify Engineering Service (x6483) if necessary. Utility failure at any other time should be reported to the Boiler Plant (x5951).

(A.35)

**VA Police & Security support**

Police may be called to provide keys, walkie-talkie radios, and knowledge about obtaining help in emergencies: officers can be contacted by phone (x7830).

(A.36)

**Chemical Spill/Release**

The medical center-wide Hazardous Material Spill Response Plan is MCM 138.22. Refer to the posted Emergency Response Guide (Attachment 15) or page 52 (P.16) of this manual for the appropriate response to a chemical spill or release.

(A.37)

**Biological Spills**

Refer to the posted Emergency Response Guide (Attachment 15) or page 42 Section “O” of the Safety Manual for the appropriate response to a biological spill.

(A.38)

**Radioactive Spills**

Refer to the posted Emergency Response (Attachment 15) Guide or the facility Radiation Safety manual.

(A.40)

**On the Job Injury or Illness**

**Employees with potentially life threatening conditions should report directly to the Emergency Care area.**

Injury or illnesses that occur at work should be reported to the employee’s supervisor. The Occupational Health Services, as described in VAMC Memorandum 558-11-11C.2, will evaluate employees during normal hours of operation. Occupational Health Services is located in Room F1177.

Monday, Wednesday and Friday	9:00 a.m. – 11:00 a.m.
Tuesday & Thursday	8:00 a.m. – 11:00 a.m.
Monday through Friday	2:00 p.m. – 4:15 p.m.

During hours when the clinic is not staffed, and on weekends and holidays, employees will be seen in the Emergency Care Area (Room F1293).

(A.41)

**Severe Injury or Illness:**

Injuries that involve broken bones, excessive bleeding, unconsciousness, extensive burns, or serious illness suggesting heart attack, stroke, shock, et cetera, should be reported by dialing the emergency telephone number 6099 and provide the nature of the illness/injury and need for assistance; the exact location (building, room if possible) and if known, the identification of the person requiring assistance including age and sex. The telephone operator will then either call a code over the audible paging system, or override the paging system to activate the Cardiopulmonary Resuscitation Team pagers. If possible, send someone to meet and direct the code team to the location since most medical personnel in the hospital are not familiar with the research areas. If serious bleeding occurs, use direct pressure on the wound with a gauze pad, towel, et cetera, until medical assistance arrives.

**Do NOT apply tourniquets.**

(A.42)

**Chemical Burns**

If a chemical burn occurs (e.g., to the eye or skin), flush with cool water or sterile saline (if available) while transporting the victim to Emergency Care Area (ECA) (F1293). Have someone call ahead (x6304) to alert the ECA that you are coming. Bring along a labeled bottle, the MSDS, or any other available information about the chemical.

(A.43)

**Thermal Burns**

Thermal burns such as those caused by hot plates or flames should be immersed in cold water, but AVOID the use of ointments. After you have cooled the burn, report to Emergency Care Area (F1293).

(A.44)

**Acute Inhalation**

Inhalation of gas, fumes, dust, et cetera can cause severe illness, unconsciousness, or even death. Some examples are chlorine, hydrogen sulfide, carbon monoxide, hydrogen cyanide, and hydrochloric acid. Gases such as nitrogen and carbon dioxide (from dry ice) are not corrosive or toxic but are injurious due to the lack of oxygen. First aid in all such circumstances requires the quick removal of the victim from the affected area. If the victim is breathing, notify Urgent Care and transport the victim if possible. If the victim has stopped breathing, call a *Code Blue* (x6099) and begin resuscitation until help arrives. If a self-contained breathing apparatus is needed for rescue, remember that city firemen are our resource for this.

(A.45)

**Animal Bites**

The threat of rabies is a legitimate concern for those labs working with cats or dogs. In the event of a bite, flush the wound with soap and water and report to Employee Health for treatment and consultation. The event must be reported and a CA-1 form completed. The offending animal must be kept for observation or tested for rabies. A prophylactic rabies immunization program is available from the Occupational

Health Services (x6300). Rodent bites do *not* pose a rabies threat, but this type of wound can be severe, with the potential for infection and sepsis. Bitten employees should report to Occupational Health Services for treatment of the wound and a prophylactic tetanus shot if it has been more than 5 years since their last DPT immunization. Duke employees (VA-WOC employees) should report to the Duke University Emergency Room for treatment of any wounds. The individual should then report to the VA Occupational Health Office for initiation of a stub record.

**(A.46)**

**A VA Form 2162 “Report of Accident or Injury” will be generated by the individual’s supervisor.**

## Durham VA New Research Employee Orientation *(Form: RSF-001)*

**Principal Investigator :** \_\_\_\_\_  
**Building:** \_\_\_\_\_  
**Lab Room Number(s):** \_\_\_\_\_

**Employee :** \_\_\_\_\_  
**Employee Email:** \_\_\_\_\_  
**Lab Safety Rep/Trainer:** \_\_\_\_\_

Employee Initial When Informed	***Items To Be Discussed With New Employee*** (Mark "N/A" if Not Applicable)
1	The nature of the research being conducted in the laboratory
2	Occupational Health Program, if animal
3	Location of the Laboratory Safety Manual
4	Review and sign Laboratory Safety Manual
5	Location and Review of the Chemical Hygiene Plan
6	Review of the Research Hazardous Agent Control Program
8	Location of Chemical Inventory
9	Location of MSDS
10	Identify hazardous and infectious agents used in lab
11	Proper Handling, Storage and Disposal of Chemicals
13	Location, use, and maintenance of safety equipment to include: <input type="checkbox"/> Safety Shower <input type="checkbox"/> Eye Wash <input type="checkbox"/> Fume Hood <input type="checkbox"/> Biological Safety Cabinet <input type="checkbox"/> Chemical Spill Kit <input type="checkbox"/> Flammable Storage Cabinet <input type="checkbox"/> Corrosive Storage <input type="checkbox"/> Flammable Refrigerator <input type="checkbox"/> Cryostat/Microtome <input type="checkbox"/> Microwave <input type="checkbox"/> Autoclave <input type="checkbox"/> Sharps Container
14	Lockout / Tagout

Employee Initial When Informed	***Items To Be Discussed With New Employee*** (Mark "N/A" if Not Applicable)
15	General Requirements <input type="checkbox"/> No food or drink in lab areas <input type="checkbox"/> Closed toe shoes required in lab <input type="checkbox"/> Long pants and lab coat required when handling chemicals <input type="checkbox"/> Clean and disinfect work station each day <input type="checkbox"/> No boxes directly on floor or closer than 18" from ceiling <input type="checkbox"/> Use of power strips and extension cords
16	Gas/Liquid Cylinders <input type="checkbox"/> Double chain compressed gases <input type="checkbox"/> Separate storage for full and empty compressed gas cylinders <input type="checkbox"/> Store with regulator off and cap on when not in use <input type="checkbox"/> Secure when transporting <input type="checkbox"/> Appropriate PPE when dispensing Liquid Nitrogen
17	Emergency Management <input type="checkbox"/> Location of Emergency Response Guide <input type="checkbox"/> Location of Fire Extinguisher <input type="checkbox"/> Location of Alarm Pull station <input type="checkbox"/> Evacuation Route <input type="checkbox"/> Evacuation Meeting Spot <input type="checkbox"/> Location of Employee Health <input type="checkbox"/> Location of Emergency Department <input type="checkbox"/> Signage Requirements <input type="checkbox"/> Reporting System for Incidents/Accidents
18	New Employee Training on Hazards and PPE (ATTACHED RSF-003)

I have informed the new employee about the nature and location(s) of potentially hazardous equipment and/or materials within the workspace. Furthermore, I have informed the new employee that he/she may not begin work until he/she has satisfactorily completed the safety training courses described in the New Employee Training Checklist (RSF-002).

\_\_\_\_\_  
 (Trainer signature) \_\_\_\_\_  
 (date)

I acknowledge that I have received and understood the Safety Orientation described above, and that I understand the training requirements that I must satisfy before being allowed to work. Likewise, I acknowledge that I have been encouraged to ask questions about any procedures or safety guidelines that are unclear to me.

\_\_\_\_\_  
 (New Employee signature) \_\_\_\_\_  
 (date)

# **ATTACHMENT 3**

## **Training Supplemental Guide 2013 Proper Shipment of Patient Specimens and Infectious Substances**

**Patient Specimens:**

Specimens collected from humans or animals including, but not limited to, excreta, secretions, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment or prevention

Note: If specimen has a high likelihood that it contains a human or animal pathogen, then it should be shipped as an Infectious Substance. An element of professional judgment is required when making such a decision. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, and endemic local conditions.

**Infectious Substances:**

Substances which are known or reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals

1. **Category A Infectious Substances:** An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. See page 4 for a list of example agents.

2. **Category B Infectious Substances:** An infectious substance which does not meet the criteria for inclusion in Category A. An example includes clinical specimens containing common infectious microbiological organism(s).

**Genetically Modified Microorganisms (GMMO) and Organisms (GMO):**

Microorganisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally

UN Number and Proper Shipping Name	Microorganism Classified as Category A in any Form (Always Classified as Category A)	Microorganisms Classified as Category A only when cultured
UN 2814 Infectious substance, affecting humans	Crimean-Congo hemorrhagic fever virus Ebola virus Flexal virus Guanarito virus Hantaan virus Hantavirus causing hemorrhagic fever with renal syndrome Hantavirus causing pulmonary syndrome Hendra virus Herpes B virus (Cercopithecine Herpesvirus-1) Junin virus Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus	Bacillus anthracis Brucella abortus Brucella melitensis Brucella suis Burkholderia mallei-Pseudomonas mallei-Glanders Burkholderia pseudomallei- Pseudomonas pseudomallei Chlamydia psittaci- avian strains Clostridium botulinum Coccidioides immitis Coxiella burnetii Dengue virus Eastern equine encephalitis virus Escherichia coli, verotoxigenic Francisella tularensis Hepatitis B virus Herpes B virus

	<p>Monkeypox virus  Nipah virus  Omsk hemorrhagic fever virus  Russian spring-summer encephalitis virus  Sabia virus  Variola virus</p>	<p>Herpesvirus simiae  Human immunodeficiency virus  Human Coronavirus- Severe acute respiratory Syndrome (SARS)  Highly pathogenic avian influenza virus  Japanese Encephalitis virus  Mycobacterium tuberculosis  Monkey B virus  Poliovirus  Rabies virus  Rickettsia prowazekii  Rickettsiae rickettsia  Rift Valley fever virus  Russian spring-summer encephalitis virus  Shigella dysenteriae type 1  Tick borne encephalitis virus  Venezuelan equine encephalitis virus  West Nile virus  Yellow Fever virus  Yersinia pestis</p>
<p><b>UN 2900 Infectious substance, affecting animals only</b></p>	<p><i>*NOTE: The list of indicative examples of Category A Infectious substances is not exhaustive as there may be new or emerging pathogens. If a pathogen has the ability to cause permanent disability, or a life-threatening or fatal disease in otherwise healthy humans or animals, it <b>must</b> be classified as a Category A Infectious substance.</i></p>	<p>African swine fever virus  Avian paramyxovirus Type 1- Velogenic  Newcastle disease virus  Classical swine fever virus  Foot and mouth disease virus  Goatpox virus  Hog Cholera virus- Classical Swine Fever  Lumpy skin disease virus  Mycoplasma mycoides- Contagious bovine pleuropneumonia  Peste de petits ruminants virus  Rinderpest virus  Sheep-pox virus  Swine vesicular disease virus  Vesicular stomatitis virus</p>

**Checklist for Shipping**  
***Patient Specimens (animal or human)***  
**(for which there is minimal likelihood that pathogens are present)**

Specimen Packaging

- Specimen in leakproof primary container
- Closures of primary containers are required be held securely by secondary means, such as adhesive tape, or friction sleeves. When it is not possible to apply a secondary means of closure a leakproof liner must be used.
- Primary containers are wrapped individually
- Absorbent material sufficient to absorb entire contents of primary container(s)
- Leakproof secondary container (**Outer containers MUST NOT be only Styrofoam**)

Labeling Outer Container

- Statement: "Exempt human specimen" or "Exempt animal specimen"
- Miscellaneous Class 9 label(2) if shipment contains dry ice, "UN 1845" and amount used in kg
- Shipper and consignee details should be on the same surface of the package near the proper shipping name marking, if the package dimensions are adequate.

Completing the Airbill

- Name and address of shipper and recipient
- Check "Saturday Delivery" box if applicable
- In Section 6 (Special Handling) of the airbill, indicate that the shipment is NOT a dangerous good
- Check the "Dry Ice" box if applicable and indicate "UN 1845" and the quantity of dry ice in kg
- Shipper's signature (optional)

Note: In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required. That judgment should be based on the known medical history, symptoms and individual circumstances of the source and endemic local conditions.

## Checklist for Shipping

*Non-infectious Specimens containing small quantities of flammable preservative in the following categories:*

*UN 1170 (Ethanol, Ethanol solution),  
UN 1198 (Formalin, Formaldehyde solution),  
UN 1987 (Alcohols, n.o.s. \*) or  
UN 1219 (Isopropyl alcohol, Isopropanol)*

### Specimen Packaging

Wrapped in paper towel and/or cheesecloth moistened with alcohol or an alcohol solution and then placed in a plastic bag that is heat-sealed. Any free liquid in the bag must not exceed 30 mL **OR**

Placed in vials or other rigid containers with no more than 30 mL of alcohol or an alcohol solution

Prepared specimens are then placed in a plastic bag that is then heat-sealed

The bagged specimens are then placed inside a another plastic bag with absorbent material then heat-sealed

The finished bag is then placed in a strong outer packaging (**Styrofoam must be in an outer cardboard box**) with suitable cushioning material

The total quantity of flammable liquid per outer packaging must not exceed 1 L Labeling Outer Container

The completed package is marked “scientific research specimens, not restricted Special Provision A180 applies” Completing the Airbill

The words “not restricted” and the special provision number A180 must be included in the description of the substance on the Air Waybill as required by 8.2.6, when an Air Waybill is issued.

***\*Not otherwise specified***

## **Checklist for Shipping**

### ***Category A Infectious Substances***

Packing Instruction (PI) 620

Specimen Packaging (primary or secondary is pressure and drop test approved: see PI 620)

Specimen in leak proof primary container

Closures of primary containers are required be held securely by secondary means, such as adhesive tape or friction sleeves. When it is not possible to apply a secondary means of closure, a leak proof liner must be used.

Primary containers are wrapped individually

Absorbent material sufficient to absorb entire contents of primary container(s)

Leakproof secondary container

Itemized list of contents placed between secondary and outer container

Labeling Outer Container

Infectious Substance, Class 6 label

“Infectious Substance Affecting Humans”, “UN 2814” or “Infectious Substance Affecting Animals, “UN 2900” and net quantity of infectious substance

Miscellaneous Class 9 label if shipment contains dry ice, “UN 1845” and amount used in kg

Name and telephone number of the responsible party, knowledgeable of the package contents and available 24 hours a day

If shipment includes >50mL or 50g of a Category A infectious substance, then add a “Danger, do not load in passenger aircraft” label to the outer container

Shipper and consignee details should be on the same surface of the package near the proper shipping name marking, if the package dimensions are adequate.

Dangerous Goods Declaration Form\*

Name, address and phone number of shipper and recipient

Mark out non-applicable “Aircraft Box”

Mark out non-applicable “Radioactive” box

24-hour emergency response telephone number for the responsible party, knowledgeable of the package contents in the “Handling Information” box

Name and title of signatory, place, and date

Shipper’s signature

\*Retention of a copy of the Shipper's Declaration for a minimum period of 3 months is mandatory.

“Nature and Quantity of Dangerous Goods” section of the Declaration Form

## Checklist for Shipping *Category B Infectious Substances*

Packing Instructions (PI) 650

Specimen Packaging (primary or secondary is pressure and drop test approved: see PI 650)

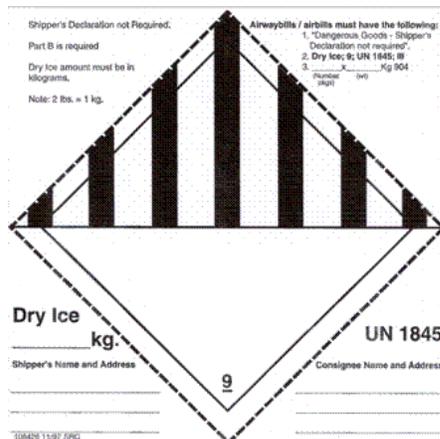
- Specimen in leakproof primary container
- Closures of primary containers are required be held securely by secondary means, such as adhesive tape or friction sleeves. When it is not possible to apply a secondary means of closure a leakproof liner must be used.
- Primary containers are wrapped individually
- Absorbent material is sufficient to absorb entire contents of primary container(s)
- Leakproof secondary container
- Itemized list of contents placed between secondary and outer container

Labeling Outer Container

- UN 3373 label(1)
- Statement: "Biological Substance, Category B" adjacent to UN 3373 label
- Miscellaneous Class 9 label(2) if shipment contains dry ice, "UN 1845" and amount used in kg
- Shipper and consignee details should be on the same surface of the package near the proper shipping name marking, if the package dimensions are adequate.

Completing the Airbill

- Name and address of shipper and recipient
- Check "Saturday Delivery" box if applicable
- In Section 6 (Special Handling) of the airbill, indicate that the shipment is a dangerous good, which does NOT require a Shipper's Declaration
- Check the "Dry Ice" box if applicable and indicate "UN 1845" and the quantity of dry ice in kg
- Shipper's signature (optional)



## **Checklist for Shipping** ***Genetically Modified Micro-organisms & Organisms***

**Note:** If a GMMO or GMO is a Category A or Category B Infectious Substance, package the material accordingly.

### Specimen Packaging

- Specimen in leakproof primary container
- Closures of primary containers are required be held securely by secondary means, such as adhesive tape or friction sleeves. When it is not possible to apply a secondary means of closure a leakproof liner must be used.
- Absorbent material is sufficient to absorb entire contents of primary container(s)
- Primary containers are wrapped individually
- Leakproof secondary container
- Itemized list of contents placed between secondary and outer container

### Labeling Outer Container

- Miscellaneous Class 9 label
  - “Genetically modified micro-organism” or “Genetically modified organism”, “UN 3245(3)”
  - If shipment contains dry ice, “UN 1845” and amount used in kg
  - Shipper and consignee details should be on the same surface of the package near the proper shipping name marking, if the package dimensions are adequate.
- Dangerous Goods Declaration Form (if required)
- Name, address and phone number of shipper and recipient
  - Mark out non-applicable “Aircraft Box”
  - Mark out non-applicable “Radioactive” box
  - 24-hour emergency response telephone number for the responsible party, knowledgeable of the package contents
  - Name and title of signatory, place, and date
  - Shipper’s signature
- “Nature and Quantity of Dangerous Goods” section of the Declaration Form



## Completing the Top-half of a Dangerous Goods Declaration

SHIPPER'S DECLARATION FOR DANGEROUS GOODS				
<p>Shipper</p> <p style="text-align: center;"><b>A</b></p>	<p>Air Waybill No.</p> <p>Page of Pages</p> <p>Shipper's Reference Number (optional)</p>			
<p>Consignee</p> <p style="text-align: center;"><b>B</b></p>				
<p>Two completed and signed copies of this Declaration must be handed to the operator.</p>				
<p style="text-align: center;"><b>TRANSPORT DETAILS</b></p>				
<p>This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i></p> <table border="1"> <tr> <td>PASSENGER AND CARGO AIRCRAFT</td> <td>CARGO AIRCRAFT ONLY</td> <td style="text-align: center;"><b>C</b></td> </tr> </table>	PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY	<b>C</b>	<p>Airport of Departure</p>
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY	<b>C</b>		
<p>Airport of Destination</p>	<p style="text-align: center;"><b>D</b></p> <p>Shipment Type <i>(delete non-applicable)</i></p> <table border="1"> <tr> <td>NON-RADIOACTIVE</td> <td>RADIOACTIVE</td> </tr> </table>	NON-RADIOACTIVE	RADIOACTIVE	
NON-RADIOACTIVE	RADIOACTIVE			
<p style="text-align: center;"><b>WARNING</b></p> <p>Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.</p>				

\* Remember, FedEx Express® dangerous goods shipments originating in the U.S. must be prepared using FedEx specific software with dangerous goods compliance edit checks!

**A – Shipper:** Enter your full name, address and telephone number.

**B – Consignee:** Enter full name and address of recipient. When shipping infectious substances, include the text, “Person responsible:” plus his/her name and phone number at the bottom of “Consignee” box.

**C – Transport Details:** Indicate here if your shipment is restricted to cargo aircraft only (if it is > 50ml or 50g of an infectious substance). Airport of departure and airport of destination will be filled out by the carrier, leave blank.

**D – Shipment Type:** Cross out “radioactive” to indicate you are shipping a non-radioactive substance.

## Completing the Bottom-half of a Dangerous Goods Declaration

NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and Type of Packing	Packing Instructions	Authorization
E	F	G	H	I	J	K
Additional Handling Information						
Emergency Telephone Number <b>L</b>						
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to the applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.			Name/ Title of Signatory			
			Place and Date <b>M</b>			
			Signature <i>(see warning above)</i>			

Created by Andy Glode at the University of New Hampshire Office of Environmental Health and Safety

**E – UN or ID Number:** Enter appropriate UN number (i.e. UN 2814 or UN 2900).

**F – Proper Shipping Name:** Enter the proper shipping name with the technical name in parentheses – i.e. “Infectious substance, affecting humans (Hepatitis B virus)”. UN 2814 or UN 2900 that is suspected to contain an unknown Category A infectious substance must have the words “suspected Category A infectious substance” next to the Proper Shipping Name.

**G – Class or Division:** Enter appropriate hazard class (i.e. 6.2 or 9).

**H – Packing Group:** For dry ice, enter “III” in this column. Biological materials are not assigned packing groups.

**I – Quantity and Type of Packaging:** Enter the net quantity for each material here. Use only metric units. At the bottom of this column, indicate the number and type of packages. If multiple packages are packed in one overpak state (“All packed in one fibreboard box.”). Do not spell like “fiberboard.” If using an overpack, indicate here with “Overpack Used.”

**J – Packing Instructions:** Enter appropriate packing instruction number. The Packing Instruction for infectious substances is 620. The Packing Instruction for dry ice is 954.

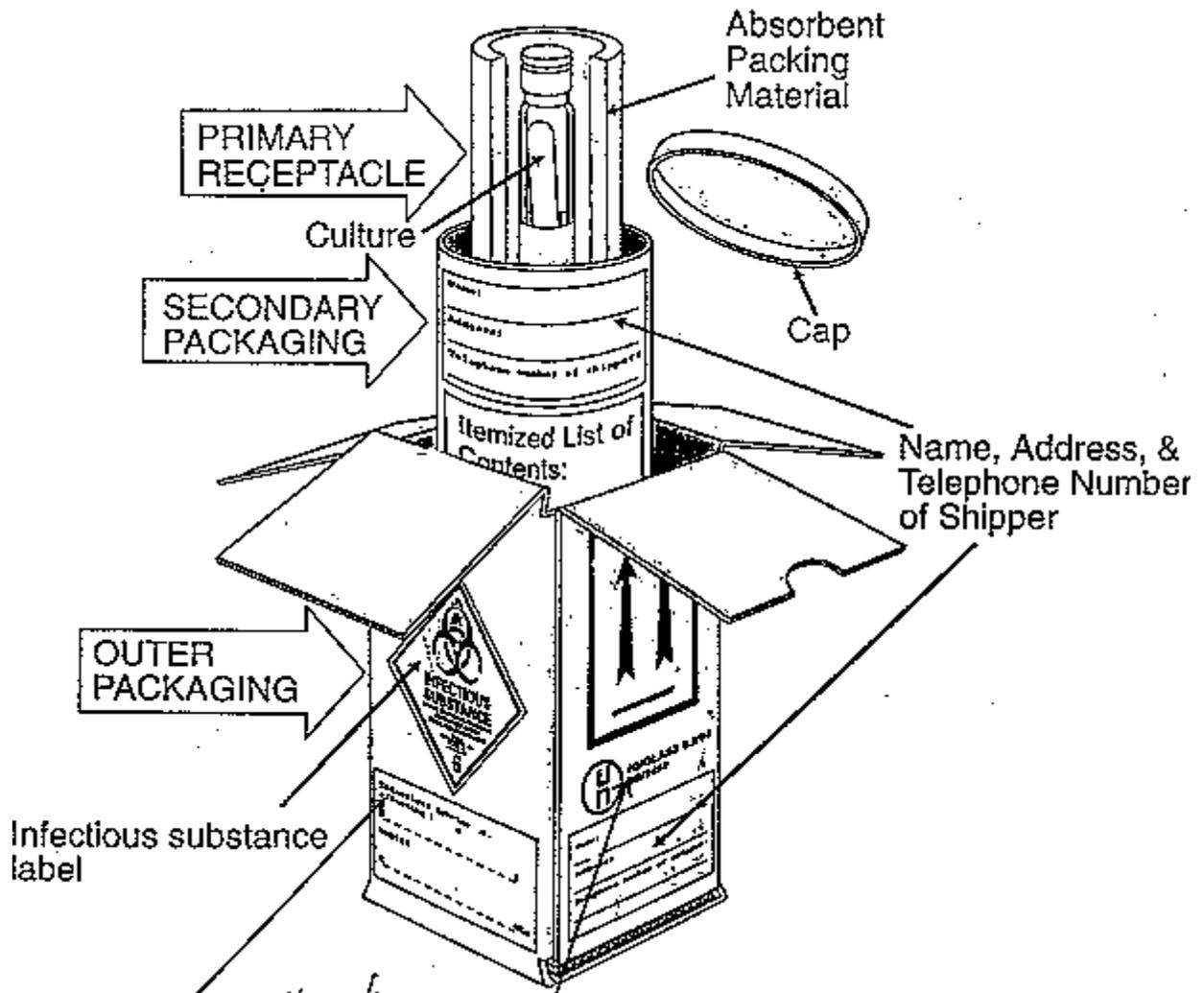
**K – Authorization:** Note any Special Provisions, if applicable (i.e. if you choose to not include the technical name on outer package, you must list A140 in this column).

**L – Additional Handling Instructions:** The statement “Emergency Contact:” followed by a 24-hour emergency telephone response number where the shipper can be reached.

**M – Sign and date each copy of your Shipper’s Declaration.**

**\*\* A statement must appear on the Shipper’s Declaration. The statement reads as follows: “I declare that all of the applicable air transport requirements have been met.”** This statement is often pre-printed on the form (see above). If this statement does not appear on the form then it should be typed in the “Additional Handling” section of the form.

# Packed in Compliance with IATA Packing Instruction 620 (Category A Infectious Substances)



**Proper shipping name, UN#  
and amount of material**

**UN packaging specification markings  
(IATA 6.0.6)**

## Does your shipment need a permit?

### **CDC Import Permit:**

- Is required if you import:
  - o any etiologic agent
  - o any arthropod or other animal host or vector of human disease
  - o any exotic living arthropod or other animal capable of being a host or vector of human disease

### • **CDC: Etiologic Agent Import Permit Program**

- o Website: <http://www.cdc.gov/od/eaipp/>
- o Telephone: 404-498-2260; FAX: 404-498-2275
- o Permit Application: <http://www.cdc.gov/od/eaipp/importApplicationForms.htm>

### **USDA/ APHIS Permit:**

- May be required for all imports/ exports, **and** inter-state transport of:
  - o animal or plant pathogens
  - o specimens reasonably believed to contain animal or plant pathogens
  - o any pest or vector of animal or plant disease
  - o potentially hazardous animal or plant products
- **APHIS: Import and Export** o [http://www.aphis.usda.gov/import\\_export/index.shtml](http://www.aphis.usda.gov/import_export/index.shtml)
- o Telephone: 301-734-0841(plants), 301-734-3277 (animals)

### **Department of Commerce (DOC) Export License:**

- May be required when exporting:
  - o infectious agents of human, plant and animal diseases
  - o genetic material, and products which might be used for culture of large amounts of agents

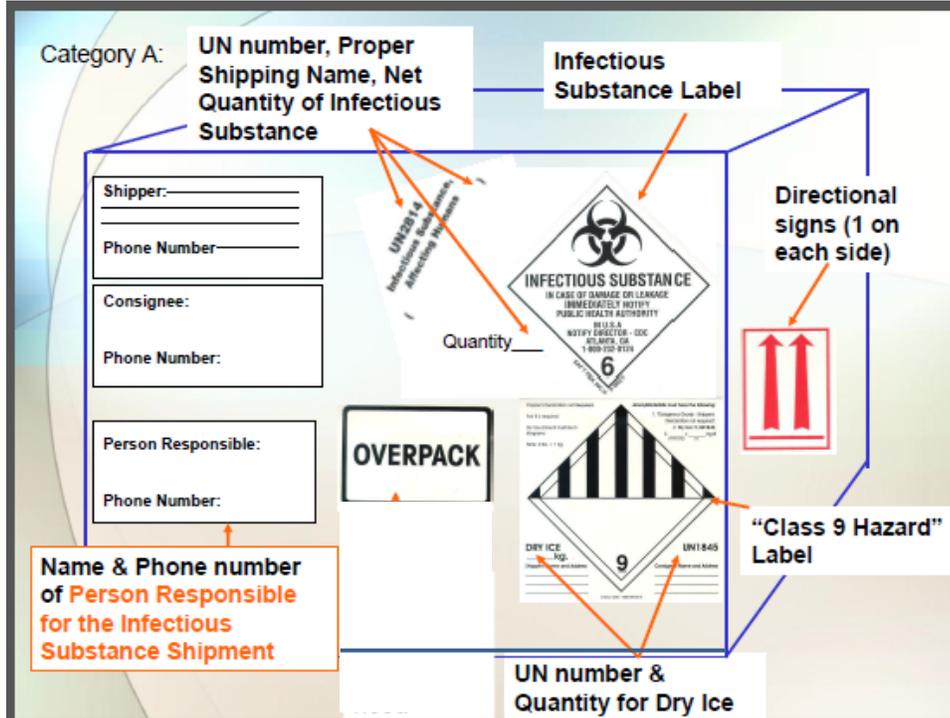
### **For general questions contact:**

**NC State Laboratory of Public Health**  
**306 North Wilmington Street**  
**Raleigh, NC 27601**  
**(919) 733-7834**  
**Fax (919) 733-8695**

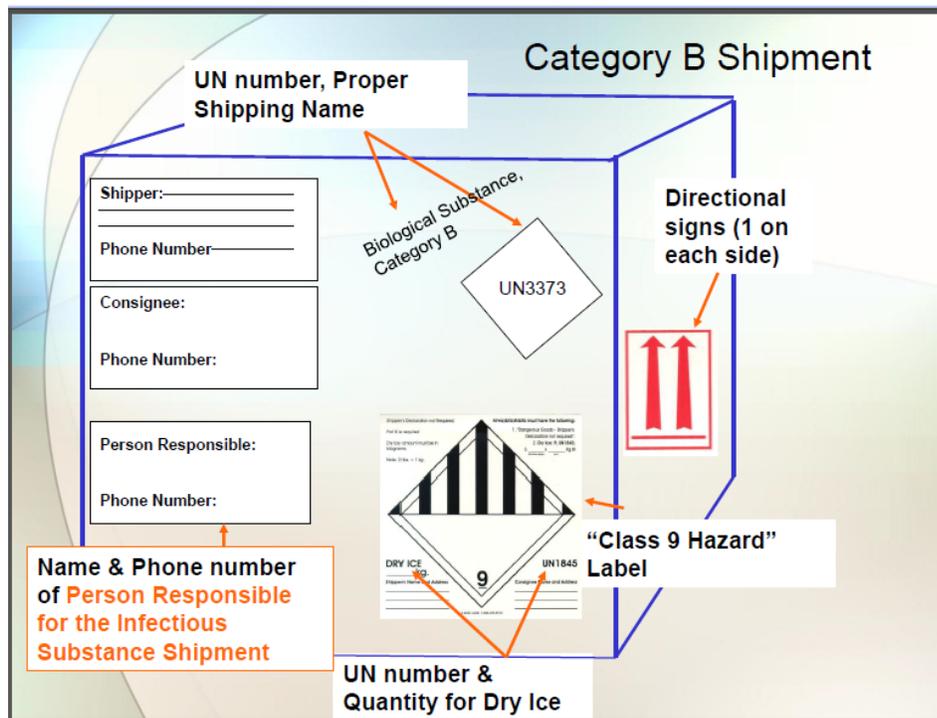
## Manufacturers of Certified Shipping Containers for Infectious Substances,

<p>Patient Specimens &amp; Dry Ice Air Sea Atlanta 1234 Logan Circle Atlanta, GA 30318 Phone: 404-351-8600 www.airseatlanta.com</p>	<p>Berlin Packaging 1195 Washington Pike Bridgeville, PA 15017 Phone: 800-2-BERLIN www.berlinpackaging.com/</p>	<p>CARGOpak Corporation PO Box 98686 Raleigh, NC 27615 Phone: 800-266-0652 www.cargopak.com</p>
<p>Inmark, Inc. 675 Hartman Road, Suite 100 Austell, GA 30168 Phone: 800-646-6275 www.inmarkinc.com ThermoSafe 3930 N. Ventura Drive Arlington Heights, IL 60004 Phone: 800-323-7442 www.thermosafe.com</p>	<p>SAF-T-PAK, Inc. 899 Airport Park Rd Ste A Glen Burnie, MD 21061-2557 Phone: 800-814-7484 www.saftpak.com. FedEx-recognized shipper's declaration available at the "On-line Forms/Shipper's Declaration" link: (<a href="http://www.saftpak.com/Support/Support.aspx">http://www.saftpak.com/Support/Support.aspx</a>).</p>	<p>Therapak Corporation 4305 Hamilton Mill Road Suite 200 Buford, Georgia 30518 Phone: 888-505-7377 www.therapak.com</p>

# Category A Shipment



# Category B Shipment



# ATTACHMENT 4

## BLOODBORNE PATHOGEN STANDARD



### Regulations (Standards - 29 CFR) Bloodborne pathogens. - 1910.1030

[← Regulations \(Standards - 29 CFR\) - Table of Contents](#)

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• Part Number:	1910
• Part Title:	Occupational Safety and Health Standards
• Subpart:	Z
• Subpart Title:	Toxic and Hazardous Substances
• Standard Number:	<u>1910.1030</u>
• Title:	Bloodborne pathogens.
• Appendix:	<u>A</u>

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#### [1910.1030\(a\)](#)

**Scope and Application.** This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

#### [1910.1030\(b\)](#)

**Definitions.** For purposes of this section, the following shall apply:

**Assistant Secretary** means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

**Blood** means human blood, human blood components, and products made from human blood.

**Bloodborne Pathogens** means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

**Clinical Laboratory** means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

**Contaminated** means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

**Contaminated Laundry** means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

**Contaminated Sharps** means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

**Decontamination** means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer

capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

**Director** means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

**Engineering Controls** means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

**Exposure Incident** means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

**Handwashing Facilities** means a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

**Licensed Healthcare Professional** is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

**HBV** means hepatitis B virus.

**HIV** means human immunodeficiency virus.

**Needleless systems** means a device that does not use needles for:

(1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) The administration of medication or fluids; or (3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

**Occupational Exposure** means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

**Other Potentially Infectious Materials** means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

**Parenteral** means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

**Personal Protective Equipment** is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

**Production Facility** means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

**Regulated Waste** means liquid or semi-liquid blood or other potentially infectious materials;

contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

**Research Laboratory** means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

**Sharps with engineered sharps injury protections** means a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

**Source Individual** means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

**Sterilize** means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

**Universal Precautions** is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

**Work Practice Controls** means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

[1910.1030\(c\)](#)

**Exposure Control --**

[1910.1030\(c\)\(1\)](#)

**Exposure Control Plan.**

[1910.1030\(c\)\(1\)\(i\)](#)

Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

[1910.1030\(c\)\(1\)\(ii\)](#)

The Exposure Control Plan shall contain at least the following elements:

[1910.1030\(c\)\(1\)\(ii\)\(A\)](#)

The exposure determination required by paragraph (c)(2),

[1910.1030\(c\)\(1\)\(ii\)\(B\)](#)

The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this standard, and

[1910.1030\(c\)\(1\)\(ii\)\(C\)](#)

The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.

[1910.1030\(c\)\(1\)\(iii\)](#)

Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.1020(e).

[1910.1030\(c\)\(1\)\(iv\)](#)

The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:

[1910.1030\(c\)\(1\)\(iv\)\(A\)](#)

Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens;  
and

[1910.1030\(c\)\(1\)\(iv\)\(B\)](#)

Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

[1910.1030\(c\)\(1\)\(v\)](#)

An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

[1910.1030\(c\)\(1\)\(vi\)](#)

The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying.

[1910.1030\(c\)\(2\)](#)

***Exposure Determination.***

[1910.1030\(c\)\(2\)\(i\)](#)

Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

[1910.1030\(c\)\(2\)\(i\)\(A\)](#)

A list of all job classifications in which all employees in those job classifications have occupational exposure;

[1910.1030\(c\)\(2\)\(i\)\(B\)](#)

A list of job classifications in which some employees have occupational exposure, and

[1910.1030\(c\)\(2\)\(i\)\(C\)](#)

A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard.

[1910.1030\(c\)\(2\)\(ii\)](#)

This exposure determination shall be made without regard to the use of personal protective equipment.

[1910.1030\(d\)](#)

***Methods of Compliance --***

[1910.1030\(d\)\(1\)](#)

***General.*** Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

[1910.1030\(d\)\(2\)](#)

***Engineering and Work Practice Controls.***

[1910.1030\(d\)\(2\)\(i\)](#)

Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used.

[1910.1030\(d\)\(2\)\(ii\)](#)

Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

[1910.1030\(d\)\(2\)\(iii\)](#)

Employers shall provide handwashing facilities which are readily accessible to employees.

[1910.1030\(d\)\(2\)\(iv\)](#)

When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

[1910.1030\(d\)\(2\)\(v\)](#)

Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

[1910.1030\(d\)\(2\)\(vi\)](#)

Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

[1910.1030\(d\)\(2\)\(vii\)](#)

Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.

[1910.1030\(d\)\(2\)\(vii\)\(A\)](#)

Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.

[1910.1030\(d\)\(2\)\(vii\)\(B\)](#)

Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

[1910.1030\(d\)\(2\)\(viii\)](#)

Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

[1910.1030\(d\)\(2\)\(viii\)\(A\)](#)

Puncture resistant;

[1910.1030\(d\)\(2\)\(viii\)\(B\)](#)

Labeled or color-coded in accordance with this standard;

[1910.1030\(d\)\(2\)\(viii\)\(C\)](#)

Leakproof on the sides and bottom; and

[1910.1030\(d\)\(2\)\(viii\)\(D\)](#)

In accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

[1910.1030\(d\)\(2\)\(ix\)](#)

Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.

[1910.1030\(d\)\(2\)\(x\)](#)

Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.

[1910.1030\(d\)\(2\)\(xi\)](#)

All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

[1910.1030\(d\)\(2\)\(xii\)](#)

Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

[1910.1030\(d\)\(2\)\(xiii\)](#)

Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

[1910.1030\(d\)\(2\)\(xiii\)\(A\)](#)

The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens.

This exemption only applies while such specimens/containers remain within the facility.

Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility.

[1910.1030\(d\)\(2\)\(xiii\)\(B\)](#)

If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.

[1910.1030\(d\)\(2\)\(xiii\)\(C\)](#)

If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

[1910.1030\(d\)\(2\)\(xiv\)](#)

Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

[1910.1030\(d\)\(2\)\(xiv\)\(A\)](#)

A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the

equipment stating which portions remain contaminated.

1910.1030(d)(2)(xiv)(B)

The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

[1910.1030\(d\)\(3\)](#)

#### **Personal Protective Equipment --**

[1910.1030\(d\)\(3\)\(i\)](#)

**Provision.** When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

1910.1030(d)(3)(ii)

**Use.** The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgement, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

[1910.1030\(d\)\(3\)\(iii\)](#)

**Accessibility.** The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

1910.1030(d)(3)(iv)

**Cleaning, Laundering, and Disposal.** The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee.

1910.1030(d)(3)(v)

**Repair and Replacement.** The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.

1910.1030(d)(3)(vi)

If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.

1910.1030(d)(3)(vii)

All personal protective equipment shall be removed prior to leaving the work area.

1910.1030(d)(3)(viii)

When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

1910.1030(d)(3)(ix)

**Gloves.** Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

1910.1030(d)(3)(ix)(A)

Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

1910.1030(d)(3)(ix)(B)

Disposable (single use) gloves shall not be washed or decontaminated for re-use.

1910.1030(d)(3)(ix)(C)

Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

1910.1030(d)(3)(ix)(D)

If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall:

1910.1030(d)(3)(ix)(D)(1)

Periodically reevaluate this policy;

1910.1030(d)(3)(ix)(D)(2)

Make gloves available to all employees who wish to use them for phlebotomy;

1910.1030(d)(3)(ix)(D)(3)

Not discourage the use of gloves for phlebotomy; and

1910.1030(d)(3)(ix)(D)(4)

Require that gloves be used for phlebotomy in the following circumstances:

1910.1030(d)(3)(ix)(D)(4)(i)

When the employee has cuts, scratches, or other breaks in his or her skin;

1910.1030(d)(3)(ix)(D)(4)(ii)

When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and

1910.1030(d)(3)(ix)(D)(4)(iii)

When the employee is receiving training in phlebotomy.

1910.1030(d)(3)(x)

**Masks, Eye Protection, and Face Shields.** Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

1910.1030(d)(3)(xi)

**Gowns, Aprons, and Other Protective Body Clothing.** Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.

1910.1030(d)(3)(xii)

Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery).

1910.1030(d)(4)

#### **Housekeeping --**

[1910.1030\(d\)\(4\)\(i\)](#)

**General.** Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

[1910.1030\(d\)\(4\)\(ii\)](#)

All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

[1910.1030\(d\)\(4\)\(ii\)\(A\)](#)

Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

1910.1030(d)(4)(ii)(B)

Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the workshift if they may have become contaminated during the shift.

1910.1030(d)(4)(ii)(C)

All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

1910.1030(d)(4)(ii)(D)

Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.

1910.1030(d)(4)(ii)(E)

Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

[1910.1030\(d\)\(4\)\(iii\)](#)

**Regulated Waste --**

[1910.1030\(d\)\(4\)\(iii\)\(A\)](#)

**Contaminated Sharps Discarding and Containment.**

[1910.1030\(d\)\(4\)\(iii\)\(A\)\(1\)](#)

Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

[1910.1030\(d\)\(4\)\(iii\)\(A\)\(1\)\(i\)](#)

Closable;

[1910.1030\(d\)\(4\)\(iii\)\(A\)\(1\)\(ii\)](#)

Puncture resistant;

[1910.1030\(d\)\(4\)\(iii\)\(A\)\(1\)\(iii\)](#)

Leakproof on sides and bottom; and

[1910.1030\(d\)\(4\)\(iii\)\(A\)\(1\)\(iv\)](#)

Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

[1910.1030\(d\)\(4\)\(iii\)\(A\)\(2\)](#)

During use, containers for contaminated sharps shall be:

[1910.1030\(d\)\(4\)\(iii\)\(A\)\(2\)\(i\)](#)

Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);

[1910.1030\(d\)\(4\)\(iii\)\(A\)\(2\)\(ii\)](#)

Maintained upright throughout use; and

[1910.1030\(d\)\(4\)\(iii\)\(A\)\(2\)\(iii\)](#)

Replaced routinely and not be allowed to overfill.

[1910.1030\(d\)\(4\)\(iii\)\(A\)\(3\)](#)

When moving containers of contaminated sharps from the area of use, the containers shall be:

[1910.1030\(d\)\(4\)\(iii\)\(A\)\(3\)\(i\)](#)

Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;

[1910.1030\(d\)\(4\)\(iii\)\(A\)\(3\)\(ii\)](#)

Placed in a secondary container if leakage is possible. The second container shall be:

[1910.1030\(d\)\(4\)\(iii\)\(A\)\(3\)\(ii\)\(A\)](#)

Closable;

[1910.1030\(d\)\(4\)\(iii\)\(A\)\(3\)\(ii\)\(B\)](#)

Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and

[1910.1030\(d\)\(4\)\(iii\)\(A\)\(3\)\(ii\)\(C\)](#)

Labeled or color-coded according to paragraph (g)(1)(i) of this standard.

[1910.1030\(d\)\(4\)\(iii\)\(A\)\(4\)](#)

Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

[1910.1030\(d\)\(4\)\(iii\)\(B\)](#)

**Other Regulated Waste Containment --**

[1910.1030\(d\)\(4\)\(iii\)\(B\)\(1\)](#)

Regulated waste shall be placed in containers which are:

[1910.1030\(d\)\(4\)\(iii\)\(B\)\(1\)\(i\)](#)

Closable;

[1910.1030\(d\)\(4\)\(iii\)\(B\)\(1\)\(ii\)](#)

Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

[1910.1030\(d\)\(4\)\(iii\)\(B\)\(1\)\(iii\)](#)

Labeled or color-coded in accordance with paragraph (g)(1)(i) this standard; and

[1910.1030\(d\)\(4\)\(iii\)\(B\)\(1\)\(iv\)](#)

Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

[1910.1030\(d\)\(4\)\(iii\)\(B\)\(2\)](#)

If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be:

[1910.1030\(d\)\(4\)\(iii\)\(B\)\(2\)\(i\)](#)

Closable;

[1910.1030\(d\)\(4\)\(iii\)\(B\)\(2\)\(ii\)](#)

Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

1910.1030(d)(4)(iii)(B)(2)(iii)

Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and

1910.1030(d)(4)(iii)(B)(2)(iv)

Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

[1910.1030\(d\)\(4\)\(iii\)\(C\)](#)

Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

[1910.1030\(d\)\(4\)\(iv\)](#)

#### **Laundry.**

[1910.1030\(d\)\(4\)\(iv\)\(A\)](#)

Contaminated laundry shall be handled as little as possible with a minimum of agitation.

[1910.1030\(d\)\(4\)\(iv\)\(A\)\(1\)](#)

Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

1910.1030(d)(4)(iv)(A)(2)

Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

[1910.1030\(d\)\(4\)\(iv\)\(A\)\(3\)](#)

Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior.

1910.1030(d)(4)(iv)(B)

The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.

[1910.1030\(d\)\(4\)\(iv\)\(C\)](#)

When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i).

[1910.1030\(e\)](#)

#### **HIV and HBV Research Laboratories and Production Facilities.**

1910.1030(e)(1)

This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.

1910.1030(e)(2)

Research laboratories and production facilities shall meet the following criteria:

1910.1030(e)(2)(i)

**Standard Microbiological Practices.** All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

1910.1030(e)(2)(ii)

#### **Special Practices.**

1910.1030(e)(2)(ii)(A)

Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

[1910.1030\(e\)\(2\)\(ii\)\(B\)](#)

Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.

1910.1030(e)(2)(ii)(C)

Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

1910.1030(e)(2)(ii)(D)

When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(ii) of this standard.

1910.1030(e)(2)(ii)(E)

All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.

1910.1030(e)(2)(ii)(F)

Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.

1910.1030(e)(2)(ii)(G)

Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

1910.1030(e)(2)(ii)(H)

Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

1910.1030(e)(2)(ii)(I)

Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

1910.1030(e)(2)(ii)(J)

Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.

1910.1030(e)(2)(ii)(K)

All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

1910.1030(e)(2)(ii)(L)

A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

1910.1030(e)(2)(ii)(M)

A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

1910.1030(e)(2)(iii)

#### **Containment Equipment.**

1910.1030(e)(2)(iii)(A)

Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

1910.1030(e)(2)(iii)(B)

Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

1910.1030(e)(3)

HIV and HBV research laboratories shall meet the following criteria:

1910.1030(e)(3)(i)

Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.

1910.1030(e)(3)(ii)

An autoclave for decontamination of regulated waste shall be available.

1910.1030(e)(4)

HIV and HBV production facilities shall meet the following criteria:

1910.1030(e)(4)(i)

The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

1910.1030(e)(4)(ii)

The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

1910.1030(e)(4)(iii)

Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

1910.1030(e)(4)(iv)

Access doors to the work area or containment module shall be self-closing.

1910.1030(e)(4)(v)

An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

1910.1030(e)(4)(vi)

A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

1910.1030(e)(5)

**Training Requirements.** Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).

[1910.1030\(f\)](#)

**Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up --**

[1910.1030\(f\)\(1\)](#)

**General.**

[1910.1030\(f\)\(1\)\(i\)](#)

The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

[1910.1030\(f\)\(1\)\(ii\)](#)

The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

1910.1030(f)(1)(ii)(A)

Made available at no cost to the employee;

1910.1030(f)(1)(ii)(B)

Made available to the employee at a reasonable time and place;

1910.1030(f)(1)(ii)(C)

Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

[1910.1030\(f\)\(1\)\(ii\)\(D\)](#)

Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

1910.1030(f)(1)(iii)

The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

[1910.1030\(f\)\(2\)](#)

**Hepatitis B Vaccination.**

1910.1030(f)(2)(i)

Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

1910.1030(f)(2)(ii)

The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.

1910.1030(f)(2)(iii)

If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

1910.1030(f)(2)(iv)

The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in Appendix A.

[1910.1030\(f\)\(2\)\(v\)](#)

If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

[1910.1030\(f\)\(3\)](#)

**Post-exposure Evaluation and Follow-up.** Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

1910.1030(f)(3)(i)

Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

1910.1030(f)(3)(ii)

Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

1910.1030(f)(3)(ii)(A)

The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

1910.1030(f)(3)(ii)(B)

When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

1910.1030(f)(3)(ii)(C)

Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

1910.1030(f)(3)(iii)

Collection and testing of blood for HBV and HIV serological status;

1910.1030(f)(3)(iii)(A)

The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

1910.1030(f)(3)(iii)(B)

If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

1910.1030(f)(3)(iv)

Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

1910.1030(f)(3)(v)

Counseling; and

1910.1030(f)(3)(vi)

Evaluation of reported illnesses.

1910.1030(f)(4)

**Information Provided to the Healthcare Professional.**

1910.1030(f)(4)(i)

The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

1910.1030(f)(4)(ii)

The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

1910.1030(f)(4)(ii)(A)

A copy of this regulation;

1910.1030(f)(4)(ii)(B)

A description of the exposed employee's duties as they relate to the exposure incident;

1910.1030(f)(4)(ii)(C)

Documentation of the route(s) of exposure and circumstances under which exposure occurred;

1910.1030(f)(4)(ii)(D)

Results of the source individual's blood testing, if available; and

1910.1030(f)(4)(ii)(E)

All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

[1910.1030\(f\)\(5\)](#)

**Healthcare Professional's Written Opinion.** The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

1910.1030(f)(5)(i)

The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

1910.1030(f)(5)(ii)

The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

1910.1030(f)(5)(ii)(A)

That the employee has been informed of the results of the evaluation; and

1910.1030(f)(5)(ii)(B)

That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

1910.1030(f)(5)(iii)

All other findings or diagnoses shall remain confidential and shall not be included in the written report.

1910.1030(f)(6)

**Medical Recordkeeping.** Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

1910.1030(g)

**Communication of Hazards to Employees --**

[1910.1030\(g\)\(1\)](#)

**Labels and Signs --**

[1910.1030\(g\)\(1\)\(i\)](#)

**Labels.**

1910.1030(g)(1)(i)(A)

Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

1910.1030(g)(1)(i)(B)

Labels required by this section shall include the following legend:

1910.1030(g)(1)(i)(C)

These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

1910.1030(g)(1)(i)(D)

Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

1910.1030(g)(1)(i)(E)

Red bags or red containers may be substituted for labels.

1910.1030(g)(1)(i)(F)

Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).

1910.1030(g)(1)(i)(G)

Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

[1910.1030\(g\)\(1\)\(i\)\(H\)](#)

Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

1910.1030(g)(1)(i)(I)

Regulated waste that has been decontaminated need not be labeled or color-coded.

1910.1030(g)(1)(ii)

**Signs.**

1910.1030(g)(1)(ii)(A)

The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:



(Name of the Infectious Agent)

(Special requirements for entering the area)

(Name, telephone number of the laboratory director or other responsible person.)

1910.1030(g)(1)(ii)(B)

These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.

[1910.1030\(g\)\(2\)](#)

**Information and Training.**

1910.1030(g)(2)(i)

The employer shall train each employee with occupational exposure in accordance with the requirements of this section. Such training must be provided at no cost to the employee and during working hours. The employer shall institute a training program and ensure employee participation in the program.

1910.1030(g)(2)(ii)

Training shall be provided as follows:

1910.1030(g)(2)(ii)(A)

At the time of initial assignment to tasks where occupational exposure may take place;

1910.1030(g)(2)(ii)(B)

At least annually thereafter.

1910.1030(g)(2)(iii)

[Reserved]

1910.1030(g)(2)(iv)

Annual training for all employees shall be provided within one year of their previous training.

1910.1030(g)(2)(v)

Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

1910.1030(g)(2)(vi)

Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

1910.1030(g)(2)(vii)

The training program shall contain at a minimum the following elements:

1910.1030(g)(2)(vii)(A)

An accessible copy of the regulatory text of this standard and an explanation of its contents;

1910.1030(g)(2)(vii)(B)

A general explanation of the epidemiology and symptoms of bloodborne diseases;

1910.1030(g)(2)(vii)(C)

An explanation of the modes of transmission of bloodborne pathogens;

1910.1030(g)(2)(vii)(D)

An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

1910.1030(g)(2)(vii)(E)

An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

1910.1030(g)(2)(vii)(F)

An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;

1910.1030(g)(2)(vii)(G)

Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

1910.1030(g)(2)(vii)(H)

An explanation of the basis for selection of personal protective equipment;

1910.1030(g)(2)(vii)(I)

Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

1910.1030(g)(2)(vii)(J)

Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

1910.1030(g)(2)(vii)(K)

An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;

1910.1030(g)(2)(vii)(L)

Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

1910.1030(g)(2)(vii)(M)

An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and [1910.1030\(g\)\(2\)\(vii\)\(N\)](#)

An opportunity for interactive questions and answers with the person conducting the training session.

[1910.1030\(g\)\(2\)\(viii\)](#)

The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

1910.1030(g)(2)(ix)

Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

1910.1030(g)(2)(ix)(A)

The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

1910.1030(g)(2)(ix)(B)

The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

1910.1030(g)(2)(ix)(C)

The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

[1910.1030\(h\)](#)

**Recordkeeping --**

1910.1030(h)(1)

**Medical Records.**

1910.1030(h)(1)(i)

The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

1910.1030(h)(1)(ii)

This record shall include:

1910.1030(h)(1)(ii)(A)

The name and social security number of the employee;

1910.1030(h)(1)(ii)(B)

A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

1910.1030(h)(1)(ii)(C)

A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);

1910.1030(h)(1)(ii)(D)

The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and

1910.1030(h)(1)(ii)(E)

A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).

1910.1030(h)(1)(iii)

Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are:

1910.1030(h)(1)(iii)(A)

Kept confidential; and

1910.1030(h)(1)(iii)(B)

Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

1910.1030(h)(1)(iv)

The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.

1910.1030(h)(2)

**Training Records.**

1910.1030(h)(2)(i)

Training records shall include the following information:

1910.1030(h)(2)(i)(A)

The dates of the training sessions;

1910.1030(h)(2)(i)(B)

The contents or a summary of the training sessions;

1910.1030(h)(2)(i)(C)

The names and qualifications of persons conducting the training; and

1910.1030(h)(2)(i)(D)

The names and job titles of all persons attending the training sessions.

1910.1030(h)(2)(ii)

Training records shall be maintained for 3 years from the date on which the training occurred.

1910.1030(h)(3)

**Availability.**

1910.1030(h)(3)(i)

The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

[1910.1030\(h\)\(3\)\(ii\)](#)

Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary.

[1910.1030\(h\)\(3\)\(iii\)](#)

Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR

1910.1020.

[1910.1030\(h\)\(4\)](#)

**Transfer of Records.**

1910.1030(h)(4)(i)

The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

1910.1030(h)(4)(ii)

If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so, within that three month period.

[1910.1030\(h\)\(5\)](#)

**Sharps injury log.**

1910.1030(h)(5)(i)

The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

[1910.1030\(h\)\(5\)\(i\)\(A\)](#)

The type and brand of device involved in the incident,

1910.1030(h)(5)(i)(B)

The department or work area where the exposure incident occurred, and

[1910.1030\(h\)\(5\)\(i\)\(C\)](#)

An explanation of how the incident occurred.

1910.1030(h)(5)(ii)

The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR 1904.

1910.1030(h)(5)(iii)

The sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

1910.1030(i)

**Dates --**

1910.1030(i)(1)

**Effective Date.** The standard shall become effective on March 6, 1992.

1910.1030(i)(2)

The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992.

1910.1030(i)(3)

Paragraph (g)(2) Information and Training and (h) Recordkeeping shall take effect on or before June 4, 1992.

1910.1030(i)(4)

Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs, shall take effect July 6, 1992.

[56 FR 64004, Dec. 06, 1991, as amended at 57 FR 12717, April 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5507, Feb. 13, 1996; 66 FR 5325 Jan., 18, 2001; 71 FR 16672 and 16673, April 3, 2006; 73 FR 75586, Dec. 12, 2008]



[Next Standard \(1910.1030 App A\)](#)



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**ATTACHMENT 5**

**OCCUPATIONAL EXPOSURE TO  
HAZARDOUS CHEMICALS LABORATORY  
STANDARD**

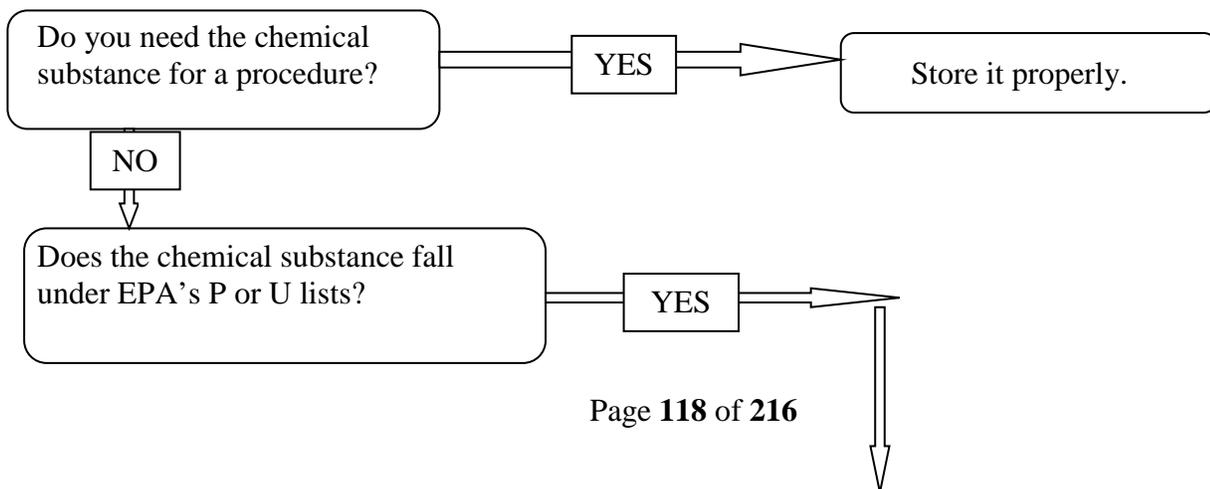
- Please visit the Department of Labor, Health Occupational Safety and Health Administration website for updated Occupational Exposure To Hazardous Chemicals Laboratory Standards updates.

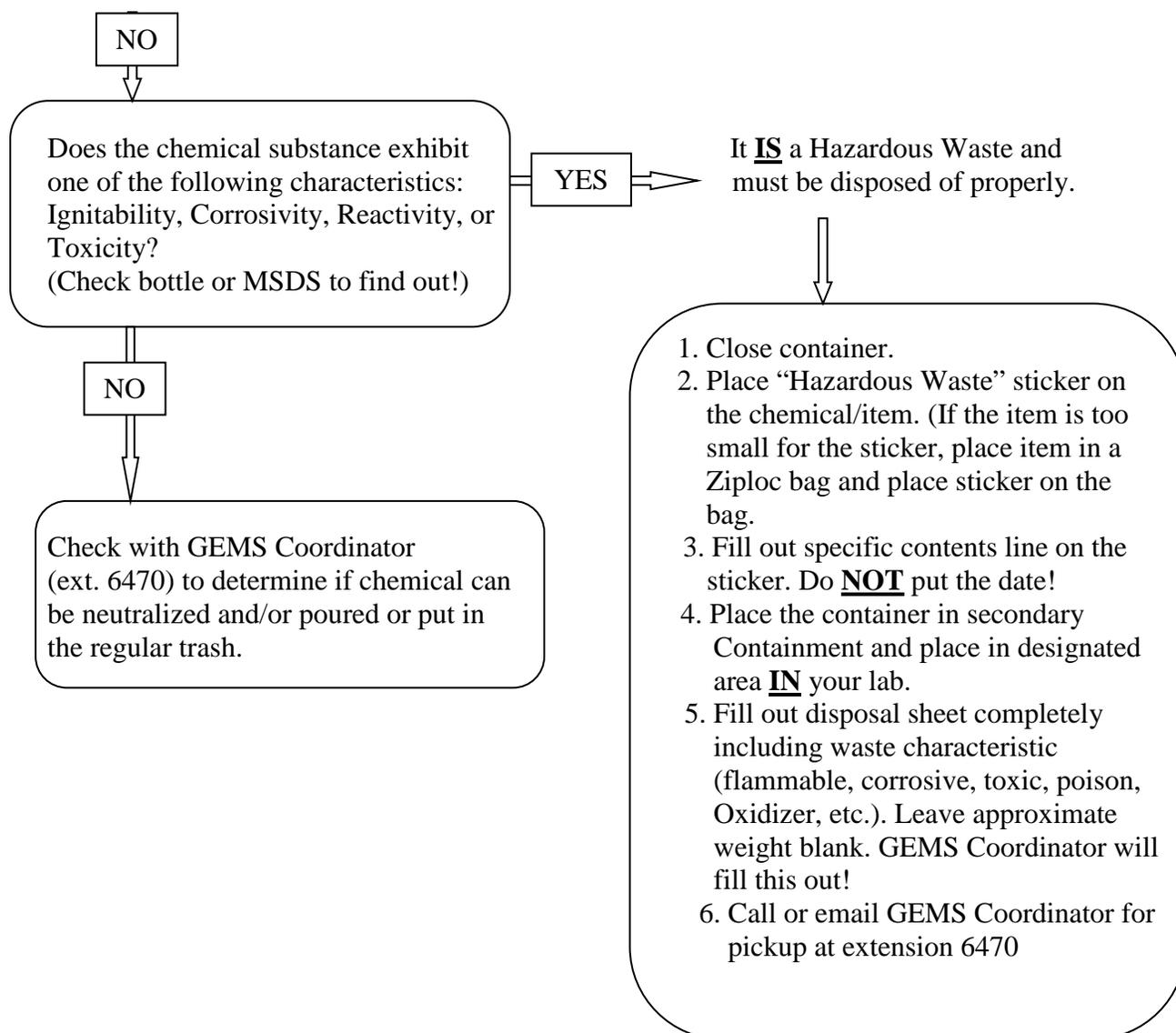
Go to <https://www.gpo.gov/fdsys/pkg/CFR-2015-time29-vol16-sec1900-1450.xml>

## ATTACHMENT 6

Flow Chart for determining if a Chemical should be disposed of as Waste and if it is Hazardous

### How to determine whether your chemical is a waste and is hazardous:





## ATTACHMENT 7 ALDEHYDE NEUTRALIZATION PROCEDURE

### NEUTRALIZATION OF ALDEHYDES USING LIQUID ALDEX®

#### INTRODUCTION

Aldex® neutralizes and crosslink's used 10% formalin or up to 4% glutaraldehyde and converts the waste to a non-toxic, non-hazardous water soluble polymer. Once neutralized, the waste is safe to dispose of down the drain.

#### PERSONAL PROTECTIVE EQUIPMENT

1. Nitrile gloves
2. Lab coat or apron
3. Goggles
4. Face Shield

**EQUIPMENT/SUPPLIES**

- 1. Fume hood or ventilated work station
- 2. Mixing container
- 3. Secondary container tray
- 4. Stirrer
- 5. Aldex® Aldehyde Management System – Cardinal Health Catalog #AMSG15 (1 gallon size bottle)

**PROCEDURE**

- 1. Don PPE
- 2. In a fume hood or ventilated work station, place the mixing container in a secondary containment tray.
- 3. Add one part Aldex® to every 15 parts of waste (200 mL to 3 L or 1 oz. to 15 oz.)
- 4. Mix the solution by stirring or by sealing the container and tipping or swirling side to side.
- 5. Let the solution set for 24 hours.
- 6. Pour down the drain and follow with 5 minutes of running water.

**SAFETY PRECAUTIONS**

- 1. All work must be conducted in a fume hood or a ventilated work station.
- 2. Use goggles and a face shield when working on a ventilated work station.
- 3. Aldex® contains 5 % acetic acid, so always add Aldex® to Aldehyde waste.
- 4. Use and absorber pad to clean up spills of Aldex®
- 5. Use Aldex® to clean up Aldehyde spills.
- 6. Wash hands after each glove removal.
- 7. Review the MSDS.

## Attachment 8

# LABORATORY START-UP & CLOSEOUT

**A. INTRODUCTION**

This document provides guidance to all principal investigators (PIs) on appropriate start-up and decommissioning of laboratories. This includes reassigning, vacating, converting to non-laboratory use, or otherwise modifying procedures in a VA research laboratory. It is imperative that these procedures be followed to ensure compliance with all applicable federal, state and local requirements and to ensure safe and compliant transitions in laboratory occupancy.

Jamece  
Petteway  
Budget  
Manager  
X6544

**B. LABORATORY START-UP**

It is necessary that each new principal investigator (PI) be made aware of all applicable safety requirements. Failure to incorporate required work practices may lead to an unsafe occupational setting. Non-compliance

Kevin  
Henry  
X7335

Noel  
Perez  
Quinoes  
X7027

with policies and regulations have specific reporting requirements to local officials and the VA Office of Research Oversight (ORO) and may result in fines from external regulatory agencies such as the Occupational Safety and Health Administration (OSHA).

New PIs will complete the “[Notice of Laboratory Occupancy](#)” form. The PI should request assistance in completing the form and answering questions regarding special safety requirements applicable to the laboratory operation by contacting the Research Laboratory Safety Coordinator at 919-286-0411 X 7341, or the Research Occupational Health and Safety Specialist.

## **C. LABORATORY DECOMMISSIONING**

The PI or Laboratory director must obtain authorization (i.e., permission) from the Subcommittee on Research Safety (SRS) and the ACOS for Research prior to decommissioning (including reassigning, vacating, converting to non-laboratory use, or otherwise modifying) existing laboratory space.

### **1. Notice of Laboratory Decommissioning**

The process below must be completed as soon as possible, but **no later than 30 days**, prior to any anticipated departure:

- a) Contact the Research Occupational Health and Safety Specialist (OH&S) at 919-286-0411 x 7341 to receive a Laboratory Decommission Notice.
- b) Complete the Laboratory Decommission Notice and return to the Research OH&S. The Research OH&S will forward the completed Laboratory Decommission Notice to the Chair of the SRS.
- c) Once the Chair of the SRS approves the decommission, the Laboratory Decommission Notice will be signed and dated.
- d) The Chair of the SRS will then forward the Laboratory Decommission Notice to the ACOS for Research.
- e) The ACOS for Research, upon receiving the request, must notify the VISN 6 Safety Office.
- f) Once the decommission is reported to the VISN 6 Safety Office, the ACOS for Research will sign and date the Laboratory Decommission Notice.
- g) The ACOS for Research will then forward the Laboratory Decommission Notice to the Research OH&S.
- h) Upon decommission approval, the PI will be contacted by the OH&S and instructed to begin the Decommissioning Requirements Checklist (See below).
- i) The Research OH&S will contact Radiation Safety Officer, Industrial Hygiene and GEMS for initial and final surveys to be conducted of all laboratory areas being vacated for decommission.
- j) Once the Radiation Safety Officer, Research Industrial Hygienist and GEMS have completed all surveys and approved/cleared the area for decommission, the Research OH&S will forward the completed R&D Laboratory Decommissioning Survey Form to the Facility Safety Officer.

- k) The Facility Safety Officer will send, in writing, a notice of “Cleared for Decommission” to the SRS, ACOS for Research and the AO of the acquiring service.
- l) The Facility Safety Officer will then forward the R&D Laboratory Decommissioning Survey Form to the Research OH&S to be filed.

## **2. Decommissioning Requirements**

- a) When an investigator vacates laboratory space, none of the research materials will be left behind in the laboratory.
- b) The Investigator must assure that all laboratory equipment, fixtures, furniture and space are properly cleaned and decontaminated.
- c) The departing PI will be held fully responsible for all facility requirements. The laboratory will be cleared for new occupancy only after all requirements are met.
- d) Should proper notification not be given or facility requirements not met, the PI will be held responsible for all cost incurred for safe disposal of remaining hazardous material wastes.
- e) Laboratory must be empty except for furniture, fixtures, chemical hoods and biological safety cabinets.

## **3. Decommissioning Requirements For Classes of Hazardous Agents**

❖ The applicable requirements below must be met prior to the initial surveys of the Radiation Safety Officer, Research Industrial Hygienist and GEMS.

### **a) Biological Hazards:**

- i. All biological materials (i.e. blood, fresh tissue, bacterial cultures, etc.) are removed from the laboratory according to Institutional policy, by shipping to another facility while conforming to Federal/State shipping regulations, or by transferring to another PI.
- ii. All biological materials (i.e. blood, fresh tissue, bacterial cultures, etc.) are removed from refrigerators, freezers, incubators and cold rooms.
- iii. All equipment which has been exposed to potentially infectious materials has been properly decontaminated.
- iv. All biological waste has been properly decontaminated and disposed of appropriately.
- v. All bench tops and work surfaces are wiped down with an approved disinfectant.
- vi. All biological safety cabinets were decontaminated.
- vii. If Formaldehyde gas decontamination is necessary, the departing PI is financially responsible.
- viii. All placards and/or biohazard signs from doors, walls, shelves, cabinets and areas of the lab are removed

**b) Chemical Hazards:**

- i.** Hazardous waste disposal request forms for all chemicals not transferred to another laboratory are properly completed.
- ii.** All hazardous waste and unwanted empty chemical containers have been disposed of through the GEMS Coordinator.
- iii.** Chemicals being shipped or transferred to another facility are packaged and labeled according to approved regulations.
- iv.** All chemical containers moved to another VA laboratory are labeled with the chemical name.
- v.** Compressed gas cylinders were returned to their supplier (e.g., Clean Air).
- vi.** Compressed gas cylinders regulators are removed and valve protection caps are securely in place.
- vii.** Chemical fume hoods are clean of all debris.
- viii.** Chemical fume hood base, surface and walls have been decontaminated and wiped clean.
- ix.** All Laboratory bench tops were washed with soap and water.
- x.** Sink traps and floor drains (if applicable) have been flushed with water to prevent backflow of sewer gas.

**c) Controlled Drugs:**

- i.** Green drug inventory sheets have been validated.
- ii.** All green sheets and controlled drugs were return to the VA pharmacy.
- iii.** Clearance from the pharmacy was obtained.
- iv.** Pharmacy clearance documentation was returned to the Research Laboratory Safety Coordinator in Building 8 Room 125.

**d) Toxins:**

- i.** Appropriate procedure was used to transfer or destroy toxins.
- ii.** Approval to transfer toxins was received from Research Industrial Hygienist.

**e) General:**

- i.** All equipment and supplies are removed from the laboratory
- ii.** All desk and cabinet drawers are emptied, cleaned and wiped down.

**f) Radiological Material Hazards:**

- i. All Disposal and transfer of radioactive materials were coordinated with the Radiation Safety Officer (RSO) at 7909.

**4. Non-Compliance with Decommissioning Requirements**

- a) The Research Service is required to report non-compliance regarding the laboratory decommissioning requirement.
- b) Within five business days of discovering, receiving a credible report of, or otherwise becoming aware of any decommissioning implemented without the required authorization, the ACOS for Research must report the incident directly to the facility Director and the VISN6 Safety Office.
- c) The facility Director must report any unauthorized decommissioning to ORO CO within 5 business days after being notified.

**Laboratory Decommission Notice  
Durham VAMC  
Research and Development  
(Page 1 of 2)**

**Attachment 9**

Complete the decommission notice as soon as a move is indicated (preferably 3-4 months) and no less than 30 days prior to departure. Forward the completed Decommission Notice to Research Occupational Health and Safety Specialist (OH&S) **via** Fax # 919-286-6824 or deliver to Building 8 room 125. Once the notice is received, it will be forwarded to Chair of the SRS, ACOS for Research and the VISN 6 Safety Office will be notified. Upon decommission approval, the PI will be contacted by the Research OH&S and instructed to begin the Decommissioning Requirements Checklist. The Radiation Safety Officer, Research Industrial Hygienist and GEMS will be contacted for initial and final surveys to be conducted of all laboratory areas being vacated for decommission.

P.I.: \_\_\_\_\_

Safety Contact: \_\_\_\_\_

Email: \_\_\_\_\_

Email: \_\_\_\_\_

Phone: \_\_\_\_\_

Phone: \_\_\_\_\_

Box #: \_\_\_\_\_

Building: \_\_\_\_\_ Room(s): \_\_\_\_\_

Please check all that apply:

Permanent Lab Closeout  Laboratory Relocation  Lab Renovation  Converting to Non-Lab Use

Other \_\_\_\_\_

**Anticipated Date of Decommission (Departure):** \_\_\_\_\_

**\* Note:** If this decommission is for a lab that will be relocating to a new location on the Durham VAMC campus, please also complete the laboratory occupancy procedures for Durham VAMC.

**Hazardous Material Inventory**

List the laboratory's hazardous materials while segregating by the categories below. A brief description of each material (i.e. quantity) will be helpful when preparing site-specific instructions for decommission

**Biological Materials: (i.e. viruses, bacteria, human blood, etc.):**


**Laboratory Decommission Notice  
Durham VAMC  
Research and Development  
(Page 2 of 2)**

**Attachment 10**

**Radioactive Materials:**


**Chemicals** (List all particularly hazardous chemicals – Categorize others by hazard class – Attach your current chemical inventory.):



**Drugs/Toxins/Select Agents: (List all)**


**Equipment (List all)**


**AUTHORIZATION:**

Order	Title	Date Notified	Signature for Approval of Decommission	Date Approved	Date Forwarded	Comment
1st	Research OH&S		N/A	N/A		
2nd	SRS Chair					
3rd	ACOS-R					Date VISN 6 Safety Office was notified:
4th	Research OH&S		N/A	N/A	N/A	

**Attachment 10**

**R&D Laboratory Decommissioning Survey Form**

This form is for use and by Radiation Safety, Industrial Hygiene and GEMS only. Once survey is completed, return to Research Occupational Health and Safety Specialist. A copy will be posted on door of surveyed area.

Principal Investigator: \_\_\_\_\_ Phone Number: \_\_\_\_\_ Department: \_\_\_\_\_  
 Projected Start Date: \_\_\_\_\_ First Inspection Date: \_\_\_\_\_ Final Inspection Date: \_\_\_\_\_  
 Building: \_\_\_\_\_ Room: \_\_\_\_\_

**\*\*Surveyors please initial after each inspection item\*\***

**Radiation Safety Survey**

Initial Survey Date: \_\_\_\_\_

Final Survey Date: \_\_\_\_\_

Inspection Criteria	Initial Survey			Final Survey		
	YES	NO	N/A	YES	NO	N/A
Lab/ Area is free of radioactive contamination, Lab/Area is cleared for use						
Radiation Safety Officer removed "Radioactive Warning" signage						

**\*\*Sign below after final survey\*\***

**Research Industrial Hygiene Survey**

**Initial Survey  
Date:**

**Final Survey Date:**

Inspection Criteria	Initial Survey			Final Survey		
	YES	NO	N/A	YES	NO	N/A
Chemicals are properly removed/disposed/stored						
All compressed gas cylinders have been removed						
Chemical storage areas are clean, w/surfaces wiped down						
All biohazards have been disposed of properly						
Biosafety Cabinet(s) are decontaminated						
All visible insulation is intact						
Fume hood(s) are clean						
Asbestos identified / Lead Paint identified						
General cleanliness & hygiene acceptable						
All special in-house equipment removed						
All signage removed (Walls/Doors/Cabinets)						

**\*\*Sign below after final survey\*\***

**GEMS Survey**

**Initial Survey  
Date:**

**Final Survey Date:**

Inspection Criteria	Initial Survey			Final Survey		
	YES	NO	N/A	YES	NO	N/A
Hazardous Waste Materials are removed from lab for disposal						
Hazardous Waste storage areas are clean, w/surfaces wiped down						

**\*\*Sign below after final survey\*\***

**Decommission Approval / Disapproval**

**Radiation Safety Officer** Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Decommission Approved: YES NO Approval Contingent Upon: \_\_\_\_\_

**Research Industrial Hygiene** Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Decommission Approved: YES NO Approval Contingent Upon: \_\_\_\_\_

**GEMS** Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Decommission Approved: YES NO Approval Contingent Upon: \_\_\_\_\_

**Facility Safety Officer** Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Laboratory / Area is Cleared for Decommission: YES NO

**Notice of Laboratory Occupancy  
Durham VAMC  
Research and Development  
(Page 1 of 2)**

**Attachment 11**

In order to assure total compliance with all applicable safety policies and procedures, it is necessary for new principal investigators to communicate with the Research Occupational Health and Safety Specialist. The PI will need to complete this form and submit it to the Research Occupational Health and Safety Specialist at Fax # 286-6824 or deliver to building 8, room 125. Upon receipt of the following list, an on-site visit to discuss all applicable safety policies and procedures will be scheduled.

P.I.: \_\_\_\_\_ Safety Rep: \_\_\_\_\_

Current Building: \_\_\_\_\_ Current Room(s): \_\_\_\_\_

New Building: \_\_\_\_\_ New Room(s): \_\_\_\_\_

Current Phone: \_\_\_\_\_ New Phone: \_\_\_\_\_

Current E-mail: \_\_\_\_\_ New E-mail: \_\_\_\_\_

**Start Date of Lab Work:** \_\_\_\_\_

In the space provided, give a general description of all hazardous agents to be used in the new laboratory (including all materials that are anticipated to be used in the future). If you are uncertain whether an agent should be considered “hazardous”, list it below so it can be discussed during the Industrial Hygienist on-site visit. Use back of form if needed.

**Biological Materials** (i.e. viruses, bacteria, human blood, etc.):


**Chemicals** (list all Particularly Hazardous Substances – see Duke’s PHS List at <http://www.safety.duke> or the VA Research Chemical Hygiene Plan. *A complete chemical inventory must be attached and an SOP for each PHS listed.*) Contact Research Occupational Health and Safety Specialist for electronic forms:



TemplateSOP (1).doc HCINVENTORYForm.xls

**Particularly Hazardous Substances**


**Notice of Laboratory Occupancy  
Durham VAMC  
Research and Development  
(Page 2 of 2)**

**Radioactive Materials:**


**Animals** (List all to be used):


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**Drugs/Toxins/Select Agents** (List all to be used):


**Equipment** (List all to be used):


**Special Requirements** (Fume Hood, Bio Safety Cabinet, Freezer, etc.):


Fax completed form to the Research Occupational Health and Safety Specialist at 286-6824 or deliver to building 8, room 125. For questions, call x7341.

## EMERGENCY RESPONSE AND INCIDENT REPORTING GUIDE

### DURHAM VAMC RESEARCH LABORATORIES

## FIRE

### Activate the **RACE** Procedure

<b><u>Rescue</u></b> anyone in danger	Pull the <b><u>Alarm</u></b> and dial 6099
<b><u>Contain</u></b> by closing doors and windows	<b><u>Extinguish</u></b> fire and/or evacuate

## BLOODBORNE PATHOGEN EXPOSURE OR ACCIDENT

### BBP Spill Clean-up

- Don gloves, gown, safety glasses
- Absorb spill with disposable towels
- Clean area with a detergent solution
- Decontaminate the area with freshly made 10% bleach
- Dispose of all materials used in cleanup in a bio-waste bag

### Care of Exposed Employee

- Flush exposed area with water for 15 minutes
- Employee Reports to Employee Health (If closed go to ED)
- EH/ED Evaluates Employee and Create a Stub Record
- Supervisor Completes VA Form 2162
- Employee Completes Form CA-1 or CA-2
- Supervisor Completes Form CA-1 or CA-2

## CHEMICAL SPILL/RELEASE

### Minor

### Moderate

### Major

<i>Small volume spill; one person can clean-up</i>	<i>Volume requiring more than one person to clean-up</i>	<i>Large volume spill requiring a Spill Response Team</i>
<i>Clean-up using spill kit Call GEMS Coordinator at 6470 for pick up</i>	<i>Call for assistance of co-worker, EMS, or IH Clean-up using spill kit Call GEMS Coordinator at 6470 for pick up</i>	<i>Evacuate area Call 6099</i>

## RADIOLOGICAL SPILL

**Minor Spill:** Clean up Spill and Notify RSO

**Major Spill:** Contain spill & notify RSO  
6952/pager 820 or 522/after hours 7888

## POLICE AND SECURITY

Routine call 6230  
Emergencies call 7888

02/08

# A Laboratory Annual Self-Inspection Form

A. PRINCIPAL INVESTIGATOR/ LAB SAFETY REPRESENTATIVE			
	2. Telephone:	3. Pager:	4. Mail Code
PRINCIPAL INVESTIGATOR:			
E-Mail:			
	2. Telephone:	3. Pager:	4. Mail Code
LAB SAFETY REP:			
E-Mail:			

B. LABORATORY. List <u>all</u> rooms in which the PI conducts research, including storage space and Animal Facility space. Please list laboratory phone extensions by the laboratory room number as well (Include VA and Non-VA).			
Room (include building/campus if non-VA)	Phone/ext.	Room (include building/campus if non-VA)	Phone/ext.

C. PERSONNEL. List the names of all personnel who will work with the PI on this research proposal. Include the name of the Principal Investigator. List non-VA personnel only if working in a VA laboratory. Use additional pages as necessary.			
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			

12.			
13.			
14.			

**D. RESEARCH OVERVIEW** *What type of research is performed in your laboratory? (Check all that apply)*

<input type="checkbox"/> Basic	<input type="checkbox"/> Animal	<input type="checkbox"/> Human, including human cell work
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**E Training** SRS Use Only

1. Have all personnel received the following mandatory training?			
a. Fire Safety (Annual)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
b. Chemical Hygiene Plan Orientation (At Hire)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
c. Chemical Hygiene Plan Update (Annual)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
d. Basic VAMC Radiation Safety (Annual)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
f. Bloodborne Pathogens (Annual)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
g. Packaging of Biological Materials (Biennial)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
h. General Lab Safety (At Hire)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
i. Radiation User Safety (Annual)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
j. Formaldehyde Awareness (At Hire)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
k. Personal Protective Equipment (At Hire)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
l. Spill Kit (At Hire)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
m. Laboratory Orientation (At Hire)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Have non-VA personnel working in VA labs received appropriate safety instructions and safety procedures training?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Are all personnel aware of the procedure for reporting accidents, illnesses or injuries?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
4. Are all personnel aware of the procedure for reporting fires?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
5. Are all personnel aware of the procedure for reporting unsafe working conditions?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

**F Fire Safety** SRS Use Only

1. Do all personnel understand the R.A.C.E. and P.A.S.S. Fire Response Procedures? (listed on the back of VA ID badges)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Is the corridor outside your laboratory unobstructed, not cluttered with lab materials or equipment.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Are all doors exiting out of your laboratory unobstructed, not cluttered with lab materials/equipment? Are all exit signs lit?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A



8. Are personnel aware of special handling procedures for each chemical employed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
9. Are hazardous chemicals stored above eye level?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
10. Are all incompatible chemicals appropriately separated during storage to reduce the risk of potential reactivity?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
11. Are all chemicals that can form peroxides upon aging or exposure to air dated when received?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
12. Are all chemical waste containers properly labeled, properly sealed, and in a secondary container in the event of a spill?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
13. Are there flammable chemicals stored in a regular refrigerator? If so, they must be moved to an explosion proof refrigerator or a flammable safety cabinet.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
14. Are there any mercury thermometers present in the lab? If so, they should be disposed of properly through the Industrial Hygienist.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
15. Are chemical spill kits available? Are staff trained in chemical spill clean up?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
16. Has your lab's Chemical Hygiene Plan Attachment 1 Appendix A "Standard Operating Procedures" been evaluated in the last year? If yes, provide date _____.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
17. Are all of the lab chemicals listed on the Chemical Inventory?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
18a. Is isoflurane used by anyone in your lab?	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
18b. Have staff been trained on the F/Air canister SOP?	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
18c. List staff that have been trained on the F/Air canister SOP.				
<b>H-B CHEMICAL HAZARDS</b>				SRS Use Only
1. Does your research involve the use of Potentially Hazardous Substances (PHS's)? If so, please list and verify you have an SOP for each. Use the back of the form if you need more space.	<input type="checkbox"/> Yes		<input type="checkbox"/> No	
<b>PHS</b>	<b>SOP Available</b>		<b>SRS Use Only</b>	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No		

	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

<b>H-C TIME SENSITIVE CHEMICALS</b>			SRS Use Only
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1. Does your research involve the use time sensitive chemicals? If so, please list and verify you are tracking changes and/or disposal date. Use the back of the form if you need more space.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
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Time Sensitive Chemicals	Tracked for Changes and/or Disposal Date		SRS Use Only
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

<b>I. Biological Hazards</b>			SRS Use Only
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1a. Does your research involve the use of microbiological or viral agents, pathogens, toxins, poisons or venom? If so, please list. Use the back of the form if you need more space.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
--	------------------------------	-----------------------------	--

Organism/Agent/Toxin	Select Agent Registration #	Biosafety Level	Room# Kept	SRS Use Only

1b. Are any of the biohazard us agents listed above classified as a “Select Agent” by the CDC? The Select Agents list can be found at: <a href="http://www.cdc.gov/od/ohs/lrsat/42cfr72.htm">http://www.cdc.gov/od/ohs/lrsat/42cfr72.htm</a> If YES, enter the required registration number for the transfer of the agent(s) in the table above.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
2. Are biological hazards used with the appropriate class of biological safety cabinets?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Are biological hazardous wastes disposed of properly?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
4. Are biological warning labels placed on all refrigerators and freezers being used to store potentially infectious materials?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
5. Are doorways leading into rooms where potentially infectious materials are manipulated and stored labeled with biological warning labels? (BSL-2 Sign)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
6. Are any biological materials shipped by the lab? If yes, what transport vender(s) is used? <div style="background-color: yellow; height: 15px; width: 100%;"></div>	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
7. Have employees been trained in the clean- up of a biological spill?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
8. Have all employees who handle human blood, body fluids, and cells been offered the Hepatitis B vaccination?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
9. Have all employees who handle TB specimens and/or live animals been offered a TB skin test?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

<b>J. Cells, Tissue Samples and Fluids</b>			SRS Use Only
1. Does your research involve work with blood, body fluids, organs, tissues, cell lines or cell clones from <b>human, non-human primate or animal sources</b> ? If YES, please describe:	Yes <input type="checkbox"/> No <input type="checkbox"/>		
2. If your research involves studies with human or non-human primate tissues or body fluids: (a) are all personnel aware of the hazards involved, and (b) are appropriate precautions employed during use?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

<b>K. RADIOACTIVE MATERIAL USE INFORMATION</b>			
1. List <u>all</u> rooms in which radioactive materials are used or stored, and the date of most recent use.			
<b>Room/ Building</b>	<b>Date of Most Recent Use</b>	<b>Room/Building</b>	<b>Date of Most Recent Use</b>



<b>L. CONTROLLED SUBSTANCES</b>		<b>SRS Use Only</b>
1. Does your research involve the use of any substances regulated by the Drug Enforcement Agency?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2. Is there an inventory of regulated substances readily available and categorized as to usage?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3. Are controlled substances stored in a double-locked vault?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>4. List the controlled substances used in your laboratory:</b>		

<b>M. Toxins and Chemotherapy Drugs</b>		<b>SRS Use Only</b>
1. Does your research involve the use of any toxins or chemotherapy drugs?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>2. List the Toxins used in your laboratory:</b>		
<b>3. List the Chemotherapy Drugs used in your laboratory:</b>		
4. Is there documentation of the quantity used and stored for the toxins?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5. Are toxins stored in a double-locked environment?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6. Is a Chemo Spill Kit available?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
7. Are toxins and chemotherapy drugs disposed of properly?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

<b>N. LASER USE INFORMATION</b>		<b>SRS Use Only</b>
<b>1. List all of the rooms in which you use class 3A or 4 lasers.</b>		
2. Is correct signage used?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	

3. Are SOP's written for lasers?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
----------------------------------	------------------------------	-----------------------------	------------------------------	--

<b>O. SHARPS</b>	<b>SRS Use Only</b>
------------------	---------------------

1. Does your laboratory have and use containers for the safe disposal of needles, broken glass, pipettes, etc (i.e., sharps)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
2a. Do you adhere to the VA policy requiring the use of sharps with engineered sharps injury protection or needleless systems?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
2b. If 2a. is "No", did you obtain authorization from the Safety Committee?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
3a. Does your laboratory perform blood draws, insert IVs or administer injections?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
3b. If "YES" to 3a, does your laboratory use VA approved devices?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
3c. If "YES" to 3a, list <b>manufacturer and part number</b> for each needled devices "Currently" used in your laboratory:				
<u>Manufacturer</u>	<u>Part Number</u>			

<b>P. SHARPS SAFETY MECHANISM COMPETENCY</b>	<b>SRS Use Only</b>
--	---------------------

<b>Have all Staff that use needled devices print, sign and date. This confirms they have been instructed on the use and limitations of the safety mechanisms on the devices you listed above in Section O.3c.</b>		
<u>Print</u>	<u>Sign</u>	<u>Date</u>

\_\_\_\_\_  
 PI's Signature Date

\_\_\_\_\_  
 Lab Safety Reps Signature Date

**DURHAM VAMC RESEARCH & DEVELOPMENT**

**SHARPS DECISION FORM**

The purpose of this form is to document your decision NOT to adopt a sharps safety device (a needleless system or a device with engineered sharps injury protection features) for a specific procedure. Work through the steps, sign the form and submit it with VA Form 10-0398 Research Protocol Safety Survey (RPSS). If you need assistance please contact the Research Laboratory Safety Coordinator at X7341.

**(1) Describe the procedure requiring the use of sharps, the sharp devices currently in use and how they are used:** \_\_\_\_\_

\_\_\_\_\_

**(2) Is it possible to replace the sharp used in this procedure with a blunt alternative (blunt needle, micropipette, small tube)?**       YES       NO

(a) If YES, discontinue use of sharp and replace with appropriate blunt.

(b) If NO, proceed to item #3

**(3) Is there a safety sharp that will work for this purpose?**      |  YES      |  NO

(a) If YES, discontinue use of standard sharp and replace with safety sharp.

(b) If NO, proceed to item #4

**(4) Determine which of the four following exclusions apply:**

**Market Availability.** The safe device I would need to replace the standard device is not available in the marketplace.

**Subject Safety.** As a medical/biomedical professional, I have determined that use of any available safety device will jeopardize the safety of the experimental animal or the success of the procedure involving an experimental animal. If a human patient is involved, there are special documentation requirements or contact the Committee on Human Studies office at 956-5007 for details.

**Safety Performance.** For this purpose, based on objective product evaluation criteria, the safe devices available are not more effective in preventing exposure incidents than the device currently in use.

**Availability of Safety Performance Information.** Reasonably specific and reliable information is not available on the safety performance of the safe device for this procedure. I am in the process of determining, using objective product evaluation criteria, whether the use of the safe device will reduce the risk of exposure incidents in my laboratory.

**(5) Briefly justify your selection of any exclusions checked:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
PI Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
IBC Chair Signature

\_\_\_\_\_  
Date



# VAMC Research and Development Particularly Hazardous Substance Use Approval Form

## Page 1 of 2

Prior to purchasing or bringing a new particularly hazardous substance (PHS) (carcinogen, reproductive toxin, or chemical causing acute toxicity) into a VA research laboratory, please complete this form and have it approved by the Industrial Hygienist for Research. See the "[Key to Form](#)" for more complete definitions of a particularly hazardous substances and instructions for completing this form.

Name \_\_\_\_\_ Phone \_\_\_\_\_ Building \_\_\_\_\_

PI/Supervisor \_\_\_\_\_

### 1. Substance Information

A. Chemical name \_\_\_\_\_ CAS number \_\_\_\_\_

B. Check all that apply.     Carcinogen     Reproductive Toxin     High Acute Toxicity

C. Estimated Rate of Use (e.g., grams/month) \_\_\_\_\_

D. MSDS reviewed and readily available     Yes     No (If available, attach a copy to this form.)

### 2. Hazards

#### **Physical Hazards**

A. Flammable     Yes     No

B. Corrosive     Yes     No

C. Reactive     Yes     No

D. Temperature sensitive     Yes     No

E. Stability (e.g., decomposes, forms peroxides, polymerizes, shelf-life concerns)     Stable     Unstable

F. Known incompatibilities \_\_\_\_\_

#### **Health Hazards**

G. Significant Route(s) of Exposure

Inhalation Hazard     Yes     No

Skin Absorption     Yes     No

H. Sensitizer     Yes     No

I. Medical Consultation Needed     Yes     No

### 3. Procedure

A. Briefly describe how the material will be used.

B. Vacuum system used     Yes     No

C. If yes, describe method for trapping effluents \_\_\_\_\_

### 4. Exposure Controls

#### **Ventilation/Isolation**

A. Fume Hood required     Yes     No    *See hood sticker for the following information*

If yes, hood currently operates at 95 - 125 feet per minute face velocity     Yes     No

EE Hood number \_\_\_\_\_

B. Glove box required     Yes     No

**VAMC Research and Development**  
**Particularly Hazardous Substance Use Approval Form**

Page 2 of 2

C. Vented gas cabinet required  Yes  No

**D. Personal Protective Equipment (PPE)** (Check all that apply)

- Safety glasses                       Chemical splash goggles                       Face shield  
 Gloves ( type \_\_\_\_\_ )                       Lab coat                       Apron  
 Respirator (*Respirators require Industrial Hygiene approval*)  
 Other, please describe \_\_\_\_\_

**5. Location/Designated Area**

A. Building \_\_\_\_\_ B. Room \_\_\_\_\_

C. Describe below the area where substance(s) will be used and the method of posting as a designated area.

D. Location where substances will be stored \_\_\_\_\_

E. Storage Method/Precautions

- refrigerator/freezer                       hood  
 double containment                       vented cabinet  
 flammable liquid storage cabinet                       other, describe \_\_\_\_\_

**6. Spills and Decontamination**

A. Spill control materials readily available  Yes  No

B. Special personal protective equipment needed  Yes  No  
Describe \_\_\_\_\_

C. Decontamination method \_\_\_\_\_

**7. Waste Disposal**

A. In-lab neutralization  Yes  No                      B. Deactivation  Yes  No

C. Dispose as hazardous waste  Yes  No

**8. Authorization**

This individual has demonstrated an understanding of the hazards of the listed substance and plans to handle the substance in a manner that minimizes risk to health and property. He/she is authorized to use the substance in the manner described.

This individual has not demonstrated an understanding of the hazards of the listed substance nor how to handle the substance in a manner that minimizes risk to health and property. He/she is denied authorization to use the substance.

\_\_\_\_\_  
Industrial Hygienist, Research

\_\_\_\_\_  
Date

# Key to Using the Particularly Hazardous Substance Use Approval Form

## Using this form

For purposes of this form, a particularly hazardous substance (PHS) includes known or suspected human carcinogens, reproductive toxins, and substances with acute toxicity above certain thresholds. A more complete definition is included in your departmental Chemical Hygiene Plan

Each individual planning to bring a new PHS into a VA Research Lab must complete this form and have it approved by the Industrial Hygienist (IH) for Research prior to purchase and their initial use.

Responsibility for determining whether a chemical is a PHS and completing this form rests with the individual seeking use approval.

To simplify the approval process, a list of the more commonly used PHS are in the Research Chemical Hygiene Plan; however, this list is not exhaustive. For help in determining whether a substance meets the PHS criteria, call the IH at x7807.

<p><b>1. Substance Information</b></p> <p>Enter name and CAS (Chemical Abstract Service) number of the PHS.</p> <p><i>Carcinogen:</i> if on IARC, OSHA or NTP list  <i>Reproductive toxin:</i> mutagens, teratogens, embryotoxins  <i>High Acute Toxicity:</i> oral LD<sub>50</sub> ≤ 50 mg/kg, skin LD<sub>50</sub> ≤ 200 mg, air LC<sub>50</sub> ≤ 200 ppm or ≤ 2 mg/l.          See Chemical Hygiene Plan for more information.</p> <p>Self-explanatory</p> <p>MSDS may be available in hard copy or via the internet.</p>	<p>List chemicals or materials that might cause instability or adverse conditions if mixed with the particularly hazardous substance(s).</p> <p><i>Inhalation:</i> inhalation of the substance may cause adverse health effects.</p> <p><i>Skin exposure:</i> substance is readily absorbed through the skin or can cause significant damage to skin upon contact.</p> <p>Certain chemicals are known to effect the immune system, causing a person to experience allergic reactions, up to and including anaphylactic shock, upon exposure to the chemical, after the initial sensitization.</p> <p>Some chemicals can accumulate in body tissues and may require initial or periodic medical surveillance. Contact IH or Employee Health for more information.</p>
<p><b>2. Hazards</b></p> <p>Refer to <i>Physical Properties</i> section of MSDS</p> <p><i>Flammable liquid:</i> flashpoint ≤ 100° F  <i>Flammable solid:</i> liable to cause fire through friction, absorption of moisture, spontaneous chemical change, or which can be ignited readily and when ignited burns vigorously</p> <p><i>Corrosive:</i> Causes visible destruction of, or irreversible alterations in, living tissue by chemical action at the site of contact.</p> <p><i>Reactive:</i> May become unstable or contact with water produces flammable or toxic gas.</p> <p><i>Temperature Sensitive:</i> Must be kept within a certain temperature range to ensure stability.</p> <p><i>Unstable:</i> substance will vigorously polymerize, decompose, condense, or will become self-reactive under conditions of shock, or high or elevated pressure or temperature. Also</p>	<p><b>3. Procedure</b></p> <p>Briefly describe the part of the experimental procedure that involves the substance, with particular attention to how the chemical will be manipulated.</p> <p>Vacuum systems include central vacuum systems and vacuum pumps within the lab.</p> <p>Describe what will be done to ensure that the substance is not accidentally drawn into the vacuum system. Cold traps or filters are some examples of such measures.</p>

<p>includes time-sensitive materials, particularly those that produce peroxides over time.</p>	
<p><b>4. <u>Exposure Controls</u></b></p> <p>A fume hood should be used for chemicals that may produce vapors, mists, or fumes, or if the procedure may cause generation of aerosols.</p> <p>The hood must have an average face velocity of between 95 and 125 feet per minute. This measurement is noted on the hood survey sticker. If the hood has not been inspected within the past year, contact EHS at 8-5294 for re-inspection before using the hood.</p> <p>The EE hood number is noted on the top of the fume hood inspection sticker.</p> <p>A glove box should be used if protection from atmospheric moisture or oxygen is needed or when a fume hood may not provide adequate protection from exposure to the substance; e.g., a protection factor of 10,000 or more is needed.</p> <p>Highly toxic gases must be used and stored in a vented gas cabinet connected to a laboratory exhaust system. Gas feed lines operating above atmospheric pressure must use coaxial tubing.</p> <p><i>Safety glasses</i> protect from flying particles and minor chemical splashes, for instance, from opening a centrifuge tube.</p> <p><i>Chemical splash goggles</i> should be worn when there is a possibility of a significant chemical splash. Most chemical manipulations, particularly where pressure is involved, warrant chemical splash goggles.</p> <p><i>Face shield</i>, worn with splash goggles, provides full face protection when working with large volumes of chemicals.</p> <p><i>Gloves</i> should be worn when working with any particularly hazardous substance. Since not all gloves offer significant protection from every chemical, it is important to choose the glove that offers the best resistance. See the MSDS, the EHS web page or glove manufacturer compatibility charts for more information.</p> <p><i>Lab coats</i> should be worn when working with hazardous substances. The coat should not be worn outside the laboratory and should be laundered separately from other clothing.</p> <p><i>Aprons</i> offer chemical resistance and protection from splashes and can be used in conjunction with a lab coat.</p> <p><i>Respirators</i> offer protection from inhalation of substances when engineering controls are not sufficient. Use of respirators must be approved by Industrial Hygiene. Contact IH at X7807 if a respirator is needed.</p>	<p><b><u>Location/Designated Area</u></b></p> <p><b>A and B.</b> Building and room number where the substance will be used.</p> <p>Describe where in this room the substance will be used. For example, in a hood, on a specific benchtop, in several areas of the laboratory, etc. This room or area must be posted with a <i>Designated Area</i> sticker available through your department Chemical Hygiene Officer or Laboratory Safety Coordinator.</p> <p>Describe where the substance will be stored. Be specific, e.g, on a shelf, in a refrigerator, in a hood, etc.</p> <p>Self-explanatory. <i>Double containment</i> means that the container will be placed inside another container that is capable of holding the contents in the event of a leak and provides a protective outer covering in the event of contamination of the primary container.</p> <p><b>6. <u>Spills and Decontamination</u></b></p> <p><b>A and B.</b> Self-explanatory.</p> <p>Describe how the work area will be decontaminated after use, in the event of a spill, or upon completion of the work and before removal of the designated area signage.</p> <p><b>7. <u>Waste Disposal</u></b></p> <p>Some corrosive chemicals may be neutralized before disposal via the drain or the hazardous waste program.</p> <p>Some materials, such as ethidium bromide, can be chemically deactivated before disposal via the drain or the hazardous waste program.</p> <p><b>C.</b> Particularly hazardous substances must not be poured down the drain without consulting the GEMS coordinator</p>

**HAZARDOUS WASTE DISPOSAL FORM**

Contact Person: \_\_\_\_\_

Location: \_\_\_\_\_ Bld. \_\_\_\_\_  
 \_\_\_\_\_ - Room # \_\_\_\_\_

**FORM 6**

Service: Research \_\_\_\_\_

Date: Contacted GEMS Coordinator \_\_\_\_\_

EXT: \_\_\_\_\_

Date: GEMS Coordinator Pick-up \_\_\_\_\_

**Instructions:**

1. Place Hazard Label on Waste.      2. Complete Content Name on Label.      3. Do not complete start date on label.
4. Complete disposal form.      5. Call GEMS Coordinator at X6470      6. Record date of call
7. Call Research Safety Officer at X7341 if waste has not been picked up by GEMS coordinator within two weeks after notified.

Item #	Contents	# of Containers	Type of Container	Size of Container	Quantity of material	Waste Characteristics	Approx. Weight
1							
2							
3							
4							
5							
6							

7							
8							
9							
10							
11							
12							
13						Page ___ of ___	

# Packaging Records for Shipment

## **READ ENTIRE INSTRUCTIONS BEFORE STARTING**

- (1) Paper Documents are stored in a Standard Record Storage Box
- (a) Call X7341 for storage boxes and packing supplies.
  - (b) Assemble a box.
  - (c) Write consecutive numbers, two inches high beginning with “1”, following the “#” sign in the upper right hand corner of the front of the box.

**NOTE 1:** Do not put any other markings on the outside of the box at this time.

- (d) The Research Safety office will email you an electronic GMR-1 Form to document the contents stored in each box. This form will be a fillable PDF that you will email back to the Safety Office when completed.

**NOTE 2:** Recording must be legible or shipment will be rejected.

- (d) Pack boxes as follows preserving the existing arrangement of the files:
  - 1. Letter-size folders upright facing the front of the box.
  - 2. Legal-size folders upright facing the left side of the box.

**NOTE 3:** Leave at least two inches of space in the box.

**NOTE 4:** Do not over pack boxes and never add additional files on the bottom, sides, or top of the paper records in the box.

**NOTE 5:** If the box is not completely full, add packing material to strengthen the box.

- (e) Continue steps (a) – (d) until the complete study has been packed.
- (f) Record the total # of boxes on form GMR-1.
- (j) Call x7341 to inform boxes are ready for shipping.

- (2) Packing odd-size material (microfilm, index cards, CD-ROMS, diskettes, tapes) - Call x7341 for special instructions.

Attachment 22  
Of The R&D Safety Manual

DURHAM VETERANS AFFAIRS  
MEDICAL CENTER

RESEARCH AND  
DEVELOPMENT SERVICE  
HAZARDOUS AGENTS  
CONTROL PROGRAM

**(Research Security Plan)**

Reviewed/Revised: 03/15/2013

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Reviewed: 12/2016

**2016 RESEARCH AND DEVELOPMENT  
SERVICE HAZARDOUS AGENTS CONTROL PROGRAM  
(Attachment 22 of the R&D Safety Manual)**

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**DURHAM VETERANS AFFAIRS MEDICAL CENTER RESEARCH AND DEVELOPMENT  
SERVICE**

**HAZARDOUS AGENTS CONTROL PROGRAM**

**1.0 INTRODUCTION**

The purpose of this document is to establish policy and guidance related to select agents and toxins and the prevention and/or detection of terrorist events occurring in or origination from the Durham Veterans Affairs Medical Center Research facilities and laboratories (DVAMC/R&D). The program is written to ensure the security of Research and Development (R&D) facilities and laboratories in accordance with the guidelines set forth in the Veterans Health Administration (VHA) Handbook 1200.06. The scope of this plan includes R&D located within the Durham VA Medical Center campus, Medical Center research space leased to private entities, and in approved off-site facilities. The Medical Center Director is the Responsible Official (RO) and has formally designated the Research Industrial Hygienist as the Alternate Responsible Official (ARO) for this program. This 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. An annual review of this security plan will be conducted by the Institutional Biosafety Committee (IBC) and Subcommittee on Research Safety (SRS) and revised as needed.

**The DVAMC currently does not maintain the permits and facilities required for working with select agents or non-exempt quantities of select toxins.** Investigators who wish to use select agents and/or non-exempt quantities of select toxins must work with the research office to identify an appropriate offsite permitted facility or to obtain the required permits, authorizations, and background checks before these agents or toxins are brought to the DVAMC.

**2.0 BACKGROUND**

**2.1** The scope of this document includes the physical and organizational controls for the storage and use of select agents, toxins and other highly dangerous agents.

**2.2** The availability of human pathogens, their products, chemicals, gases, radioactive materials and/or radioactive sources for DVAMC 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 have become a reality. The protection of personnel, patients, visitors, and the surrounding community from terrorist events demands stringent controls for the use of hazardous agents capable of being used as weapons of mass destruction.

**2.3** The DVAMC operates its research laboratories in compliance with policies, statutes, and regulations of appropriate Federal agencies including Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Nuclear Regulatory Commission (NRC), Department of

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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), the USDA and the Animal and Plant Health Inspection Service (APHIS), must be followed. This document 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 research laboratory security, personnel identification and training, inventory controls, and the interactions with other DVAMC facility personnel such as security and law enforcement, human resources, cyber security, and environmental services personnel are also addressed.

**2.4 Penalties:** Failure to conform to the requirements and standards of this program may result in immediate withdrawal of research funding and/or suspension of the research program. Individuals who knowingly fail to follow the provisions of this plan are subject to disciplinary action proportionate to the severity of the violation, up to and including termination of 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.

**2.5 Vulnerabilities:** R&D Service contains valuable research equipment, samples, work in progress, notes, and data. In addition, research laboratories contain hazardous chemicals, radioactive materials, biological agents, and/or toxins. All of these assets must be protected from unauthorized access, mishandling, or removal. To mitigate the risks associated with the vulnerabilities posed by the possession, use, and storage of the aforementioned hazardous materials, security measures have been identified to reduce the probability of security breach. A vulnerability assessment is conducted annually by the Research Vulnerability Assessment committee members (Administrative Officer [AO] for Research, Chair of IBC/SRS committee, Chief of Police or designee, Research Industrial Hygienist [RIH], Medical Center Safety Manager, Emergency Management Coordinator, Radiation Protection Manager, Animal Research Facility Supervisor, and Research Safety and Occupational Health Specialist [RSOHS]).

### **3.0 DEFINITIONS**

For purposes of this policy, the following definitions apply.

**3.1 Approved Individual:** An approved individual is a VA employee appointed on a full-time, part-time, intermittent, fee basis or without compensation (WOC) who 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. Approved individuals may work with exempt quantities of toxins if they are listed on an SRS-approved SOP for that toxin.

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**3.2 Authorized Individual:** An authorized individual is a VA employee appointed on a full-time, part-time, intermittent, fee basis, or WOC who 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 42 CFR 73.10, 7CFR 331.10, or 9 CFR 121.10. An approved individual may also be a contractor who has undergone the required credentialing and background check and approved security risk assessment. Security risk assessments are required only for individuals working with select agents and/or non-exempt quantities of toxins. **The DVAMC currently does not maintain the permits and facilities required for working with select agents or non-exempt quantities of select toxins.** Investigators who wish to use select agents and/or non-exempt quantities of select toxins must work with the research office to identify an appropriate offsite permitted facility or to obtain the required permits, authorizations, and background checks before these agents or toxins are brought to the DVAMC.

**3.3 Chemical Hygiene Officer (CHO):** An Industrial Hygienist, who trains employees in appropriate use of chemicals and other hazardous materials, oversees the Chemical Hygiene Plan, sits on the Subcommittee on Research Safety (SRS) as a voting member, and works with the Research Service as a full partner in areas of industrial hygiene and safety.

**3.4 Excluded Select Agents and Toxins:** Excluded select agents and toxins are attenuated strains of select agents or toxins that have been determined not to 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. The terms excluded select agents and toxins used in this policy refer to attenuated strains listed by the Center for Disease Control (CDC) and Animal and Plant Health Inspection Service (APHIS).

**3.5 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 exempt quantities of toxins this policy refers to are listed on <http://www.cdc.gov/od/sap>.

**3.6 Facility Safety Officer (FSO):** A Safety and Occupational Health Specialist who is responsible for evaluating Research space for Fire and Life Safety codes and sits on the SRS as a representative for the Facility Safety Officer as a voting member.

**3.7 GEMS Coordinator:** Coordinates the Green Environmental Management Program and assists the Research and Development Service in proper disposal of and reduction in chemical waste.

**3.8 Hazardous Agent:** A hazardous agent is biological material including the CDC (<http://www.cdc.gov/od/sap/>) list of select agents and toxins (42 CFR Part 73), APHIS (<http://www.aphis.usda.gov/>) biological agents (7 CFR Part 331, 9 CFR Part 121), and products of such biological material, i.e., toxins. For purposes of this Plan, the term also includes the highly toxic chemicals and gases listed in Appendix A (2c) of VHA Handbook 1200.06 that have the potential for being used as weapons of mass destruction, as well as radioactive materials and/or radioactive sources. The terms select agents and toxins used in this Plan refer to both the CDC select agents and toxins and the APHIS biological agents and toxins. The DVAMC has sought guidance from Washington regarding

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the level of security appropriate for **exempt** quantities of select toxins, and because the security appropriate for exempt quantities of toxins is lower than that required for non-exempt quantities, exempt quantities are addressed separately in section 7.4.2

**3.9 Radiation Safety Officer (RSO):** The RSO is responsible for the oversight and approval of the use of radioactive materials at DVAMC.

**3.10 Research Laboratory Staff:** Any DVAMC employee, compensated or without compensation (WOC), or a student over the age of 18 who has fulfilled the required security clearance to work in a DVAMC research laboratory.

**3.11 Research Security Officer:** The AO/R&D serves as the security officer for research and will make all administrative decisions related to the security of research laboratories.

**3.12 Research Safety Coordinator:** The ACOS/R&D serves as the safety coordinator for research and is responsible for supervising and operating the Research Safety Program to include:

3.12.1 Implementing all research safety requirements

3.12.2 Reporting to the facility Director on research safety related matters and activities

3.12.3 Ensuring the safety and security of research laboratories and facilities

3.12.4 Ensuring the annual conduct of a vulnerability assessment and safety audit.

**3.13 Secured Areas:** The secured areas refer to research laboratories containing hazardous and/or select agents, toxins (exempt and non-exempt) highly toxic chemicals, and classified data. At the DVAMC these areas include: Building 1 E-wing, A-wing 2<sup>nd</sup> floor, and Rooms EG005, C2009, C2011; Building 14, Building 16 1<sup>st</sup> floor, Building 23 3<sup>rd</sup> floor.

**3.14 Select Agent:** A select agent is 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). All Select Agents are included in the list of hazardous agents listed in Attachment A. 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); they are included in Attachment A of this Program.

**3.15 Sensitive Materials:** Sensitive materials include, but are not limited to, any hazardous agents as defined in subparagraph 3d of VHA Handbook 1200.06 and 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.

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**3.16 Subcommittee for Research Safety (SRS):** The SRS is a subcommittee of the Research and Development (R&D) Committee, which is delegated oversight of matters relating to security and safety of the secured areas of Research and Development Service. The SRS also serves as the Institutional Biosafety Committee (IBC).

**3.17 Terrorist Event:** A terrorist event is the unauthorized removal or theft of hazardous agents capable of being used as weapons of mass destruction from Durham VAMC research laboratories, including leased and off-site space, and/or the unlawful use of such hazardous agents. It specifically encompasses the illicit and unauthorized use of 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 research laboratories and other research space such as the Animal Research Facility (ARF), storage areas, and offices. The term may also refer to activities such as dissemination, detonation, and contamination of hazardous agents, select agents, toxins or sensitive materials within DVAMC research laboratories or the building(s) housing these laboratories.

**3.18 USA Patriot Act:** The USA Patriot Act, Public law 107-188, 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 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:

- 3.18.1** Is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;
- 3.18.2** Has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;
- 3.18.3** Is a fugitive from justice;
- 3.18.4** Is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));
- 3.18.5** Is an alien illegally or unlawfully in the United States;
- 3.18.6** Have been adjudicated as a mental defective or has been committed to any mental institution;
- 3.18.7** 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 has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism.

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**3.18.8** Was discharged from the Armed Services of the United States under dishonorable conditions.

**3.19 Weapons of Mass Destruction:** Weapons of mass destruction include any of the classes of hazardous agents as defined in subparagraph 3d and identified in Appendix A of VHA Handbook 1200.06, or combinations of these agents that are capable of inflicting morbidity and mortality on a widespread basis.

## **4.0 ROLES AND RESPONSIBILITIES**

**4.1 Hazardous Agents Control Program:** The DVAMC must ensure the security of research laboratories and the security of hazardous agents including select agents, toxins and associated sensitive materials, which are stored in or used by research laboratories through the development of a Hazardous Agents Control Program. The DVAMC Director must ensure that a Research Laboratory Hazardous Agents Control Program is developed. This program is a comprehensive approach to ensuring that:

**4.1.1** Research laboratories maintain an appropriate level of security.

**4.1.2** All research laboratory staff receive the appropriate training related to the use of hazardous agents, including select agents and toxins. (See Section 11 of this document.)

**4.1.3** The SRS monitors and evaluates the program at least annually.

**4.1.4** The SRS monitors and evaluates status of appropriate personnel in laboratories to preclude restricted persons from gaining access to areas.

**4.1.5** All appropriate officials, committees and individuals coordinate efforts to ensure the successful implementation of the program.

**4.2 Medical Center Director:** The Medical Center Director is the Responsible Official (RO). 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, and must meet all qualifications for a RO.

**4.2.1** The Medical Center Director is responsible for granting requests for authorization for access to research 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.

**4.2.2** The Medical Center Director is responsible for ensuring that adequate staffing and resources are available to comply with Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories.

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**4.2.3** The Medical Center Director 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:

**4.2.3.1** 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 in Handbook 1200.06.

**4.2.3.2** 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.

**4.2.3.3** Ensuring that all specifications for personnel, facility security and law enforcement contained in VA Handbook 0730, "Security and Law Enforcement," and facility staff, patients, visitors, and guests adhere to VHA Handbook 0710 Personnel Suitability and Security Program.

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

**4.2.3.5** 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 working with select agents, toxins and hazardous agents.

**4.3 Human Resource Management:** Human Resource (HR) Management 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. HR is also responsible for reviewing applications for employment (salaried, WOC, or fee basis) for citizenship and visa status. See Section 6.0 Personnel for HR responsibilities.

**4.4 Police and Security:** The Police Service is responsible for assisting with security of research laboratories, emergency response, vulnerability assessments and assisting the Research Office with the development and implementation of a Hazardous Agents Control Program.

**4.5 Responsible Official (RO) and Alternate Responsible Official (ARO):** The RO and ARO must:

**4.5.1** Be familiar with all applicable regulations, policies and guidance.

**4.5.2** Oversee the development, implementation and evaluation of all components of the VA Research Laboratory Hazardous Agents Control Program as required by this document and VHA Handbook 1200.06, and applicable VA and Federal regulations. This requires:

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**4.5.2.1** Developing and implementing safety, containment, security and emergency response plans.

**4.5.2.2** Granting requests for authorization for access to research areas (laboratories or storage areas) in which select agents or toxins are used or stored after reviewing the recommendations of the R&D Committee in compliance with the USA Patriot Act and other applicable criteria, regulations, and policies.

**4.5.2.3** Providing appropriate training for safety, containment, security and emergency response.

**4.5.2.4** Maintaining, using, purchasing, transferring and destroying select agents or toxins in accordance with applicable regulations and policies, e.g., VA, HHS, DOT, and EPA.

**4.5.2.5** Maintaining detailed records of information necessary to give a complete accounting of all activities related to select agents or toxins.

**4.5.2.6** Conducting annual inspections of DVAMC research laboratories, including all locations 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. The inspections must be conducted at least annually and after each security violation. Findings must be documented and any deficiencies corrected. Inspections are conducted by the CHO, FSO, GEMS coordinator, RSO, and Police service.

**4.5.2.7** Reviewing the Biosecurity/Biosafety plan annually and after each incident, if an incident occurs. The review must be documented and any deficiencies corrected.

**4.5.2.8** Completing the annual vulnerability assessment of VA research areas, and informing appropriate facility personnel of the assessment results and correcting any deficiency.

**4.6 The Associate Chief of Staff for Research and Development (ACOS/R&D)** by and through the Administrative Officer for Research and Development (AO/R&D), will maintain laboratory security and hazardous agent access and inventory control policies in keeping with VA directives and policy, and ensure compliance with established policies. The ACOS/R&D is responsible for:

**4.6.1** All activities in the Research Service, including the implementation of all requirements set forth in this document and VHA Handbook 1200.06.

**4.6.2** 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], and Radiation Safety Committee).

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

**4.6.4** Ensuring that changes in facility security procedures are made known to all staff in the research service expeditiously

**4.6.5** Ensuring that all non-DVAMC persons (i.e., those that are not appointed as VA employees or VA contractors) working in the research laboratories conform to all VA standards for security described in this DOCUMENT and VHA Handbook 1200.06.

**4.6.6** In conjunction with the RO or alternate RO(s), completing the annual vulnerability assessment of research areas.

**4.6.7** Informing Police and Security of any changes in research affecting the facility security.

**4.6.8** Reviewing records of access to the VA research laboratories as required in this document and VHA Handbook 1200.06 and recording the results of this review. The ACOS for R&D may delegate this responsibility to another appropriate administrator such as the Administrative Officer (AO) for R&D.

**4.6.9** Notifying ORD and ORO if a new BSL-3 research laboratory is planned.

**4.7 R&D Committee:** The R&D Committee may serve as the primary committee responsible for the following areas or it may delegate them to the Subcommittee on Research Safety (SRS). The subcommittees report to the R&D Committee.

**4.7.1** If the responsibilities are delegated to a subcommittee, the R&D Committee must oversee the functions of the subcommittee through review of minutes and reports or other appropriate mechanisms. The subcommittee must be notified in writing of their responsibility.

**4.7.2** The R&D Committee may add to subcommittee requirements to obtain approval or may disapprove an action approved by the subcommittees. It may not approve an action that the subcommittees have disapproved.

**4.7.3** 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 document and the VHA Handbook 1200.06. Handbook 1200.08 "Safety of Personnel Engaged in Research" contains additional information on the functions and responsibilities of the R&D Committee and the 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:

**4.7.3.1** Assisting the Medical Center Director in carrying out his or her responsibilities as the RO.

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**4.7.3.2** Controlling access to VA research laboratory areas housing select agents, toxins, or other hazardous agents by:

**4.7.3.3** 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.

**4.7.3.4** Reviewing the status of personnel granted access to VA research laboratories at least semi-annually. 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, and appointment status.

**4.7.3.5** Approving or disapproving requests to purchase, transfer, use, or destroy select agents or toxins, including exempt quantities of toxins.

**4.7.3.6** Approval for purchase may only be granted 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.

**4.7.3.7** Transfer of select agents or toxins may only be approved if the transfer is completed in compliance with this DOCUMENT and VHA Handbook 1200.06 and is transferred (intra-facility or outside the facility) to a laboratory holding a CDC or APHIS registration number and in accordance with all DOT and other applicable regulations.

**4.7.3.8** Destruction of a select agent or toxin following requirements in this document and VHA Handbook 1200.06 must be ensured.

**NOTE:** Handbook 1200.08, Safety of Personnel Engaged in Research, also contains applicable requirements.

**4.7.3.9** Conducting inventory of all hazardous agents or reviewing inventory if responsibility is delegated to an individual or individuals.

**4.7.3.10** All R&D Committee, SR Security and SRS activities should be documented in meeting minutes or by the use of specific reports.

**4.8 VA Investigators, Laboratory Directors, Research Investigators and Research Staff:** VA research investigators and staff, regardless of appointment status (paid WOC, or fee basis), are required to comply with all provisions of this DOCUMENT and VHA Handbook 1200.06.

**NOTE:** Those requiring WOC appointments include, but are not limited to, students, fellows, university employees, other non-DVAMC employees working at DVAMC, and visiting scientists who are not compensated by DVAMC for their employment. All contractors must comply with all requirements of this document and VHA Handbook 1200.06. For requirements that differ from those for appointed VA employees (compensated, fee basis, or WOC), this document and VHA Handbook 1200.06 contain alternate language that is applicable to contractors.

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**4.8.1** Appropriate authorizations and approvals must be obtained prior to beginning work in research laboratories.

**4.8.2 Responsibilities of Principal Investigator (PI):** All research laboratory directors and investigators must ensure that those they supervise have received approval to access laboratories prior to beginning work. If it is a laboratory using or storing select agents or toxins, employees must have an authorization to both access these areas and to work within them. Laboratory directors and investigators are responsible for all aspects of their research including the supervision of their staff and:

**4.8.2.1** Identify the level of security access required for VA research laboratory staff (paid or WOC) being considered for employment or being approved to work within the investigator's research laboratory by submitting the Request for Staff Access to Research Secured Laboratory (Attachment B) on behalf of each staff member being considered for employment or work within the investigator's research laboratory.

**4.8.2.2** Notify the AO/R&D immediately when any research laboratory staff no longer has a work-related need for authorized access, to include leaving DVAMC employment.

**4.8.2.3** Ensure that all their staff have received the required training and are familiar 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. Ensuring that all their staff follows all safety and security procedures, including those of the VMU.

**4.8.2.4** Submit the Laboratory Annual Self-Inspection Form (See Research Laboratory Safety Manual).

**4.8.2.5** Complete and submit a current chemical inventory semiannually to the Research Industrial Hygienist and a biological hazardous inventory annually as part of the Laboratory Self-Assessment. Review and certify the accuracy of radiochemical and controlled substance inventory on a quarterly basis. The more potentially hazardous chemicals and biological items will also require frequent review per guidelines in the Research Laboratory Safety Manual.

**4.8.2.7** Ensure select agents or toxins (non-exempt and exempt quantities) are transferred, procured, or used only after receiving appropriate approvals.

**4.8.2.8** Ensure that research laboratory staff follows all safety and security procedures, including those of the ARF when applicable.

**4.8.2.9** Other PI responsibilities are described throughout this document.

**4.8.3 Responsibilities of Research Laboratory Staff:** All personnel must obtain formal authorization from the AO/R&D before entering research laboratories. An electronic keycard programmed for access

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to specific areas and access times is granted to those with a documented access need. At DVAMC the AO/ R&D is the Research Safety Security Officer.

**4.8.3.1** All authorized/approved individuals must wear their VA ID above the waist at all times.

**4.8.3.2** Personnel may enter the secured area only to perform required duties.

**4.8.3.3** Unauthorized/unapproved persons entering the secured area will be reported to Police Service by the AO/R&D and/or the Research Security Officer.

**4.8.3.4** It is the responsibility of each authorized/approved individual to:

**4.8.3.4.1** Use their keycard only for personal entrance into the secured area.

**4.8.3.4.2** Use their keycard on each entry into the secured area.

**4.8.3.4.3** Not allow any individual to follow them through the door.

**4.8.3.4.4** Report any security violations, including unauthorized/ unapproved individuals, to the AO/R&D or Police Service.

**4.8.3.4.5** Turn in their keycard to the Police Service immediately when laboratory access is no longer necessary.

**4.8.3.5** Prohibited persons will not be granted access to the Biosafety Level Two (BSL2) laboratories or the VMU. Prohibited persons may be granted access to the general secured area on a case-by-case basis, as approved by the SRS with concurrence of the R&D Committee.

**4.8.3.6** Authorized/approved individuals must complete all mandatory training (see section 11 of this document.) and provide Research Administration with verification of training.

**4.8.3.7** Each individual must immediately report the following to the ARO:

**4.8.3.7.1** Any loss or compromise of their keys, passwords, combinations, etc.

**4.8.3.7.2** Any suspicious persons or activities.

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

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

**NOTE:** Personnel procedures must not preclude or interfere with employee or worker opportunity to report safety and/or security concerns or to participate in other protected activities under 10 CFR Parts 19 and 30, the Civil Services Reform Act of 1978, and the Whistleblower Protection Act of 1989.

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**4.8.3.8** Authorized individuals must use their own card to enter the secured area. Multiple individuals, even when each person has authorization to enter the area, may not enter on one person's card access.

**4.8.3.9** In the event of a loss of a DVAMC ID the Police must be notified immediately so that the ID number can be terminated. Individuals must obtain permission from the AO/R&D and pay five dollars to obtain a replacement ID badge.

**4.8.3.10** Authorized individuals that habitually allow other persons to follow them through a secured door must be reported to the AO/R&D by all staff who observe the violation. The abuser will lose his/her own security access until review by the SRS and R&D committees.

**4.8.4 Visitors:** Investigators and Research Staff must adhere to the process below. All personnel must obtain authorization from the AO/R&D or designee and complete the required training before entering research laboratories.

**4.8.4.1** Visitor's access is limited to hours where authorized individuals are present. These individuals will have a *sponsor*. The sponsor must have authorized access to the secured area. The sponsor will be responsible for the visitor. The visitor must be in the presence of their sponsor at all times.

**4.8.4.2** All visitors must obtain a visitor pass, which will include the individuals' name, and date of validity. The visitor pass will be obtained from the R&D Service Secretary in Research Office by the authorized escort. Visitors must wear their Visitor Pass above the waist at all times and be accompanied by their authorized escort.

**4.8.4.3** Following receipt of a visitor pass, visitors must sign in and out in the Research Office, specifying name, affiliation, purpose for visit, time in and out. Long-term visitors may be given keycard access and exempted from escort requirements if a background check has been completed and it is approved by the AO/R&D.

**4.8.5 Minors:**

**4.8.5.1** No minor below the age of eighteen years of age shall work or volunteer in DVAMC Veterinary Medical Unit (VMU).

**4.8.5.2** Minors under the age of eighteen years shall not enter research areas without written approval from the AO/R&D, facility Voluntary Services, and their legal guardian. Attachment C must be completed by the mentoring laboratory.

**4.8.5.3** Prior to entering a research laboratory, an approved minor must complete the following training: Bloodborne Pathogens, Chemical Safety, and Research General Laboratory Safety.

**4.8.5.4** Prior to working or volunteering in a research area, a minor must complete the required paperwork to include training documentation.

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**4.8.5.5** No minor shall work or volunteer in a capacity that is determined to be hazardous or potentially detrimental to the minor's health or well-being including but not limited to the following:

**4.8.5.5.1** Where it is determined that there is an increased risk of exposure to infectious diseases transmitted via the aerosol route

**4.8.5.5.2** A task that would potentially expose the minor to blood or body fluids, infectious diseases or hazardous chemicals, as defined by the Chemical Hygiene Plan, and controlled or chemotherapy drugs.

**4.8.5.5.3** Any area where there is potential exposure to radiation in excess of 0.1 rem (0.001 sievert) total effective dose equivalent or in excess of 10% of the limits for general employees specified by regulatory authority. Furthermore, no minor is permitted to work directly with or handle radioactive materials. Authorized Users of radioactive materials who plan to involve minors in activities in their laboratories shall notify the Radiation Safety Officer prior to beginning work in the laboratory.

**4.8.5.5.4** Any area under construction or renovation.

**4.8.5.6** When minors under the age of eighteen are allowed to visit in research areas, their activity should be limited to non-laboratory areas, such as offices, break rooms, etc.

**4.8.5.7** Under no circumstance shall a minor be allowed in any work area where he or she presents a distraction to the area employees.

**4.8.5.8** Minors with approval to enter the laboratory must be directly supervised by a responsible employee of the laboratory and allowed access to a laboratory only during daytime hours.

**4.8.5.9** Where deemed appropriate, the Principal Investigator may place additional restrictions on the presence of minors.

**4.8.6 Support Services:**

**4.8.6.1** Support persons (e.g. Package delivery/pickup, vendor) that have not been issued a DVAMC ID Badge must sign in and out using sign in sheets located near each entry. These persons must display current identification and must be accompanied at all times by the authorized/approved individual who granted access to the building/laboratory. Sign in/out sheets are maintained in a notebook and are periodically reviewed.

**4.8.6.2** DVAMC Support Service Personnel may enter research areas by one of the following ways:

**4.8.6.2.1** By obtaining a DVAMC ID badge clearance by the AO/R&D and their service.

**4.8.6.2.2** Being accompanied by an approved individual as stated in 4.8.6.2.1.

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**4.8.6.3** Contractors and Service Representatives can obtain entrance by one of the following ways:

**4.8.6.3.1** By obtaining a contractor's ID badge from the DVAMC Police Service. The approved individual who accompanies the contractor or service representative to the Police Service is responsible for signing the individual in and out at the Police Service and accompanying the individual while they are in the secured area.

**4.8.6.3.2** By obtaining a visitor's badge from the AO/R&D. The approved individual who accompanies the individual to the AO/R&D's office is responsible for both signing the individual in and out and accompanying the individual while they are in the secured area.

**4.8.6.4** Suspicious persons should be asked to present VA identification, and if they are not able to produce such, they should be reported immediately to Police Service by calling extension 7888.

**4.8.6.5** Persons without security clearance may be granted access to a general secured area on a case-by-case basis, as approved by the SRS committee with concurrence by the R&D Committee.

## **5.0 PROCEDURES**

**5.1 Safety Plan/Program:** The DVAMC/R&D Safety guidelines are outlined in the Research Laboratory Safety Manual and the Chemical Hygiene Plan and includes all DVAMC research laboratories, including those in leased space and approved off-site locations. The Program includes requirements found in paragraph 3a of Handbook 1200.8 / Safety of Personnel Engaged in Research.

**This safety program:**

**5.1.1** Meets the Biosafety standards and requirements for BSL-2 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 ([www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm](http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm)) and all updates on the CDC website;

**5.1.2** Meets all applicable OSHA regulations, including, but not limited to, requirements for handling toxins found in 29 CFR 1910.1450, "Occupational Exposure to Hazardous Chemicals in Laboratories," and/or 29 CFR 1910.1200, "Hazard Communication," 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; and

**5.1.3** Incorporates 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.

**5.1.4** The Safety Plan includes the mandatory emergency response program, in accordance and its requirement for drills to test implementation of the plan MCM-558-12-00.2.

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**5.1.5** The Safety Plan is reviewed annually.

**5.1.6** Safety Inspections are conducted as follows and any deficiencies identified are corrected:

SRS Committee.....	Annually
RIH for Health and Hygiene.....	Semi-annually
Safety Manager for General Safety.....	Semi-annually
RSO for Radiation.....	Quarterly
GEMS Coordinator.....	Annually
Environment of Care Committee.....	Monthly
VISN 6 IH/GEMS Coordinator & Safety Manager.....	Annually
Police Service.....	Semi-annually

**5.2 Security Plan:** This Research Laboratory Security Plan was developed and implemented by the VAMC/R&D.

**5.2.1** The plan is based on a systematic approach that defines threats, identifies and examines vulnerabilities, and mitigates risks associated with any identified vulnerabilities using a security systems approach.

**5.2.2** The security plan includes a description of security for: Inventory control; Physical security; Cyber security; Access control (keycards, logs, etc.); and Background and security clearances.

**5.2.3** Investigators are primarily responsible for inventory control. They and their laboratory staff will maintain accurate inventories of hazardous chemicals and substances. A full listing of this inventory is provided at least semi-annually to the healthcare system Chemical Hygiene Officer. All laboratory staff, including Principal Investigators, have an obligation to report all instances of loss, theft or release of select agents or toxins (exempt and non-exempt quantities), and the confirmed or suspected alteration of inventory records to the Research Office.

**5.2.4 Investigators are primarily responsible for ensuring physical security in their laboratories, and for ensuring that their laboratory personnel are well trained in physical security procedures.** These procedures include ensuring that passive access is not permitted when entering or exiting the building, wearing of a DVAMC identification card at all times, only entering laboratory areas where they are assigned, challenging persons not displaying a DVAMC identification badge, and notifying Research Administration and Police and Security of suspicious activity. Investigators and staff will not access or attempt access of restricted areas in the research buildings unless they are explicitly authorized access by Research Administration. In all instances, Principal Investigators and their staff will report suspicious persons or activities to the Research Office and/or Police and Security. Investigators will ensure that unless a staff member is in the immediate vicinity, their laboratories are locked and secured at all times. Investigators will ensure that they and their staff do not provide unauthorized access to vendors, contracted repair personnel, or any other persons not previously authorized unescorted access. Electronic keycard access codes and cards are issued to individuals, and will not be shared. All authorized personnel granted

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unescorted access to research laboratories are issued electronic access control cards or are otherwise cleared for access by Research Administration. All laboratory staff, including Principal Investigators, have an obligation to report all instances of confirmed or suspected unauthorized access to the Research Office and Police and Security who in turn have joint responsibility for removing unauthorized persons from the Research Building.

**5.2.5** Investigators will ensure they and their staff comply with healthcare system cyber security policies.

**5.2.6** Investigators will ensure that they process all new employee requests through the Research Office, and that their staff submits all documents necessary to conduct a background check. New staff members are not allowed unescorted access to the Research Building until they have submitted background check documents, have been fingerprinted, have taken all mandatory training as outlined on page 6 of the Research Laboratory Safety manual, and have been issued an access control keycard. Investigators will not use Voluntary Service procedures to circumvent processing new staff through the Research Office.

**5.2.7** The security plan has provisions for routine cleaning, maintenance, and repairs. These provisions include granting of electronic keycard access to EMS staff assigned to the Research Building, to Engineering staff with a recurring verified need for access, and to supervisory staff in Environmental Management Service (EMS) and Engineering. Electronic keycard access is coordinated with both Research Administration and Police and Security.

**5.2.8** The security plan requires that all Research Employees have background and security clearances appropriate to their work assignment. At a minimum, all Research Employees (including WOC employees) will have an Office of Personnel Management (OPM) background check.

**5.2.9** For research laboratories not containing hazardous agents, procedures described above will govern how personnel from Environmental Management Service, Engineering Service, or others either obtain approval to access research laboratories or are escorted and monitored by an approved individual to complete their duties. Research laboratories containing hazardous agents will further document the dates and times when non-VA persons enter or otherwise access their laboratories.

**5.2.10** Principal Investigators will evaluate/train all employees, including those with a legitimate need to access hazardous agents, to ensure they are knowledgeable of procedures for control of access to containers, cabinets, refrigerators, freezers, and other areas where hazardous agents, including select agents and toxins (exempt or nonexempt quantities) are used or stored. Principal Investigators will document 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.

**5.2.11** Deliveries of all equipment and supplies to the Research Building are coordinated through the Research Office. All supplies and small equipment are delivered to the Research Office.

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**5.2.12** The ACOS/R&D is responsible for reviewing access records on a weekly basis. He/she can delegate this responsibility to the AO/R&D.

**5.2.13** The RO will review the security plan annually and after each incident, if an incident occurs.

## **6.0 PERSONNEL**

All individuals must obtain formal approval prior to beginning work in the research laboratories and must be appointed as full-time, part-time or intermittent, as compensated, uncompensated (WOC) employee, or fee basis.

### **6.1 All Research Employees:**

**6.1.1** Prior to beginning work in a DVAMC research laboratory that does not use or store select agents or toxins there are two general levels of approval that must be obtained. The first involves approval from Human Resources and the second approval from the AO/R&D.

**6.1.2** Prior to beginning work Human Resources (HR) will verify the person's credentials. HR will submit both a Standard Form (SF)-85, Questionnaire for Non-Sensitive Positions, for low-risk level positions and fingerprints to the Office of Personnel Management for completion of a background check. The AO for R&D or designee will verify that this has been done. Once it has been verified DVAMC that this process has been initiated, the individual is considered approved to enter VA research laboratories unescorted and begin work. HR will update the results of the background investigation once it has been completed and a suitability determination made according to VA and other Federal regulations.

**6.1.3** HR will review applications from non-United States citizens for their current residency status in the United States prior to employment or granting access to research laboratory areas.

**6.1.3.1** HR 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.

**6.1.3.2** The individual's status as a legal alien will be verified annually.

**6.1.4** Students, fellows, residents, visiting scientists, and others who may be at the DVAMC for short periods of time may be granted limited approval to access VA research laboratories or storage areas if:

**6.1.4.1** Their credentials have been verified.

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**6.1.4.2** A background check has been completed as required by VA

Directive and Handbook 0710, Personnel Suitability and Security.

**6.1.4.3** Their citizenship status is verified and they are either citizens or legal aliens.

**6.1.4.4** A determination has been made that they are in a low-risk category.

**6.1.4.5.5** Access is limited to daytime hours when approved or authorized VA employees are present.

**6.1.4.6** If access is requested to a BSL-3 research laboratory, the R&D Committee must approve the request.

**6.1.5** Individuals leaving DVAMC employment or no longer working in the DVAMC research laboratory are expected to comply with the clearance procedures: turning in identification badges, keycards, and other access items.

**6.1.6** In the event an individual with access to a research laboratory inexplicably disappears, is suspected to have violated procedures, or committed a security breach, VA Police Service and other security officials will be notified immediately.

**6.1.7** WOC appointments for those individuals who have been granted authorization to enter research laboratories will be reviewed annually by the AO/R&D to determine the appropriateness of their WOC appointment. The results of this review must be submitted to the SR Security or R&D Committee for its concurrence, if done by Research Service personnel or HR.

**6.1.7.1** The SRS and R&D Committee will record its concurrence in the minutes of the meeting where the issue was reviewed.

**6.1.7.2** The findings will be conveyed to the ACOS/R&D, and the individual. If the SRS or R&D Committee does not concur, HR must also be notified and the individual's WOC appointment and authorization terminated.

**6.1.8** Personnel are to enter research laboratory areas only when required to perform their duties and responsibilities.

**6.2 Research Personnel Working in Laboratories Using or Storing Toxins:**

**6.2.1** Personnel must obtain authorization from the RO or ARO to access laboratories using or storing toxins.

**6.2.2** Personnel may need to complete additional security training from the RIH or RSOHS regarding receipt, tracking, transferring and destruction of toxins.

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**7.0 SECURITY CLEARANCE, ACCESS and SURVEILLANCE**

**7.1 Access to Research Laboratories:** is controlled and limited to authorized individuals. Authorization is contingent on initial and ongoing training in safe handling and security of all hazardous and/or sensitive materials used and stored in the designated research laboratory.

**7.1.1** No research laboratories will be open to the public.

**7.1.2** All laboratory areas, including the Animal Research Facility (ARF) and storage areas, include a keycard system 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.

**7.1.3** An intrusion alarm system is present and monitored by Police Service for the ARF. The other locations are monitored by the access card reader log.

**7.1.4** Unauthorized personnel, delivery personnel and visitors are to be provided access to research laboratory areas only by the AO/R&D. They must make an entry in the security logbook for the areas when entering and exiting the area.

**7.1.5** Current VA Identification badges are used as keycards into secured areas. For employees and WOC's, the VA ID will be electronically programmed to allow entry into designated areas. Visitors may be issued visitor passes by the R&D office, which will not act as keycards

**7.1.6** A record of keycard assignments must be current at all times. Personnel leaving Durham VAMC employment or no longer working in the research laboratory must adhere to full clearance and checkout procedures to include turning in all identifications, keys, keycards, and other access items.

**7.1.7** Personnel from DVAMC EMS or Engineering Service needing to enter secured areas for routine housekeeping and maintenance will be admitted only if deemed an approved individual or when approved individuals are present to monitor their activities.

**7.1.8** 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.

**7.2 Requirements of Individuals Granted Secured Access:** All personnel must obtain formal authorization from the AO/R&D before entering the secured laboratory area. A DVAMC ID badge may be programmed as the secured area keycard or the AO/R&D may instruct the Police Service to issue a Visitor Pass.

**7.2.1** All authorized/approved individuals must wear their VA ID above the waist at all times.

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**7.2.2** Personnel may enter the secured area only to perform required duties.

**7.2.3** Unauthorized/unapproved persons entering the secured area will be reported to the Police Service by calling 7888.

**7.2.4** Authorized/approved individuals must use their own card to enter the secured area. Multiple individuals, even when each person has authorization to enter the area, may not enter on one person's card access.

**7.2.5** In the event of a loss of a DVAMC ID the Police must be notified immediately so that the ID number can be terminated. Individuals must obtain permission from the AO/R&D and pay five dollars to obtain a replacement ID badge.

**7.2.6** It is the responsibility of each authorized/approved individual to:

**7.2.6.1** Use their keycard only for personal entrance into the secured area.

**7.2.6.2** Use their keycard on each entry into the secured area.

**7.2.6.3** Not allow any individual to follow them through the door.

**7.2.6.4** Report any security violations, including unauthorized individuals, to the AO/R&D or Police Service.

**7.2.6.5** Turn in their keycard and keys to the AO/R&D immediately when laboratory access is no longer necessary. See the Secretary for R&D for instructions on termination and/or clearance of station.

**7.2.7** Authorized persons who allow other authorized co-workers who have lost/forgotten their keycard to access restricted areas are responsible for the actions of the co-worker.

**7.3 Process to Obtain Authorized Entry:**

**7.3.1** The AO/R&D, as a designee of the SRS, will grant authorized access. The SRS is responsible for the review of processes and decisions made by the AO/R&D in relation to secured access.

**7.3.2** The AO/R&D is responsible for approving security access according to policy. Criteria and elements to be considered when granting approval: completion of Durham VAMC appointment; acceptable and work-related need to be in secured area; certification that individual is not a prohibited person; required paperwork completed; and verification that required training has been completed.

**7.3.3** The process of obtaining initial authorization to enter the secured area is:

**7.3.3.1** The PI must make a formal request to identify the staff member by completing Attachment B (Request for Staff Access to Research Secure Area)

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**7.3.3.2** Employee/WOC completes Attachment D (Request for Staff Access to Research Secured Laboratory) and gives it to the PI.

**7.3.3.3** The PI submits Attachment B and F to the AO/R&D for verification of the following:

**7.3.3.3.1** Required training listed in the Research New Staff Orientation Packet

**7.3.3.3.2** Background check conducted by HR,

**7.3.3.3.3** Credentialing

**7.3.4** The AO/R&D or designee must review the continued status of staff access semiannually. The review will include an inquiry from the AO/R&D to the PI, to determine whether specific staff requires continued access to the secured area. Factors that will be considered when addressing requested renewal include:

**7.3.4.1** The number and nature of security exceptions by the individual;

**7.3.4.2** Whether required training is current

**7.3.4.3** Security-related information deemed pertinent.

**NOTE:** If an employee/WOC is noncompliant with the semi-annual review as stated in 7.3.4, security access will be denied.

**7.4 Physical Security:** Physical security of research laboratories and other research areas of the facility housing hazardous agents, meet appropriate standards determined by the VA Directive and Handbook 0730. As allowed under current regulations, graded levels of security based on site-specific risks, which include the chemicals, agents, or toxins stored or used, may be appropriate.

**7.4.1** Security for all Research Laboratories. All research laboratory security includes the following:

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

**7.4.1.2** Access to the research building is by keycard and to the lab by key. Police Service access to the area must be permitted during an emergency.

**7.4.1.3** Records of access must be reviewed weekly and the findings documented. Irregularities identified during a review or in the course of daily activities, must be reported immediately to the DVAMC police service.

**7.4.1.4** The presence of an intrusion alarm system that is connected to, and otherwise monitored by, the facility VA Police Service. A video surveillance system is also used.

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**7.4.1.5** Facility security standards are reviewed on an annual basis by the Research Vulnerability Assessment committee.

**7.4.1.6** The ACOS/R&D is responsible for informing the Police Service of any changes in research affecting a laboratory's security.

**7.4.1.7** All entry doors from non-research areas into the research laboratory areas must be self-closing and secured at all times.

**7.4.2 Procedures for control of exempt quantities of select toxins:**

**7.4.2.1** The R&D committee delegates the responsibility for overseeing the use of exempt quantities of select toxins to the SRS.

**7.4.2.2** Before beginning work with an exempt quantity of a select toxin, a Principal Investigator must submit a standard operating procedure (SOP) to the SRS for approval. The SRS approval of the SOP grants the investigator permission to use and store exempt quantities of toxin.

**7.4.2.3** Approved Individuals working with exempt quantities of a select toxin must be listed on an approved SOP for that toxin and must comply with the requirements of that SOP. The Principal Investigator is responsible for training their staff in correct use and documentation of exempt quantities of toxin.

**7.4.2.4** The SRS designates responsibility for approving requests to purchase, transfer, or destroy exempt quantities of select toxins to the ARO.

**7.4.2.5** Security for exempt quantities of select toxins must prevent unapproved use or theft. Exempt quantities of select toxins must be secured behind a lock when they are not in use or in the direct view of an approved individual. Security of exempt quantities in VA-leased space must be as good as in onsite space.

**7.4.2.6** Exempt quantities of toxins must be stored in a secured container to assure access only by approved individuals and police.

**7.4.2.7** Each Principal Investigator must maintain up-to-date records of the amount of select toxin stored in the laboratory.

**7.4.2.8** The ARO will forward laboratory inventories of exempt quantities of select toxins to the SRS once every 6 months for review. This review will be noted in the SRS minutes.

**7.4.2.9** Approved individuals must report to their supervisor any loss or theft of exempt quantities and any sign that inventory records have been altered or compromised.

**7.4.2.10** Regardless of funding source, all purchases of exempt quantities of select toxins must be approved by the ARO.

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**7.4.2.11** Exempt quantities of select toxins that are not currently in use on an approved protocol must be transferred to another laboratory or destroyed. The transfer or destruction must be approved by the ARO and documented.

**7.5 Security Checks:** Medical Center Police Service officers conduct physical security checks of all research areas after normal business hours, on weekends, and holidays to ensure security.

**7.6 Access Cards:** Entrance doors to all R&D areas are secured by electronic locking mechanisms and accessible only through the use of a proximity access card specifically encoded for each areas or level of access. Photo identification cards issued by the Medical Center serve a dual role as personal identification and as an access card. AO/R&D identifies the level of access authorization an individual is permitted. The Medical Center Police Service activates access cards via a computerized system. When a staff member departs, their card is deactivated.

**7.7 Keys:** Keys to buildings and rooms (laboratories, storage areas, offices, and conference rooms) are issued to PIs through the AO/R&D. PIs will be fined for lost keys. Keys to containment, i.e., lock boxes and refrigerators and rooms, are assigned by the PI. In the event of loss of a key or a security compromise to containment, a new lock is to be installed and new keys issued to approved staff.

**7.8 Keypads:** Keypad locks are used to control access to research areas where non-exempt quantities of select toxins are stored. The code to the keypad will be issued to research staff who have been approved by the research security officer. Only staff with appropriate authorization will be allowed access into keypad secured areas. A roster of staff with authorization will be maintained. The code will be changed if there is a security breach or an employee with the current code resigns or is terminated. Persons without security clearance, to include EMS and engineering staff, service vendors, research staff, and visitors must be escorted at all time while in these secured areas.

**7.9 Reporting:** Suspicious persons or activities, loss or compromise of access cards or keys, or other security breaches are to be reported immediately to both the AO/R&D and the Medical Center Police Service. Police Service will respond and handle the situation as appropriate.

## **8.0 INVENTORY CONTROL**

The Principal Investigators (PI) must maintain an up-to-date record of all select agents, toxins, exempt quantities of toxins, and other hazardous agents in DVAMC research laboratories. Principal Investigators (PI) provide a current chemical inventory semi-annually for review by the Research Industrial Hygienist (RIH). Inventory control of exempt quantities of toxins includes documenting the amount of toxin removed along with the quantity remaining for each date of use. Inventory control also includes following the applicable regulations for the acquisition, transfer, and destruction of these agents.

**8.1 Accountability for Radioactive materials and/or Radioactive sources:** The Radiation Safety Officer maintains accountability for radioactive materials and/or radioactive sources by enforcing the

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existing DVAMC policies: MCM-1.2(B) and the DVAMC Radiation Safety Manual. This manual includes regulations for acquisition, inventory, use, and disposal of all radioactive materials used in research.

**8.2 Accountability for select agents, toxins and other hazardous chemicals and equipment:** Prior to purchasing or bringing in new equipment, approval must be obtained through the R&D Business Office. Prior to purchasing or bringing in a new substances (carcinogen, reproductive toxin, or an acute toxicity chemical) approval must be obtained from the Research IH/Chemical Hygiene Officer. (Refer to the Research Laboratory Safety)

**8.3** Only laboratories holding a CDC or APHIS Certificate of Registration and/or registration number may acquire select agents or non-exempt quantities of toxins. At this time, no DVAMC R&D laboratory maintains any select agents or non-exempt toxins. PIs will submit a current inventory of chemicals and hazardous materials semi-annually to the Research IH.

**8.4 In the event any select agents or toxins are requested for use; the following Inventory Control Procedures will be implemented:**

**8.4.1 Inventory Lists:** A current, complete list of select agents, toxins and other hazardous chemicals, as defined by OSHA and EPA, will be maintained for each DVAMC research laboratory and when required, be made available to the Local Emergency Management committee.

**8.4.2 Acquisition of Agents:** The acquisition of these agents may only occur when there is an approved DVAMC protocol that requires their use and storage. Orders received in Research Acquisition must be approved by the CHO before the order can be placed.

**8.4.3 Inventory Transfers:** Transfers of inventory must be in compliance with DOT, OSHA, NRC, CDC 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 73.14, 7 CFR 331.13, or 9 CFR 121.14). Attachment H must be completed with an inventory transfer.

**8.4.5 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.

**8.4.6 Hazardous agents (includes 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 as described in VHA Handbook 1200.06.

**8.4.7 Destruction of Select Agents and Toxins Including Exempt Quantities:** For a procedure to implement destruction of agents no longer required for use see Attachment G (Select Agent or

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Toxin Destruction). This procedure does 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 consumed during the research.

**8.5 Storage:** Toxins (exempt or non-exempt) and controlled drugs are secured in either a locked storage container or refrigerator and are tracked on written inventory logs monitored via inventory control and routine physical site audits.

## **9.0 CYBER SECURITY**

The AO/R&D under the direction of the Medical Center Informational Security Officer and in compliance with MCM 1.25 oversees cyber security for R&D as follows:

- 9.1** Ensures computer security and the continuity and integrity of computer based records.
- 9.2** Restricts access to computers and enforces adherence to password and data backup procedures.
- 9.3** Secures computer work areas and computers within these areas.
- 9.4** Restricts sensitive information on hard drives.
- 9.5** Reports loss or compromise of computer software or hardware with respect to sensitive information.
- 9.6** Ensures erasure of any sensitive information from computers prior to disposing.

## **10.0 EMERGENCY PREPAREDNESS AND RESPONSE**

**10.1** The DVAMC developed and implemented an emergency preparedness and response plan that incorporates research laboratories. All individuals given authorized access to the laboratory area must be knowledgeable of the DVAMC MCM 558-11-00.2, Comprehensive Emergency Management Plan and section III, (Emergency Response and Disaster) in the Research Laboratory Safety Manual.

**10.2** The plan addresses 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, and other natural disasters or emergencies.

**10.3** Drills or exercises must be conducted annually to test and evaluate the effectiveness of the safety, security, and emergency preparedness and response plans. The drills or exercises must be documented and any deficiencies corrected.

**10.4** A vulnerability assessment of all DVAMC research laboratories is conducted by the Vulnerability Assessment multidisciplinary team consisting of the Administrative Officer [AO] for Research, Chair of IBC/SRS committee, Chief of Police or designee, Research Industrial Hygienist (RIH), Medical Center

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Safety Manager, Emergency management Coordinator, Animal Research Facility Supervisor and Research Environmental Technician (RET). The assessment is conducted annually and after any incident.

**10.4.1** 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).

**10.4.2** The results of the assessment must be provided to the local Subcommittee on Research Safety (SRS), Subcommittee on Research Security (SR Security), the R&D Committee, and the RO.

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

**10.4.4** 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.

## **11.0 TRAINING REQUIREMENTS**

**11.1** All individuals (VA employees appointed as full-time, part-time or intermittent paid employees, and WOC employees, as well as contractors) working in a research laboratory, those working with hazardous agents including select agents or toxins, those working within BSL-2, or BSL-3 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 security of select agents, toxins or other hazardous agents.

### **11.2 Training will include:**

**11.2.1** Annual training in Emergency Procedures, Lab Safety Procedures, Information Security and Cyber Security.

**11.2.2** General information on safety and security within VA research laboratories as listed in the Research Laboratory Safety Manual.

**11.2.3** Safety, security, acquisition, use, containment, transfer, and destruction of hazardous agents including select agents or toxins.

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**11.2.4** VA ORD Biosecurity found at CITIProgram.org.

**11.2.5** Specific information related to the laboratory in which they will work and to the agents with which they will work.

**11.2.6** Training requirements set forth by OSHA, CDC, other applicable Federal agencies and other VA policies.

**11.3** The Principal Investigator will ensure that all required personnel complete such training and its completion is documented.

**11.4** All new research staff and new administrators (e.g., ACOS/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.

**11.5** The RO or designee will certify individuals that have the required knowledge, skill, and abilities to safely carry out their duties and responsibilities in handling select agents or toxins.

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

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

**11.8** The RO or ARO(s) have oversight over 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 or designee. The written certification for these individuals must also be maintained on file.

## **12.0 RECORD KEEPING**

### **12.1 Records must include:**

**12.1.1** An up-to-date, accurate list of all individuals approved to work within or enter VA research laboratories unescorted.

**12.1.2** 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.

**12.1.3** Training Records as described in section 11 of this document.

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**12.1.4 Safety and Security Incident Reports including:**

**12.1.4.1** All safety and health notices issued by OSHA; the VISN; and the facility safety, health, fire protection, security, and infection control staff.

**12.1.4.2** All incidents reported to the VISN and VA Central Office.

**12.2** A mechanism must be implemented to ensure that all records (written, computer databases, spreadsheets) are accurate and allow for the authenticity of these, records being verified.

**12.3** A record must be kept of all inspections of the VA research laboratories covered by this Handbook, including:

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

**12.3.2** All inspections of the VA research laboratories covered and required by this document.

**12.4** A record of all findings, deficiencies and corrective action based on the inspections listed in this document.

**12.5** 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 affected research staff) must be maintained and available for inspections.

**12.6** Records of distribution of keycards, passwords, including the date distributed, the person receiving it and the date of termination or return of them.

**12.7** Access and, if applicable, egress records and the results of the weekly review of the records.

**12.8** Records related to any review of visa status for employees that are not United States citizens.

**12.9** Copies of applicable current policies and procedures.

**12.10** Records must be maintained for a minimum of 5 years.

**13.0 REVIEW OF PROGRAM COMPONENTS OR ACTIONS**

**13.1 Annual.** On an annual basis the following components need to be reviewed:

**13.1.1** Review of training records and requirements.

**13.1.2** Inspection of laboratories as required by this document.

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**13.1.3** Review of the safety (Biosafety) plan.

**13.1.4** Safety (Biosafety) inspection.

**13.1.5** Review of the security plan.

*NOTE: The security plan must also be reviewed after each incident.*

**13.1.6** Vulnerability assessment must be conducted and results reviewed.

**13.1.7** Review of the emergency response plan.

**13.1.8** Emergency preparedness and response drill must be conducted.

**13.1.9** Visa status of non-citizens.

**13.1.10** Status of WOCs.

**13.1.11** Review of the Control of Hazardous Agents Plan.

**13.1.12** Recordkeeping Review

**13.2 Required Semi-Annual Review**

**13.2.1** Inventory of Hazardous Agents.

**13.2.2** Status of those persons approved to enter VA research laboratories.

**14.0 REFERENCES**

**14.1** Public Law 107-188, Public Health Security and Bioterrorism Preparedness and Response Act of 2002

**14.2** Title 5 CFR Parts 731 and 736

**14.3** Title 18 U.S.C. § 175b

**14.4** Title 7 CFR Part 331

**14.5** Title 9 CFR Part 121

**14.6** Title 10 CFR Parts 19 and 30, the Civil Service Reform Act of 1978, and the Whistleblower Protection Act of 1989

**14.7** Title 29 CFR 1910.38, 1910.120, 1910.1450 and 1960

**14.8** Title 42 CFR Parts 72 and 73

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**14.9** CDC-NIH —Biosafety in Microbiological and Biomedical Laboratories, 4th edition

**14.10** NIH Guidelines: —Recombinant DNA and Gene Transfer, April 2002

**14.11** VA Directive and Handbook 0710

**14.12** VA Directive and Handbook 0730

**14.13** VHA Handbook 1200.7

**14.14** VHA Handbook 1200.08

**14.15** VHA Handbook 7701.1

**14.16** VHA Handbook 1200.06

# **Attachments**

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**15. ATTACHMENTS**

- A. Hazardous Biological and Chemical Agents
- B. PI Request for Staff Access to a Research Secured Area
- C. Minor Request to Volunteer in A DVAMC Research Laboratory Checklist
- D. Application for Access to Research Secured Areas:
  - Document #1 : New Human Research Staff Orientation Checklist
  - Document #2 : New Animal Research Staff Orientation Checklist
  - Document #3 : New VA Staff Orientation Checklist
- E. Validation to Work With Toxins
- F. Toxins and Hazardous Agents Inventory Log
- G. Select Agent or Toxin Destruction
- H. Intra-Entity Select Agent/Toxin Transfer Request Form
- I. Toxins and Hazardous Substances Key Control Log

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**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 (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.** As of the date of publication of Handbook 1200.06, 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);
- (6) Lewisite (L); **NOTE:** *There are three individual chemicals included in this category.*
- (7) Lysergic acid diethylamide (LSD);
- (8) Nitrogen mustard (FIN-i, HN-2, or I{N-3);
- (9) Phosgene (CG), also known as carbonyl chloride;
- (10) Phosgene oxime (CX);
- (11) Sarin (GB);
- (12) Soman (GD);

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- (13) Sulfur mustard (H, or HD, or HT), also called mustard gas or mustard agents;
- (14) Tabun (GA); and
- (15) 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, stored, 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.

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**ATTACHMENT B**

**PI REQUEST FOR STAFF ACCESS TO A RESEARCH SECURED AREA**

1. PURPOSE: To formally request access for Investigator's employees and staff to the Research Secured Area.
2. POLICY: The information requested in this document must be supplied via submission of this form or Email before access to the secured area will be considered.
3. RESPONSIBILITY: It is the responsibility of each Investigator to formally identify the staff that must have access to the secured area in order to complete their research-related duties.
4. PROCEDURE: The Investigator submits the information requested to the R&D Secretary, (Nancy Dixon, Room A2017 via this document (hand deliver to Research Administration).

5. REQUESTED INFORMATION:

a. Person making request:

---

b. Name of person for whom access is requested:

---

c. The person named above is  $\geq$  18 years of age? YES \_\_\_\_ NO \_\_\_\_

d. Immediate supervisor of person for whom access is requested:

---

e. Brief description of duties of person for whom access is requested  
(lab support, research assistant, etc): \_\_\_\_\_

---

---

f. Areas to which access is needed. Check all that apply:

(1)  General Laboratory Area

(2)  VMU (only mark this box if you expect to work with animal subjects and are > 18 years of age)

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**ATTACHMENT C**

**Minor Request to Volunteer in A DVAMC Research Laboratory Checklist**

Note: Minors can volunteer in research for administrative duties or observation only. They can not be allowed to participate in any laboratory procedures. This form must be completed and returned to the AO/R&D.

**Full Legal Name:** \_\_\_\_\_

**Home Address (not Post Office Box):** \_\_\_\_\_  
\_\_\_\_\_

**Date of Birth:** \_\_\_\_\_

**Place of Birth** \_\_\_\_\_

**Citizenship Status:** U.S. Citizen  Other

**Completed**  
**Yes No**

- |     |     |  |
|-----|-----|--|
| ___ | ___ | <b>1. Parent Consent</b>                                   |
| ___ | ___ | <b>2. Voluntary Approval Form</b>                          |
| ___ | ___ | <b>3. Met with Voluntary Services</b>                      |
| ___ | ___ | <b>4. Voluntary Services Approval</b>                      |
| ___ | ___ | <b>5. Obtained Voluntary ID Badge</b>                      |
| ___ | ___ | <b>6. Read Section 4.8.5 of the Research Security Plan</b> |
| ___ | ___ | <b>7. Completed the following training:</b>                |
| ___ | ___ | <b>a. Bloodborne Pathogens</b>                             |
| ___ | ___ | <b>b. Chemical Safety</b>                                  |
| ___ | ___ | <b>c. General Laboratory Safety for Researchers</b>        |

\_\_\_\_\_  
Mentor's Signature \_\_\_\_\_  
Date

\_\_\_\_\_  
PI's Signature \_\_\_\_\_  
Date

**Note:** Upon leaving the VA as a volunteer contact Voluntary Services and return your ID badge.

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**ATTACHMENT D**

**APPLICATION FOR ACCESS TO RESEARCH SECURED AREA**

1. PURPOSE: To formally apply for access to Research Secured Area.
2. POLICY: In order to be considered for access to the secured laboratory area, the applicant must submit the attached documents to Nancy Dixon (hand deliver to Research Administration Building 8, Room 101).

Note: the Principal Investigator must also complete Attachment B.

Document #	Document Name
1	New Human Research Staff Orientation Checklist
2	New Animal Research Staff Orientation Checklist
3	New VA Research Staff Orientation Checklist

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**ATTACHMENT E  
VALIDATION TO WORK WITH TOXINS**

Approval to work with toxin \_\_\_\_\_

to be used in \_\_\_\_\_ Laboratory

located in Building \_\_\_\_\_ Room \_\_\_\_\_

on protocol(s) \_\_\_\_\_

has been granted to

Name: \_\_\_\_\_.

by

\_\_\_\_\_  
Alternate Responsible Official

\_\_\_\_\_  
Date

\*\*\*\*\*

Termination of Approval:

Reason: \_\_\_\_\_

\_\_\_\_\_  
Alternate Responsible Official

\_\_\_\_\_  
Date



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**ATTACHMENT G  
Select Agent or Toxin Destruction**

<b>Principal Investigator:</b>		<b>Phone</b>	
<b>Department:</b>		<b>Laboratory location (building &amp; room):</b>	
<b>Select Agent Description:</b>			
<b>Use</b> <input type="checkbox"/> Biomedical Research <input type="checkbox"/> Medical <input type="checkbox"/> Vaccine (inactivated form) <input type="checkbox"/> Clinical specimen <input type="checkbox"/> Other—please describe ⇒		<b>Exemption Status</b> <input type="checkbox"/> 42 CFR 73 Exempt <input type="checkbox"/> 42 CFR 73 Non-exempt	
		<b>Registration</b> <input type="checkbox"/> 42 CFR 73 Registered <input type="checkbox"/> Not registered	
<b>Destruction Procedure (Provide reference):</b>			
<b>REFERENCES:</b> Cornell University: <a href="http://www.med.cornell.edu/ehs/guides/sa/Select_Agent_Destruction.pdf">http://www.med.cornell.edu/ehs/guides/sa/Select_Agent_Destruction.pdf</a> University of Pennsylvania: <a href="http://www.ehrs.upenn.edu/protocols/sa_destruct.html">http://www.ehrs.upenn.edu/protocols/sa_destruct.html</a>			
<b>Destroyed By (Print Name):</b>		<b>Engineering Witness (Print Name):</b>	
<b>Destroyed By (Signature):</b>		<b>Signature of Engineering Witness:</b>	
<b>Signature of Principal Investigator:</b>		<b>Date Destroyed:</b>	
<b>I certify that the agent is accurately described (attach MSDS if available) and that it is no longer in my possession or in possession of persons who work under my direction.</b>			
<b>Signature of Responsible Facility official:</b>		<b>Date:</b>	
<b>I certify that the agent has been destroyed as per guidelines outlined and it is no longer in use.</b>			
<b>After destruction, please dispose of residue via the facility GEMS Program.</b>			
<b>Transfer Request Date:</b>	<b>Date of GEMS Pick up:</b>	<b>Signature of GEMS Coordinator:</b>	

Please complete this form for the final destruction of your Select Agent or Toxin stocks. Before you do so, contact the Industrial Hygenist (IH) for Research to verify the procedure and arrange for a witness. Per 42 CFR 73.7(h) and 73.21, **the U.S. Department of Health and Human Services must be notified in writing** of any destruction for the purpose of discontinuing activities of a non-exempt registered Select Agent or Toxin five business days prior to destruction. Please call Research Industrial Hygenist (IH) for questions.

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**ATTACHMENT G (Continued)**

**Procedure for Select Agent Destruction**

**Security Precautions:**

- The select agent must be secure at all times—even when in storage prior to disposal.
- Destruction of source material must be witnessed by the Research Industrial Hygienist and the Research Safety Technician.. Call X7341 to arrange a destruction meeting.

**Safety Precautions:** Destruction procedures should be performed in a laboratory hood or a biological safety cabinet. At a minimum, Personal Protective Equipment for all procedures should include:

- Disposable long-sleeved protective clothing (gown, coverall or similar garment).
- Appropriate gloves
- Eye protection

**Bacteria and viruses:** For destruction of bacteria and viruses, use steam sterilization procedures.

**Tetrodotoxin, Staphylococcus Enterotoxin B, Ricin, Aflatoxin:** Destruction in 2.5% NaOCl (sodium hypochlorite). Use a fume hood, and lower sash to lowest possible working level. Place a warning/do not use sign on hood during the procedure.

1. In a fume hood, Place plastic backed absorbent paper on bottom of hood
2. The Select Agent should be in solution in primary container
3. Place primary container in secondary container, such as a beaker
4. Slowly dispense an equal volume of full strength bleach into Select Agent solution
5. Do not place cap on primary container
6. Allow 30 minutes exposure time

**Staphylococcus Enterotoxin B, Ricin, and Botulinum:** Use autoclave for heat destruction.

1. In a fume hood or biological safety cabinet, loosen cap of primary container
2. Place primary container into secondary container, such as a beaker
3. Place container into a biohazard autoclave bag
4. Place bag into autoclavable tray
5. Autoclave at 121° C for 45 minutes on liquid cycle (slow exhaust).
6. After autoclaving, allow time for material to cool before handling.

**Disposal:** After destruction of the Select Agent, seal the top to the primary container and place into a zip-lock plastic bag. GEMS personnel will collect inactivated Select Agent for incineration.

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**ATTACHMENT G (Continued)**

**Procedure for Select Agent Destruction**

**References:**

Morin, R.S., and Kozlovac, J.P. 2000. Biological Select Agents, p. 261-272. In D.O. Fleming, and D. L. Hunt (ed.), *Biological Safety, Principles and Practices*. ASM Press, Washington, D.C.

Slein, M.W., and Sansone, E.B. 1980. *Degradation of Chemical Carcinogens, An Annotated Bibliography*. Van Nostrand Reinhold Company, New York, N.Y.

Lunn, George and Sansone, Eric B., 1994, *Destruction of Hazardous Chemicals in the Laboratory*, 2nd Edition, Wiley, New York, N.Y.

Armour, Margaret-Ann, 1996, *Hazardous Laboratory Chemicals Disposal Guide*, Second Edition, Lewis Publishers, Boca Raton, FL

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**ATTACHMENT H  
INTRA-ENTITY SELECT AGENT/TOXIN TRANSFER REQUEST FORM**

**Requestor:** Complete block 1 and transmit to transferring lab.

**Transferor:** Complete block 2 and transmit form to the Alternate Responsible Official (ARO).

**ARO:** Assign a tracking number in block 3 and transmit form to the RO for approval.

**RO:** Indicate approval of transfer with signature in block 4 and returns form to the ARO to initiate agent transfer.

**Requestor:** Complete block 5 and return form to the ARO.

**NOTE:** This tracking document must have Responsible Official (RO) approval before transferring select agents from one entity lab to another.

<b>BLOCK 1</b>			
Requestor Name:	Signature:	Date:	
Protocol ID Number:		Lab Location(bldg., room):	
Select Agent Type: Genus/Species:	Toxin:	Recombinant Organism:	Recombinant Molecule:
Intended Use (Select one):	Diagnostics <input type="checkbox"/>	Research <input type="checkbox"/>	Production <input type="checkbox"/>
Material (Select one):	Activated <input type="checkbox"/>	Inactivated <input type="checkbox"/>	Explain How:
<b>BLOCK 2</b>			
Transferor's Name	Signature:	Date:	Lab Location(bldg., room):
Agent Characterization:			
# Vials :	Vol or wt per vial:	Form: Liquid <input type="checkbox"/> Solid <input type="checkbox"/> Powder <input type="checkbox"/>	Total Quantity:
<b>BLOCK 3</b>			
Tracking #:	ARO:	Signature:	Date:
<b>BLOCK 4</b>			
RO:	Signature:	Date:	
<b>BLOCK 5</b>			
Amount per Primary Receptacle::	Number of Primary Receptacles per Container.	Number of Outer Packages:	
Receipt Acknowledged by Recipient:			Date:

