SFG2985

INTERNATIONAL AIDS VACCINE INITIATIVE

SUPPORT TO RESEARCH AND DEVELOPMENT AT THE INTERNATIONAL AIDS VACCINE INITIATIVE

(P161232)

ENVIRONMENTAL MANAGEMENT PLAN

JANUARY 2017

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1. Introduction

1.1 Background

IAVI's mission is to ensure the development of a safe, effective, and accessible preventive HIV vaccine for use throughout the world. IAVI is a global, not-for-profit, organization working to accelerate the development of a vaccine to prevent HIV infection and AIDS. It researches and develops vaccine candidates, conducts policy analyses, and serves as an advocate for the field with offices in Africa, South Asia, and Europe. IAVI supports a comprehensive approach to HIV and AIDS that balances the expansion and strengthening of existing HIV prevention and treatment programs with targeted investments in new AIDS prevention technologies. IAVI is the world's only organization focused solely on the development of an AIDS vaccine.

1.2 Project Description

The Project consists of the following components that focus on activities that support the development of one HIV vaccine candidate: virulence and pre-clinical safety studies, manufacturing of a vaccine candidate.

The project will entail further research to optimize the replicating vector platform. The applied research required to optimize vaccine vector design to ensure efficacy and safety of a vaccine for wide-scale usage is considerable. Informed by the studies conducted as part of the project P119051 using a Sendai virus vector candidate, research in the current project will include iterative design and the systematic investigation of modified vectors and vaccination regimens in order to identify the most practical effective route and dose, mainly in a series of monkey studies. The research will help identify and characterize the immunologic mechanisms that provide protection, which will inform improvements in the HIV vaccine candidates as well as direct how the vector can be used to develop vaccine candidates against pathogens of poverty.

Component I. Vector optimization: The Project will target the following activities within the vector optimization component.

(a) Generate five new recombinants from the VSVΔG-Env.BG505 prototype by changing the position of the Env gene relative to the promoter. Characterize the properties of the new viruses *in vitro*.

(b) Isolate VSVΔG-Env.BG505 mutants by evolving strains with increased replicative fitness in cultured CD4+/CCR5+ cells. Characterize the properties of the new viruses *in vitro*.

(c) New vaccine vectors developed from the activities above will be characterized in vitro to rank the lead candidates. Determining whether a vector merits testing in macaques will be based on performance in multiple in vitro assays and a direct comparison to the VSVΔG-Env.BG505 prototype. This is not a final list, but characteristics that would be evaluated and compare will include:

(i) Env abundance and antigenic profile on infected cells;
(ii) Env abundance and antigenic profile on virus particles;
(iii) Replication rate;
(iv) Virus yields from infected cultures;
(v) Stability at 37 degrees in extracellular environment.

Component II. Vector testing:

IAVI will incorporate all aspects of conducting a comparative vaccine study in Indian rhesus macaques to analyze safety, immunogenicity, and efficacy. The overall study, which incorporates SHIV challenge, will last approximately 2 years. It is understood that this primate study will be initiated as part of this funding but, that the study will continue beyond the term of this funding. IAVI is willing to accept the responsibility to continue this primate study beyond the term of this funding and will work to identify other funding opportunities to enable completion of the study.

The development and characterization of modified VSVΔG-Env.BG505 vaccines might demonstrate that the new variants are not substantially improved compared to the prototype. This negative result would be highly informative and redirect our focus to another important topic of research, which would be related to optimizing the vaccination regimen. IAVI would redesign the macaque study to focus on testing the VSVΔG-Env.BG505 prototype and specifically study whether three doses of vaccine are required for efficacy. A vaccine regimen based on fewer immunizations would be simpler to execute in a clinical setting.

2. Policy and Legal Framework

2.1 World Bank Safeguard Policies

The World Bank's policy on Environmental Assessment (OP/BP 4.01) is triggered for this project and the project is classified as Category 'B', with preparation of an Environmental Management Plan (EMP) identified as the appropriate safeguard instrument to manage adverse environmental and social risks and impacts.

OP/BP 4.01 on Environmental Assessment is triggered if a project is likely to have significant adverse environmental impacts in its area of influence. Category B projects have limited adverse environmental or social risks and/or impacts that are few in number, generally site-specific, largely reversible, and readily addressed through mitigation measures.

The project will also comply with the World Bank Environmental Health and Safety Guidelines comprising of both the General Guidelines and the relevant Industry Sector Guidelines. Both contain performance levels and specific parameters considered achievable in terms of processes, descriptions, and suggested good practices. The General Guidelines contain requirements and good practice on Environmental, Occupational Health and Safety, Community Health and Safety and other aspects of project implementation. The industry-specific standards cover a number of different sectors including Pharmaceuticals and Biotechnology Manufacturing include information relevant to pharmaceuticals and biotechnology manufacturing facilities. They cover the production of active pharmaceutical ingredients and secondary processing, including intermediates, formulation, blending, and packaging, and related activities research, including biotechnology research and production. To the extent that any of these are relevant, the project will also need to comply with the guidelines.

The EMP, as the identified safeguard instrument, should examine the project's potential negative and positive environmental impacts and recommends any measures needed to prevent, minimize, mitigate, or compensate for adverse impacts.

2.2 Legal Framework

Although the project will not support the procurement of Non-Human Primates (NHPs), animal subjects are expected to be used for the vaccine research to be undertaken as part of the project. In operating research laboratories and conducting research on animal subjects, including NHPs, IAVI complies with all relevant and applicable laws and regulations of the City of New York, the State of New York and the United States, including the U.S. Animal Welfare Act and OSHA regulation 1910.1450 on occupational exposure to hazardous chemicals in laboratories. In addition, IAVI maintains animal welfare accreditations from the U.S. Department of Agriculture and AAALAC International, the latter being a voluntary third party animal welfare accreditation standard for use of animals in scientific research.

3.1 Risk and Impact Identification

Key environmental and social risks and impacts relating to IAVI's activities under this project include: biosafety; occupational health and safety, including exposure to hazardous materials and biohazards; management of hazardous materials; and storage and disposal of hazardous waste and biohazardous/medical waste.

Biosafety risks are particularly high, relating exposure of AIDS culture by researchers, AIDS vaccine prototype by production facility personnel, or HIV infected blood by such personnel at the clinics as nurses, physicians, laboratory analysts, technicians, and other health workers. These exposures may result through an intact or broken skin or a puncture wound, or through the eyes or other mucous membranes such as nose and mouth. Sharps or broken glass contribute to injuries leading to human exposure. Another area of biosafety risk is associated with the handling of animals, including non-human primates (NHPs), during testing and disposal of animal carcasses.

3.2 Management Program

IAVI's existing environmental, health and safety management program includes documented specific management plans and standard operating procedures (SOPs) that address management of key risks and impacts, including a chemical hygiene plan, a biosafety and security plan, a biosafety manual, a safety SOP, a safety audit checklist, a post exposure plan, and biosafety objectives, among others.

The following specific management plans have been developed and implemented IAVI to manage key risks and impacts, with samples of these plans annexed to the EMP:

- Chemical Hygiene Plan (Annex 1)
- Laboratory Biosafety and Security Plan (Annex II)
- Biosafety Manual
- Post Exposure Plan for the Occupational Exposure to Simian Immunodeficiency Virus (SIV) or Simian-Human Immunodeficiency Virus (SHIV) (Annex III)

The following environment, health and safety SOPs have been developed and implemented by IAVI:

- Chemical Decontamination of Biohazardous Material
- Transport of Biohazardous Material
- Cleaning Biological Spills
- Use of Dry Ice
- Preparation of Disinfectants
- Safe Handling of Broken Glass and Biohazard Sharps
- Standard Microbiological Practices
- Storage Use and Disposal of Paraformaldehyde

- Agent Inventory SOP
- Oxygen monitor use and testing
- Post-Exposure Plan for SIV or SHIV
- BSL2 Laboratory Safety Procedures
- Exposure to Hazardous Chemicals
- Exposure to Infectious Agents
- Disposal of Chemical Waste
- Disposal of Empty Chemical Containers
- Operation of Autoclaves
- Handling of E coli cultures
- Working with Human and Animal Cell Cultures
- Safe Handling of Ultra Low Temperature Freezers
- Use and disposal of ethidium bromide waste
- Liquid biohazardous waste disposal
- Solid biohazardous waste disposal
- Disposal of Syber Green and Syber Safe

4. Implementation Arrangements and Monitoring

IAVI's management program is managed by a safety committee comprised of twelve members with representatives from each of the laboratory research teams that meets monthly and is responsible for training, recording and monitoring of incidents and revisions to specific management plans and SOPs.

Each specific management plan and SOP includes procedures and responsibilities for surveillance, monitoring and reporting on performance related to the relevant risks and impacts for that plan or procedure. In addition, IAVI maintains an audit checklist (Annex 4) to conduct regular spot checks of work areas and implementation of environment, health and safety measures. The safety committee collects and compiles relevant data for regular review at the monthly meetings.

The work program and action items for the safety committee are organized and managed through an action plan (Table 1) that is revised and updated regularly.

Table 1. Sample Safety Committee Action Plan

Task	2016												2017	
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
Chemical Inventory				ALL										
SDS switchover				ALL										
Container label switchover				ALL										
Online Safety Training Revision- MC?						ALL/MFL								
First aid kit annual check (Contents/ Exp. Dates)											?			
Schedule fire extinguisher annual inspection											JG			
Safety SOP next review date											ALL			
Create safety shower flush schedule for 2017												?		
Create biohazard waste schedule for 2017												?		
Plan safety meeting schedule for 2017												HA		
Send out safety audit schedule for 2017												HA		
OSHA 300/300A Forms													HA/FF	
Review and revise safety training slides as needed													ALL	
Safety Week														ALL

4. Annexes

ANNEX 1

Sample Chemical Hygiene Plan

1. Background Information

On 31 January, 1990 the Occupational Safety and Health Administration (OSHA) promulgated a final rule for occupational exposure to hazardous chemicals in laboratories. The standard was incorporated into Occupational Exposure to Hazardous Chemical for *IAVI Vaccine Design and Development Laboratory* in July of 2009. Compliance will be enforced by IAVI Chemical Hygiene Officer and his/her designees as well as Quality Assurance. Included in the standard, is a requirement for all employers covered by the standard to develop and carry out the provisions of a Chemical Hygiene Plan (CHP).

A CHP is defined as a written program which sets forth procedures, equipment, personal protective equipment and work practices that are capable of protecting employees from the health hazards presented by hazardous chemicals used in that particular workplace. Components of the CHP must include standard operating procedures for safety and health, criteria for the implementation of control measures, measures to ensure proper operation of engineering controls, provisions for training and information dissemination, permitting requirements, provisions for medical consultation, designation of responsible personnel, and identification of particularly hazardous substances.

This plan is the Chemical Hygiene Plan developed for *IAVI Vaccine Design and Development Laboratory.* All laboratory personnel must know and follow the procedures outlined in this plan. All operations performed in the laboratory must be planned and executed in accordance with the enclosed procedures. In addition, each employee is expected to develop safe personal chemical hygiene habits aimed at the reduction of chemical exposures to themselves and coworkers.

This document was developed to comply with paragraph (e) of the OSHA 1910.1450 regulation. *IAVI Vaccine Design and Development Laboratory* will maintain facilities and procedures in laboratories compatible with current knowledge and regulations in laboratory safety. This CHP will be reviewed, evaluated and updated at least annually and is readily available to employees, their representatives and any representative for OSHA.

2. Definitions

Departmental Organization

Currently, there are three active R&D programs at the IAVI Vaccine Design and Development Laboratory: Candidate Design, Candidate Evaluation and Candidate Development. Each program is headed by a Program Director.

Chemical Hygiene Officer (CHO)

A Chemical Hygiene Officer is appointed by the Chair of Safety Committee of the Laboratory. The Chemical Hygiene Officer is responsible for the maintenance of the Chemical Hygiene Plan and Material Safety Data Sheet (MSDS) database and file.

Safety Person

Chair of the Safety Committee shall appoint a safety person responsible for chemical safety in each respective program.

Organization of Chemicals

The National Fire Rating System has been adopted as the standard for the *IAVI Vaccine Design and Development Laboratory*. The National Fire Rating System uses a color-coded alpha numeric description to identify hazards associated with health, flammability, reactivity and special notice hazards. The hazards for about 1,300 chemicals are described in the National Fire Rating System Reference Guide. For a description of safe chemical storage contact the Chemical Hygiene Officer.

Material Safety Data Sheet (MSDS) Database and File

MSDSs provide basic information about the safety and health hazards posed by a chemical and precautions to take when using it (see Appendix A). Hard copies of MSDSs of all chemicals stored or used must be kept on file readily accessible to all laboratory personnel. A departmental MSDS file (hard copy) is located in hallway 854. A database listing the MSDSs organized by location, manufacturer and product name is available on the Design Lab Portal on SharePoint in PDF format. The Principal Investigator may elect to maintain a separate file of MSDSs for their chemicals in their laboratories.

2. Standard Operating Procedures for Laboratory Chemicals

Chemical Procurement

The decision to procure a chemical shall be a commitment to handle and use the chemical properly from initial receipt to ultimate disposal.

Information on proper handling, storage and disposal shall be known to all involved personnel prior to the procurement of the chemical. Chemicals utilized in the laboratory shall be those which are appropriate for the ventilation system.

All chemicals shall be received centrally in *IAVI Vaccine Design and Development Laboratory*. Personnel who receive chemical shipments shall be knowledgeable of the proper procedures for receipt. Chemical containers shall not be accepted without proper labels, material safety data sheets and packaging in accordance with all appropriate regulations. All chemical shipments shall be dated when received and opened.

Chemicals shall be entered into the laboratory inventory system by the laboratory Safety Person and the MSDSs shall be entered into the MSDS database by the Safety Person or the CHO.

Chemical Storage

Guidelines for proper segregation of incompatible chemicals can be found in Appendix B.
Received chemicals shall be immediately moved to the designated storage area. Large glass containers shall be placed in carrying containers or shipping containers during transportation.
The storage area shall be well-illuminated, with all storage maintained below eye level. Large bottles (greater than 1 liter) shall be stored no more than two feet from ground level.

Chemicals shall be segregated by hazard classification and compatibility in a well-identified and ventilated area.

Mineral acids should be separated from flammable and combustible materials. Separation is defined by NFPA 49 as storage within the same fire area but separated by as much space as practicable or by intervening storage from incompatible materials.

Acid-resistant trays should be placed under bottles of mineral acids.

Acid-sensitive materials such as cyanides and sulfides shall be separated from acids or protected from contact with acids.

Highly toxic chemicals or other chemicals whose containers have been opened shall be stored in unbreakable secondary containers.

When chemicals are taken from the storage area, they shall be placed in an outside container or bucket.

Storage of chemicals at the lab bench or other work areas shall be limited to those amounts necessary for one operation or one day's worth of work. The container size and the amounts of chemicals at the lab bench shall be as small as practical.

Stored chemicals shall be examined at least annually by the safety person for replacement, deterioration, and container integrity. The inspection should determine whether any corrosion, deterioration, or damage has occurred to the storage facility as a result of leaking chemicals.

Periodic inventories of chemicals outside the storage area shall be conducted by the safety person. Unneeded items shall be properly discarded.

Chemical Handling

Each laboratory employee with the training, education and resources provided by his or her supervisor, shall develop and implement work habits consistent with this Chemical Hygiene Plan to minimize personal and coworker exposure to the chemicals in the laboratory.

Based on the realization that all chemicals inherently present hazards in certain conditions, exposure to all chemicals shall be minimized. General precautions which shall be followed for the handling and use of all chemicals are:

- The intent and procedures of this Chemical Hygiene Plan shall be continuously applied.
- Skin contact with all chemicals shall be avoided.
- All employees shall wash all areas of exposed skin prior to leaving the laboratory.
- Mouth suction for pipetting or starting a siphon is prohibited.
- Eating, drinking, smoking, gum chewing, or application of cosmetics in areas where laboratory chemicals are present shall be avoided.
- Storage, handling and consumption of food or beverages shall not occur.
- Risk determinations shall be conservative in nature.
- Any chemical mixture shall be assumed to be as toxic as its most toxic component.
- Substances of unknown toxicity shall be assumed to be toxic.
- Laboratory employees shall be familiar with the symptoms of exposure for the chemicals with which they work and the precautions necessary to prevent exposure.
- In all cases of chemical exposure, neither the Permissible Exposure Limits (PELs) of OSHA or the Threshold Limit Values (TLVs) of the American Conference of Governmental Industrial Hygienists (ACGIH) shall be exceeded. The PELs of OSHA are based on the TLVs developed by the ACGIH. A listing of the TLVs can be found in Appendix B of the book Prudent Practices for Handling Hazardous Chemicals in Laboratories published by the National Academy Press.
- The engineering controls and safety equipment in the laboratory shall be utilized as described in Sections 4 and 5.
- Specific precautions based on the toxicological characteristics of individual chemicals shall be implemented as deemed necessary.

Laboratory Equipment and Glassware

- Each employee shall keep the work area clean and uncluttered. All chemicals and equipment shall be properly labeled as described in Section 3 (Labeling). At the completion of each work day or operation, the work area shall be thoroughly cleaned and all equipment properly cleaned and stored.

  In addition, the following procedures shall apply to the use of laboratory equipment:
  - All laboratory equipment shall be used only for its intended purpose, and repaired and replaced as needed.
  - All glassware will be handled and stored with care to minimize breakage; all broken glassware will be immediately disposed of in the broken glass container.
  - All evacuated glass apparatus shall be shielded to contain chemicals and glass fragments should implosion occur.
  - Labels shall be attached to all chemical containers, identifying the contents and related hazards.

- All waste receptacles shall be identified according to the type of waste - biohazard, ordinary waste, waste glass, etc.

Personal Protective Equipment

Personal protective equipment includes appropriate lab coats or gowns, shoes, safety glasses, gloves, etc.

Safety glasses meeting ANSI (American National Standards Institute, www.ansi.org) Z87.1 should be used by employees and visitors to the laboratory and will be worn as needed in the laboratory. Contact lenses are prohibited in the laboratory.

- Chemical goggles and/or a full face shield shall be worn during chemical transfer and handling operations as procedures dictate.
- Sandals, perforated shoes and bare feet are prohibited. Safety shoes, per ANSI 47 are required where employees routinely lift heavy objects.
- Lab coats should be worn in the laboratory. Laboratory coats should be laundered on a periodic basis, not to exceed monthly. Laboratory coats shall be removed immediately upon discovery of significant contamination and laundered or disposed of as needed. Lab coats should not be worn outside of the laboratory.
- Appropriate chemical-resistant gloves shall be worn at all times when there may be skin contact with chemicals. Used gloves shall be inspected and washed prior to reuse. Damaged or deteriorated gloves will be immediately replaced. Gloves shall be washed prior to removal from the hands. Disposable gloves shall not be reused.
- Thermal-resistant gloves shall be worn for operations involving the handling of heated materials and exothermic reaction vessels. Thermal-resistant gloves shall be non-asbestos and shall be replaced when damaged or deteriorated.
- Respirator usage shall comply with the OSHA Respiratory Protection Standard, 29 CFR 1910.134. The use of respirators must be determined on an individual basis. The situation must be analyzed and the risk determined by qualified individuals.
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Personal Work Practices

Chemical Hygiene Officer must ensure that each employee knows and follows the rules and procedures established in this plan.

All employees shall remain vigilant to unsafe practices and conditions in the laboratory and shall immediately report such practices and/or conditions to the Principal Investigator. The Principal Investigator must correct unsafe practices and or conditions promptly.

- Long hair and loose-fitting clothing shall be confined close to the body to avoid being caught in moving machine/equipment parts.
- Use only those chemicals appropriate for the ventilation system.
- Avoid unnecessary exposure to all chemicals by any route.
- Do not smell or taste any chemicals.
- Encourage safe work practices in coworkers by setting the proper example. Horseplay is strictly forbidden.
- Seek information and advice from knowledgeable persons, standards and codes about the hazards present in the laboratory. Plan operations, equipment and protective measures accordingly.
- Use engineering controls in accordance with Section 5 of this document.
- Inspect personal protective equipment prior to use, and wear appropriate protective equipment as procedures dictate and when necessary to avoid exposure.

Labeling

All containers in the laboratory shall be labeled. This includes chemical containers and waste containers. The label shall be informative and durable, and at a minimum, will identify contents, source, and date of acquisition and indication of hazard.
The labeling program shall be periodically inspected by the Safety Person to ensure that labels have not been defaced or removed.

3. Criteria For Implementation Of Control Measures

Air Sampling

Air sampling for evaluating employee exposure to chemical substances shall be conducted periodically or as specified by specific codes, regulations or IAVI senior management. The sampling shall be done by a qualified air sampling firm.

Housekeeping

Each laboratory worker is directly responsible for the cleanliness of his or her work space, and jointly responsible for common areas of the laboratory. Laboratory management shall insist on the maintenance of housekeeping standards.

The following procedures apply to the housekeeping standards of the laboratory:

- All spills on lab benches or floors shall be immediately cleaned and disposed of properly. Large spills will necessitate the implementation of the Emergency Action Plan per OSHA 29 CFR 1910.38 and 1910.120. The Chemical Hygiene Officer shall be notified immediately. The Fire Department or local Police should be notified as needed.
- The lab benches shall be kept clear of equipment and chemicals except those necessary for the work currently being performed.
- The work area shall be cleaned at the end of each operation and each shift.
- All apparatus shall be thoroughly cleaned and returned to storage upon completion of usage.
- All floors, aisles, exits, fire extinguishing equipment, eyewashes, and showers, electrical disconnects and other emergency equipment shall remain unobstructed.
- All labels shall face front.
- Chemical containers shall be clean, properly labeled and returned to storage upon completion of usage.
- All chemical wastes will be disposed of in accordance with the Hazardous Materials Policies of IAVI *Vaccine Design and Development Laboratory* (see Appendix C).

Safety and Emergency Equipment

Telephone numbers of emergency personnel, supervisors and other workers as deemed appropriate shall be posted on laboratory doors and Safety Bulletin Board (located in corridor 861). All laboratory personnel will be trained in the proper use of fire extinguishers when hired and annually thereafter. Prior to the procurement of new chemicals, the safety person shall verify that existing extinguishers and other emergency equipment are appropriate for such chemicals.

All employees who might be exposed to chemical splashes shall be instructed in the location and proper usage of emergency showers and eyewashes. The eyewash shall be inspected weekly and emergency shower shall be inspected at least monthly. These inspections shall be performed by the laboratory employees. These inspections shall be in accordance with ANSI Z358.1 and manufacturer's specifications. Records shall be maintained on equipment.

Location signs for safety and emergency equipment have been posted.

4. Engineering Controls

Intent

Engineering controls include electrical switches, thermostats, safety interlocks and other control devices. The engineering controls installed in the laboratory are intended to minimize employee exposure to chemical and physical hazards in the workplace. These controls must be maintained in proper working order for this goal to be realized.

Modification

No modification of engineering controls will occur unless testing indicates that worker protection will continue to be adequate.

Improper Function

Improper function of engineering controls must be reported to the Safety Person immediately. The system shall be taken out of service until proper repairs have been executed.

Usage

All employees shall follow proper work practices when using the engineering controls.

Local Exhaust Ventilation

The following procedures shall apply to the use of local exhaust ventilation, if laboratory ventilation exists:

- Hood fans shall operate when hoods are being used.
- After using hoods, operate the fan for an additional period of time sufficient to clear residual contaminants from the ductwork.
- The ventilation system shall be inspected semi-annually. The duct velocity shall be maintained at 3500 feet per minute, minimum. A record of each inspection shall be maintained by the "responsible person".
- Prior to a change in chemicals or procedures, the adequacy of the ventilation system shall be determined by the "responsible person".

Laboratory Fume Hoods

The laboratory hoods shall be utilized for all chemical procedures which might result in release of hazardous chemical vapors or dust. As a general rule, the hood shall be used for all chemical procedures involving substances which are appreciably volatile and have a permissible exposure limit (PEL) less than 50 ppm. The following work practices shall apply to the use of hoods:

- Confirm adequate hood ventilation performance prior to opening chemical containers inside the hood. An inward flow of air can be confirmed by holding a piece of paper at the face of the hood and observing the movement of the paper.
- Keep the sash of the hood closed at all times except when work is being done inside the hood. When working inside the hood, maintain the sash height as low as possible.
- Storage of chemicals and equipment inside the hood shall be kept to a minimum.
- Minimize interference with the inward flow of air into the hood.
- Leave the hood operating when it is not in active use if hazardous chemicals are contained inside the hood or if it is uncertain whether adequate general laboratory ventilation will be maintained when the hood is non-operational.
- The ventilation system shall be inspected every semi-annually. The hood face velocity shall be maintained between 75 and 125 feet per minute. A record of each inspection shall be maintained by the Safety Person and attach an inspection label. The hood shall not be used as a means of disposal for volatile chemicals.
- Prior to the introduction of new chemicals, the adequacy of hood ventilation systems shall be determined by the Safety Person.

Storage Cabinets

Storage cabinets for flammable and hazardous chemicals will be ventilated as needed.

5. Employee Information And Training

Hazard Information

All employees will be apprised of the hazards presented by the chemicals in use in the laboratory. Each employee shall receive training at the time of initial assignment to the laboratory, prior to assignments involving new exposure situations, and at a regular frequency as determined by the CHO.

Training

This training shall include methods of detecting the presence of a hazardous chemical, physical and health hazards of chemicals in the lab, and measures employees can take to protect themselves from these hazards. The training shall present the details of the Chemical Hygiene Plan and shall include:

- The contents, location and availability of the Chemical Hygiene Plan.
- Signs and symptoms associated with exposure to the chemicals present in the laboratory (see Appendix D).
- Location and availability of reference material on chemical hygiene (Safety Bulletin Board).
- Training shall be conducted by the Chemical Hygiene Officer or the Safety Person as described in this section.

6. Prior Approval Of Laboratory Activities

Permit System

A permit system is not a reasonable precaution to improve safety in the IAVI Design and Vaccine Development Laboratory. It is more prudent to use adequate training to prevent unforeseen situations.

Off-Hours Work Procedures

Laboratory personnel are not permitted to work after hours in the lab, except when specifically permitted by Laboratory Head.

Sole Occupancy

At no time should work be performed in the laboratory when the only person in the building is the laboratory person performing the work.

Hazardous Work

All hazardous operations are to be performed during a time when at least two personnel are present at the laboratory. At no time shall a laboratory person, while working alone in the laboratory, perform work which is considered hazardous. The determination of hazardous operations shall be made by the Laboratory Head.

Unattended Operations

When laboratory operations are performed which will be unattended by laboratory personnel (continuous operations, overnight reactions, etc.), the following procedures will be employed:

- The Principal Investigator will review work procedures to ensure for the safe completion of the operation.
- An appropriate sign will be posted at all entrances to the laboratory.
- The overhead lights in the laboratory will be left on.
- Precautions shall be made for the interruption of utility service during the unattended operation (loss of water pressure, electricity, etc.).
- The person responsible for the operation will return to the laboratory at the conclusion of the operation to assist in the dismantling of the apparatus.

7. Medical Consultations And Examinations

An opportunity to receive medical attention is available to all employees who work with hazardous chemicals in the laboratory. The opportunity for medical attention will be made available to employees under the following circumstances:

- Whenever an employee develops signs or symptoms associated with a hazardous chemical to which the employee may have been exposed in the laboratory,
- Whenever an event takes place in the laboratory such as a spill, leak, explosion or other occurrence resulting in the likelihood of a hazardous exposure the employee will be provided an opportunity for medical consultation for the purpose of determining the need for medical examination.
- These medical consultations and examinations shall be provided without cost to the employees, without loss of pay and at a reasonable time and place.
- These medical consultations and examinations shall be administered by or under the direct supervision of a licensed physician

8. Chemical Hygiene Responsibilities

Laboratory Head

The Laboratory Head has the ultimate responsibility for chemical hygiene throughout the laboratories and will provide continued support for chemical hygiene and appoints the Chemical Hygiene Officer.

Laboratory Directors

Each Laboratory Director has the responsibility for chemical hygiene within their department and will provide support for chemical hygiene.

Principal Investigators

The Principal Investigators are responsible for chemical hygiene within their laboratory and shall appoint a Safety Person.

Chemical Hygiene Officer

The Chemical Hygiene Officer shall:

- Work with the Biosafety Officer and scientific staff to develop and implement appropriate chemical hygiene policies and practices.
- Monitor the use of chemicals in the lab, including determining that facilities and training levels are adequate for the chemicals in use.
- Help Principal Investigators develop precautions and adequate facilities.
- Review and improve the Chemical Hygiene Plan on an annual basis.

- Maintain overall responsibility for the safe operation of the laboratories. Ensure that workers know and follow the chemical hygiene rules,
- Ensure that appropriate training has been provided to employees,
- Monitor the waste disposal program,
- Maintain the MSDS database and file.

Safety Person

The responsibilities of the Safety Person overlap and integrate with the responsibilities of the Chemical Hygiene Officer and shall include:

- Monitor the use of chemicals in the lab, including determining that facilities and training levels are adequate for the chemicals in use.
- Ensure that workers know and follow the chemical hygiene rules,
- Ensure that appropriate training has been provided to employees,
- Monitor the waste disposal program,
- Maintain the chemical inventory.

Laboratory Workers

The laboratory workers are individually responsible for:

- Planning and conducting each laboratory operation in accordance with the Chemical Hygiene Plan,
- Developing good personal chemical hygiene habits.

9. Special Precautions

When laboratory procedures change to require the use of additional classifications of chemicals (embryotoxins, teratogens, carcinogens, etc.), additional special precautions shall be implemented as deemed necessary by the Chemical Hygiene Officer. A list of these chemicals is included in Appendix E.

Working with Embryotoxins (Reproductive Toxins) and Carcinogens

Women of child-bearing age will handle embryotoxins only in a hood with confirmed satisfactory performance and will use protective equipment to prevent skin contact as prescribed by the Principal Investigator and Chemical Hygiene Officer.
Embryotoxins will be stored in adequately ventilated areas in unbreakable secondary containers.
The Principal Investigator and Chemical Hygiene Officer will be notified of spills and other exposure incidents. A physician will be consulted when appropriate.

Working with Chemicals of Moderate Chronic or High Acute Toxicity

Areas where these chemicals are stored and used are of restricted access and have special warning signs.
Gloves and long sleeves will be used. Hands and arms will be washed immediately after working with these chemicals.
Two people will always be present during work with these chemicals.

10. Recordkeeping

Accident investigations will be conducted by the Biosafety Officer in cooperation with the Laboratory Head with assistance from other personnel as deemed necessary.

Accident reports will be rewritten and retained in the individual's personnel file. Medical records for employees exposed to hazardous chemicals and/or harmful physical agents will be maintained for the duration of employment and kept in individual's personnel file, per 29 CFR 1910.20. MSDS(s) of chemicals involved in the accident will be included in the report.
Records of inspections of equipment will be maintained for five years.

Records of employee training will be maintained for five years.

11. Chemical Spills, Releases And Accidents

In the event of a chemical spill, release or other accident, immediately notify the Safety Person, Chemical Hygiene Officer. If they are not available directly call 911.

12. Annual Chemical Hygiene Plan Audit

The Chemical Hygiene Officer will conduct an audit of all phases of the Chemical Hygiene Plan each year. Results will be provided to the Biosafety Officer and Laboratory Head. Laboratory directors are responsible for taking corrective action.

13. References And Recommended Reading

National Research Council, Prudent Practices for Handling Hazardous Chemicals in Laboratories, National Academy Press, Washington, D.C.1981.

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ANNEX 2

Sample Laboratory Biosafety and Security Plan

Overview

This Plan sets forth policies to work within a laboratory environment classified as Biosafety Level 2 (BSL-2). The definition of Agent is: any virus, virus-infected cell, recombinant virus or vector system which meets requirements of a BSL-2 (Attachment 1 and 2).

The Biosafety Officer or his/her designee must be present on-site when BSL-2 Agents are being used. These officials must conduct regular inspections (at least semi-annually) and document their results and any deficiencies identified during inspections must be documented.

I. Containment

PHYSICAL SECURITY SYSTEMS

Purpose: This sections sets policy to:

i. Ensure appropriate levels of protection against unauthorized access, theft, diversion, or loss of custody of BSL-2 Agents; loss or theft of information may cause unacceptable adverse impacts on the health and safety of IAVI Employees, the public, or the environment;
ii. Provide levels of protection in a graded manner in accordance with the potential consequences;
iii. Ensure effective planning of graded protection levels and prudent application of resources.

Risk Assessment. The physical security system shall be designed according to a site-specific risk assessment. The risk assessment shall be developed by qualified individuals who have expertise in physical and biological security. The objectives and performance of the physical security system shall be reviewed regularly, but no less than every 5 years, by qualified individuals who have expertise in physical and biological security.

Site-Specific Considerations. The physical security systems will be tailored to address site-specific characteristics and requirements, ongoing programs, and operational needs, and to achieve acceptable protection levels using current technology in a cost-effective manner.

Graded Protection. Physical security systems shall provide graded protection in accordance with the importance of the asset. Therefore, protection of Agents will be given the highest level of protection. Protection of other Interests will have lower levels of protection. The plans shall be reviewed and updated annually.

Security and Restricted Access Areas:

i. Unescorted access shall be limited to authorized individuals. Any unauthorized individual will be escorted at all times by an authorized individual. Laboratory management shall establish appropriate escort-to-visitor ratios. Controls shall be established to detect, assess, and deter unauthorized access to security areas. Access control requirements may be layered as appropriate for the situation. At succeeding boundaries, access controls may be increased. Means shall be provided to deter and detect unauthorized intrusion into limited and exclusion areas as defined below.
ii. During Agent storage only predetermined, selected employees have necessary code or key access to freezers holding cultures. Each Agent has an accompanying inventory card, which fully identifies the agent, the quantity, and its location. Approved employees must sign off on the inventory card(s) for each Agent.

Lobby, Conference rooms and office areas- Lowest Level of Protection. Means include: badge key access, buzzer entry or visitor badge.

Design and Development Laboratories-Intermediate Level of Protection. Only authorized personnel are allowed to enter and exit the area without escort. Signage is clearly posted on entry doors; entry is by key card only. Unauthorized personnel are escorted at all times by authorized personnel during visit.

Exclusion Area. Reserved for BSL-3 Agents, highest level of Protection.

Reagent Storage. BSL-2 Agents are stored in various freezers located in the equipment hallways (lab areas 854, 865, 865) and Freezer Farm (lab area 839).

Access Control. Automated access control systems shall read data entered by the person requesting access, and if the data are successfully validated, the portal shall be electrically unlocked. Door locks opened by badge readers shall be designed to relock immediately after the door has closed to deter another person from opening the door without following procedures. The system shall record all transactions - authorized access (for tracking purposes) and attempted unauthorized access.

Intrusion Detection and Assessment Systems. Intrusion detection systems shall be installed to provide reasonable assurance that breaches of security boundaries are detected and that assessment information is provided to protective personnel.
The intrusion detection systems shall be: (1) monitored by assigned personnel to assess alarms and initiate appropriate responses; and (2) tamper-resistant or tamper-alarmed.

Systems shall be functionally tested in accordance with established procedures at a frequency that is documented.
Doors and hatches which provide access to limited and exclusion areas shall be equipped with intrusion detection system devices.

Protection of Access Control and Intrusion Detection Systems. Security-related equipment shall be protected from unauthorized access in a graded manner consistent with its importance; all detection/alarm devices and access control system components, including transmission lines to enunciators, shall be tamper-indicating in both the access and secure modes. Electronics enclosures and junction boxes shall be: under lock and key control; have tamper switches; or, have tamper-resistant hardware. Access to records and information concerning encoded data and personal identification numbers shall be restricted to authorized individuals. All records for access control and intrusion detection systems, including personnel removed from the system, shall be retained for 1 year.

Auxiliary power sources. Auxiliary power shall be available and shall be capable of maintaining full operation of the intrusion detection and assessment system for 8 hours or for such time as would be needed to implement contingency plans. The period of time necessary to implement contingency plans shall be documented. Auxiliary power sources shall have the capability to facilitate operational testing or routine maintenance.

Transfer to auxiliary power shall be automatic upon failure of the primary source and shall not effect operation of the security system or device.

Maintenance. Security-related subsystems and components shall be maintained in an operable condition. A regularly scheduled testing and maintenance program is required if compensatory measures are necessary.

The following system elements shall be included in a preventive maintenance program: intrusion detection and assessment systems, central alarm station alarm enunciators, protective force equipment, personnel access control and inspection equipment, security lighting, and security system-related emergency power or auxiliary power supplies.

Personnel, who test, maintain, or service security system elements shall have access authorization consistent with the protection level where the maintenance is being performed.

Maintenance records shall be retained for 1 year.

Performance Testing. Performance assurance programs shall provide for operability and effectiveness tests of security systems and/or components of systems. Testing frequencies shall reflect site-specific conditions, operational needs, and threat levels.

The performance assurance program shall provide for operability and effectiveness tests. The program will be implemented in a graded manner. Elements that are determined to be most significant are those that provide protection for Agents and information related to Agents.

Response Forces. Response to intrusion detection alarms shall be by protective personnel, private security firms, or local law enforcement personnel.

Prohibited Articles. The following articles are prohibited from Agents areas, any dangerous weapon, explosive, or other dangerous instrument or material likely to produce substantial injury or damage to persons or property. Sites shall, at a minimum, employ administrative procedures to prohibit these articles.

Visitor Logs. Visitor logs are required for limited areas and exclusion areas and shall be retained for 1 year. The logs must include time of access and egress and person accompanying the visitor.

CYBERSECURITY SYSTEMS

These systems are under control of the IT department and will be addressed in their own security plan.

II. Personnel Safety and Health

Purpose: Suitability of personnel requiring access to Agents.

i. Background Investigations. The following investigations will be conducted to determine the personnel suitability:
   (a) References from University investigators
   (b) Limited Background Investigation
ii. Pre-employment**.** Recruitment announcements will notify all candidates for permanent and non-permanent positions that the position is located within a BSL-2 facility and appointment to the position is subject to a background investigation.
iii. IAVI Employees. Appointees to work with Agents, *positions* must have a completed and favorably adjudicated background investigation prior to assuming duties with the BSL-2 facility.
iv. Non-IAVI Personnel. Includes personnel from universities, cooperators, contractors, students, visiting scientists, laboratory visitors, seminar attendees, etc. Non-company personnel will be escorted at all times by staff members.

Training.

i. The Biosafety Officer or his/her designee must provide appropriate training in biosafety, containment, and security procedures to all individuals with access to Agents.

ii. The Biosafety Officer or his/her designee must provide information and training to an individual at the time the individual is assigned to work with Agents. The Biosafety Officer or his/her designee must provide refresher training annually.

III. Inventory Control

Purpose: The purpose of this section is to set policies on the handling, storage, shipping, disposal, record keeping and monitoring of BSL2 Agents.

Accountability Records. A detailed inventory of viral seed cultures on premises. A current master database of inventory will be maintained by the Principal Investigator, which should be updated monthly. Facility Inventory Information in the Agents database is as follows:

i. Number of vials;
ii. Storage Location;
iii. Date of change of status (removal of vials);
iv. Disposition of removed inventory;
v. Signature or initials.

New working cultures that become new depository must be added to inventory.

Packaging and shipping of Infectious Material. Packaging and shipping of Agents *will* meet current national and international regulations and guidelines.

Physical Review of Accountability Records. Laboratory workers working with Agents are responsible for the accuracy of inventory cards and laboratory notebook records, which are subject to review by their supervisor. Physical review will be at least annually (refer to attachment 3).

Pathogen Security. All Agents cultures shall be stored in secure freezers within the high containment areas. Only personnel with the appropriate Personnel Security Level (PSL) will have access to freezer keys and codes.

Sample Labeling. All sample vials in the inventory shall be labeled in a permanent manner so that all information is readable. All boxes which contain samples must be labeled as well.

Inactivation and Disposal of Pathogens. Procedures must be in place at each location for this purpose and must include, as appropriate, autoclaving, other thermal inactivation technology, chemical treatment, or an equally effective comparable process. All Agents and contaminated supplies will be treated.

IV. IAVI Policies

The following are IAVI policies, which have been presented to all employees working with Agents.

Facility Access by Others

i. *Routine cleaning:* Conducted by bonded contract cleaners.
ii. *Routine maintenance:* IAVI employs outside contractors. All repair and maintenance workers will be accompanied by approved employees as designated in I.A. (e).

General Policies

i. No permission is given, either expressed or implied to employees to remove cultures from the laboratory facility, except by written authorization (signed memos or emails) by Laboratory Director.
ii. No permission is given either expressed or implied for employees to transfer any cultures identified as Agents, except by written authorization (signed memos or emails) by Laboratory Director.

Incident Response

i. *Accidental Spills:* Laboratory Supervisors have proper personal equipment and respirators for addressing spills. Additionally, each laboratory has appropriate disinfectant solutions on site for use in clean up. These are mentioned in the Biosafety Manual and Biological Exposure SOP BSL2-02-3.x.
ii. *Missing or un-accounted for cultures, altered records, or loss of Access Cards.:* Laboratory personnel approved to work with each Agent are required to report any missing or lost Agents, Keys, etc., to both the Biosafety Officer and Laboratory Director.
iii. *Unapproved Visitors:* Access to all of the IAVI's Laboratory facilities is limited to designated personnel.
iv. *Outside Responders:* Brooklyn Fire Department must be apprised of the nature of Agents stored in the Laboratory Freezers and work areas.

Ordering, Receiving Agents

i. Ordering and Receiving will be conducted through approval of the Laboratory Director.
ii. Records of each order, all necessary permits and receipts will be maintained in files under the control of the Laboratory Director.
iii. Containers of properly received Agents will be opened in biosafety cabinets by appropriate personnel using adequate safety equipment. Conditions of such materials will be recorded and any breakage, spillage or the like will be reported according to established protocols. Inventory cards will be prepared for each Agent received and will be handled as described in previous sections.

Transfer or Shipping of Agents. Any shipment of Agents by IAVI must be according to national and International guidelines.

ANNEX 3

SAMPLE POST EXPOSURE PLAN FOR THE OCCUPATIONAL EXPOSURE TO SIMIAN IMMUNODEFICIENCY VIRUS (SIV) OR SIMIAN-HUMAN IMMUNODEFICIENCY VIRUS (SHIV)

1. 1. PURPOSE

The purpose of this protocol is to describe how to respond to an accidental exposure to Simian Immunodeficiency Virus (SIV) or Simian-Human Immunodeficiency Virus (SHIV).

2. SCOPE

Individuals working with SIV or SHIV in the laboratory, individuals working with non-human primates (NHPs) who have been experimentally challenged with SIV or SHIV, or individuals working with tissues/blood products/mucosal swabs/fluids collected from experimentally challenged NHPs must adhere to these guidelines.

3. DEFINITIONS

3.1 Simian Immunodeficiency Virus (SIV) – a lentivirus whose natural host is Old World NHPs; Causes AIDS-like symptoms in some species of NHPs but is not fully understood if it is non-pathogenic in humans. SIVs from chimpanzees, gorillas, and sooty mangabey monkeys crossed into humans to become the precursors of HIV-1 and HIV-2.

3.2 Simian-Human Immunodeficiency Virus (SHIV) – a laboratory engineered virus which consists of genes from both HIV and SIV

3.3 EDTA-Coated Tubes – blood collection tubes coated with EDTA as an anticoagulant are used when collecting blood from an individual who has been exposed to SIV or SHIV

4. RESPONSIBILITIES

4.1 IAVI research staff must adhere to the guidelines set forth by this SOP following an accidental exposure to SIV/SHIV

4.2 IAVI research staff must adhere to the guidelines set in this SOP following an accidental exposure to tissues or fluids from an NHP that has been experimentally infected with SIV or SHIV

4.3 IAVIs Associate Director of Vector Immunobiology is responsible for ensuring the immediate shipment and testing of specimens from the exposed individual

4.4 The laboratory of Bill Switzer at the CDC will be performing the anonymous testing and archiving of samples provided by the IAVI Associate Director of Vector Immunobiology

5. MATERIALS AND EQUIPMENT

5.1 Materials

5.1.1 Disposable gloves (VWR Catalog # MF300S, MF300M, MF300L or equivalent), face shield or safety glasses, lab coat

5.1.2 BD™ E-Z Scrub™ Surgical Scrub Brush (Fisher Scientific Catalog # 22-265-650

5.1.3 Timer

5.2 Equipment

5.2.1 Eyewash station/ sink

6. PROCEDURE

6.1 Process Flow

6.2 Overview

6.2.1 When an exposure to SIV or SHIV occurs, the first priority is to flush or wash the site of exposure

6.2.2 When working with SIV or SHIV virus stock or tissues or body fluids from infected NHPs, routes of exposure may be percutaneous (via a cut, needle-stick, abrasion, open wound, or otherwise non-intact skin) or mucosal (via a splash to the eyes, mouth, or nose)

6.2.3 When working with SIV or SHIV challenged NHPs, routes of exposure may be percutaneous (via a needle stick, scratch, or bite from a SIV or SHIV challenged NHP) or mucosal (via a splash)

6.3 First aid response to a percutaneous exposure

6.3.1 Immediately cleanse the exposed site under running water while scrubbing with a betadine Surgi-Prep brush for 15 minutes (use timer to ensure a full 15 minute scrub and rinse)

6.4 First aid response to a mucosal exposure

6.4.1 Immediately irrigate the site with running water for 15 minutes, using an eyewash station if the exposure was to the eyes (use timer to ensure a full 15 minute flush)

6.5 Collection and shipment of whole blood specimens to the CDC

6.5.1 If at **Brooklyn Army Terminal**, proceed to:

Lutheran Hospital ER
150 55th Street at 2nd Ave.

If at **SUNY Downstate**, proceed to:

SUNY Downstate Student Health
440 Lenox Road, Apartment 1S

OR

SUNY Downstate ER (if after-hours)

6.5.2 Take a copy of this SOP with you and tell the physician that you have had a potential exposure to SIV or SHIV

6.5.3 **Request that 20 mL of EDTA-treated blood be collected and inform the physician that you will take your samples with you and label and ship them to the CDC yourself**

6.5.4 Label the specimen tubes and paperwork in a manner that does not include personally identifiable information. Specifically, label the tubes with "IAVI", the date the blood was collected, and how much time has passed since the exposure (i.e. Day 0, Week 3, Week 6, etc)

6.5.5 Ship the package at **room temperature** to the CDC Serum Bank using an overnight, next morning delivery service to the address below:

CDC Serum Bank (STAT)
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, GA 30329
"Attention: Project 139"

6.5.6 Provide email notification with package tracking number to CDC Diagnostics and Incidence Team Lead at the Laboratory Branch, Division of HIV/AIDS Prevention

It should also detail when, where, and how the exposure occurred, the strain of SIV or SHIV involved, animal species (if the exposure was through a challenged/infected laboratory animal or their tissues), occupation of exposed individual, and any antiretroviral treatment the individual is receiving.

6.5.7 Exposed individual must fill out an IAVI incident report which may be found on the IAVI Portal:

https://www.iaviteam.org/programmes/researchdev/Design%20Lab/Pages/LabBioSafety2.aspx

6.6 Post exposure prophylaxis should be discussed with the physician

6.6.1 Post Exposure Prophylaxis (PEP) regimens for SIV or SHIV recommended by the CDC clinic:

HIV PEP Regimen

Raltegravir (Isentress; RAL) 400 mg PO twice daily

Plus

Truvada, 1 PO once daily

(Tenofovir DF [Viread; TDF] 300 mg _ emtricitabine [Emtriva; FTC] 200 mg)

6.7 Continued surveillance

6.7.1 Post Exposure, the exposed individual should be re-tested at 3 weeks, 6 weeks, 3 months, and 6 months

7. REFERENCES

- Occupational Health and Safety in the Care and Use of Nonhuman Primates
  http://www.nap.edu/catalog/10713.html for free pdf download (pages 28-29 focus on SIV)

8. FORMS, Records, tools

- IAVI Incident Report
  https://www.iaviteam.org/programmes/researchdev/Design%20Lab/Pages/LabBioSafety2.aspx

ANNEX 4

IAVI-DDL Laboratory Safety Audit Checklist

Laboratory
Proper signage: ultraviolet light, laser,
Appropriate biosafety guidelines available and followed
Laboratory equipment properly labeled
Laboratory design
Designed for easy cleaning ...
All shelves secured
Bench-tops waterproof and resistant to Chemicals and Heat
Adequate illumination provided
Adequate storage space available and appropriately used ...
Gas cylinders
All cylinders secured
Caps on reserve cylinders
Asphyxiating and hazardous gases only in ventilated rooms
Excess or empty cylinders present ...
Refrigerators/freezers/cold rooms
Food for human consumption present.
Flammables in explosion-proof/-safe units
Labeled externally if containing
carcinogens, and/or biohazards
Electrical equipment
Extension cords present
Outlets earthed/grounded and with proper polarity
Connections by sinks, under showers,
Equipment with frayed or damaged wiring
Overloaded outlets or electrical strips...
Power strips mounted off the floor ...
Proper fuses in conduits ...
Electrical outlets near water sources meet local codes
Grounds present on electrical cords
Portable space heaters ...
Personal protective equipment
Eyewash available in laboratory
Safety shower available
Personal protective equipment (PPE) available
Occupants properly attired
PPE not worn outside the laboratory
Personal protective equipment available for cryogenic storage
Waste management
Evidence of improper waste disposal
Wastes segregated in proper containers
Sharps containers used and disposed of properly
No trash on floor ...
Waste disposal procedures posted in laboratory
Biological Safety Cabinets
Date Last Certification Present
BSC compromised by room air or location
BSC used when there is potential for creating aerosols
Laboratory
Access limited and restricted to authorized personnel
Biohazard sign posted on laboratory door as appropriate ...
Information on sign accurate and current
Sign legible and not defaced
All doors closed
Handling of contaminated waste
Infectious waste containers properly used ...
Containers not overfilled ...
Containers properly labeled and closed
Culture stocks and other regulated waste properly decontaminated before disposal
Materials decontaminated outside the Laboratory transported in closed containers
Mixed waste biologically decontaminated
Personal protection

Laboratory personnel reminded of appropriate immunizations/tests for agents handled
Appropriate medical services contacted for medical evaluations, surveillance and treatment of occupational exposures
Gloves worn when handling infectious material or contaminated equipment
Face protection provided when working outside the BSC with infectious material
Hands washed after removing gloves, after working with infectious agents
Antimicrobial agent available for immediate first aid