

# UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES



# SUBJECT: Biohazard Suite Management

Instruction 6403

MAY 1 8 2012

(BIC)

#### ABSTRACT

This Instruction prescribes the safety practices, equipment and biohazard suite requirements for conducting research at the Uniformed Services University of the Health Sciences (USUHS) involving agents assigned to Biosafety Level 3 (BSL-3).

#### A. Reissuance and Purpose.

This Instruction reissues USUHS Instruction 6403 to establish guidelines for the safe operation of the Biosafety Level-3 suite at the USUHS.

B. References. See Enclosure 1.

#### C. Applicability.

The provisions of this Instruction apply to all research personnel conducting work in the USUHS BSL-3 suite.

#### D. Responsibilities.

1. The <u>President, USUHS</u> is responsible for prescribing guidelines for safe operations in the USUHS BSL-3 suite to protect all personnel and the environment.

2. BSL-3 Oversight Committee is responsible for:

a. Reviewing all requests to use the BSL-3 suite.

b. For developing uniform guidelines for safe working practices within the BSL-3 suite.

c. Considering the safety needs of all workers in the suite when diverse agents are concurrently used.

d. For establishing special training requirements for Principal Investigators (PIs) and the staff, as needed.

e. Maintaining a list of the etiological agents under study in the suite.

3. The Institutional Biosafety Committee (IBC) is responsible for:

a. Reviewing protocols that utilize recombinant DNA, genetic materials, and Centers for Disease Control and Prevention (CDC) Select Agents, or other hazardous biological agents to ensure USUHS can adequately and safely support the proposed research.

b. Forwarding all protocols requiring BSL-3 containment to the Director of BIC.

 c. Forwarding all protocols requesting the use of CDC Select Agents to the CDC Select Agent Responsible Official (EHS).

4. The <u>Director of BIC</u> is responsible for the physical integrity and maintenance of the BSL-3 suite. The Director, BIC ensures that safety guidelines are adhered to, and responds to requests and concerns raised by Principal Investigators and others regarding the work environment or work practices in the BSL-3 suite.

5. The EHS Department shall:

a. Respond to, and evaluate emergency situations.

 b. Provide a Biological Safety Officer, and CDC Select Agent Responsible Official (RO) and Alternate Responsible Officials (ARO) as necessary.

c. Ensure the annual certification and any required repair of the biosafety cabinets are completed in accordance with Occupational Safety and Health Administration's (OSHA) 29 CFR Part 1910.1030.

d. Using Biosafety in Microbiological and Biomedical Laboratories as a reference, inspect the suite to ensure effective operation (29 CFR 1910.1450, App. A, Ch. 6.C.7.1).

 Make recommendations to PIs and the Director, BIC concerning safety equipment maintenance or replacement.

f. Maintain programs to comply with requirements of the CDC Select Agents (42 CFR Part 73), OSHA Standards for Hazard Communication (29 CFR 1910.1200), Bloodborne Pathogens (29 CFR Part 1910.1030), and Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR 1910.1450). The EHS Department shall also ensure PIs have all appropriate Material Safety Data Sheets (MSDS) and has informed all staff of the hazards they will be using while working in the BSL-3 suite.

g. Conduct annual safety audits of the suite to help identify potential problems using the safety survey at *Enclosure 3*.

 h. Ensure appropriate monitoring for safe work practices regarding the use of biological safety cabinets.

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 Acquire, develop and update training programs (including self-paced training programs) to meet the general safety requirements of personnel working with etiological agents and chemical hazards in the bio-containment laboratory.

j. Ensure appropriate decontamination procedures are being implemented.

k. Investigate the cause of every BSL-3 accident and may only cite the specifics of the accident to the Director of BIC, VP Finance and Administration, USUHS President, and then CDC, if appropriate.

 Ensure appropriate use, selection, maintenance, training, and cleaning of respirators when required. Once trained, cleaning and maintenance of respirators are the PI and laboratory staffs responsibility.

m. Provide medical clearance for respirator use when required.

n. Coordinate with U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Office of Research and Technology Applications, to provide immunization to researchers based on the etiological agent in use.

 Posting and maintaining emergency numbers (see Enclosure 2), and ensuring that appropriate biohazard warning signs are posted.

6. The Veterinary Sciences Department (AFRRI) shall:

a. Provide overall responsibility for the care and use of laboratory animals and associated training.

b. Maintain animal care and use in the BSL-3 suite to comply with the Animal Welfare Regulation (PL.99-198), the "Guide for the Care and Use of Laboratory Animals," AR 70-18, DOD Policy for the Protection of Animals in DOD-Sponsored Programs, and DOD Directive 3216.1.

c. Approve the use of animals within the BSL-3 suite.

d. Conduct inspections of animals and animal areas in accordance with laws, regulations, guidelines and Laboratory of Animal Medicine (LAM) SOPs.

7. The Facilities Division (AFRRI) shall:

a. Ensure facilities personnel are properly escorted and wear appropriate Personal Protective Equipment (PPE) before entering the BSL-3 space to perform required maintenance.

b. Assist in re-verifying the complete BSL-3 suite design and operational parameters at least annually.

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8. The Security Department (AFRRI) shall:

 Maintain a complete listing of all individuals who have access to the BSL-3 suite; a copy should be provided to EHS.

b. Manage the electronic key card access system to include:

 Issuing new cards to individuals who have been approved through the Director, BIC and EHS.

(2) Deactivating lost, stolen or terminated employee's cards.

(3) Providing EHS with an access log.

 Advising PIs in matters pertaining to the physical security of the suite and the biological security of CDC select agents.

d. Conducting annual security reviews.

e. Notify EHS as soon as any incident or condition is noticed which may involve the biohazard suite, to include water leakage into any affected area. In the event of a water leak as described above, or any other malfunction in the biohazard suite, the Director, Facilities Division (AFRRI), or his representative, will also be notified by the Security Guard. Cleanup or repair operations, to include removal of water from the area, shall not be attempted or started until specifically approved by EHS after consultation with the appropriate users of the suite.

9. The Principal Investigator (PI) is responsible for:

a. Implementing safe working practices for researchers working under his/her supervision.

b. Ensuring the microbiological safety of personnel.

c. Ensuring that appropriate safety orientation and training is conducted and documented for each new employee whose duties require entry into the BSL-3 suite. The PI will ensure that employee attends the laboratory safety operations training conducted by EHS and any other training, which may be deemed appropriate before they enter the BSL-3 suite. Training will include mandatory reading of this Instruction and an orientation by the PI (or his designated representative) in the general practices, procedures, and techniques specific to the BSL-3 suite. Orientation on agent-specific techniques must be accomplished before performing work involving an etiological agent in the BSL-3 suite. Documentation of the training for each employee will be maintained by the PI, and should be available for audit by EHS or extramural inspection teams. (For a checklist of suite-specific training, see Enclosure 4). Persons performing daily animal husbandry will receive documented training in proper husbandry procedures.

d. Complying with appropriate safety procedures for etiological agents used within the suite.

 c. Cooperating with the Center for Environmental Health/Occupational Safety during safety inspections and for implementing recommendations.

f. Ensuring that etiological agents, biological products, or diagnostic specimens shipped from the suite are correctly processed and packaged.

g. Ensuring that all individuals entering or working in the BSL-3 suite receive the required vaccination or have sufficient Personal Protection Equipment (PPE).

h. Notifying the Director of Veterinary Sciences Department (AFRRI) whenever animals are housed in the BSL-3 suite and when they are no longer used. Maintaining a VSD animal room and monitoring sheet whenever animals are present, and turning completed sheets to the VSD Animal Husbandry Chief within 3 working days.

i. Appointing a supervisor to act for the PI when the PI is not physically present in the suite. Whenever an etiological agent is being used in the suite, a designated "supervisor" or "lead" among the trained staff shall be present if the PI is not present in the BSL-3 suite.

#### E. Training.

1. The Director, BIC ensures that:

a. PIs have satisfactory knowledge, training, and experience with the proposed biological agent, assume full responsibility for the training of researchers working under their protocol, and are mindful of the additional health, safety, and security requirements of concurrent BSL-3 suite users.

b. If PIs require additional training or experience with the agent or in the BSL-3 environment, the Director, BIC, in coordination with the BSL-3 Oversight Committee, ensures that this training is successfully completed before recommending approval to use the BSL-3 suite in an unescorted status.

#### 2. Principal Investigator (PI)

PIs or their designated representatives (supervisors) are primarily responsible for ensuring that all researchers working under their protocols have the requisite training to safely and healthfully perform work with the etiological agent. At a minimum, this should include:

a. Review and comprehension of this Instruction and the Biohazard Suite User's Guide.

b. Affirming that researchers have received the general lab safety training provided by EHS, security training provided by Security, and CDC select Agent Training.

 c. Provide agent specific training to researchers including a detailed explanation of the SOPs unique to the research protocol.

d. Perform an annual "walk-through" of the BSL-3 suite identifying and remarking on the items listed under the Suite Specific Training Guidelines (see Enclosure 4).

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3. The Center for Environmental Health and Occupational Safety (EHS) shall:

Acquire, develop and update training programs, to include self-paced training programs, to meet the CDC Select Agent, general safety requirements of personnel working with etiological agents, and chemical hazards in the bio-containment laboratory.

4. The Veterinary Sciences Department (AFRRI) shall:

Acquire, develop and update training programs, to include self-paced training programs, to meet the proper animal husbandry procedures in the BSL-3 suite.

The <u>Security Department (AFRRI)</u> shall acquire, develop and update training programs to meet the security requirements of working with CDC Select Agents and the BSL-3 suite.

#### F. Effective Date.

This Instruction is effective immediately.

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Charles L. Rice, MD President

Enclosures:

1. References

- 2. Emergency Telephone Numbers
- 3. Safety Survey
- 4. BSL-3 Suite Specific Training Checklist
- 5. BSL-3 Use Application Form

#### REFERENCES

- (a) USUHS Instruction 6403, "Biohazard Suite Management," dated June 15, 2004 (hereby canceled).
- (b) 29 CFR 1910, OSHA, current edition.
- (c) 42 CFR Part 73, Possession, Use, and Transfer of Select Agents and Toxins; Final Rule, current edition.
- (d) PL.99-198, Guide for the Care and Use of Laboratory Animals.

(e) AR 70-18, DoD Policy for the Protection of Animals in DoD-Sponsored Programs.

(f) DoD Directive 3216.1.

(g) USUHS Biohazard Suite User's Guidelines SOP, 2012.

## EMERGENCY TELEPHONE NUMBERS

MEDICAL EMERGENCY	777
FIRE	777
AMBULANCE	777
EHS (EMERGENCY)	295-9443
SECURITY (AFRRI)	295-0539
SECURITY (USUHS)	295-3038
BIOMEDICAL INSTRUMENTATION CENTER (BIC)	295-9406

#### SAFETY SURVEY

#### SUBJECT: Biosafety Level 3 Safety Survey

#### **REFERENCES:** (a) ICH Guideline for Good Clinical Practice E6

- (b) Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, U.S. Department of Health and Human Services (HHS), 2007.
- (c) NIH Guidelines for Research Involving Recombinant DNA Molecules, HHS, 2009.
- (d) USUHS Instruction 6401

#### A. PURPOSE.

The purpose of this SOP is to establish uniform Biosafety Level 3 survey procedures. Surveys will be conducted annually and will be performed as part of the orientation when new research endeavors are commenced.

#### B. APPLICABILITY.

This procedure applies to all participants who need access to the BSL-3 suite and will be performed by

the Center of Environmental Health and Occupational Safety (EHS).

#### C. RESPONSIBILITIES.

1. The Biomedical Instrumentation Center (BIC) identifies the environmental/safety training requirements

of researchers working in the BSL-3 suite at AFRRI.

EHS inspects all workspaces within the University in order to ensure a safe and healthful workplace.
 EHS will use, at a minimum, the following Safety Survey tool (or its equivalent) to perform periodic inspections of the BSL-3 suite.

#### D. PROCEDURES - Biosafety Level 3 Suite Safety Survey.

The following items, at a minimum, will be incorporated into any survey tool used in safety inspections of

the Biosafety Level 3 suite and may be incorporated into the safe work practices orientation of new suite users, at the discretion of the PI:

Components	Y	es	N	0	Comments
Medical Surveillance					
<ul> <li>An appropriate medical surveillance program is in place.</li> <li>All personnel receive appropriate immunizations or tests for the agents handled or potentially present in the lab</li> </ul>	((	)	(	))	
<ul> <li>and periodic testing as recommended for the agents handled.</li> <li>If appropriate, a serum surveillance system is in place.</li> </ul>	(	)	(	)	
<ul> <li>Persons at increased risk are not allowed in the suite without medical clearance from the occupational health physician.</li> </ul>	(	)	ć	)	

Riogafaty Manual				Er	iclosi	ire 3	
Biosarety Manual							
<ul> <li>This Instruction serves as the Bio-Safety Manual; procedures are adopted.</li> </ul>	(	)	(	)			
- Personnel are advised of hazards.	(	)	(	)			
<ul> <li>Personnel are required to read the Instruction and follow guidelines on practices and procedures.</li> </ul>	(	)	(	)			
Components	5	es	1	٩o	Cor	nmen	its
Training							
- Suite Specific training conducted and documented for each worker.	1	)	(	)			
<ul> <li>HAZCOM training current (annual).</li> </ul>	1	( )	(	)			
<ul> <li>EHS Laboratory Safety Training current (annual).</li> </ul>		2	5	2			
- CDC Select Agent Salety and Security Training current.			5	)			
<ul> <li>Personnel receive periodic updates or additional training as necessary for procedural changes.</li> </ul>		. )	(	)			
Proficient Laboratory Practice							
<ul> <li>The PI is responsible for ensuring that, before working with organisms at Bio-safety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory suite. (This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the PI or other component scientist proficient in safe microbiological practices and techniques.)</li> </ul>		( )	(	)			
<ul> <li>The PI has established policies and procedures whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements (e.g. immunization) and who comply with all entry and exit procedures, enter the laboratory or animal rooms.</li> </ul>		( )	(	)			
Suite							
- Lab is separated from unrestricted traffic flow in building.	į	)	(	)			
<ul> <li>Access to lab is through an anteroom with self-closing doors.</li> </ul>	(	)	(	)			
- All penetrations in lab are sealed.		)	(	)			
- Exhaust air is single pass and exhausted away from occupied areas.			(	)			
<ul> <li>An insect and rodent program is in effect.</li> </ul>			(	)			
<ul> <li>Laboratory doors are kept closed when experiments are in progress</li> </ul>	•	()	(	)			

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### Access

<ul> <li>Director of BIC in cooperation with EHS and BSL-3 Oversight Committee controls access to BSL-3 Suite.</li> </ul>	(	)	(	)	
- No minors are allowed in BSL-3 suite	6	ñ.	C	1	
<ul> <li>Entry and exit logs are available for maintenance and housekeeping personnel</li> </ul>	ì	)	ì	ć	
- Entry and exit information is available for routine workers.	(	)	Ç	)	
Personal Protection					
<ul> <li>Persons wash their hands after handling infectious materials, after removing gloves, and when they leave the laboratory.</li> </ul>	(	)	(	)	
- Closed front gowns or coveralls are worn in laboratory.	(	)	(	)	
- Hand-washing sink is foot, elbow or automatically controlled.	(	)	(	)	
<ul> <li>Respiratory and face protection are used when in rooms containing infected animals.</li> </ul>	(	)	(	)	
Components	Y	es	1	٥V	Comments
Hand Protection					
<ul> <li>Double gloves are worn when handling infectious material, potential contaminated equipment and work surfaces.</li> </ul>	(	)	(	)	
Respiratory Protection					
<ul> <li>Respiratory protection is worn by all non-vaccinated personnel in the lab when aerosols are not safely contained in a bio-safety cabine</li> </ul>	( et.	)	(	)	
Hazard Warning Signage					
<ul> <li>When infectious materials or infected animals are present in the laboratory or containment module, a hazard warning sign incorporating the universal biohazard symbol, is posted on all laboratory and animal many descent descent.</li> </ul>	(	)	(	)	
<ul> <li>The hazard warning sign identifies the agent, lists the name and telephone number of the PI or other responsible person(s), and indicates any special requirements for entering the laboratory,</li> </ul>	(	)	(	)	
such as the need for immunizations, respirators, or other personal					
protective equipment.					

## Practices

- Mucous membrane protection provided when working with	(	)	()	
<ul> <li>Eating, drinking, smoking, handling contact lenses, applying cosmetics and storing food for human use are not permitted in the BSL-3 suite.</li> </ul>	C	)	( )	
<ul> <li>Animals and plants not related to the work being conducted are not permitted in BSL-3 suite.</li> </ul>	¢	)	()	
<ul> <li>Personnel are required to read and follow all instructions or practices and procedures.</li> </ul>	Ç	)	()	
<ul> <li>All procedures are carefully performed to minimize the creation of aerosols or splatters.</li> </ul>	(	)	()	
- Mouth pipetting is prohibited: mechanical pipetting devices used	(	)	()	
<ul> <li>All open manipulations involving infectious materials are conducted in biological safety cabinets or other physical containment devices within the containment module.</li> </ul>	Ì	5	( )	
- No work in open vessels is conducted on the open bench	(	1	( )	
<ul> <li>Clean up is facilitated by using plastic-backed paper toweling on the non-perforated work surfaces within biological safety cabinets.</li> </ul>	ì	)	Ğ	
Decontamination				
<ul> <li>Laboratory equipment and work surfaces are decontaminated at least once a day with an effective disinfectant, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination with infectious materials.</li> <li>Spills of infectious materials are contained, decontaminated, and</li> </ul>	(	)	<ul> <li>()</li> <li>()</li> </ul>	
cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material.		i ĉ		
Components	8	Yes	No	Comments
- Spill procedures are developed and posted	1	1	$c \rightarrow$	
<ul> <li>Contaminated equipment is decontaminated before removal from the suite for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations</li> </ul>	Ì	Ś	$\langle \cdot \rangle$	
<ul> <li>Cultures, tissues, specimens of body fluids, or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.</li> </ul>	(	)	()	5 R 1
<ul> <li>All potentially contaminated waste materials (e.g. gloves, lab coats, etc.) from laboratories are decontaminated before disposal or re-</li> </ul>	euse.	()	( )	
<ul> <li>Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the PL and EHS.</li> </ul>		( )	( )	

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<ul> <li>Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained for all accidents and potential exposures.</li> </ul>		¢	)	(	)
<ul> <li>Cages are washed in a cage washer. The mechanical cage washer has a final rinse temperature of at least 180 deg F.</li> </ul>		C	)	(	)
<ul> <li>An autoclave is available which is convenient to where the biohazard is contained. The autoclave is utilized to decontaminate infectious waste before moving it to other areas of the suite.</li> </ul>		(	)	(	)
Waste Disposal					
<ul> <li>A method for decontaminating all laboratory wastes is available in the suite and utilized, preferably within the laboratory (i.e. autoclave, chemical disinfection, incineration or other approved decontamination method).</li> </ul>		(	)	(	)
<ul> <li>All cultures, stocks, potentially contaminated waste materials, (i.e. gloves, labcoats etc) and other regulated wastes are decontaminated before disposal by an approved decontamination method, such as autoclaving.</li> </ul>		C	)	(	)
<ul> <li>Infectious waste from BSL-3 laboratories is decontaminated before removal for off-site disposal</li> </ul>		(	)	(	)
<ul> <li>Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leak-proof container and closed for transport from the laboratory.</li> </ul>		(	)	(	)
<ul> <li>If waste is transported out of the laboratory, it is properly sealed and not transported in public corridors.</li> </ul>		(	)	(	)
Sharps					
<ul> <li>Policies for the safe handling of sharps are instituted.</li> <li>Needles and syringes or other sharp instruments are restricted in the laboratory for use only when there is no alternative, such as parentreral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be</li> </ul>		(	))	(	)
<ul> <li>substituted for glassware whenever possible.</li> <li>Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of infectious materials.</li> </ul>		(	)	(	)
Components	<b>Y</b> es	No	Co	mn	nents
<ul> <li>Used disposable needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they are carefully placed in conveniently located puncture-resistant containers used for sharps disposal.</li> </ul>	)	()			

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<ul> <li>Non-disposable sharps are placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving</li> </ul>	(	)	(	)		
<ul> <li>Syringes which re-sheathe the needle, needle-less systems,</li> <li>and other safe devices are used when appropriate</li> </ul>	(	)	(	)		
<ul> <li>Broken glassware is not handled directly by hand, but is removed by machanical means such as a bruch and ductors tonus or foreasts.</li> </ul>	(	)	(	)		
<ul> <li>Containers of contaminated needles, sharp equipment, and broken glass are decontaminated before disposal, and disposed of according to local, state, or federal regulations.</li> </ul>	(	)	(	)		
Safety Equipment (Primary barriers)						
<ul> <li>Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls are worn by workers when in the laboratory.</li> </ul>	(	)	(	)		
- Protective clothing is worn only in the laboratory.	(	)	(	)		
<ul> <li>Reusable clothing is decontaminated before being laundered.</li> </ul>	C	)	(	)		
- Clothing is changed when overtly contaminated.	(	)	(	)		
<ul> <li>Gloves are worn when handling infectious materials, infected animals, and when handling contaminated equipment.</li> </ul>	(	)	(	)		
<ul> <li>Frequent changing of gloves accompanied by hand washing is established policy.</li> </ul>	(	)	(	)		
<ul> <li>Disposable gloves are not reused.</li> </ul>	(	)	(	)		
<ul> <li>All manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonated eggs, etc. are conducted in a Class III biological safety cabinet.</li> </ul>	(	)	(	)		
<ul> <li>When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g. respirators, face shields) and physical containment devices (e.g. centrifuge safety cups or sealed rotors) are used.</li> </ul>	(	)	C	)		
Laboratory Facilities						
- A working eyewash station is readily available inside BSL-3 suite.		Ç	)		ç	)
<ul> <li>The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted</li> </ul>	cte	d. (	1		(	)
<ul> <li>Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors</li> </ul>		(	)	)	C	)
- Electronic key card access system is functional		(		N.	é	1
- A clothes-changing room is included in the passageway		1			č	1
- The BSL-3 suite contains a sink for hand washing.		(		)	Ì	)

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<ul> <li>The sink is hands-free or automatically operated and is located near the room exit door.</li> </ul>	(	)	(	)	
- The sink drain is filled with disinfectant after each use.	(	)	(	)	
Components	Y	es	N	lo	Comments
<ul> <li>The interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination</li> </ul>	(	)	(	)	
- Seams if present are sealed	(	3	(	)	
<ul> <li>Penetrations in floors walls and ceiling surfaces are sealed</li> </ul>	è	5	1	5	
- Walls, coilings, and floors are smooth impermeable	2	1	ì	1	
to liquids and resistant to the chemicals and disinfectants normally used in the laboratory.	X	,	7	1	
<ul> <li>Floors are monolithic and slip-resistant.</li> </ul>	(	)	(	)	
<ul> <li>Openings such as around ducts and the spaces between doors and frames are sealed to facilitate decontamination.</li> </ul>	(	)	(	)	
<ul> <li>Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.</li> </ul>	(	)	(	)	
<ul> <li>Laboratory furniture is capable of supporting anticipated loading and uses.</li> </ul>	(	)	(	)	
<ul> <li>Spaces between benches, cabinets, and equipment are accessible for cleaning.</li> </ul>	(	)	(	)	
<ul> <li>Chairs and other furniture used in laboratory work are covered with a non-fabric material that can be easily decontaminated.</li> </ul>	(	)	(	)	
Ventilation System					
- A ducted exhaust air ventilation system is provided. This system creates directional airflow which draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not re-circulated to any other area of the building	(	)	(	)	
<ul> <li>The outside exhaust is dispersed away from occupied areas and air intakes, or the exhaust is HEPA-filtered.</li> </ul>	(	)	(	)	
<ul> <li>Laboratory personnel verify that the direction of the airflow (into the laboratory) is proper.</li> </ul>		( )	(	)	
<ul> <li>A visual monitoring device that indicates and confirms directional inward airflow at the laboratory entry.</li> </ul>		( )	(	)	
<ul> <li>An HVAC control system is provided to prevent sustained positive pressurization of the laboratory.</li> </ul>		( )	) (	)	
<ul> <li>Audible alarms notifying personnel of HVAC system failure are operational and tested.</li> </ul>		( )	(	)	

<ul> <li>Class III biological safety cabinets are used and directly connected to the supply system, in a manner that prevents positive pressurization of the cabinets.</li> </ul>	(	)	(	)		
<ul> <li>Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory.</li> </ul>	Ç	)	(	)		
<ul> <li>These HEPA systems are tested at least annually.</li> </ul>	(	)	(	)		
<ul> <li>If vacuum service (i.e. central or local) is provided, each service connection should be fitted with liquid disinfectant traps and an</li> </ul>	(	)	(	)		
in-line HEPA filter, placed as near as practicable to each use point or service cock.						
<ul> <li>Filters are installed to permit in-place decontamination and replacement.</li> </ul>	(	)	(	)		
<ul> <li>Illumination is adequate from all activities, avoiding reflections and glare that could impede vision.</li> </ul>	(	)	(	)		
Components	Y	es	N	0	Comments	
<ul> <li>The completed Bio-safety suite design and operational procedures are documented. The suite was tested for verification that the design and operational parameters were met prior to operation.</li> </ul>	(	)	(	)		
<ul> <li>Facilities are re-verified at least annually against these procedures as modified by operational experience.</li> </ul>	(	)	(	)		

## BSL-3 SUITE SPECIFIC TRAINING CHECKLIST

BSL-3 Suite Specific Training will include:

Personal emergency procedures: personnel assistance alarms, communication equipment, fire alarms, emergency gas shutoff valves, fire extinguishers, and procedures during and after normal duty hours.
Operations in Class III biological safety cabinets (BSC), i.e. cabinet function and procedures within the cabinets (for example, pipetting, disposal of infectious material, and clean-up).
Use of syringes with infectious materials; the disposal of syringes, transport of syringes from cabinets to animals cages; how to expel air from loaded syringes or, when necessary, how to safely remove a needle from the syringe; and procedures for inoculating animals with infectious materials.
Centrifugation procedures: use of scaled rotors and tubes, safety cups, evacuation of certain centrifuge chambers, and rotor-lifting devices.
Use of disinfectant traps and HEPA filters on vacuum lines (central hose vacuum system, centrifuges, and portable vacuum pumps).
Management of accidents (animal bites, self-inoculation with needles, infectious spills inside and outside biological safety cabinets, centrifuge accidents, etc.).
Emergency response, training on the CDC related supplement to Instruction 3000, Occupant Emergency Plan for the Uniformed Services University of the Health Sciences.
Autoclave operation and preventive maintenance.
Use and operation of laminar flow animal housing systems.
Handling, storage, and labeling of compressed gases.

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### **BSL-3 USE APPLICATION FORM**

Revised February 2011

INVESTIGATOR: DEPT:
DATE:// PHONE:
PROTOCOL TITLE:
PROTOCOL NO NEW CRENEWAL CONVEYANCE
LIST MEMBERS PERFORMING RESEARCH TO SUPPORT PROTOCOL:
SAFETY ASSURANCE: A safety assurance will be provided by the EHS before a protocol is approved. This assurance will be primarily based upon safety training of the PI and a review of the PI's safety record. The PI is responsible for ensuring the training (to include suite-specific training) of all working protocol members.
1. WILL SCHEDULE 1 CONTROLLED SUBSTANCES BE USED?
2. WILL CLASS 4 (EXTREMELY HAZARDOUS) CHEMICALS BE USED? YES NO
3. WILL CDC SELECT AGENTS BE USED? YES NO If YES please indicate
□ I WILL NEED TO USE THE BSL-3 SUITE FOR THIS RESEARCH AND UNDERSTAND THAT MY PROPOSAL WILL BE ROUTED TO THE BSL-3 OVERSIGHT COMMITTEE FOR REVIEW AND APPROVAL. USUHS INSTRUCTION 6403, "BIOHAZARD SUITE MANAGEMENT," PROVIDES THE REQUIREMENTS FOR THIS APPROVAL. NOTE: "BIOSAFETY IN MIROBIOLOGICAL & BIOMEDICAL LABORATORIES," 5 <sup>TH</sup> EDITION, BY HHS, PROVIDES ADDITIONAL REQUIREMENTS.
4. STATE THE REASON WHY YOU ARE SEEKING ACCESS TO THE BSL-3 SUITE:
BSL-3 AGENT USED IN PROTOCOL
OTHER   5. TRAINING

□ I AM FAMILIAR WITH THE USUHS INSTRUCTION 6403, "BIOHAZARD SUITE MANAGEMENT," AND TAKE RESPONSIBILITY FOR REVIEWING THESE INSTRUCTIONS, IN DETAIL, WITH ALL PROTOCOL MEMBERS.

☐ I AM FAMILIAR WITH "BIOSAFETY IN MIROBIOLOGICAL & BIOMEDICAL LABORATORIES," 5<sup>TH</sup> EDITION BY HHS; I HAVE READ THE SECTIONS RELEVANT TO THE ANIMAL BIOSAFEY LEVEL 3 (ABSL-3) AND THE BIOHAZARDOUS AGENT USED IN MY PROTOCOL.

☐ I HAVE COMPLETED/WILL COMPLETE ALL OF THE SUITE-SPECIFIC TRAINING REQUIRED BY THE INSTRUCTION AND WILL ENSURE THAT ALL PROTOCOL MEMBERS RECEIVE TRAINING.

□ I HAVE COMPLETED/WILL COMPLETE ALL OF THE CDC SELECT AGENT TRAINING REQUIRED BY THE INSTRUCTION AND WILL ENSURE THAT ALL PROTOCOL MEMBERS RECEIVE TRAINING.

□ I HAVE CONTACTED/WILL CONTACT EHS, AND I WILL ENSURE THAT EHS SPONSORED BASIC BIOLOGICAL AND CHEMICAL SAFETY TRAINING IS COMPLETED, AND THAT ALL PROTOCOL MEMBERS RECEIVE TRAINING.

□ I HAVE CONTACTED/WILL CONTACT EHS AND WILL ENSURE THAT EHS SPONSORED MEDICAL SURVEILLANCE AND IMMUNIZATION IS COMPLETED FOR ALL PROTOCOL MEMBERS.

□ I AM FAMILIAR WITH USUHS INSTRUCTION 6401, "BIOLOGICAL SAFETY MANUAL" AND I HAVE REVIEWED THE USUHS BIOHAZARD SUITE USERS' GUIDELINES SOP; I WILL ENSURE THAT ALL PROTOCOL MEMBERS DO LIKEWISE, AND THAT ALL QUESTIONS ARE ADDRESSED.

□ I WILL ENSURE THAT PROTOCOL MEMBERS RECEIVE AGENT-SPECIFIC BIOLOGICAL/ CHEMICAL HAZARD TRAINING PRIOR TO WORKING IN THE BIOHAZARD SUITE.

□ I AM FAMILIAR WITH USUHS INSTRUCTION 6408, "CDC SELECT BIOLOGICAL AGENTS MANAGEMENT," AND TAKE RESPONSIBILITY FOR REVIEWING THIS INSTRUCTION, IN DETAIL, WITH ALL PROTOCOL MEMBERS.

☐ I AM FAMILIAR WITH USUHS INSTRUCTION 3000, "OCCUPANT EMERGENCY PLAN FOR THE UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES," AND THE SUPPLEMENT FOR ADDRESSING CDC SELECT AGENTS, AND TAKE RESPONSIBILITY FOR REVIEWING THESE INSTRUCTIONS, IN DETAIL, WITH ALL PROTOCOL MEMBERS.

Principal Investigator Signature & Date

USUHS Instruction 6403, 5/2012