2007 Inspection Report

(Inspections conducted 02/07-07/07)

Facility Inspections and Certifications

TEXAS A&M UNIVERSITY

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Institutional Biosafety Committee | Institutional Animal Care and Use Committee | Institutional Review Board

MEMORANDUM

TO: Dr. Melanie Ihrig, Director
Comparative Medicine Program (CMP)
MS 4473

FROM: Tiffany M. Agnew, Program Coordinator
Institutional Bio-Safety Program (IBSP)

DATE: June 26, 2007

REG.: Annual IBC Inspection of Select Agent Facilities- Building Ihrig/Browder

Due to a major flooding in the acility, on April 16, 2007, the following individual completed an additional Inspection of the Select Agent Facilities- Building

Ms. Nancy Eaker- EHS

The aforementioned individual utilized the Environmental Health and Safety checklist to complete the inspection of the facilities. During this inspection, the following deficiencies were noted by the inspection team:

1. As a result of the **Facility Assessment** of the *Laboratory Facilities (Secondary Barriers)*, the following was noted in respect of the interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination:
   a. Airlock
      i. Signs of damage to the ceiling around the light fixture and vent
   b. Corridor
      i. Ceiling and light fixture(s) have dropped
      ii. Seals around light fixtures and vents are broken
      iii. Two light are completely out
      iv. Coving needs to be sealed and chips in walls sealed
   c. Room
      i. Ceiling damaged around light fixtures and vents
      ii. Evidence that water was in light fixture(s)
      iii. Some bulbs are out in the light fixture(s)
   d. Room
      i. Damage to ceiling around vent(s) and light fixtures
      ii. Light fixtures have dropped
      iii. Two bulbs are out in one light fixture
      iv. There is rust damage to the light fixture
   e. Room
      i. Damage to ceiling around vent(s) and light fixtures
      ii. Light fixture has dropped

f. Room
   i. Light is out and the plastic cover is warped
   ii. Ceiling is damaged
   iii. Coving around floor sink and some places on the walls is pulling away slightly

g. Room
   i. Ceiling is damaged
   ii. Evidence that water was in light fixture(s)
   iii. Light fixture has dropped

h. Room
   i. Ceiling is damaged
   ii. Evidence that water collected on top of BSC

i. Room
   i. Evidence that water was in light fixture(s)
   ii. Seal around light and vent is broken
   iii. Electrical outlet is pulled away from wall (no longer sealed); this was not caused by the water leak, but from equipment hitting the outlet.

j. Room
   i. Evidence that water was in light fixture(s)
   ii. Two bulbs are out in fixture
   iii. Ceiling is damaged

k. Room
   i. Ceiling is damaged around vents (paint is bubbling)
   ii. Evidence that water was in light fixture(s)

l. Room
   i. Coving is pulling away from walls and cabinets
   ii. Bottom of cabinets and drawers are damaged (wood has swelled)
   iii. Seals are broken around light fixtures
   iv. Light fixtures have dropped slightly

m. Room
   i. Evidence that water was in light fixture
   ii. Ceiling is damaged around light and around BSC vent duct
   iii. Rust on BSC and evidence that water collected on top of it

n. Other
   i. Ceiling inspected from interstitial space (as much as possible)
   ii. Water stains evident on much of the ceiling board and rust noted on top of light fixture(s)
   iii. Ceiling throughout the BL3 containment area appears weakened.

The IBC requests these deficiencies are rectified before: July 26, 2007. Before the next inspection of this facility, it must be documented that these deficiencies have been rectified. Upon receipt of this correspondence, please provide written indication that you have indeed received this document, and that you agree to complete all necessary corrections.

If you have any additional questions or concerns, please feel free to contact our office.

cc: Dr. Thomas Ficht
Dr. David McMurray
Dr. Richard Ewing
Dr. James Samuel
Dr. Betsy Browder
SBAT files

IBC INSPECTION REPORT
BSL3/ABSL3 SBAT FACILITIES & Entity Program

Date: April 16, 2007
Principal Investigator/Lab Director: Melanie Ihrig
Location: Building Number -___ Room (s) _____ Airlock, & Corridor (BSL3)/ _____ (ABSL3)

Inspection Team:
Nancy Eaker

Section I - Facility Assessment (PI)

A. Safety Equipment (Primary Barriers)

☐ Yes ☐ No Protective laboratory clothing, such as solid-front or wrap-around gowns, scrub suits, or coveralls, are worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

☐ Yes ☐ No Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

☐ Yes ☐ No Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

☐ Yes ☐ No All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

☐ Yes ☐ No When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

☐ Yes ☐ No Respiratory and face protection are used when in rooms containing infected animals.

B. Laboratory Facilities (Secondary Barriers)

☑ Yes ☐ No The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

☑ Yes ☐ No Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

☐ Yes ☑ No The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and

disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

☑ Yes ☐ No Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

☑ Yes ☐ No Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

☑ Yes ☐ No Windows in the laboratory are closed and sealed.

☑ Yes ☐ No A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

☑ Yes ☐ No Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

☑ Yes ☐ No A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

☑ Yes ☐ No HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

☑ Yes ☐ No 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

☑ Yes ☐ No Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

☑ Yes ☐ No An eyewash facility is readily available inside the laboratory.

☐ Yes ☑ No Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

☑ Yes ☐ No The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as

modified by operational experience.

- Floor plan(s) include:
  - Sink location
    ☐ Yes ☐ No
  - Eyewash locations
    ☐ Yes ☐ No
  - Biosafety cabinet (BSC) locations
    ☐ Yes ☐ No
  - Fume hood locations
    ☐ Yes ☐ No
  - HVAC supply and exhaust locations
    ☐ Yes ☐ No
  - Freezer/refrigerator locations
    ☐ Yes ☐ No
  - Other large equipment locations (incubators, centrifuges, etc)
    ☐ Yes ☐ No
- Provide a description of the HVAC system (check all that are appropriate):
  - ☐ Single-pass
  - ☐ Dedicated exhaust
  - ☐ Constant air volume
  - ☐ Redundant exhaust fans
  - ☐ Emergency power back-up
  - ☐ Re-circulated
  - ☐ Shared exhaust
  - ☐ Variable air volume
- Provide information on the biosafety cabinets in use (attach additional sheets if needed):
  - Class of cabinet:
  - ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3)
  - ☐ II, B1 ☐ II, B2 ☐ III
  - Biosafety cabinet connection to the HVAC system:
  - ☐ Hard duct ☐ Thimble ☐ Re-circulating
  - Define certification period:_____
  - ☐ Annual ☐ Biannual ☐ Other (explain): _____
  - Does user verify air flow during BSC use?
    ☐ Yes ☐ No
  - If floor drains are provided, the traps are always filled with an appropriate disinfectant:
    ☐ Yes ☐ No

☑ Yes ☐ No Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

C. Standard Microbiological Practices

☐ Yes ☐ No Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

☐ Yes ☐ No Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

☐ Yes ☐ No Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

☐ Yes ☐ No Mechanical pipetting devices are used; mouth pipetting is prohibited.

☐ Yes ☐ No Policies for the safe handling of sharps are instituted.

☐ Yes ☐ No All procedures are performed carefully to minimize the creation of aerosols.

☐ Yes ☐ No Work surfaces are decontaminated at least once a day and after any spill of viable material.

☐ Yes ☐ No All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

☐ Yes ☐ No Persons under 16 years of age are not allowed to enter a BL3 laboratory.

☐ Yes ☐ No If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

☐ Yes ☐ No An insect and rodent control program is in effect.

D: Special Practices

☐ Yes ☐ No Laboratory doors are kept closed when experiments are in progress.

☐ Yes ☐ No The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

☐ Yes ☐ No The laboratory director establishes 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.

☐ Yes ☐ No When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

☐ Yes ☐ No Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled.

☐ Yes ☐ No Baseline serum samples are collected as appropriate and stored for all laboratories and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

☐ Yes ☐ No A Biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and Biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

☐ Yes ☐ No Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure

evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

☐ Yes ☐ No

The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

☐ Yes ☐ No

A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

- Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic ware should be substituted for glassware whenever possible.
- 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
- Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
- Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

☐ Yes ☐ No

All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

☐ Yes ☐ No

Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

- Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
- Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

☐ Yes ☐ No

Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

☐ Yes ☐ No

All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

☐ Yes ☐ No

Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained. Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are

immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

☐ Yes ☐ No Animals and plants not related to the work being conducted are not permitted in the laboratory.

☐ Yes ☐ No Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

Section II - Program Assessment (PI and/or Institutional BioSafety Program- IBSP)

☐ Yes ☐ No 1. An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with Select Agents at this facility:

If yes: IBC approved the work proposed for this facility on: _____ (date).

☐ Yes ☐ No 2. **Training**: Site specific and safety training is provided to individuals with access to areas where Select Agents are handled or stored:

a. Is provided prior to individuals beginning to work with Select Agents: ☐ Yes ☐ No
b. Is provided: ☐ Annually ☐ Biannually ☐ Other (specify frequency):
c. Written records of individuals are kept: ☐ Yes ☐ No
d. Personnel demonstrate proficiency in laboratory procedures prior to working with Select Agents: ☐ Yes ☐ No
e. Unannounced visits by EH&S and follow up by supervisory personnel: ☐ Yes ☐ No

3. Provide a brief explanation of the system in place to detect loss or theft of select agent(s):

4. **Inventory**: Individual responsible for inventory of select agent(s):
   a. How often is the inventory record reconciled?
   b. How is access to the inventory log limited?
   c. Inventory tracking includes the following information (list):

5. **Security**: There is a site-specific Security Plan for this laboratory: ☐ Yes ☐ No
   a. Building with Select Agent has self-closing doors: ☐ Yes ☐ No
   b. Means to limit access to buildings with laboratories with Select Agent:
      Guard station at the facility entrance: ☐ Yes ☐ No
      Card access system or locks: ☐ Yes ☐ No
      Security alarm system in the laboratory building: ☐ Yes ☐ No
      Other (describe): _____ ☐ Yes ☐ No
   f. Means to limit access to laboratories with Select Agent once inside the building:
      Door to laboratory is locked: ☐ Yes ☐ No
      Card access system or locks: ☐ Yes ☐ No
      Other (describe): _____
   g. Means to limit access to select agents once inside the laboratory:
      Locked incubators, refrigerators, freezers, etc.: ☐ Yes ☐ No
      Security alarm system that directly monitors the laboratory: ☐ Yes ☐ No
      Other (describe): _____
   h. Means to limit access to select agents in storage:
      Storage area door locked: ☐ Yes ☐ No
      Lock boxes: ☐ Yes ☐ No
      Security alarm system that directly monitors the laboratory: ☐ Yes ☐ No
      Other (describe): _____
   i. Means to monitor unauthorized entry into the laboratory where select agents are used or stored:
      Electronic logs of card access system entries are reviewed for unusual activity: ☐ Yes ☐ No
      Manual sign in and out logs are kept and monitored: ☐ Yes ☐ No
      Video camera surveillance: ☐ Yes ☐ No
      Other (describe): _____

j. The laboratory is secured when no one is present during regular working hours: ☐ Yes ☐ No

k. Number of people with access:

l. Individuals not directly involved in research activities have access to Select Agent: ☐ Yes ☐ No
If yes, please explain: _____

m. Non-laboratory personnel (visitors, including janitorial and facility maintenance personnel) have access to the laboratory with select agents: ☐ Yes ☐ No
If yes, are they allowed into the laboratory unescorted? ☐ Yes ☐ No

6. Decontamination: All cultures, stock and other regulated wastes are decontaminated before disposal by an approved decontamination method: ☐ Yes ☐ No
If yes, describe method:

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **RECOMBINANT DNA**

☐ Yes ☐ No 1. The facility has an Institutional Biosafety Committee that has approved work with recombinant DNA or has approval pending:

☐ Yes ☐ No 2. The Biosafety level listed in the *Application for IBC Permit* for this laboratory meets NIH Guidelines:

3. Will you be possessing, using, or transferring the following:
   a. Select Agent nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that are capable of infection and/or replication: ☐ Yes ☐ No
   b. Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids are in a vector or host chromosome and/or are expressed *in vivo* or *in vitro:* ☐ Yes ☐ No
   c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. ☐ Yes ☐ No

4. Are you intending to conduct the following experiments:
   a. Experiments utilizing recombinant DNA techniques that involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture: ☐ Yes ☐ No
   b. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxin molecules lethal for vertebrates at an LD50<100 ng/kg body weight: ☐ Yes ☐ No
   c. Provide a brief description of the recombinant constructs and any associated expression control of elements, including what the recombinant DNA encodes for, if known:

   d. Give an estimate of range of length of recombinant DNA to be used:

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **SMALL ANIMALS**

1. List species of small animals that will be used: _____

2. Describe route of infection:

3. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No
If yes, describe method: _____

4. The facility requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this facility? ☐ Yes ☐ No
If yes, the proposed work with Select Agents has been approved by the IACUC: ☐Yes ☐ No

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **LARGE ANIMALS**

1. List species of large animals that will be used: _____
2. Describe route of infection:
3. Carcass of animals are disposed of to avoid their use as food for human beings or animals: ☐Yes ☐ No
4. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐Yes ☐ No
   If yes, give method: _____
5. Carcass of animals are disposed of on site: ☐ Yes ☐ No
6. The facility requires that in an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at his facility: ☐ Yes ☐ No
   If yes, the proposed work has been approved by the IACUC: ☐ Yes ☐ No

Optional - TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR

1. A Chemical hygiene plan is available for the facility using toxins: ☐ Yes ☐ No
2. Maximum quantity of each toxin under the control of the Principal Investigator at a give time:
3. Form of toxins used:
   a. The toxin is produced by live agent at the facility: ☐ Liquid ☐ Lyophilized
      If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____ ☐ Yes ☐ No
   b. Dilution procedures and other manipulations of the concentrated toxins are:
      Conducted in ☐ Fume hood ☐ Biosafety cabinet
      If a fume hood is used, certification of the hood is conducted:
      ☐ Annually ☐ Biannually ☐ Other (describe): _____
      Conducted with two knowledgeable people present: ☐ Yes ☐ No
4. A hazard sign on the door when toxins are present: ☐ Yes ☐ No
5. Floor plan(s) include:
   Sink location: ☐ Yes ☐ No
   Eyewash locations: ☐ Yes ☐ No
   Biosafety cabinet (BSC) locations: ☐ Yes ☐ No
   Fume hood locations: ☐ Yes ☐ No
   HVAC supply and exhaust locations: ☐ Yes ☐ No
   Freezer/refrigerator locations: ☐ Yes ☐ No
   Other large equipment locations (incubators, centrifuges, etc): ☐ Yes ☐ No
6. Plan provides a description of the HVAC system (check all that are appropriate):
   ☐ Single-pass ☐ Re-circulated ☐ Dedicated exhaust ☐ Shared exhaust
   ☐ Constant air volume ☐ Variable air volume ☐ Redundant exhaust fans ☐ Emergency power back-up
7. Plan provides information on the biosafety cabinets in use (attach additional sheets if needed):
   Class of cabinet:
   ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III
   Biosafety cabinet connection to the HVAC system:
   ☐ Hard duct ☐ Thimble ☐ Re-circulating
   Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain): _____
   Does user verify air flow during BSC use? ☐ Yes ☐ No

Section III – Entity Program (IBSP)

☐ Yes ☐ No	Entity Program documents IBC approvals which include Select Agent required information.
☐ Yes ☐ No	Entity documents registrations.
☐ Yes ☐ No	Entity documents (IBC) are current and up to date.
☐ Yes ☐ No	Entity documents changes to the registration and does not allow access until amendments have been approved.
☐ Yes ☐ No	Entity has a current Incident Response Plan
☐ Yes ☐ No	Entity emergency response drill and evaluation is documented annually
☐ Yes ☐ No	Entity Security Plan is reviewed and documented annually.
☐ Yes ☐ No	Entity documents annual inspections and follow up requirements

Section IV – Inspection Summary

1. As a result of the **Facility Assessment** of the *Laboratory Facilities (Secondary Barriers)*, the following was noted in respect of the interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination:

   a. Airlock
      i. Signs of damage to the ceiling around the light fixture and vent

   b. Corridor
      i. Ceiling and light fixture(s) have dropped
      ii. Seals around light fixtures and vents are broken
      iii. Two light are completely out
      iv. Coving needs to be sealed and chips in walls sealed

   c. Room
      i. Ceiling damaged around light fixtures and vents
      ii. Evidence that water was in light fixture(s)
      iii. Some bulbs are out in the light fixture(s)

   d. Room
      i. Damage to ceiling around vent(s) and light fixtures
      ii. Light fixtures have dropped
      iii. Two bulbs are out in one light fixture
      iv. There is rust damage to the light fixture

   e. Room
      i. Damage to ceiling around vent(s) and light fixtures
      ii. Light fixture has dropped

   f. Room
      i. Light is out and the plastic cover is warped
      ii. Ceiling is damaged
      iii. Coving around floor sink and some places on the walls is pulling away slightly

   g. Room
      i. Ceiling is damaged
      ii. Evidence that water was in light fixture(s)
      iii. Light fixture has dropped

   h. Room
      i. Ceiling is damaged
      ii. Evidence that water collected on top of BSC

   i. Room
      i. Evidence that water was in light fixture(s)
      ii. Seal around light and vent is broken
      iii. Electrical outlet is pulled away from wall (no longer sealed); this was not caused by the water leak, but from equipment hitting the outlet.

   j. Room
      i. Evidence that water was in light fixture(s)
      ii. Two bulbs are out in fixture
      iii. Ceiling is damaged

k. Room
   i. Ceiling is damaged around vents (paint is bubbling)
   ii. Evidence that water was in light fixture(s)

l. Room
   i. Coving is pulling away from walls and cabinets
   ii. Bottom of cabinets and drawers are damaged (wood has swelled)
   iii. Seals are broken around light fixtures
   iv. Light fixtures have dropped slightly

m. Room
   i. Evidence that water was in light fixture
   ii. Ceiling is damaged around light and around BSC vent duct
   iii. Rust on BSC and evidence that water collected on top of it

n. Other
   i. Ceiling inspected from interstitial space (as much as possible)
   ii. Water stains evident on much of the ceiling board and rust noted on top of light fixture(s)
   iii. Ceiling throughout the BL3 containment area appears weakened.

TEXAS A&M UNIVERSITY

VICE PRESIDENT FOR RESEARCH - OFFICE OF RESEARCH COMPLIANCE

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Institutional Biosafety Committee | Institutional Animal Care and Use Committee | Institutional Review Board

MEMORANDUM

TO: Dr. Melanie Ihrig, Director
Comparative Medicine Program (CMP)
MS 4473

FROM: Tiffany M. Agnew, Program Coordinator
Institutional Bio-Safety Program (IBSP)

DATE: March 6, 2007

REG.: Annual IBC Inspection of Select Agent Facilities- Building . . . . . Ihrig/Browder

At 1:00 pm (CST) on February 22, 2007, the following individuals completed the Annual IBC Inspection of the Select Agent Facilities- Building.

Dr. Thomas Ficht- IBC Member (Chair)
Dr. Vernon Tesh- IBC Member
Mr. Brent Mattox- IBC Member/BSO
Ms. Nancy Eaker- EHS
Ms. Tiffany Agnew- IBSP Coordinator

The aforementioned team utilized the combined checklist from Environmental Health and Safety and the Office of Research Compliance to complete the inspection of the facilities. The use of this combined checklist marks the combined inspection by both offices, to reduce duplicated efforts for identical information. In accordance with CFR 42 § 73.9, inspection of Select Agent Facilities at Texas A&M University were due to be conducted in January. However, due to inclement weather, the inspection of this facility was rescheduled to take place on March 6, 2007. This marked the first combined IACUC & IBC inspection of a facility.

During this inspection, the following deficiencies were noted by the inspection team:

1. As a result of the **Facility Assessment** of the *Laboratory Facilities (Secondary Barriers)*, the following was noted in respect of the interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination:
   a. Room
      i. Gap at the end of the light fixture that needs to be sealed
      ii. Opening in light fixture of NuAire BSC
   b. Room
      i. Gap around wall outlet needs to be sealed
      ii. Gaps around vent for light fixtures and electrical need to be sealed
2. As a result of the **Program Assessment** in regards to site specific *Security Plans*, the following was noted:
   a. There was not a Security Plan found in place in the facility for Dr. Ficht.
   b. There was a Security Plan found for a PI that is no longer at the University.
   c. The team was told that the SOPs were updated on an annual basis, but the records reflected February 2005 on "current" documents.

The IBC requests these deficiencies are rectified before: May 7, 2007. Before the next inspection of this facility, it must be documented that these deficiencies have been rectified. Upon receipt of this

correspondence, please provide written indication that you have indeed received this document, and that you agree to complete all necessary corrections.

If you have any additional questions or concerns, please feel free to contact our office.

cc: Dr. Thomas Ficht
Dr. James Samuel
Dr. David McMurray
Dr. Betsy Browder
Dr. Richard Ewing
SBAT files

IBC INSPECTION REPORT
BSL3/ABSL3 SBAT FACILITIES & Entity Program

Date: February 22, 2007
Principal Investigator/Lab Director: Dr. Melanie Ihrig / Dr. Betsy Browder
Location: Building Number - ___ Rooms (s) _____

Inspection Team:
Tom Ficht, Vernon Tesh,
Brent Mattox, Nancy Eaker,
Tiffany Agnew

Section I - Facility Assessment (PI)

A. Safety Equipment (Primary Barriers)

☑ Yes ☐ No — Protective laboratory clothing, such as solid-front or wrap-around gowns, scrub suits, or coveralls, are worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

☑ Yes ☐ No — Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

☑ Yes ☐ No — Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

☑ Yes ☐ No — All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

☑ Yes ☐ No — When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

☑ Yes ☐ No — Respiratory and face protection are used when in rooms containing infected animals.

B. Laboratory Facilities (Secondary Barriers)

☑ Yes ☐ No — The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

☑ Yes ☐ No — Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

☐ Yes ☑ No — The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant.

Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

☑ Yes ☐ No Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

☑ Yes ☐ No Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

☑ Yes ☐ No Windows in the laboratory are closed and sealed.

☑ Yes ☐ No A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

☑ Yes ☐ No Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

☑ Yes ☐ No A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.
*** Note: Adjustments have been made; testing expected by March 2, 2007.**

☑ Yes ☐ No HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

☑ Yes ☐ No 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

☑ Yes ☐ No Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

☑ Yes ☐ No An eyewash facility is readily available inside the laboratory.
*** Note: Eyewash stations found in Rooms** **A shower is also in Room**

☑ Yes ☐ No Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

☑ Yes ☐ No The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met

prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

- Floor plan(s) include:
  - Sink location
    ☐ Yes ☐ No
  - Eyewash locations
    ☐ Yes ☐ No
  - Biosafety cabinet (BSC) locations
    ☐ Yes ☐ No
  - Fume hood locations
    ☐ Yes ☐ No
  - HVAC supply and exhaust locations
    ☐ Yes ☐ No
  - Freezer/refrigerator locations
    ☐ Yes ☐ No
  - Other large equipment locations (incubators, centrifuges, etc)
    ☐ Yes ☐ No
- Provide a description of the HVAC system (check all that are appropriate):
  - ☐ Single-pass
  - ☐ Dedicated exhaust
  - ☐ Constant air volume
  - ☐ Redundant exhaust fans
  - ☐ Emergency power back-up
  - ☐ Re-circulated
  - ☐ Shared exhaust
  - ☐ Variable air volume
- Provide information on the biosafety cabinets in use (attach additional sheets if needed):
  - Class of cabinet:
  - ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3)
  - ☐ II, B1 ☐ II, B2 ☐ III
  - Biosafety cabinet connection to the HVAC system:
  - ☑ Hard duct **(2)** ☐ Thimble ☑ Re-circulating
  - Define certification period: **Jan/Feb or July**
  - ☑ Annual ☐ Biannual ☐ Other (explain): _____
  - Does user verify air flow during BSC use?
    ☐ Yes ☐ No
  - If floor drains are provided, the traps are always filled with an appropriate disinfectant:
    ☐ Yes ☐ No

☑ Yes ☐ No Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

C. Standard Microbiological Practices

☑ Yes ☐ No Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

☑ Yes ☐ No Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

☑ Yes ☐ No Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

☑ Yes ☐ No Mechanical pipetting devices are used; mouth pipetting is prohibited.

☑ Yes ☐ No Policies for the safe handling of sharps are instituted.

☑ Yes ☐ No All procedures are performed carefully to minimize the creation of aerosols.

☑ Yes ☐ No Work surfaces are decontaminated at least once a day and after any spill of viable material.

☑ Yes ☐ No All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

☑ Yes ☐ No Persons under 16 years of age are not allowed to enter a BL3 laboratory.

☑ Yes ☐ No If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

☑ Yes ☐ No An insect and rodent control program is in effect.

D: Special Practices

☑ Yes ☐ No Laboratory doors are kept closed when experiments are in progress.

☑ Yes ☐ No The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

☑ Yes ☐ No The laboratory director establishes 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.

☑ Yes ☐ No When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

☑ Yes ☐ No Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled.

☑ Yes ☐ No Baseline serum samples are collected as appropriate and stored for all laboratories and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

☑ Yes ☐ No A Biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and Biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

☑ Yes ☐ No Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure

evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

☑ Yes ☐ No

The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

☑ Yes ☐ No

A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

- Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic ware should be substituted for glassware whenever possible.
- 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
- Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
- Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

☑ Yes ☐ No

All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

☑ Yes ☐ No

Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

- Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
- Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

☑ Yes ☐ No

Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

☑ Yes ☐ No

All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

☑ Yes ☐ No

Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained. Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are

immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

☑ Yes ☐ No — Animals and plants not related to the work being conducted are not permitted in the laboratory.

☑ Yes ☐ No — Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

Section II - Program Assessment (PI and/or Institutional BioSafety Program- IBSP)

☑ Yes ☐ No 1. An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with Select Agents at this facility: ***approved work for PI Ficht and Samuel***

If yes: IBC approved the work proposed for this facility on: _____ (date).

☑ Yes ☐ No 2. **Training**: Site specific and safety training is provided to individuals with access to areas where Select Agents are handled or stored:

a. Is provided prior to individuals beginning to work with Select Agents: ☑ Yes ☐ No
b. Is provided: ☑ Annually ☐ Biannually ☐ Other (specify frequency):
c. Written records of individuals are kept: ☑ Yes ☐ No
d. Personnel demonstrate proficiency in laboratory procedures prior to working with Select Agents: ☑ Yes ☐ No
e. Unannounced visits by EH&S and follow up by supervisory personnel: ☐ Yes ☑ No

3. Provide a brief explanation of the system in place to detect loss or theft of select agent(s): ***Located within the Incident Response Plan (Emergency Plans) – Feb. 2005***

4. **Inventory**: Individual responsible for inventory of select agent(s): ***Daily care-takers***
   a. How often is the inventory record reconciled? ***Monthly***
   b. How is access to the inventory log limited? ***These are stored within the locked SBAT rooms in BSL3 area; card access only.***
   c. Inventory tracking includes the following information (list): ***Wellness Counts (health checks completed; numbers recorded on cage cards. Daily animal census conducted for SBAT animals.***

5. **Security**: There is a site-specific Security Plan for this laboratory: ☐ Yes ☑ No
   a. Building with Select Agent has self-closing doors: ☑ Yes ☐ No
   b. Means to limit access to buildings with laboratories with Select Agent:
      Guard station at the facility entrance: ☐ Yes ☑ No
      Card access system or locks: ☑ Yes ☐ No
      Security alarm system in the laboratory building: ☑ Yes ☐ No
      Other (describe): ***There is a security alarm for the SBAT suite. In addition, there is a pressure security alarm- red ball air flow indicators***
   f. Means to limit access to laboratories with Select Agent once inside the building:
      Door to laboratory is locked: ☑ Yes ☐ No
      Card access system or locks: ☑ Yes ☐ No
      Other (describe):
   g. Means to limit access to select agents once inside the laboratory:
      Locked incubators, refrigerators, freezers, etc.: ☑ Yes ☐ No
      Security alarm system that directly monitors the laboratory: ☐ Yes ☑ No
      Other (describe): ***Although no agents are stored in the facility, there are locked freezers in the facility.***
   h. Means to limit access to select agents in storage: ***N/A*** (see previous question)
      Storage area door locked: ☐ Yes ☐ No
      Lock boxes: ☐ Yes ☐ No
      Security alarm system that directly monitors the laboratory: ☐ Yes ☐ No
      Other (describe): _____
   i. Means to monitor unauthorized entry into the laboratory where select agents are used or stored: ***N/A*** (see question "g")
      Electronic logs of card access system entries are reviewed for unusual activity: ☐ Yes ☐ No
      Manual sign in and out logs are kept and monitored: ☐ Yes ☐ No
      Video camera surveillance: ☐ Yes ☐ No
      Other (describe): _____

j. The laboratory is secured when no one is present during regular working hours: ☑ Yes ☐ No

k. Number of people with access: ***Those whom are listed on the 4B table for the facility.***

l. Individuals not directly involved in research activities have access to Select Agent: ☐ Yes ☑ No
If yes, please explain: _____

m. Non-laboratory personnel (visitors, including janitorial and facility maintenance personnel) have access to the laboratory with select agents: ☐ Yes ☑ No
No access for janitorial staff; all janitorial work completed by DOJ approved personnel.
If yes, are they allowed into the laboratory unescorted? ☐ Yes ☐ No

6. **Decontamination**: All cultures, stock and other regulated wastes are decontaminated before disposal by an approved decontamination method: ☑ Yes ☐ No
If yes, describe method: ***Autoclave***

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **RECOMBINANT DNA**

☑ Yes ☐ No 1. The facility has an Institutional Biosafety Committee that has approved work with recombinant DNA or has approval pending:

☑ Yes ☐ No 2. The Biosafety level listed in the *Application for IBC Permit* for this laboratory meets NIH Guidelines:

3. Will you be possessing, using, or transferring the following:
   a. Select Agent nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that are capable of infection and/or replication: ☐ Yes ☐ No
   b. Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids are in a vector or host chromosome and/or are expressed *in vivo* or *in vitro:* ☐ Yes ☐ No
   c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. ☐ Yes ☐ No

4. Are you intending to conduct the following experiments:
   a. Experiments utilizing recombinant DNA techniques that involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture: ☐ Yes ☐ No
   b. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxin molecules lethal for vertebrates at an LD50<100 ng/kg body weight: ☐ Yes ☐ No
   c. Provide a brief description of the recombinant constructs and any associated expression control of elements, including what the recombinant DNA encodes for, if known:

   d. Give an estimate of range of length of recombinant DNA to be used:

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **SMALL ANIMALS**

1. List species of small animals that will be used: ***Guinea pigs, mice, and rats***

2. Describe route of infection: ***Aerosol***

3. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☑ Yes ☐ No
If yes, describe method: ***Autoclave***

4. The facility requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this facility? ☑ Yes ☐ No

If yes, the proposed work with Select Agents has been approved by the IBC: ☑Yes ☐ No

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **LARGE ANIMALS**

1. List species of large animals that will be used: _____
2. Describe route of infection:
3. Carcass of animals are disposed of to avoid their use as food for human beings or animals: ☐Yes ☐ No
4. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐Yes ☐ No
   If yes, give method: _____
5. Carcass of animals are disposed of on site: ☐ Yes ☐ No
6. The facility requires that in an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at his facility: ☐ Yes ☐ No
   If yes, the proposed work has been approved by the IACUC: ☐ Yes ☐ No

Optional - TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR

1. A Chemical hygiene plan is available for the facility using toxins: ☐ Yes ☐ No
2. Maximum quantity of each toxin under the control of the Principal Investigator at a give time:
3. Form of toxins used: ☐ Liquid ☐ Lyophilized
   a. The toxin is produced by live agent at the facility: ☐ Yes ☐ No
      If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____
   b. Dilution procedures and other manipulations of the concentrated toxins are:
      Conducted in ☐ Fume hood ☐ Biosafety cabinet
      If a fume hood is used, certification of the hood is conducted:
      ☐ Annually ☐ Biannually ☐ Other (describe): _____
      Conducted with two knowledgeable people present: ☐ Yes ☐ No
4. A hazard sign on the door when toxins are present: ☐ Yes ☐ No
5. Floor plan(s) include:
   Sink location: ☐ Yes ☐ No
   Eyewash locations: ☐ Yes ☐ No
   Biosafety cabinet (BSC) locations: ☐ Yes ☐ No
   Fume hood locations: ☐ Yes ☐ No
   HVAC supply and exhaust locations: ☐ Yes ☐ No
   Freezer/refrigerator locations: ☐ Yes ☐ No
   Other large equipment locations (incubators, centrifuges, etc): ☐ Yes ☐ No
6. Plan provides a description of the HVAC system (check all that are appropriate):
   ☐ Single-pass ☐ Re-circulated ☐ Dedicated exhaust ☐ Shared exhaust
   ☐ Constant air volume ☐ Variable air volume ☐ Redundant exhaust fans ☐ Emergency power back-up
7. Plan provides information on the biosafety cabinets in use (attach additional sheets if needed):
   Class of cabinet:
   ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III
   Biosafety cabinet connection to the HVAC system:
   ☐ Hard duct ☐ Thimble ☐ Re-circulating
   Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain): _____
   Does user verify air flow during BSC use? ☐ Yes ☐ No

Section III – Entity Program (IBSP)

☐ Yes ☐ No	Entity Program documents IBC approvals which include Select Agent required information.
☐ Yes ☐ No	Entity documents registrations.
☐ Yes ☐ No	Entity documents (IBC) are current and up to date.
☐ Yes ☐ No	Entity documents changes to the registration and does not allow access until amendments have been approved.
☐ Yes ☐ No	Entity has a current Incident Response Plan
☐ Yes ☐ No	Entity emergency response drill and evaluation is documented annually
☐ Yes ☐ No	Entity Security Plan is reviewed and documented annually.
☐ Yes ☐ No	Entity documents annual inspections and follow up requirements

Section IV – Inspection Summary

1. As a result of the **Facility Assessment** of the *Laboratory Facilities (Secondary Barriers)*, the following was noted in respect of the interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination:

    a. Room
        i. Gap at the end of the light fixture that needs to be sealed
        ii. Opening in light fixture of NuAire BSC
    b. Room
        i. Gap around wall outlet needs to be sealed
        ii. Gaps around vent for light fixtures and electrical need to be sealed

7/19/07 Walk-through - CMP

✓ 5) •

- Seal coving in corner to right & behind BSC

4) • Head to Tyrex not worn

6) • Corridor
- Caulk on coving by doors to

7) • ~~Clean~~ Rm.
- Paint cracked in corner around support column Where wall & ceiling meet.

8) Rm - Seal coving around floor sink & back wall
- Paint in corner to right of autoclave needed.

9) Rm
- Seal/Paint around vents
- 2-3 paint chips on wall - need to paint

10) Rm
- Paint needed around middle light fixture

RM KID 12) Chipped paint on wall to left of sink & on. hood

11) Rm
- Caulk needed under sink (coving) 2 corner of vent

13) Rm
- seal around vents & chips in paint on cols around door

INSPECTION NOTES
CMP Facility BL3 Suite

Inspected 07/13/07 by Nancy L. Eaker

The following items were noted during an inspection of the BL3 Suite in the Comparison Medicine Program Building # n Friday, July 13, 2007.

1) Throughout the suite: Small gaps around the vents should be sealed.

2) Throughout the suite: Coving should be checked for gaps and sealed where necessary. In some locations (such as Room it was pulling away from the wall. Pieces of coving were missing in the corridor near the doors.

3) Some BSCs in the suite are due for certification. This is scheduled for the week of July 23rd.

4) Noted one person working in the BL3 who was not wearing the hood of the Tyvex suit, just the hair bonnet and PAPR. Also, the person's beard was sticking out of the PAPR on the sides.

5) Room and
- Water was seeping under the back wall of the lab.
- One outlet cover over the bench was loose. The cover should be tightened and the seal around it verified.
- Damaged cabinets have been removed. Remaining drawers, which are sitting on the bench tops, still need to be decontaminated and removed from the suite.
- The floor and the wall that were exposed when the cabinets were removed have been painted, and the floor sealed with metal strips and caulk. Only one section remained to be sealed. However, the paint is coming off the wall where it is wet and the water is seeping into the lab. Also, a small section of paint had peeled up off of the floor. These will need to be repainted.
- Upper cabinets need to be sealed at the wall.

6) Corridor:
- Lights have been repaired.
- Air flow direction has been verified: All labs and animal rooms are negative to the corridor.
- Noted chipped paint on walls around doors, on door frames, and around bumper rail.

7) Rooms
- Small holes noted in wall need to be sealed.
- Paint is cracked in corner at the wall and the ceiling around the support column and vent and also behind the BSC.

- A screw is missing from the outlet cover and a small gap was noted around it.
- Bracket needed to remount the fire extinguisher. Request has been made to Dale McCord for the bracket.
- Laminate on the top of the upper cabinets is pulling away and needs to be sealed.
- Door sweep is missing from door.

8) Room ' utoclave Room):
- Ceiling is in much better condition, but there are still small areas that need paint. Also, where the walls and ceiling meet needs to be sealed in placed.
- The inside of the door to this room is beat up, so that the raw wood is exposed in places.

9) Room
- One light bulb is out.
- Paint around the recently repaired outlet to re-seal it.
- The door to this room doesn't shut completely on its own. Was told that the closer is as tight as it can be.

10) Room
- Door sweep is missing from door.
- Vent was fixed but has dropped again, breaking the seal
- Sink has pulled away from the wall slightly and should be resealed.
- Verify that there are no holes or chips in the paint on the wall under the sink and around areas of the wall that were repaired.

11) Room
- The door to this room doesn't shut completely on its own. Was told that the closer is as tight as it can be.

12) Room
- Sink has pulled away from the wall slightly and should be resealed.
- Door sweep is missing from door.

13) Room '
- Sink has pulled away from the wall slightly and should be resealed.
- Crack in paint noted on ceiling around support column.

14) Room '
- Noted chipped paint on wall near sink.

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator
Lab Contact Person Melanie Ihrig (CMP Director)
Department CMP
Office Phone Number
Lab Phone Number
Lab Location - Bldg Rooms: , Airlock, corridor

Biological agents used:
__ Recombinant DNA
__ Human pathogens - list:

__ Animal pathogens- list:

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: __ BL2 X BL3

Results: X Meets criteria at appropriate biosafety level
__ Does not meet criteria

Comments: Facilities Inspection Only

Date of Inspection: 4/16/07

Environmental Health & Safety Inspector: MBaker

NIH BIOSAFETY LEVEL 3 CRITERIA

A. Standard Microbiological Practices

____ 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

____ 2. Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

____ 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

____ 4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

____ 5. Policies for the safe handling of sharps are instituted.

____ 6. All procedures are performed carefully to minimize the creation of aerosols.

____ 7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

____ 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

____ 9. Persons under 16 years of age are not allowed to enter a BL3 laboratory.

____10. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

____11. An insect and rodent control program is in effect.

B. Special Practices

____ 1. Laboratory doors are kept closed when experiments are in progress.

____ 2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

____ 3. The laboratory director establishes 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.

____ 4. When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

____ 5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for

the agent being handled.

____ 6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

____ 7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

____ 8. Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

____ 9. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

___10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.

b. 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

c. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.

d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

___11. All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

___12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.

b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

___13. Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

___14. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

___ 15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

___ 16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

___ 17 Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

C. Safety Equipment (Primary Barriers)

___1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

___ 2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

___ 3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

___ 4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

___ 5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

___ 6. Respiratory and face protection are used when in rooms containing infected animals.

D. Laboratory Facilities (Secondary Barriers)

✓ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

✓ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

N/A 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are contructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination. See attached notes

✓ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment. Note: cabinets in need to be sealed

✓ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

✓ 6. Windows in the laboratory are closed and sealed.

✓ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the

laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

13. An eyewash facility is readily available inside the laboratory.

14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

See attached notes corridor

rooms under neg pressure (air flows from corridor to rooms).

Damage Observed in the BL3 Containment Area of the CMP Facilities (Bldg. #

Airlock – Signs of damage to the ceiling around the light fixture and vent.

Corridor – Ceiling and light fixture(s) have dropped. Seals around light fixtures and vents are broken. Two lights are completely out. Also, coving needs to be sealed & chips in walls sealed!

Room ___ Ceiling damaged around light fixtures and vents. Evidence that water was in light fixture(s). Some bulbs are out in the light fixture(s).

Room ___ - Damage to ceiling around vent(s) and light fixtures. Light fixture has dropped. Two bulbs are out in one light fixture. There is rust damage to the light fixture.

Room ___ Damage to ceiling around vent(s) and light fixtures. Light fixture has dropped.

Room ___ - Light is out and the plastic cover is warped. Ceiling is damaged. Coving around floor sink and some places on the walls is pulling away slightly.

Room ___ - Ceiling is damaged. Evidence that water was in light fixture(s). Light fixture has dropped.

Room ___ – Ceiling is damaged. Evidence that water collected on top of BSC.

Room ___ - Evidence that water was in light fixture(s). Seal around light and vent is broken. Electrical outlet is pulled away from wall (no longer sealed); this was not caused by the water leak, but from equipment hitting the outlet.

Room ___ – Evidence that water was in light fixture(s). Two bulbs are out in fixture. Ceiling is damaged.

Room ___ - Ceiling is damaged around vents (paint is bubbling); Evidence that water was in light fixture(s).

Room ___ Coving is pulling away from walls and cabinets. Bottom of cabinets and drawers are damaged (wood has swelled). Seals are broken around light fixtures. Light fixtures have dropped slightly.

Room ___ – Evidence that water was in light fixture. Ceiling is damaged around light and around BSC vent duct. Rust on BSC and evidence that water collected on top of it.

Other – Ceiling inspected from interstitial space (as much as possible). Water stains evident on much of the ceiling board and rust noted on top of light fixture(s). Ceiling throughout the BL3 containment area appears weakened.

Inspected by: Nancy L. Eaker **Date:** April 16, 2007

TEXAS A&M UNIVERSITY

ANIMAL FACILITY INSPECTION / CERTIFICATION

Principal Investigator: various or Melanie Ihrig (CMP Director)
Lab Contact Person:
Department: CMP
Office Phone Number
Lab Phone Number
Lab Location – Bldg: _____ Rooms: _____

Biological agents used:
__ Recombinant DNA
__ Human pathogens - list:

__ Animal pathogens- list:

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: __ ABL2 X ABL3

Results: ___ Meets criteria at appropriate biosafety level
X Does not meet criteria

Comments: Facilities Inspection Only

Date of Inspection: 4/16/07

Environmental Health & Safety Inspector: MEaker

ANIMAL BIOSAFETY LEVEL 3

A. Standard Practices

___ 1. Aside from the standard policies, procedures, and protocols for emergency situations established by the facility director, appropriate special policies and procedures should be developed as needed and approved by the Institutional Animal Care and Use Committee (IACUC) and the Institutional Biosafety Committee (IBC).

___ 2. The laboratory or animal facility director limits access to the animal room to the fewest number of individuals possible. Personnel who must enter the room for program or service purposes when work is in progress are advised of the potential hazard.

___ 3. An appropriate medical surveillance program is in place. All personnel receive appropriate immunizations or tests for the agents handled or potentially present (e.g., hepatitis B vaccine, TB skin testing). When appropriate, a serum surveillance system should be implemented. In general, persons who may be at increased risk of acquiring infection, or for whom infection might have serious consequences, are not allowed in the animal facility unless special procedures can eliminate the extra risk. Assessment should be made by the occupational health physician.

___ 4. A biosafety manual is prepared or adopted. Personnel are advised of special hazards, and are required to read and to follow instructions on practices and procedures.

___ 5. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use should be done only in designated areas and are not permitted in animal or procedure rooms.

___ 6. All procedures are carefully performed to minimize the creation of aerosols or splatters.

___ 7. Equipment and work surfaces in the room are routinely decontaminated with an effective disinfectant after work with the infectious agent, and especially after overt spills, splashes, or other contamination by infectious materials.

___ 8. All wastes from the animal room (including animal tissues, carcasses, contaminated bedding, unused feed, sharps, and other refuse animal tissues) are transported from the animal room in leak-proof, covered containers for appropriate disposal in compliance with applicable institutional or local requirements. Incineration is recommended. The outer surface of the containers is disinfected prior to moving the material.

___ 9. Policies for the safe handling of sharps are instituted.
   a. Needles and syringes or other sharp instruments are restricted in the animal facility for use only when there is no alternative, such as for parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.
   b. Syringes that re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
   c. Plasticware should be substituted for glassware whenever possible.

___ 10. Personnel wash their hands after handling cultures and animals, after removing gloves, and before leaving the animal facility.

___ 11. A biohazard sign must be posted on the entrance to the animal room whenever infectious agents are present. The hazard warning sign identifies the infectious agent(s) in use, lists the name and telephone number of the responsible person(s), and indicates the special

requirements for entering the animal room (e.g., the need for immunizations and respirators).

___ 12. All infectious samples are collected, labeled, transported, and processed in a manner that contains and prevents transmission of the agent(s).

___13. Laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. As necessary, personnel receive updates and/or additional training on procedural or policy changes. Records of all training provided are maintained.

___14. An insect and rodent control program is in effect.

B. Special Practices

___1. Cages are autoclaved or thoroughly decontaminated before bedding is removed and before they are cleaned and washed. Equipment must be decontaminated according to any local, state, or federal regulations before being packaged for transport or removal from the facility for repair or maintenance.

___ 2. A spill procedure is developed and posted. Only personnel properly trained and equipped to work with infectious materials are to clean up spills. Spills and accidents that result in overt exposures to infectious materials must be immediately reported to the facility director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

___ 3. All wastes from the animal room must be autoclaved prior to incineration or other appropriate terminal treatment.

___ 4. Materials not related to the experiment (e.g., plants, animals) are not permitted in the animal room.

C. Safety Equipment (Primary Barriers)

___ 1. Uniforms or scrub suits are worn by personnel entering the animal room. Wrap-around or solid-front gowns or uniforms should be worn over this clothing. Front-button laboratory coats are unsuitable. The gown must be removed and left in the animal room. Before leaving the animal facility, scrub suits and uniforms are removed and appropriately contained and decontaminated prior to laundering or disposal.

___ 2. Personal protective equipment used is based on risk assessment determinations.
   a. Personal protective equipment is used for all activities involving manipulations of infectious material or infected animals.
   b. Personnel wear gloves when handling infected animals. Gloves are removed aseptically and autoclaved with other animal room wastes before disposal.
   c. Appropriate face/eye and respiratory protection (e.g., respirators and face shields) is worn by all personnel entering animal rooms.
   d. Boots, shoe covers, or other protective footwear, and disinfectant foot baths are available and used where indicated.

___ 3. The risk of infectious aerosols from infected animals or their bedding also can be reduced if animals are housed in containment caging systems, such as open cages placed in inward flow ventilated enclosures (e.g., laminar flow cabinets), solid wall and bottom cages covered with filter bonnets, or other equivalent primary containment systems.

___ 4. Biological safety cabinets and other physical containment devices are used whenever conducting procedures with a potential for creating aerosols. These include necropsy of infected animals, harvesting of tissues or fluids from infected animals or eggs, or intranasal inoculation of animals. At BSL-3, all work should be done in a primary barrier; otherwise respirators should be worn by personnel in the room.

D. Facilities (Secondary Barriers)

✓ 1. The animal facility is separated from areas that are open to unrestricted personnel traffic within the building.

✓ 2. Access to the facility is limited by a self-closing and self-locking door. This exterior entry door may be controlled by a key lock, card key, or proximity reader. Entry into the animal room is via a double-door entry which includes a change room and shower(s). An additional double-door access (air-lock) or double-doored autoclave may be provided for movement of supplies and wastes into and out of the facility, respectively. Doors to animal rooms open inward and are self-closing. Doors to cubicles inside an animal room may open outward or slide horizontally or vertically.

X 3. The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (walls, floors, and ceilings) are water-resistant. Penetrations in floor, walls and ceiling surfaces are sealed and openings around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination. See Notes Attached

✓ 4. A hands-free or automatically operated hand washing sink is provided in each animal room near the exit door. The sink trap is filled with an appropriate disinfectant after each use.

✓ 5. Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize horizontal surface areas.

✓ 6. Any windows must be resistant to breakage. Where possible, windows should be sealed. If the animal facility has windows that open, they are fitted with fly screens.

✓ 7. If floor drains are provided, they are always filled with an appropriate disinfectant.

✓ 8. Ventilation should be provided in accordance with criteria from the *Guide for Care and Use of Laboratory Animals*, latest edition. 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 recirculated to any other area of the building. Filtration and other treatments of the exhaust air may not be required, but should be considered based on site requirements, and specific agent manipulations and use conditions. The exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Personnel must verify that the direction of the airflow (into the animal areas) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the animal room entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the animal spaces. Audible alarms should be considered to notify personnel of HVAC system failure.

✓ 9. The HEPA filtered exhaust air from a Class II biological safety cabinet can be recirculated into the animal room if the cabinet is tested and certified at least annually. When exhaust air from Class II safety cabinets is to be discharged directly to the outside through the

building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used, they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

✓ 10. Cages are washed in a cage washer. The mechanical cage washer has a final rinse temperature of at least 180 ° F.

✓ 11. An autoclave is available which is convenient to the animal rooms where the biohazard is contained. The autoclave is utilized to decontaminate infectious waste before moving it to other areas of the facility.

✓ 12. If vacuum service (i.e., central or local) is provided, each service connection should be fitted with liquid disinfectant traps and an in-line HEPA filter, placed as near as practicable to each use point or service cock. Filters are installed to permit in-place decontamination and replacement.

X 13. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision. See Notes Attached (some lights out)

? 14. The completed Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified at least annually against these procedures as modified by operational experience.

✓ 15. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services, and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment of the site conditions, or other applicable federal, state, or local regulations.

→ Rooms are under negative pressure (air flows from corridor to rooms).

Damage Observed in the BL3 Containment Area of the CMP Facilities (Bldg.

Airlock – Signs of damage to the ceiling around the light fixture and vent.

Corridor – Ceiling and light fixture(s) have dropped. Seals around light fixtures and vents are broken. Two lights are completely out.

Room ____ · Ceiling damaged around light fixtures and vents. Evidence that water was in light fixture(s). Some bulbs are out in the light fixture(s).

Room Damage to ceiling around vent(s) and light fixtures. Light fixture has dropped. Two bulbs are out in one light fixture. There is rust damage to the light fixture.

Room Damage to ceiling around vent(s) and light fixtures. Light fixture has dropped.

Room ' Light is out and the plastic cover is warped. Ceiling is damaged. Coving around floor sink and some places on the walls is pulling away slightly.

Room Ceiling is damaged. Evidence that water was in light fixture(s). Light fixture has dropped.

Room ' – Ceiling is damaged. Evidence that water collected on top of BSC.

Room Evidence that water was in light fixture(s). Seal around light and vent is broken. Electrical outlet is pulled away from wall (no longer sealed); this was not caused by the water leak, but from equipment hitting the outlet.

Room Evidence that water was in light fixture(s). Two bulbs are out in fixture. Ceiling is damaged.

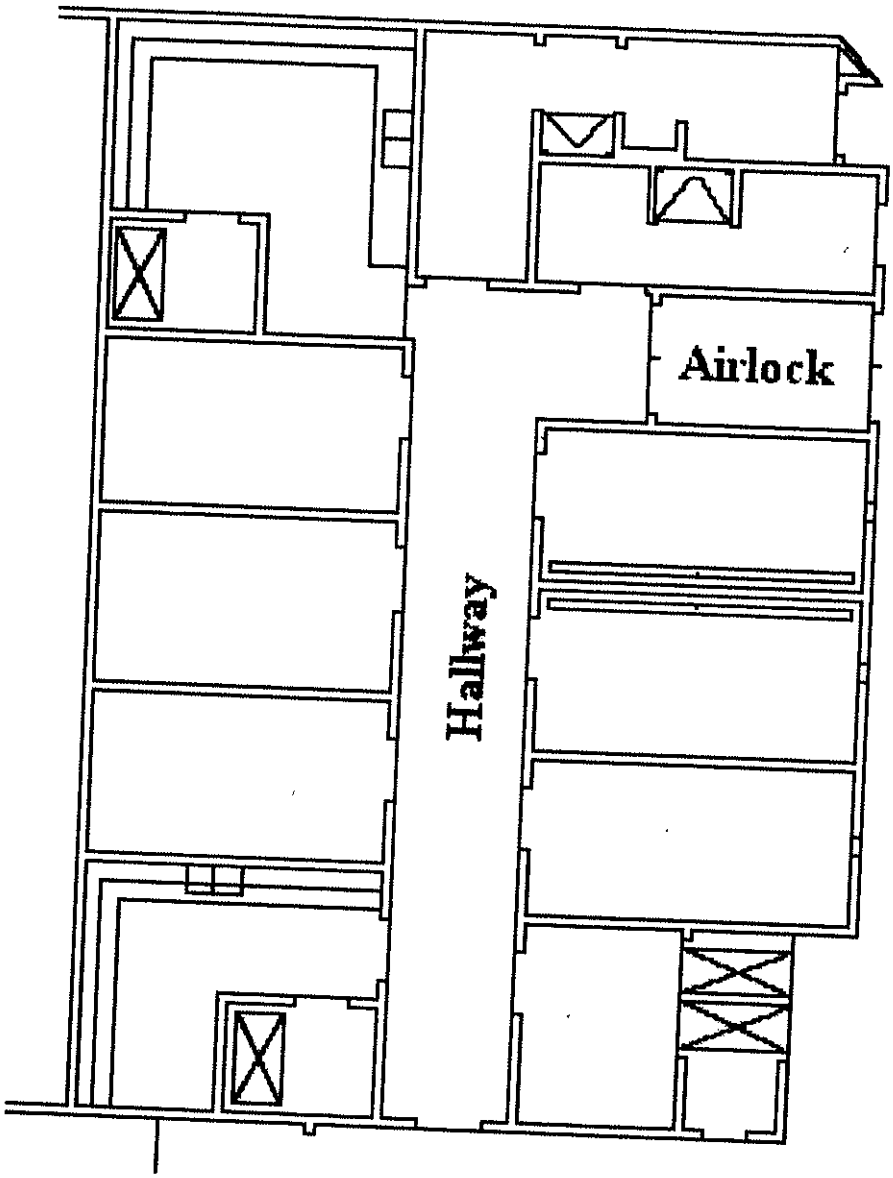
Room Ceiling is damaged around vents (paint is bubbling); Evidence that water was in light fixture(s).

Room Coving is pulling away from walls and cabinets. Bottom of cabinets and drawers are damaged (wood has swelled). Seals are broken around light fixtures. Light fixtures have dropped slightly.

Room – Evidence that water was in light fixture. Ceiling is damaged around light and around BSC vent duct. Rust on BSC and evidence that water collected on top of it.

Other – Ceiling inspected from interstitial space (as much as possible). Water stains evident on much of the ceiling board and rust noted on top of light fixture(s). Ceiling throughout the BL3 containment area appears weakened.

Inspected by: Nancy L. Eaker **Date:** April 16, 2007


Airlock
Hallway

TEXAS A&M UNIVERSITY
Environmental Health & Safety Department

To: David Carlton
Facilities Coordinator
Comparative Medicine Program
4473 TAMU

From: Nancy L. Eaker
Environmental Safety Supervisor
Environmental Health & Safety
4472 TAMU

Nancy L. Eaker 4/24/07

Date: April 24, 2007

Subject: Air Testing for Mold: Building

Per your request, an assessment of the interstitial space above the BL3 containment area in the Program Building (was conducted. While there is evidence of water damage to the ceiling of the BL3 containment area and surrounding areas, no visible mold growth was observed. An air sample was collected in the interstitial space above the BL3 airlock, and a control sample was taken in the interstitial space above the corridor outside room Results suggest that mold is not a problem, with overall levels being low and no unusual organisms detected. At the time sampling was conducted, no remediation was necessary.

Industrial Hygiene utilizes a variety of parameters when determining satisfactory counts, including outdoor air and type of organisms present. If levels of any one organism exceed 500 cfu/m^3, complaints may be related to the organism in the highest concentration. If the organisms do not match those in outdoor air or exceed outdoor air levels, disinfection is normally recommended. If total counts exceed 1500 cfu/m^3, cleaning may be advised, although that depends on a variety of environmental factors, including outdoor air. In rare instances, an individual may be allergic to a specific organism as determined by a physician, which will change recommendations.

If you have any questions concerning this report, please don't hesitate to contact me at 845-5332. Thank you for allowing us to be of service.

cc: Brent Mattox, EHS

Nancy L. Eaker, Mold Assessment Consultant
TDSHS License # MAC0377, Exp. 03/01/2009
4472 TAMU • College Station, Texas 77843-4472 • (979) 845-2132 • FAX: (979) 845-1348

J3 Resources, Inc.
5400 Mitchelldale, A9, Houston, Texas 77092
Phone: (713)290-0221 Fax: (713)290-0248
www.j3resources.com

IAQ ANALYSIS - TOTAL AIRBORNE FUNGAL SPORES

Attn: Brent Mattox
Texas A&M University - EHS
4472 TAMU
College Station, Texas 77843-4472

J3 Order #: JH0716701
Project: Wisenbaker - 04/18/07
Purchase Order #: ASB2003
Report Date: April 20, 2007

SAMPLE DATA AND FINAL RESULTS			
Sample Number	IHBL-041807-01	IHBL-041807-02	IHBL-041807-03
Location			Outside
Volume (liters)	150	150	150
Debris Rank/Comments	Medium	Medium	Medium
Sample Medium	Air-O-Cell	Air-O-Cell	Air-O-Cell
Limit of Detection (Part./Meter^3)	33	33	33
Total Fungal Count (Particles/Meter^3)	133	133	2900

INDIVIDUAL FUNGAL SPORE DETAIL (Particles/Meter^3)						
	Spore Count	%	Spore Count	%	Spore Count	%
Alternaria	33	25.0	33	25.0	33	1.1
Ascospores			33	25.0	733	25.3
Arthrinium						
Basidiospores					533	18.4
Botrytis						
Cercospora						
Chaetomium						
Cladosporium	33	25.0	33	25.0	1533	52.9
Curvularia						
Drechslera-like						
Epicoccum	33	25.0	33	25.0		
Erysiphe/Oidium						
Fusarium						
Nigrospora						
Penicillium/Aspergillus						
Perconia						
Peronospora						
Pithomyces/Ulocladium						
Rust/Smuts/Myxomycetes	33	25.0				
Stachybotrys						
Torula					67	2.3
Unidentified Spores						
Totals	133	100.0	133	100.0	2900	100.0

POLLEN GRAIN & MISCELLANEOUS PARTICLES DETAIL (Particles/Meter^3)			
Hyphae Fragments			
Grass/Shrub/Tree Pollen	33	67	267
Misc. Fibers/Insect Parts			
Total Pollen/Misc. Count (Particles/Meter^3)	33	67	267

Analyst

Final Review

This laboratory is not responsible for total counts in particles/M^3, which are dependent on volume collected by non-laboratory personnel. J3 Resources, Inc. currently scans 100% of the trace at 400X magnification and counts a minimum of 20% of the trace at 1,000X magnification. There is no current data supporting a critical or threshold exposure limit to fungal aeroallergens. To date, occupational health related organizations, such as OSHA and NIOSH have not established Permissible Exposure Limits or Recommended Action Levels, or other limit values for aeroallergens. LOD = Limit of Detection.

* PenAsp references Penicillium/Aspergillus-like fungal spores; which are spherical, morphologically indistinguishable 2-6µm spores.

TDSHS Mold License LAB0132

J3 Resources, Inc.
5400 Mitchelldale, A9, Houston, Texas 77092
Phone: (713)290-0221 Fax: (713)290-0248
www.J3resources.com

IAQ ANALYSIS - TOTAL AIRBORNE FUNGAL SPORES

Attn: Brent Mattox
Texas A&M University - EHS
4472 TAMU
College Station, Texas 77843-4472

J3 Order #: JH0716702
Project: (- 04/18/07
Purchase Order #: /
Report Date: April 20, 2007

SAMPLE DATA AND FINAL RESULTS						
Sample Number	IHNE-041807-01		IHNE-041807-02			
Location	Airlock		Outside Rm			
Volume (liters)	150		150			
Debris Rank/Comments	Low		Medium			
Sample Medium	Air-O-Cell		Air-O-Cell			
Limit of Detection (Part./Meter^3)	33		33			
Total Fungal Count (Particles/Meter^3)	600		367			
INDIVIDUAL FUNGAL SPORE DETAIL (Particles/Meter^3)						
	Spore Count	%	Spore Count	%	Spore Count	%
Alternaria						
Ascospores	133	22.2	67	18.2		
Arthrinium						
Basidiospores	100	16.7	67	18.2		
Botrytis						
Cercospora						
Chaetomium						
Cladosporium	300	50.0	233	63.6		
Curvularia						
Drechslera-like						
Epicoccum						
Erysiphe/Oidium						
Fusarium						
Nigrospora						
Penicillium/Aspergillus						
Perconia						
Peronospora						
Pithomyces/Ulocladium						
Rust/Smuts/Myxomycetes	67	11.1				
Stachybotrys						
Torula						
Unidentified Spores						
Totals	600	100.0	367	100.0		
POLLEN GRAIN & MISCELLANEOUS PARTICLES DETAIL (Particles/Meter^3)						
Hyphae Fragments						
Grass/Shrub/Tree Pollen						
Misc. Fibers/Insect Parts						
Total Pollen/Misc. Count (Particles/Meter^3)	0		0			

Analyst

Final Review

This laboratory is not responsible for total counts in particles/M^3, which are dependent on volume collected by non-laboratory personnel. J3 Resources, Inc. currently scans 100% of the trace at 400X magnification and counts a minimum of 20% of the trace at 1,000X magnification. There is no current data supporting a critical or threshold exposure limit to fungal aeroallergens. To date, occupational health related organizations, such as OSHA and NIOSH have not established Permissible Exposure Limits or Recommended Action Levels, or other limit values for aeroallergens. LOD = Limit of Detection.

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TDSHS Mold License LAB0132

Comparative Medicine Program

Office of Facilities Coordinator $ Rm 107 $ (979) 845-7433 $ FAX (979) 845-6706 $ E-mail: dcarlton@tamu.edu

4473 TAMU * Agronomy Rd, Bldg. 972 * Texas A&M University * College Station, TX 77843-4473

4/10/2007

MEMORANDUM FOR THE RECORD

FROM: David L. Carlton, LATG
Facilities Coordinator, CMP

SUBJECT: acility, Bldg ABSL3 Suite

PROBLEMS NOTED BY ANIMAL HUSBANDRY STAFF FOLLOWING FLOODING OF ABSL3 SUITE ON FEB 22, 2007.

Men's Transition area 2: Caulking around light coming loose.

Women's Transition area 2: Dirty water staining in light

BHZD Airlock: Water damage to the drywall around the lights and vent. There is also a spot of damaged drywall in the common area hallway just outside of the airlock.

Rm Dirty water spots in light fixtures, electric socket not bolted to the wall, sink separating from the wall.

Rm ight fixture separating from ceiling, 2 lights out, dirty water spots in light fixtures, small crack in ceiling by middle light, rusty sink, sink separating from wall, rust on air vent.

Rm Rust around electrical outlet.

Rm 4 light bulbs out

Rm dirty light fixtures

Rm 2 lights out, dirty light fixtures, cracks in paint on ceiling, black marks on floor.

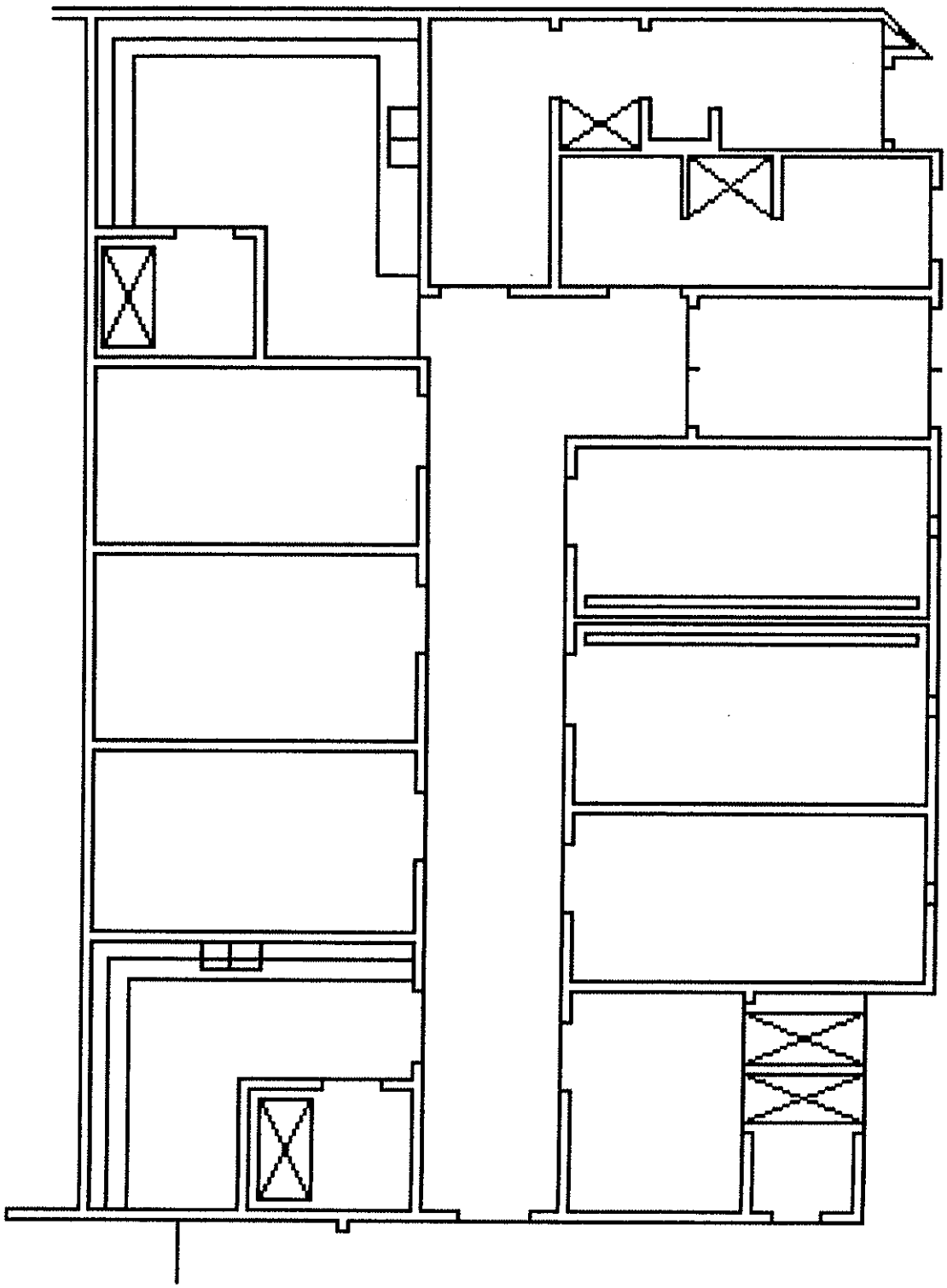
Rm Ceiling bulging by 1st A/C vent, dirty water spots in light fixtures, black marks on floor, slightly rusted drain, sink separating from wall

Rm ___ (LAB): 2 lights out, dirty water spots in lights over fixed hood, cabinets swelling (particle board)

Hallway: Cove base is coming away from the wall near autoclave door, cove base across from the autoclave door is missing, dirty water spots in ceiling light fixtures, crack in ceiling by 2nd vent, ceiling bulging (in 3 spots) between , black marks on floor, paint chipped off walls.

Autoclave Room: 4 light bulbs out, multiple cracks in paint on ceiling, ceiling seems to be hanging a bit low in one spot, floor drain rusty, floor sink drain is draining extremely slow.

ABSL3 SUITE, BLDG



IBC INSPECTION REPORT
BSL3/ABSL3 SBAT FACILITIES & Entity Program

Date: 2/22/07
Principal Investigator/Lab Director: Melanie Zhrig, Director
Location: Building Number - ____ Room (s) BSL3 Suite

Inspection Team:
Dr. Ficht (IBC), Ken (CMP),
Dr. Tesh (IBC), Chris (CMP),
Brent Matthew (EHS),
Tiffany Agnew (ORA),
Mandy Baker (EHS),

Section I - Facility Assessment (PI)

6 animal Rooms

A. Safety Equipment (Primary Barriers)

*Dr. Ficht - SBAT

☑ Yes ☐ No — Protective laboratory clothing, such as solid-front or wrap-around gowns, scrub suits, or coveralls, are worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

☑ Yes ☐ No — Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

☑ Yes ☐ No — Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused. Double glove; change outer after spraying w/ disinfectant

☑ Yes ☐ No — All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

☑ Yes ☐ No — When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

☑ Yes ☐ No — Respiratory and face protection are used when in rooms containing infected animals.

B. Laboratory Facilities (Secondary Barriers)

☑ Yes ☐ No — The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

☑ Yes ☐ No — Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

☐ Yes ☑ No — The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls,

See notes! Rm. ___ - Gap at end of light fixture. Seal
Rm. ___ - Gap around wall outlet; Seal gap(s) around vent &/or light fixtures.

prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

- Floor plan(s) include:
  - Sink location
    ☐ Yes ☐ No
  - Eyewash locations
    ☐ Yes ☐ No
  - Biosafety cabinet (BSC) locations
    ☐ Yes ☐ No
  - Fume hood locations
    ☐ Yes ☐ No
  - HVAC supply and exhaust locations
    ☐ Yes ☐ No
  - Freezer/refrigerator locations
    ☐ Yes ☐ No
  - Other large equipment locations (incubators, centrifuges, etc)
    ☐ Yes ☐ No
- Provide a description of the HVAC system (check all that are appropriate):
  - ☐ Single-pass ☐ Re-circulated
  - ☐ Dedicated exhaust ☐ Shared exhaust
  - ☐ Constant air volume ☐ Variable air volume
  - ☐ Redundant exhaust fans
  - ☐ Emergency power back-up
- Provide information on the biosafety cabinets in use (attach additional sheets if needed):
  - Class of cabinet:
  - ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3)
  - ☐ II, B1 ☐ II, B2 ☐ III
  - Biosafety cabinet connection to the HVAC system:
  - ☑ Hard duct ☐ Thimble ☑ Re-circulating unit
  - Define certification period: Jan/Feb &/or July
  - ☑ Annual ☐ Biannual ☐ Other (explain): _____
  - Does user verify air flow during BSC use?
    ☐ Yes ☐ No
  - If floor drains are provided, the traps are always filled with an appropriate disinfectant:
    ☐ Yes ☐ No

☑ Yes ☐ No Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

C. Standard Microbiological Practices

☑ Yes ☐ No Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

☑ Yes ☐ No Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

☑ Yes ☐ No Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

☑ Yes ☐ No Mechanical pipetting devices are used; mouth pipetting is prohibited.

evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

☑ Yes ☐ No

The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

☑ Yes ☐ No

A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

- Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic ware should be substituted for glassware whenever possible.
- 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
- Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
- Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

☑ Yes ☐ No

All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

☑ Yes ☐ No

Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

- Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
- Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

☑ Yes ☐ No

Cultures, tissues, specimens of body fluids or wastes are placed in a ~~Many~~ double-contained container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

☑ Yes ☐ No

All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

☑ Yes ☐ No

Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained. Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are

Section II - Program Assessment (PI and/or Institutional BioSafety Program- IBSP)

☐ Yes ☐ No An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with Select Agents at this facility:

If yes: IBC approved the work proposed for this facility on: _____ (date).

☐ Yes ☐ No Training: Site specific and safety training is provided to individuals with access to areas where Select Agents are handled or stored:

Is provided prior to individuals beginning to work with Select Agents:
Is provided: ☐ Annually ☐ Biannually ☐ Other (specify frequency):
Written records of individuals are kept: ☐ Yes ☐ No
Personnel demonstrate proficiency in laboratory procedures prior to working with Select Agents: Unannounced visits by EH&S and follow up by supervisory personnel:
☐ Yes ☐ No
Provide a brief explanation of the system in place to detect loss or theft of select agent(s):
Individual responsible for inventory of select agent(s):
How often is the inventory record reconciled?
How is access to the inventory log limited?
Inventory tracking includes the following information (list):
There is a site-specific Security Plan for each of the laboratories listed above (number 2):
☐ Yes ☐ No
Building with select agents has self-closing doors: ☐ Yes ☐ No
Means to limit access to buildings with laboratories with select agents:
Guard station at the facility entrance
Card access system or locks
Security alarm system in the laboratory building
Other (describe): _____
Means to limit access to laboratories with select agents once inside the building:
Door to laboratory is locked:
Card access system or locks
Other (describe): _____
Means to limit access to select agents once inside the laboratory:
Locked incubators, refrigerators, freezers, etc.
Security alarm system that directly monitors the laboratory
Other (describe): _____
Means to limit access to select agents in storage:
Storage area door locked
Lock boxes
Security alarm system that directly monitors the laboratory
Other (describe): _____
Means to monitor unauthorized entry into the laboratory where select agents are used or stored:
Electronic logs of card access system entries are reviewed for unusual activity
Manual sign in and out logs are kept and monitored
Video camera surveillance
Other (describe): _____

13. List species of large animals that will be used: _____
14. Describe route of infection:
15. Carcass of animals are disposed of to avoid their use as food for human beings or animals: ☐Yes ☐ No
16. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐Yes ☐ No
    a. If yes, give method: _____
17. Carcass of animals are disposed of on site: ☐ Yes ☐ No
18. The facility requires that in an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at his facility: ☐ Yes ☐ No
    a. If yes, the proposed work has been approved by the IACUC ☐ Yes ☐ No

Optional - TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR

19. A Chemical hygiene plan is available for the facility using toxins: ☐ Yes ☐ No
20. Maximum quantity of each toxin under the control of the principal investigator at a give time:
21. Form of toxins used: ☐ Liquid ☐ Lyophilized
22. The toxin is produced by live agent at the facility: ☐ Yes ☐ No
    a. If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____
23. Dilution procedures and other manipulations of the concentrated toxins are:
    a. Conducted in ☐ Fume hood ☐ Biosafety cabinet
        i. If a fume hood is used, certification of the hood is conducted:
        ☐ Annually ☐ Biannually ☐ Other (describe): _____
    b. Conducted with two knowledgeable people present: ☐ Yes ☐ No
    c. A hazard sign on the door when toxins are present: ☐ Yes ☐ No

24. Floor plan(s) include:
    a. Sink location ☐ Yes ☐ No
    b. Eyewash locations ☐ Yes ☐ No
    c. Biosafety cabinet (BSC) locations ☐ Yes ☐ No
    d. Fume hood locations ☐ Yes ☐ No
    e. HVAC supply and exhaust locations ☐ Yes ☐ No
    f. Freezer/refrigerator locations ☐ Yes ☐ No
    g. Other large equipment locations (incubators, centrifuges, etc) ☐ Yes ☐ No
25. Plan provides a description of the HVAC system (check all that are appropriate):
    a. ☐ Single-pass ☐ Re-circulated
    b. ☐ Dedicated exhaust ☐ Shared exhaust
    c. ☐ Constant air volume ☐ Variable air volume
    d. ☐ Redundant exhaust fans
    e. ☐ Emergency power back-up
26. Plan provide information on the biosafety cabinets in use (attach additional sheets if needed):
    a. Class of cabinet:
    ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3)
    ☐ II, B1 ☐ II, B2 ☐ III
    b. Biosafety cabinet connection to the HVAC system:
    ☐ Hard duct ☐ Thimble ☐ Re-circulating
    c. Define certification period:
    ☐ Annual ☐ Biannual ☐ Other (explain): _____
    d. Does user verify air flow during BSC use? ☐ Yes ☐ No

2007 Inspection Report

(Inspections conducted 01/07-07/07)

IBC INSPECTION REPORT
BSL3/ABSL3 SBAT FACILITIES & Entity Program

Date: 7/10/07
Principal Investigator/Lab Director: Dr. Adams & Dr. Fidit
Location: Building Number - _____ Room (s) BL3 Suite of rm

Inspection Team:
Brent Mattox, _____,
Nancy Faker, _____,
_____, _____,
_____, _____,
_____, _____

Section I - Facility Assessment (PI)

A. Safety Equipment (Primary Barriers)

☐ Yes ☐ No Protective laboratory clothing, such as solid-front or wrap-around gowns, scrub suits, or coveralls, are worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

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☐ Yes ☐ No Respiratory and face protection are used when in rooms containing infected animals. ~~ABSL3~~ (N2) BMBL? 4th edition, BSL3 Sect. C.6.

B. Laboratory Facilities (Secondary Barriers)

☑ Yes ☐ No The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

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prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

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  - Sink location
    ☐ Yes ☐ No
  - Eyewash locations
    ☐ Yes ☐ No
  - Biosafety cabinet (BSC) locations
    ☐ Yes ☐ No
  - Fume hood locations
    ☐ Yes ☐ No
  - HVAC supply and exhaust locations
    ☐ Yes ☐ No
  - Freezer/refrigerator locations
    ☐ Yes ☐ No
  - Other large equipment locations (incubators, centrifuges, etc)
    ☐ Yes ☐ No
- Provide a description of the HVAC system (check all that are appropriate):
  - ☐ Single-pass ☐ Re-circulated
  - ☐ Dedicated exhaust ☐ Shared exhaust
  - ☐ Constant air volume ☐ Variable air volume
  - ☐ Redundant exhaust fans
  - ☐ Emergency power back-up
- Provide information on the biosafety cabinets in use (attach additional sheets if needed):
  - Class of cabinet:
  - ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3)
  - ☐ II, B1 ☐ II, B2 ☐ III
  - Biosafety cabinet connection to the HVAC system:
  - ☐ Hard duct ☐ Thimble ☐ Re-circulating
  - Define certification period:_____
  - ☐ Annual ☐ Biannual ☐ Other (explain): _____
  - Does user verify air flow during BSC use?
    ☐ Yes ☐ No
  - If floor drains are provided, the traps are always filled with an appropriate disinfectant:
    ☐ Yes ☐ No

☐ Yes ☐ No Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

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☐ Yes ☐ No Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

☐ Yes ☐ No Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

☐ Yes ☐ No Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

☐ Yes ☐ No Mechanical pipetting devices are used; mouth pipetting is prohibited.

evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

☐ Yes ☐ No

The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

☐ Yes ☐ No

A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

- Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic ware should be substituted for glassware whenever possible.
- 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
- Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
- Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

☐ Yes ☐ No

All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

☐ Yes ☐ No

Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

- Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
- Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

☐ Yes ☐ No

Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

☐ Yes ☐ No

All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

☐ Yes ☐ No

Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained. Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are

Section II - Program Assessment (PI and/or Institutional BioSafety Program- IBSP)

☐ Yes ☐ No 1. An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with Select Agents at this facility:

If yes: IBC approved the work proposed for this facility on: _____ (date).

☐ Yes ☐ No 2. **Training**: Site specific and safety training is provided to individuals with access to areas where Select Agents are handled or stored:

a. Is provided prior to individuals beginning to work with Select Agents: ☐ Yes ☐ No
b. Is provided: ☐ Annually ☐ Biannually ☐ Other (specify frequency):
c. Written records of individuals are kept: ☐ Yes ☐ No
d. Personnel demonstrate proficiency in laboratory procedures prior to working with Select Agents: ☐ Yes ☐ No
e. Unannounced visits by EH&S and follow up by supervisory personnel: ☐ Yes ☐ No

3. Provide a brief explanation of the system in place to detect loss or theft of select agent(s):

4. **Inventory**: Individual responsible for inventory of select agent(s):
   a. How often is the inventory record reconciled?
   b. How is access to the inventory log limited?
   c. Inventory tracking includes the following information (list):

5. **Security**: There is a site-specific Security Plan for this laboratory: ☐ Yes ☐ No
   a. Building with Select Agent has self-closing doors: ☐ Yes ☐ No
   b. Means to limit access to buildings with laboratories with Select Agent:
      Guard station at the facility entrance: ☐ Yes ☐ No
      Card access system or locks: ☐ Yes ☐ No
      Security alarm system in the laboratory building: ☐ Yes ☐ No
      Other (describe): _____
   f. Means to limit access to laboratories with Select Agent once inside the building:
      Door to laboratory is locked: ☐ Yes ☐ No
      Card access system or locks: ☐ Yes ☐ No
      Other (describe): _____
   g. Means to limit access to select agents once inside the laboratory:
      Locked incubators, refrigerators, freezers, etc.: ☐ Yes ☐ No
      Security alarm system that directly monitors the laboratory: ☐ Yes ☐ No
      Other (describe): _____
   h. Means to limit access to select agents in storage:
      Storage area door locked: ☐ Yes ☐ No
      Lock boxes: ☐ Yes ☐ No
      Security alarm system that directly monitors the laboratory: ☐ Yes ☐ No
      Other (describe): _____
   i. Means to monitor unauthorized entry into the laboratory where select agents are used or stored:
      Electronic logs of card access system entries are reviewed for unusual activity: ☐ Yes ☐ No
      Manual sign in and out logs are kept and monitored: ☐ Yes ☐ No
      Video camera surveillance: ☐ Yes ☐ No
      Other (describe): _____

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **LARGE ANIMALS**

1. List species of large animals that will be used: _____
2. Describe route of infection:
3. Carcass of animals are disposed of to avoid their use as food for human beings or animals: ☐Yes ☐ No
4. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐Yes ☐ No
   If yes, give method: _____
5. Carcass of animals are disposed of on site: ☐ Yes ☐ No
6. The facility requires that in an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at his facility: ☐ Yes ☐ No
   If yes, the proposed work has been approved by the IACUC: ☐ Yes ☐ No

Optional - TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR

1. A Chemical hygiene plan is available for the facility using toxins: ☐ Yes ☐ No
2. Maximum quantity of each toxin under the control of the Principal Investigator at a give time:
3. Form of toxins used: ☐ Liquid ☐ Lyophilized
   a. The toxin is produced by live agent at the facility: ☐ Yes ☐ No
      If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____
   b. Dilution procedures and other manipulations of the concentrated toxins are:
      Conducted in ☐ Fume hood ☐ Biosafety cabinet
      If a fume hood is used, certification of the hood is conducted:
      ☐ Annually ☐ Biannually ☐ Other (describe): _____
      Conducted with two knowledgeable people present: ☐ Yes ☐ No
4. A hazard sign on the door when toxins are present: ☐ Yes ☐ No
5. Floor plan(s) include:
   Sink location: ☐ Yes ☐ No
   Eyewash locations: ☐ Yes ☐ No
   Biosafety cabinet (BSC) locations: ☐ Yes ☐ No
   Fume hood locations: ☐ Yes ☐ No
   HVAC supply and exhaust locations: ☐ Yes ☐ No
   Freezer/refrigerator locations: ☐ Yes ☐ No
   Other large equipment locations (incubators, centrifuges, etc): ☐ Yes ☐ No
6. Plan provides a description of the HVAC system (check all that are appropriate):
   ☐ Single-pass ☐ Re-circulated ☐ Dedicated exhaust ☐ Shared exhaust
   ☐ Constant air volume ☐ Variable air volume ☐ Redundant exhaust fans ☐ Emergency power back-up
7. Plan provides information on the biosafety cabinets in use (attach additional sheets if needed):
   Class of cabinet:
   ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III
   Biosafety cabinet connection to the HVAC system:
   ☐ Hard duct ☐ Thimble ☐ Re-circulating
   Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain): _____
   Does user verify air flow during BSC use? ☐ Yes ☐ No

Section IV – Inspection Summary

1. As a result of the **Facility Assessment** of the *Laboratory Facilities (Secondary Barriers)*, the following was noted in respect of the interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination:

Rm [redacted] Locked, sealed, has not been opened.
Also, Under negative pressure.
NLE & TSM 7/101

IBC INSPECTION REPORT
BSL3/ABSL3 SBAT FACILITIES & Entity Program

Date: 01/23/07
Principal Investigator/Lab Director: Dr. Adams/Dr. Ficht
Location: Building Number - _____ Room (s) _____

Inspection Team:
Brent Mattox, _____,
Nancy Baker, _____,
_____, _____,
_____, _____,
_____, _____

Section I - Facility Assessment (PI)

A. Safety Equipment (Primary Barriers)

☐ Yes ☐ No — Protective laboratory clothing, such as solid-front or wrap-around gowns, scrub suits, or coveralls, are worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

☐ Yes ☐ No — Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

☐ Yes ☐ No — Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

☐ Yes ☐ No — All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

☐ Yes ☐ No — When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

☐ Yes ☐ No — Respiratory and face protection are used when in rooms containing infected animals.

B. Laboratory Facilities (Secondary Barriers)

☑ Yes ☐ No — The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

☑ Yes ☐ No — Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

☐ Yes ☐ No — The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and

See notes (Attached)

disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

☑ Yes ☐ No Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

☑ Yes ☐ No Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

☑ Yes ☐ No Windows in the laboratory are closed and sealed.

☑ Yes ☐ No A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

☑ Yes ☐ No Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

☑ Yes ☐ No A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

☑ Yes ☐ No HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

☑ Yes ☐ No 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

☑ Yes ☐ No Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

☐ Yes ☑ No An eyewash facility is readily available inside the laboratory. Showers & eyewashes are in the corridor.

☑ Yes ☐ No Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

☑ Yes ☐ No The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

- Floor plan(s) include:
  - Sink location
    ☑ Yes ☐ No
  - Eyewash locations
    ☑ Yes ☐ No
  - Biosafety cabinet (BSC) locations
    ☑ Yes ☐ No
  - Fume hood locations
    ☑ Yes ☐ No
  - HVAC supply and exhaust locations
    ☑ Yes ☐ No
  - Freezer/refrigerator locations
    ☑ Yes ☐ No
  - Other large equipment locations (incubators, centrifuges, etc)
    ☑ Yes ☐ No
- Provide a description of the HVAC system (check all that are appropriate):
  - ☑ Single-pass ☐ Re-circulated
  - ☑ Dedicated exhaust ☐ Shared exhaust
  - ☑ Constant air volume ☑ Variable air volume
  - ☑ Redundant exhaust fans
  - ☑ Emergency power back-up
- Provide information on the biosafety cabinets in use (attach additional sheets if needed):
  - Class of cabinet:
  - ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3)
  - ☑ II, B1 (5) ☐ II, B2 ☐ III
  - Biosafety cabinet connection to the HVAC system:
  - ☑ Hard duct ☐ Thimble ☐ Re-circulating
  - Define certification period: Jan (2007); not scheduled for 1/24/07
  - ☑ Annual ☐ Biannual ☐ Other (explain): _____
  - Does user verify air flow during BSC use?
    ☑ Yes ☐ No
  - If floor drains are provided, the traps are always filled with an appropriate disinfectant:
    ☑ Yes ☐ No

Verify Cert. Reports to Tiffany

☑ Yes ☐ No Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

C. Standard Microbiological Practices

☑ Yes ☐ No Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

☑ Yes ☐ No Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

☑ Yes ☐ No Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

☑ Yes ☐ No Mechanical pipetting devices are used; mouth pipetting is prohibited.

☑ Yes ☐ No Policies for the safe handling of sharps are instituted.

☑ Yes ☐ No All procedures are performed carefully to minimize the creation of aerosols.

(when in use)

☑ Yes ☐ No Work surfaces are decontaminated at least once a day and after any spill of viable material.

☑ Yes ☐ No All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

☑ Yes ☐ No Persons under 16 years of age are not allowed to enter a BL3 laboratory.

☑ Yes ☐ No If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

☑ Yes ☐ No An insect and rodent control program is in effect.

D: Special Practices

☑ Yes ☐ No Laboratory doors are kept closed when experiments are in progress.

☑ Yes ☐ No The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

☑ Yes ☐ No The laboratory director establishes 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.

☑ Yes ☐ No When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

☑ Yes ☐ No Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled.

☑ Yes ☐ No Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

☑ Yes ☐ No A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

☑ Yes ☐ No Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

☑ Yes ☐ No The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices

and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

☑ Yes ☐ No

A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

- Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic ware should be substituted for glassware whenever possible.
- 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
- Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
- Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

☑ Yes ☐ No

All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

☑ Yes ☐ No

Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

Bleach → 5 mins → immediate
Virion
documented
Experimentally determined which disinfectant was effective

- Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
- Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

☑ Yes ☐ No

Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

☑ Yes ☐ No

All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

☑ Yes ☐ No

Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained. Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

☑ Yes ☐ No

Animals and plants not related to the work being conducted are not permitted in the laboratory.

☑ Yes ☐ No Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

Section II - Program Assessment (PI and/or Institutional BioSafety Program- IBSP)

☐ Yes ☐ No An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with Select Agents at this facility:

If yes: IBC approved the work proposed for this facility on: _____ (date).

☐ Yes ☐ No Training: Site specific and safety training is provided to individuals with access to areas where Select Agents are handled or stored:

Is provided prior to individuals beginning to work with Select Agents:
Is provided: ☐ Annually ☐ Biannually ☐ Other (specify frequency):
Written records of individuals are kept: ☐ Yes ☐ No
Personnel demonstrate proficiency in laboratory procedures prior to working with Select Agents: Unannounced visits by EH&S and follow up by supervisory personnel:
☐ Yes ☐ No
Provide a brief explanation of the system in place to detect loss or theft of select agent(s):
Individual responsible for inventory of select agent(s):
How often is the inventory record reconciled?
How is access to the inventory log limited?
Inventory tracking includes the following information (list):
There is a site-specific Security Plan for each of the laboratories listed above (number 2):
☐ Yes ☐ No
Building with select agents has self-closing doors: ☐ Yes ☐ No
Means to limit access to buildings with laboratories with select agents:
Guard station at the facility entrance
Card access system or locks
Security alarm system in the laboratory building
Other (describe): _____
Means to limit access to laboratories with select agents once inside the building:
Door to laboratory is locked:
Card access system or locks
Other (describe): _____
Means to limit access to select agents once inside the laboratory:
Locked incubators, refrigerators, freezers, etc.
Security alarm system that directly monitors the laboratory
Other (describe): _____
Means to limit access to select agents in storage:
Storage area door locked
Lock boxes
Security alarm system that directly monitors the laboratory
Other (describe): _____
Means to monitor unauthorized entry into the laboratory where select agents are used or stored:
Electronic logs of card access system entries are reviewed for unusual activity
Manual sign in and out logs are kept and monitored
Video camera surveillance
Other (describe): _____

a. The laboratory is secured when no one is present during regular working hours:
☐ Yes ☐ No
b. Number of people with access:
c. Individuals not directly involved in research activities have access to select agents:
☐ Yes ☐ No
If yes, please explain: _____
d. Non-laboratory personnel (visitors, including janitorial and facility maintenance personnel) have access to the laboratory with select agents: ☐ Yes ☐ No
If yes, are they allowed into the laboratory unescorted? ☐ Yes ☐ No

2. All cultures, stock and other regulated wastes are decontaminated before disposal by an approved decontamination method: ☐ Yes ☐ No
a. If yes, describe method:

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH RECOMBINANT DNA

3. The facility has an Institutional Biosafety Committee that has approved work with recombinant DNA or has approval pending: ☐ Yes ☐ No
4. The biosafety level listed in Section 4A for this laboratory meets NIH guidelines: ☐ Yes ☐ No
5. Will you be possessing, using, or transferring the following:
a. Select Agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that are capable of infection and/or replication.
☐ Yes ☐ No
b. Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids are in a vector or host chromosome and/or are expressed *in vivo* or *in vitro*.
☐ Yes ☐ No
c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified.
☐ Yes ☐ No
6. Are you intending to conduct the following experiments:
a. Experiments utilizing recombinant DNA techniques that involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.
☐ Yes ☐ No
b. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxin molecules lethal for vertebrates at an LD50<100 ng/kg body weight.
☐ Yes ☐ No
7. Provide a brief description of the recombinant constructs and any associated expression control of elements, including what the recombinant DNA encodes for, if known:
8. Give an estimate of range of length of recombinant DNA to be used:

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **SMALL ANIMALS**

9. List species of small animals that will be used: _____
10. Describe route of infection:
11. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No
a. If yes, describe method: _____
12. The facility requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this facility: ☐ Yes ☐ No
If yes, the proposed work with select agents has been approved by the IACUC: ☐Yes ☐ No

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **LARGE ANIMALS**

13. List species of large animals that will be used: _____

14. Describe route of infection:
15. Carcass of animals are disposed of to avoid their use as food for human beings or animals: ☐Yes ☐ No
16. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐Yes ☐ No
    a. If yes, give method: _____
17. Carcass of animals are disposed of on site: ☐ Yes ☐ No
18. The facility requires that in an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at his facility: ☐ Yes ☐ No
    a. If yes, the proposed work has been approved by the IACUC ☐ Yes ☐ No

Optional - TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR

19. A Chemical hygiene plan is available for the facility using toxins: ☐ Yes ☐ No
20. Maximum quantity of each toxin under the control of the principal investigator at a give time:
21. Form of toxins used: ☐ Liquid ☐ Lyophilized
22. The toxin is produced by live agent at the facility: ☐ Yes ☐ No
    a. If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____
23. Dilution procedures and other manipulations of the concentrated toxins are:
    a. Conducted in ☐ Fume hood ☐ Biosafety cabinet
        i. If a fume hood is used, certification of the hood is conducted:
        ☐ Annually ☐ Biannually ☐ Other (describe): _____
    b. Conducted with two knowledgeable people present: ☐ Yes ☐ No
    c. A hazard sign on the door when toxins are present: ☐ Yes ☐ No

24. Floor plan(s) include:
    a. Sink location ☐ Yes ☐ No
    b. Eyewash locations ☐ Yes ☐ No
    c. Biosafety cabinet (BSC) locations ☐ Yes ☐ No
    d. Fume hood locations ☐ Yes ☐ No
    e. HVAC supply and exhaust locations ☐ Yes ☐ No
    f. Freezer/refrigerator locations ☐ Yes ☐ No
    g. Other large equipment locations (incubators, centrifuges, etc) ☐ Yes ☐ No
25. Plan provides a description of the HVAC system (check all that are appropriate):
    a. ☐ Single-pass ☐ Re-circulated
    b. ☐ Dedicated exhaust ☐ Shared exhaust
    c. ☐ Constant air volume ☐ Variable air volume
    d. ☐ Redundant exhaust fans
    e. ☐ Emergency power back-up
26. Plan provide information on the biosafety cabinets in use (attach additional sheets if needed):
    a. Class of cabinet:
    ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3)
    ☐ II, B1 ☐ II, B2 ☐ III
    b. Biosafety cabinet connection to the HVAC system:
    ☐ Hard duct ☐ Thimble ☐ Re-circulating
    c. Define certification period:
    ☐ Annual ☐ Biannual ☐ Other (explain): _____
    d. Does user verify air flow during BSC use? ☐ Yes ☐ No

Section III – Entity Program (IBSP)

☐ Yes ☐ No Entity Program documents IBC approvals which include Select Agent required information.

☐ Yes ☐ No Entity documents registrations.

☐ Yes ☐ No Entity documents (IBC) are current and up to date.

☐ Yes ☐ No Entity documents changes to the registration and does not allow access until amendments have been approved.

☐ Yes ☐ No Entity has a current Incident Response Plan

☐ Yes ☐ No Entity emergency response drill and evaluation is documented annually

☐ Yes ☐ No Entity Security Plan is reviewed and documented annually.

☐ Yes ☐ No Entity documents annual inspections and follow up requirements

BL3 Laboratory Inspection, Bldg.
Inspected by Nancy Eaker and Brent Mattox
01/23/07

Women's Outer Locker

Small cracks in paint in ceiling need to be sealed.
Crack on wall above lockers needs to be sealed.
Openings in ceiling around conduits need to be sealed.

Women's Inner Locker

Cracks in paint on wall near door(s) and above lockers need to be sealed.
Openings in ceiling around conduits need to be sealed.
Return air vent(s) need to be cleaned.

Room

Cracks in paint in the corner behind the biosafety cabinet (to the left or on far side of the room) need to be sealed. The A/C diffuser box may need to be repainted; boxes in other labs have peeling paint.
Biosafety cabinet ductwork needs to be resealed where it meets the ceiling (both cabinets).
Noted there are radioactive materials in the lab that are no longer in use.

Room

Biosafety cabinet ductwork needs to be resealed where it meets the ceiling (both cabinets).
Cracks and/or seams in coving around cabinets needs to be sealed.
Paint on the A/C diffuser box is peeling; box should be repainted.
Small cracks in paint on the ceiling and wall near the fume hood (in the corner) need to be sealed.

Room

Noted that someone entered the wrong year (2006 rather than 2007) in the access log for one of the freezers.

Room

Cracks in paint and/or wall coving need to be sealed. Noted small crack(s) where wall coving meets the door frame. Also noted cracks in corner behind the right fume hood and along the ceiling in the corner behind the left fume hood.
Paint on the A/C diffuser box is peeling; box should be repainted.
Biosafety cabinet and fume hood ductwork need to be resealed where they meet the ceiling (hood next to biosafety cabinet; seal may just be very dirty).
Coving around bench needs to be sealed in corner on right side of bench (where it meets the wall) and in recessed area of bench. Also needs to be sealed at front left corner.

Room Animal Room)

Small cracks in paint need to be sealed. Cracks noted on ceiling next to light fixture and over door to the autoclave.
Door sweep needed on door to the autoclave.
Isolation hoods are/were certified by Alan Boedecker of Service Tech

Men's Inner Locker

Leaking shower needs to be fixed.
Large crack in wall above door between the locker rooms needs to be sealed.

Men's Outer Locker

Hole and peeling paint around in ceiling next to light fixture needs to be repaired.
Large crack in wall above door between the locker rooms needs to be sealed.
Openings in ceiling around conduits need to be sealed.

BL3 Corridor

Ceiling tile was moved several months ago by Physical Plant personnel and has not been replaced.

not draft, but official doc. (FMO)

TEXAS A&M UNIVERSITY

VICE PRESIDENT FOR RESEARCH - OFFICE OF RESEARCH COMPLIANCE
1186 TAMU
College Station, TX 77843-1186
1500 Research Parkway, Suite B-150
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Institutional Biosafety Committee | Institutional Animal Care and Use Committee | Institutional Review Board

MEMORANDUM

TO: Dr. Thomas A. Ficht
VTPB
MS 4467

FROM: Tiffany M. Agnew, Program Coordinator
Institutional Bio-Safety Program

DATE: February 6, 2007

REG.: Annual IBC Inspection of Select Agent Facilities- Building (Ficht)

At 9:15 a.m. (CST) on January 23, 2007, the following individuals completed the Annual IBC Inspection of the Select Agent Facilities- Building (Ficht):

Ms. Angelia Raines- IBC Member/Director, ORC
Mr. Brent Mattox- IBC Member/EHS
Ms. Nancy Eaker- EHS
Ms. Tiffany Agnew- IBSP Coordinator

The aforementioned team utilized the combined checklist from Environmental Health and Safety and the Office of Research Compliance to complete the inspection of the facilities. The use of this combined checklist marks the combined inspection by both offices, to reduce duplicated efforts for identical information. In accordance with CFR 42 § 73.9, inspection of Select Agent Facilities at Texas A&M University have been conducted in December. However, in an attempt to give the Select Agent investigators an opportunity to review the combined checklist, the inspections of all Select Agent Facilities were scheduled to be completed in January.

During this inspection, the following deficiencies were noted by the inspection team:

1. As a result of the **Facility Assessment** of the *Laboratory Facilities (Secondary Barriers)*, the following was noted in respect of the interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination:
   a. Women's Outer Locker Room
      i. Small cracks in paint in ceiling need to be sealed
      ii. Cracks on walls above lockers need to be sealed
      iii. Openings in ceiling around conduits need to be sealed

   b. Women's Inner Locker Room
      i. Cracks in paint on wall near door(s) and above lockers need to be sealed
      ii. Openings in ceiling around conduits need to be sealed
      iii. Return air vent(s) need to be cleaned

   c. Room
      i. Cracks in paint in the corner behind the biosafety cabinet (to the left or on far side of the room) need to be sealed
      ii. A/C diffuser box needs to be repainted- boxes in other rooms have peeling paint
      iii. Biosafety cabinet (BSC) ductwork needs to be resealed where it meets the ceiling (both BSCs)
      iv. Radioactive materials were found in the lab that are no longer in use

d. Room
   i. BSC ductwork needs to be resealed where it meets the ceiling (both BSCs)
   ii. Cracks and/or seams in coving around cabinets need to be sealed
   iii. Paint on the A/C diffuser box is peeling; box should be repainted
   iv. Small cracks in paint on the ceiling and wall near the fume hood (in the corner) needs to be sealed

e. Room
   i. Wrong year entered in the Access Log for one of the freezers (2006 logged instead of 2007)

f. Room
   i. Cracks in paint and/or wall coving needs to be sealed (small crack(s) where wall coving meets the door frame); cracks in corner behind the right fume hood and along the ceiling in the corner behind the left fume hood
   ii. Paint on the A/C diffuser box is peeling; box should be repainted
   iii. BSC and fume hood ductwork need to be resealed where they meet the ceiling (hood next to BSC; seal may just be very dirty)
   iv. Coving around bench needs to be sealed in corner on right side of bench (where it meets the wall) and in recessed area of bench; front left corner also needs to be sealed

g. Room nimal Room)
   i. Small cracks in paint need to be sealed; cracks also noted on ceiling next to the light fixture and over the door to the autoclave unit
   ii. Door sweep needed on the door to the autoclave
   iii. Isolation hoods were certified by: Alan Boedecker of *Service Tech*

h. Men's Inner Locker Room
   i. Leaking shower needs to be repaired
   ii. Large crack in wall above door between the locker rooms need to be resealed

i. Men's Outer Locker Room
   i. Hole and peeling paint around in ceiling next to light fixture needs to be repaired
   ii. Large crack in wall above door between the locker rooms needs to be sealed
   iii. Openings in ceiling around conduits need to be sealed

j. BSL-3 Corridor
   i. Ceiling tile was moved several months ago by Physical Plant personnel, but have not been replaced

2. As a result of the **Program Assessment** in regards to the *Agent Access Log,* the following was noted:
   a. Inconsistencies in signage were noted. In particular, escort accompanying non DOJ approved person does not sign in. DOJ approved personnel need additional training regarding signing in and out of the lab. (Once training is completed, updates will be placed in SOPs/Biosafety Plan.)

3. As a result of the **Program Assessment** in regards to the *Standard Operating Procedures (SOP)/Biosafety Plan)*, the following was noted:

a. SOPs need to be updated to reflect modified procedures regarding waste disposal in laboratory.

The IBC requests these deficiencies are rectified before the next inspection of this facility, which is scheduled to take place* **March 2007.** Upon receipt of this correspondence, please provide written indication that you have indeed received this document, and that you agree to complete all necessary corrections.

*Inspection date modified to: May 2007 gma

IBC INSPECTION REPORT
BSL3/ABSL3 SBAT FACILITIES & Entity Program

Date: January 23, 2007
Principal Investigator/Lab Director: Dr. Thomas A. Ficht
Location: Building Number - Room (s) (storage), (animal room)

Inspection Team:

Angelia Raines, Brent Mattox, Nancy Eaker, Tiffany Agnew

Section I - Facility Assessment (PI)

A. Safety Equipment (Primary Barriers)

☑ Yes ☐ No Protective laboratory clothing, such as solid-front or wrap-around gowns, scrub suits, or coveralls, are worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

☑ Yes ☐ No Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

☑ Yes ☐ No Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

☑ Yes ☐ No All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

☑ Yes ☐ No When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

☑ Yes ☐ No Respiratory and face protection are used when in rooms containing infected animals.

B. Laboratory Facilities (Secondary Barriers)

☑ Yes ☐ No The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

☑ Yes ☐ No Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

☐ Yes ☑ No The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls,

prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

- Floor plan(s) include:
  - Sink location
    ☑ Yes ☐ No
  - Eyewash locations
    ☑ Yes ☐ No
  - Biosafety cabinet (BSC) locations
    ☑ Yes ☐ No
  - Fume hood locations
    ☑ Yes ☐ No
  - HVAC supply and exhaust locations
    ☑ Yes ☐ No
  - Freezer/refrigerator locations
    ☑ Yes ☐ No
  - Other large equipment locations (incubators, centrifuges, etc)
    ☑ Yes ☐ No
- Provide a description of the HVAC system (check all that are appropriate):
  - ☑ Single-pass ☐ Re-circulated
  - ☑ Dedicated exhaust ☐ Shared exhaust
  - ☐ Constant air volume ☑ Variable air volume
  - ☑ Redundant exhaust fans
  - ☑ Emergency power back-up
- Provide information on the biosafety cabinets in use (attach additional sheets if needed):
  - Class of cabinet: **(5 total in suite)**
  - ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3)
  - ☑ II, B1 ☐ II, B2 ☐ III
  - Biosafety cabinet connection to the HVAC system:
  - ☑ Hard duct ☐ Thimble ☐ Re-circulating
  - Define certification period: **January 2007**
  - ☑ Annual ☐ Biannual ☐ Other (explain): _____
  - Does user verify air flow during BSC use?
    ☑ Yes ☐ No
  - If floor drains are provided, the traps are always filled with an appropriate disinfectant:
    ☑ Yes ☐ No

☑ Yes ☐ No Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

C. Standard Microbiological Practices

☑ Yes ☐ No Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

☑ Yes ☐ No Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

☑ Yes ☐ No Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

☑ Yes ☐ No Mechanical pipetting devices are used; mouth pipetting is prohibited.

evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

☑ Yes ☐ No

The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

☑ Yes ☐ No

A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

- Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic ware should be substituted for glassware whenever possible.
- 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
- Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
- Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

☑ Yes ☐ No

All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

☑ Yes ☐ No

Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

- Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
- Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

☑ Yes ☐ No

Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

☑ Yes ☐ No

All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

☑ Yes ☐ No

Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained. Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are

Section II - Program Assessment (PI and/or Institutional BioSafety Program- IBSP)

☑ Yes ☐ No An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with Select Agents at this facility:
If yes: IBC approved the work proposed for this facility on: **1/18/2004** (date).

Renewal in progress.

☑ Yes ☐ No 2. **Training**: Site specific and safety training is provided to individuals with access to areas where Select Agents are handled or stored:
   a. Is provided prior to individuals beginning to work with Select Agents: ☑ Yes ☐ No
   b. Is provided: ☑ Annually ☐ Biannually ☐ Other (specify frequency):
   c. Written records of individuals are kept: ☑ Yes ☐ No
   d. Personnel demonstrate proficiency in laboratory procedures prior to working with Select Agents: ☑ Yes ☐ No
   e. Unannounced visits by EH&S and follow up by supervisory personnel: ☐ Yes ☐ No

3. Provide a brief explanation of the system in place to detect loss or theft of select agent(s): **within the Incident Response Plan**

4. **Inventory**: Individual responsible for inventory of select agent(s): **Dr. Ficht**
   a. How often is the inventory record reconciled? **Annually**
   b. How is access to the inventory log limited? **Dr. Ficht's computer that is locked.**
   c. Inventory tracking includes the following information (list): **Agent Access Log; reconcile position of each individual strain accessed**

5. **Security**: There is a site-specific Security Plan for this laboratory: ☑ Yes ☐ No
   a. Building with Select Agent has self-closing doors: ☑ Yes ☐ No
   b. Means to limit access to buildings with laboratories with Select Agent:
      Guard station at the facility entrance: ☐ Yes ☑ No
      Card access system or locks: ☑ Yes ☐ No
      Security alarm system in the laboratory building: ☑ Yes ☐ No
      Other (describe):
   f. Means to limit access to laboratories with Select Agent once inside the building:
      Door to laboratory is locked: ☑ Yes ☐ No
      Card access system or locks: ☑ Yes ☐ No
      Other (describe): _____
   g. Means to limit access to select agents once inside the laboratory:
      Locked incubators, refrigerators, freezers, etc.: ☑ Yes ☐ No
      Security alarm system that directly monitors the laboratory: ☑ Yes ☐ No
      Other (describe): **Air flow monitored.**
   h. Means to limit access to select agents in storage:
      Storage area door locked: ☑ Yes ☐ No
      Lock boxes: ☐ Yes ☑ No
      Security alarm system that directly monitors the laboratory: ☐ Yes ☐ No
      Other (describe): _____
   i. Means to monitor unauthorized entry into the laboratory where select agents are used or stored: **Facility Access Log**
      Electronic logs of card access system entries are reviewed for unusual activity: ☑ Yes ☐ No
      Manual sign in and out logs are kept and monitored: ☑ Yes ☐ No
      Video camera surveillance: ☑ Yes ☐ No
      Other (describe): **Located outside of the BSL3 suite**

If yes, the proposed work with Select Agents has been approved by the IACUC: ☑Yes ☐ No

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **LARGE ANIMALS**

1. List species of large animals that will be used: _____
2. Describe route of infection:
3. Carcass of animals are disposed of to avoid their use as food for human beings or animals: ☐Yes ☐ No
4. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐Yes ☐ No
   If yes, give method: _____
5. Carcass of animals are disposed of on site: ☐ Yes ☐ No
6. The facility requires that in an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at his facility: ☐ Yes ☐ No
   If yes, the proposed work has been approved by the IACUC: ☐ Yes ☐ No

Optional - TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR

1. A Chemical hygiene plan is available for the facility using toxins: ☐ Yes ☐ No
2. Maximum quantity of each toxin under the control of the Principal Investigator at a give time:
3. Form of toxins used: ☐ Liquid ☐ Lyophilized
   a. The toxin is produced by live agent at the facility: ☐ Yes ☐ No
      If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____
   b. Dilution procedures and other manipulations of the concentrated toxins are:
      Conducted in ☐ Fume hood ☐ Biosafety cabinet
      If a fume hood is used, certification of the hood is conducted:
      ☐ Annually ☐ Biannually ☐ Other (describe): _____
      Conducted with two knowledgeable people present: ☐ Yes ☐ No
4. A hazard sign on the door when toxins are present: ☐ Yes ☐ No
5. Floor plan(s) include:
   Sink location: ☐ Yes ☐ No
   Eyewash locations: ☐ Yes ☐ No
   Biosafety cabinet (BSC) locations: ☐ Yes ☐ No
   Fume hood locations: ☐ Yes ☐ No
   HVAC supply and exhaust locations: ☐ Yes ☐ No
   Freezer/refrigerator locations: ☐ Yes ☐ No
   Other large equipment locations (incubators, centrifuges, etc): ☐ Yes ☐ No
6. Plan provides a description of the HVAC system (check all that are appropriate):
   ☐ Single-pass ☐ Re-circulated ☐ Dedicated exhaust ☐ Shared exhaust
   ☐ Constant air volume ☐ Variable air volume ☐ Redundant exhaust fans ☐ Emergency power back-up
7. Plan provides information on the biosafety cabinets in use (attach additional sheets if needed):
   Class of cabinet:
   ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III
   Biosafety cabinet connection to the HVAC system:
   ☐ Hard duct ☐ Thimble ☐ Re-circulating
   Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain): _____
   Does user verify air flow during BSC use? ☐ Yes ☐ No

Section IV – Inspection Summary

1. As a result of the **Facility Assessment** of the *Laboratory Facilities (Secondary Barriers)*, the following was noted in respect of the interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination:
    a. Women's Outer Locker Room
        i. Small cracks in paint in ceiling need to be sealed
        ii. Cracks on walls above lockers need to be sealed
        iii. Openings in ceiling around conduits need to be sealed

    b. Women's Inner Locker Room
        i. Cracks in paint on wall near door(s) and above lockers need to be sealed
        ii. Openings in ceiling around conduits need to be sealed
        iii. Return air vent(s) need to be cleaned

    c. Room
        i. Cracks in paint in the corner behind the biosafety cabinet (to the left or on far side of the room) need to be sealed
        ii. A/C diffuser box needs to be repainted- boxes in other rooms have peeling paint
        iii. Biosafety cabinet (BSC) ductwork needs to be resealed where it meets the ceiling (both BSCs)
        iv. Radioactive materials were found in the lab that are no longer in use

    d. Room
        i. BSC ductwork needs to be resealed where it meets the ceiling (both BSCs)
        ii. Cracks and/or seams in coving around cabinets need to be sealed
        iii. Paint on the A/C diffuser box is peeling; box should be repainted
        iv. Small cracks in paint on the ceiling and wall near the fume hood (in the corner) needs to be sealed

    e. Room
        i. Wrong year entered in the Access Log for one of the freezers (2006 logged instead of 2007)

    f. Room
        i. Cracks in paint and/or wall coving needs to be sealed (small crack(s) where wall coving meets the door frame); cracks in corner behind the right fume hood and along the ceiling in the corner behind the left fume hood
        ii. Paint on the A/C diffuser box is peeling; box should be repainted
        iii. BSC and fume hood ductwork need to be resealed where they meet the ceiling (hood next to BSC; seal may just be very dirty)
        iv. Coving around bench needs to be sealed in corner on right side of bench (where it meets the wall) and in recessed area of bench; front left corner also needs to be sealed

    g. Room (Animal Room)
        i. Small cracks in paint need to be sealed; cracks also noted on ceiling next to the light fixture and over the door to the autoclave unit
        ii. Door sweep needed on the door to the autoclave
        iii. Isolation hoods were certified by: Alan Boedecker of *Service Tech*

    h. Men's Inner Locker Room
        i. Leaking shower needs to be repaired
        ii. Large crack in wall above door between the locker rooms need to be resealed

2006 Inspection Report

(Inspections conducted (Missing)

2006 inspection performed 12/9/05 ~~ar~~
7/20/06

2005 Inspection Report

(Inspections conducted 05/05)

& 12/05

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator
Lab Contact Person
Department
Office Phone Number
Lab Phone Number
Lab Location - Bldg _____ BL3 Suite Room

Biological agents used:
__ Recombinant DNA
✓ Human pathogens - list:
Mycobacterium

✓ Animal pathogens- list:
Brucella sp.
Coxiella burnetii
__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: __ BL2 ✓ BL3

Results: ✓ Meets criteria at appropriate biosafety level
_____ Does not meet criteria

Comments: Looks good, no lab activities occurring at time of inspection.

Date of Inspection: 12 - 9 - 05

Environmental Health & Safety Inspector:

NIH BIOSAFETY LEVEL 3 CRITERIA

A. Standard Microbiological Practices

✓ 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

✓ 2. Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

✓ 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

N/A 4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

✓ 5. Policies for the safe handling of sharps are instituted.

✓ 6. All procedures are performed carefully to minimize the creation of aerosols.

✓ 7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

✓ 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

✓ 9. Persons under 16 years of age are not allowed to enter a BL3 laboratory.

✓ 10. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

✓ 11. An insect and rodent control program is in effect.

B. Special Practices

✓ 1. Laboratory doors are kept closed when experiments are in progress.

✓ 2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

✓ 3. The laboratory director establishes 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.

✓ 4. When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

✓ 5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for

the agent being handled.

✓ 6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

✓ 7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

✓ 8. Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

✓ 9. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

✓ 10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.

b. 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

c. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.

d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

✓ 11. All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

✓ 12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.

b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

✓ 13. Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

✓ 14. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

✓ 15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

___16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

___17 Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

C. Safety Equipment (Primary Barriers)

___1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

___2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

___3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

___4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

___5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

___6. Respiratory and face protection are used when in rooms containing infected animals. (PAPR)

D. Laboratory Facilities (Secondary Barriers)

___1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

___2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

___3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are contructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

___4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

___5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

___6. Windows in the laboratory are closed and sealed.

___7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the

laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

___ 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

___ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

___ 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

___ 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

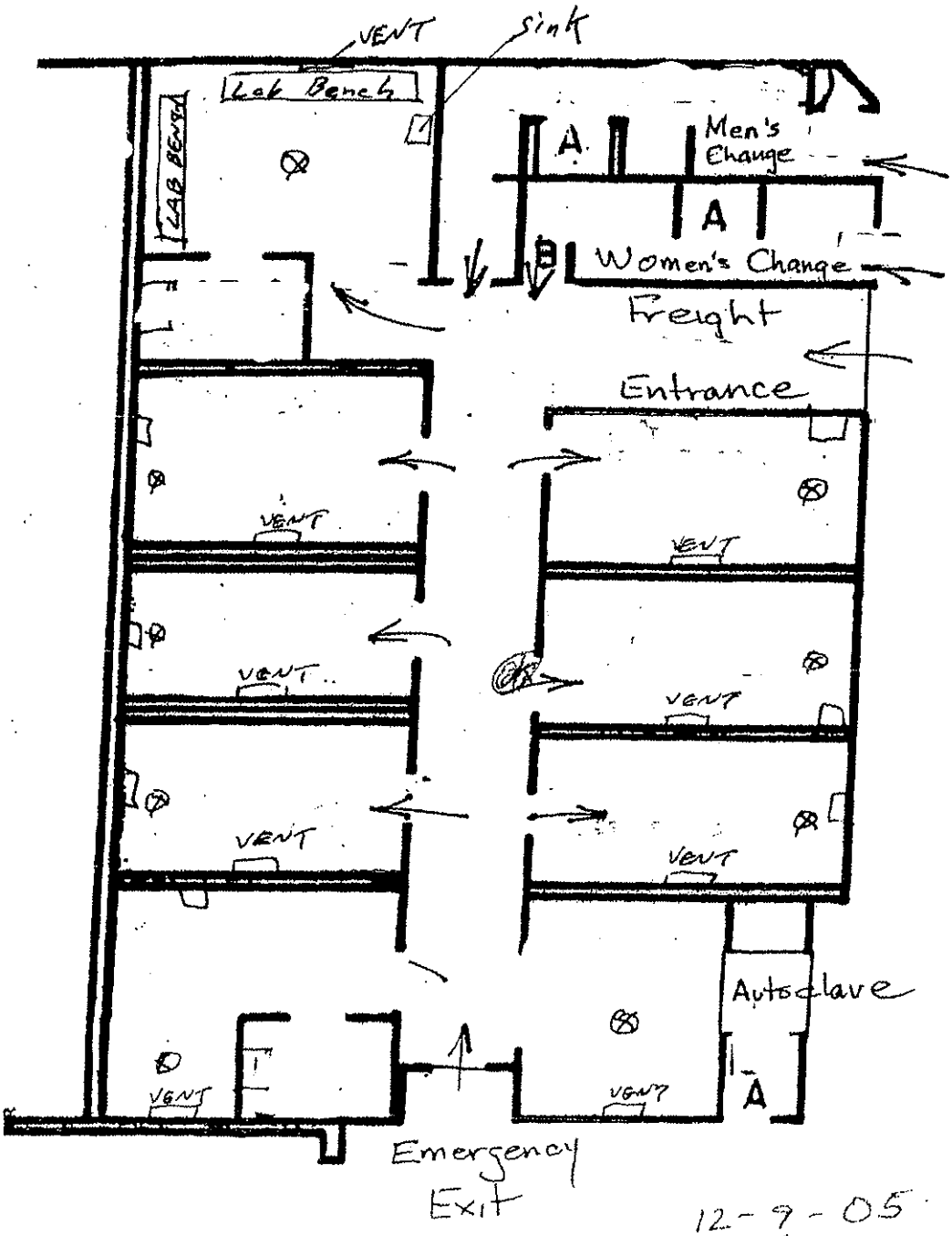
___ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

___ 13. An eyewash facility is readily available inside the laboratory.

___ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

___ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

___ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.


VENT
Sink
Lab Bench
LAB BENCH
A
Men's Change
A
B
Women's Change
Freight
Entrance
VENT
VENT
VENT
VENT
VENT
VENT
VENT
VENT
Autoclave
A
Emergency Exit

12-9-05

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator Dr. L.G. Adams / Dr. Thomas Ficht / Dr. James Samuel / Dr. Renee Tsolis

Lab Location - Bldg _____ Room _____

Biological agents used:

__ Recombinant DNA

_✔_ Human pathogens - list: *Coxiella burnetii, Rickettsia prowazekii, Brucella abortus, Brucella melitensis, Brucella suis*

_✔_ Animal pathogens- list: *Coxiella burnetii, Rickettsia prowazekii, Brucella abortus, Brucella melitensis, Brucella suis*

__ Human tissues or body fluids

__ Non-pathogenic biological materials

Biosafety Level: BL3

Results: ___✔___ Meets criteria at appropriate biosafety level

_____ Does not meet criteria

Comments:

Date of Inspection: May 21, 2005

Environmental Health & Safety Inspector: Brent S. Mattox

NIH BIOSAFETY LEVEL 3 CRITERIA

A. Standard Microbiological Practices

__✔__ 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

__✔__ 2. Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

__✔__ 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

__✔__ 4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

__✔__ 5. Policies for the safe handling of sharps are instituted.

__✔__ 6. All procedures are performed carefully to minimize the creation of aerosols.

__✔__ 7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

__✔__ 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

__✔__ 9. Persons under 16 years of age are not allowed to enter a BL3 laboratory.

__✔__ 10. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

__✔__ 11. An insect and rodent control program is in effect.

B. Special Practices

__✔__ 1. Laboratory doors are kept closed when experiments are in progress.

__✔__ 2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

__✔__ 3. The laboratory director establishes 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.

__✔__ 4. When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

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present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled.

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a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.

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___✔___ 12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.

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___✔___ 15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported

to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.
Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

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✔ 17 Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

C. Safety Equipment (Primary Barriers)

✔ 1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

✔ 2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

✔ 3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

✔ 4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

✔ 5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

✔ 6. Respiratory and face protection are used when in rooms containing infected animals.

D. Laboratory Facilities (Secondary Barriers)

✔ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

✔ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

✔ 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are contructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

✔ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

✔ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

✔ 6. Windows in the laboratory are closed and sealed.

✔ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

✔ 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✔ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

✔ 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

✔ 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

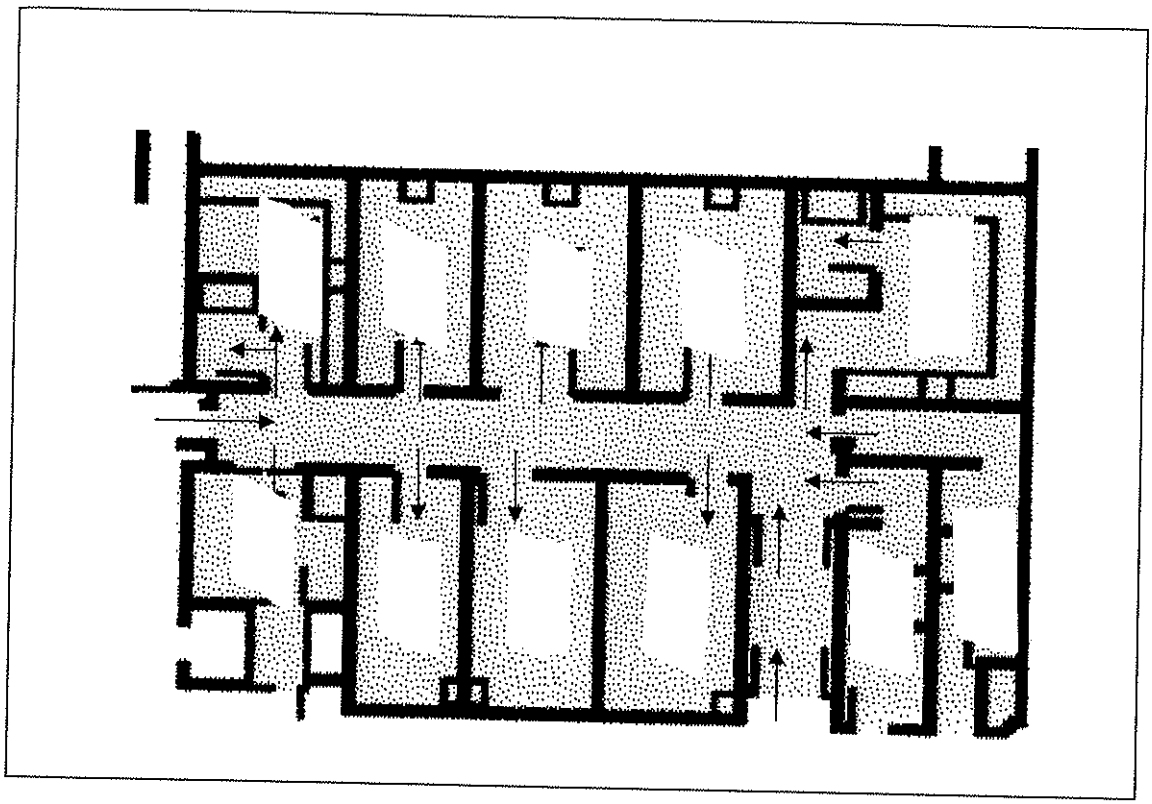
✔ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

✔ 13. An eyewash facility is readily available inside the laboratory.

✔ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

✔ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

✔ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.



May 21, 2005

2006 Inspection Report

(Inspections conducted 01/06)

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator: Dr. Thomas Ficht
Lab Contact Person: Melissa Kahl-McDonagh
Department: VTPB
Office Phone Number: 845-4185 or 845-4118
Lab Phone Number: 845-4185
Lab Location - Bldg: _____ Room _____

Biological agents used:

✔ Recombinant DNA

✔ Human pathogens - list: *Brucella melitensis*

✔ Animal pathogens- list: *Brucella abortus, Brucella melitensis, Brucella suis*

__ Human tissues or body fluids

__ Non-pathogenic biological materials

Biosafety Level: BL3

Results: ✔ Meets criteria at appropriate biosafety level

_____ Does not meet criteria

Comments:

Date of Inspection: 01/10/2006

Environmental Health & Safety Inspector: Nancy Eaker

NIH BIOSAFETY LEVEL 3 CRITERIA

A. Standard Microbiological Practices

✔ 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

✔ 2. Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

✔ 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

✔ 4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

✔ 5. Policies for the safe handling of sharps are instituted.

✔ 6. All procedures are performed carefully to minimize the creation of aerosols.

✔ 7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

✔ 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

✔ 9. Persons under 16 years of age are not allowed to enter a BL3 laboratory.

✔ 10. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

✔ 11. An insect and rodent control program is in effect.

B. Special Practices

✔ 1. Laboratory doors are kept closed when experiments are in progress.

✔ 2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

✔ 3. The laboratory director establishes 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.

✔ 4. When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

✔ 5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled.

✔ 6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

✔ 7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

✔ 8. Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

✔ 9. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

✔ 10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.
   a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
   b. 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
   c. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
   d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

✔ 11. All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

✔ 12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.
   a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
   b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

✔ 13. Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

✔ 14. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms

are decontaminated before disposal or reuse.

✔ 15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.
Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

✔ 16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

✔ 17 Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

C. Safety Equipment (Primary Barriers)

✔ 1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

✔ 2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

✔ 3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

✔ 4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

✔ 5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

✔ 6. Respiratory and face protection are used when in rooms containing infected animals.

D. Laboratory Facilities (Secondary Barriers)

✔ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway. ***NOTE: Doors to individual labs were not shutting completely on their own. Area Maintenance was notified by lab personnel.***

✔ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

✔ 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are contructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination. ***NOTE: Molding around cabinets in rooms) need to be sealed with silicone caulk. Noted cracks in paint along joint***

between bricks and solid wall piece and in the corner of roor . Noted chips in the paint on walls in room .

✔ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

✔ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

N/A 6. Windows in the laboratory are closed and sealed.

✔ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

✔ 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✔ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

✔ 10.HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

✔ 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

✔ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

✔ 13. An eyewash facility is readily available inside the laboratory.

✔ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

✔ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

✔ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

TEXAS A&M UNIVERSITY

ANIMAL FACILITY INSPECTION / CERTIFICATION

Principal Investigator: Dr. L.G. Adams / Dr. Thomas Ficht
Lab Contact Person: Doris Hunter / Melissa Kahl-McDonagh
Department: VTPB
Office Phone Number: 845-4185 or 845-4118
Lab Phone Number: 845-4185
Lab Location - Bldg: _____ Room _____

Biological agents used:
Recombinant DNA
✔ Human pathogens - list: *Brucella abortus, Brucella melitensis, Mycobacterium bovis*

✔ Animal pathogens- list: *Brucella abortus, Brucella melitensis, Mycobacterium bovis*

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: ABL3

Results: ✔ Meets criteria at appropriate biosafety level
_____ Does not meet criteria

Comments:

Date of Inspection: 01/10/2006

Environmental Health & Safety Inspector: Nancy Eaker

ANIMAL BIOSAFETY LEVEL 3

A. Standard Practices

✓ 1. Aside from the standard policies, procedures, and protocols for emergency situations established by the facility director, appropriate special policies and procedures should be developed as needed and approved by the Institutional Animal Care and Use Committee (IACUC) and the Institutional Biosafety Committee (IBC).

✓ 2. The laboratory or animal facility director limits access to the animal room to the fewest number of individuals possible. Personnel who must enter the room for program or service purposes when work is in progress are advised of the potential hazard.

✓ 3. An appropriate medical surveillance program is in place. All personnel receive appropriate immunizations or tests for the agents handled or potentially present (e.g., hepatitis B vaccine, TB skin testing). When appropriate, a serum surveillance system should be implemented. In general, persons who may be at increased risk of acquiring infection, or for whom infection might have serious consequences, are not allowed in the animal facility unless special procedures can eliminate the extra risk. Assessment should be made by the occupational health physician.

✓ 4. A biosafety manual is prepared or adopted. Personnel are advised of special hazards, and are required to read and to follow instructions on practices and procedures.

✓ 5. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use should be done only in designated areas and are not permitted in animal or procedure rooms.

✓ 6. All procedures are carefully performed to minimize the creation of aerosols or splatters.

✓ 7. Equipment and work surfaces in the room are routinely decontaminated with an effective disinfectant after work with the infectious agent, and especially after overt spills, splashes, or other contamination by infectious materials.

✓ 8. All wastes from the animal room (including animal tissues, carcasses, contaminated bedding, unused feed, sharps, and other refuse animal tissues) are transported from the animal room in leak-proof, covered containers for appropriate disposal in compliance with applicable institutional or local requirements. Incineration is recommended. The outer surface of the containers is disinfected prior to moving the material.

✓ 9. Policies for the safe handling of sharps are instituted.

a. Needles and syringes or other sharp instruments are restricted in the animal facility for use only when there is no alternative, such as for parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.

b. Syringes that re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.

c. Plasticware should be substituted for glassware whenever possible.

✓ 10. Personnel wash their hands after handling cultures and animals, after removing gloves, and before leaving the animal facility.

✓ 11. A biohazard sign must be posted on the entrance to the animal room whenever infectious agents are present. The hazard warning sign identifies the infectious agent(s) in use, lists the name and telephone number of the responsible person(s), and indicates the special

requirements for entering the animal room (e.g., the need for immunizations and respirators).

✓ 12. All infectious samples are collected, labeled, transported, and processed in a manner that contains and prevents transmission of the agent(s).

✓ 13. Laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. As necessary, personnel receive updates and/or additional training on procedural or policy changes. Records of all training provided are maintained.

✓ 14. An insect and rodent control program is in effect.

B. Special Practices

✓ 1. Cages are autoclaved or thoroughly decontaminated before bedding is removed and before they are cleaned and washed. Equipment must be decontaminated according to any local, state, or federal regulations before being packaged for transport or removal from the facility for repair or maintenance.

✓ 2. A spill procedure is developed and posted. Only personnel properly trained and equipped to work with infectious materials are to clean up spills. Spills and accidents that result in overt exposures to infectious materials must be immediately reported to the facility director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

✓ 3. All wastes from the animal room must be autoclaved prior to incineration or other appropriate terminal treatment.

✓ 4. Materials not related to the experiment (e.g., plants, animals) are not permitted in the animal room.

C. Safety Equipment (Primary Barriers)

✓ 1. Uniforms or scrub suits are worn by personnel entering the animal room. Wrap-around or solid-front gowns or uniforms should be worn over this clothing. Front-button laboratory coats are unsuitable. The gown must be removed and left in the animal room. Before leaving the animal facility, scrub suits and uniforms are removed and appropriately contained and decontaminated prior to laundering or disposal.

✓ 2. Personal protective equipment used is based on risk assessment determinations.
   a. Personal protective equipment is used for all activities involving manipulations of infectious material or infected animals.
   b. Personnel wear gloves when handling infected animals. Gloves are removed aseptically and autoclaved with other animal room wastes before disposal.
   c. Appropriate face/eye and respiratory protection (e.g., respirators and face shields) is worn by all personnel entering animal rooms.
   d. Boots, shoe covers, or other protective footwear, and disinfectant foot baths are available and used where indicated.

✓ 3. The risk of infectious aerosols from infected animals or their bedding also can be reduced if animals are housed in containment caging systems, such as open cages placed in inward flow ventilated enclosures (e.g., laminar flow cabinets), solid wall and bottom cages covered with filter bonnets, or other equivalent primary containment systems.

✓ 4. Biological safety cabinets and other physical containment devices are used whenever conducting procedures with a potential for creating aerosols. These include necropsy of infected animals, harvesting of tissues or fluids from infected animals or eggs, or intranasal inoculation of animals. At BSL-3, all work should be done in a primary barrier; otherwise respirators should be worn by personnel in the room.

D. Facilities (Secondary Barriers)

✓ 1. The animal facility is separated from areas that are open to unrestricted personnel traffic within the building.

✓ 2. Access to the facility is limited by a self-closing and self-locking door. This exterior entry door may be controlled by a key lock, card key, or proximity reader. Entry into the animal room is via a double-door entry which includes a change room and shower(s). An additional double-door access (air-lock) or double-doored autoclave may be provided for movement of supplies and wastes into and out of the facility, respectively. Doors to animal rooms open inward and are self-closing. Doors to cubicles inside an animal room may open outward or slide horizontally or vertically.

✓ 3. The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (walls, floors, and ceilings) are water-resistant. Penetrations in floor, walls and ceiling surfaces are sealed and openings around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination. ***NOTE: Noted chipped and/or cracked paint in this lab room.***

✓ 4. A hands-free or automatically operated hand washing sink is provided in each animal room near the exit door. The sink trap is filled with an appropriate disinfectant after each use.

✓ 5. Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize horizontal surface areas.

N/A 6. Any windows must be resistant to breakage. Where possible, windows should be sealed. If the animal facility has windows that open, they are fitted with fly screens.

✓ 7. If floor drains are provided, they are always filled with an appropriate disinfectant.

✓ 8. Ventilation should be provided in accordance with criteria from the *Guide for Care and Use of Laboratory Animals*, latest edition. 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 recirculated to any other area of the building. Filtration and other treatments of the exhaust air may not be required, but should be considered based on site requirements, and specific agent manipulations and use conditions. The exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Personnel must verify that the direction of the airflow (into the animal areas) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the animal room entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the animal spaces. Audible alarms should be considered to notify personnel of HVAC system failure.

✓ 9. The HEPA filtered exhaust air from a Class II biological safety cabinet can be recirculated into the animal room if the cabinet is tested and certified at least annually. When exhaust air from Class II safety cabinets is to be discharged directly to the outside through the

building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used, they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

✔ 10. Cages are washed in a cage washer. The mechanical cage washer has a final rinse temperature of at least 180 ° F.

✔ 11. An autoclave is available which is convenient to the animal rooms where the biohazard is contained. The autoclave is utilized to decontaminate infectious waste before moving it to other areas of the facility.

✔ 12. If vacuum service (i.e., central or local) is provided, each service connection should be fitted with liquid disinfectant traps and an in-line HEPA filter, placed as near as practicable to each use point or service cock. Filters are installed to permit in-place decontamination and replacement.

✔ 13. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

✔ 14. The completed Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified at least annually against these procedures as modified by operational experience.

✔ 15. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services, and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment of the site conditions, or other applicable federal, state, or local regulations.

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator Dr. L.G. Adams
Lab Contact Person Doris Hunter
Department VTPB
Office Phone Number 845-9814
Lab Phone Number 845-9814
Lab Location - Bldg _____ Room ____

Biological agents used:
✔ Recombinant DNA
✔ Human pathogens - list: *Brucella abortus, Brucella melitensis, Mycobacterium bovis*

✔ Animal pathogens- list: *Brucella abortus, Brucella melitensis, Mycobacterium bovis*

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: BL3

Results: ✔ Meets criteria at appropriate biosafety level
____ Does not meet criteria

Comments:

Date of Inspection: 01/10/2006

Environmental Health & Safety Inspector: Nancy Eaker

NIH BIOSAFETY LEVEL 3 CRITERIA

A. Standard Microbiological Practices

✔ 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

✔ 2. Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

✔ 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

✔ 4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

✔ 5. Policies for the safe handling of sharps are instituted.

✔ 6. All procedures are performed carefully to minimize the creation of aerosols.

✔ 7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

✔ 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

✔ 9. Persons under 16 years of age are not allowed to enter a BL3 laboratory.

✔ 10. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

✔ 11. An insect and rodent control program is in effect.

B. Special Practices

✔ 1. Laboratory doors are kept closed when experiments are in progress.

✔ 2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

✔ 3. The laboratory director establishes 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.

✔ 4. When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

✔ 5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled.

✔ 6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

✔ 7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

✔ 8. Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

✔ 9. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

✔ 10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.
   a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
   b. 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
   c. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
   d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

✔ 11. All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

✔ 12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.
   a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
   b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

✔ 13. Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

✔ 14. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms

are decontaminated before disposal or reuse.

✔ 15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.
Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

✔ 16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

✔ 17 Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

C. Safety Equipment (Primary Barriers)

✔ 1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

✔ 2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

✔ 3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

✔ 4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

✔ 5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

✔ 6. Respiratory and face protection are used when in rooms containing infected animals.

D. Laboratory Facilities (Secondary Barriers)

✔ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway. ***NOTE: Door does not shut completely on its own. Area Maintenance was notified by lab personnel.***

✔ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

✔ 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are contructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination. ***NOTE: Molding around cabinets needs to be sealed with silicone caulk. Noted a few small cracks/chips in paint.***

✔ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

✔ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

N/A 6. Windows in the laboratory are closed and sealed.

✔ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

✔ 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✔ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

✔ 10.HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

✔ 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

✔ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

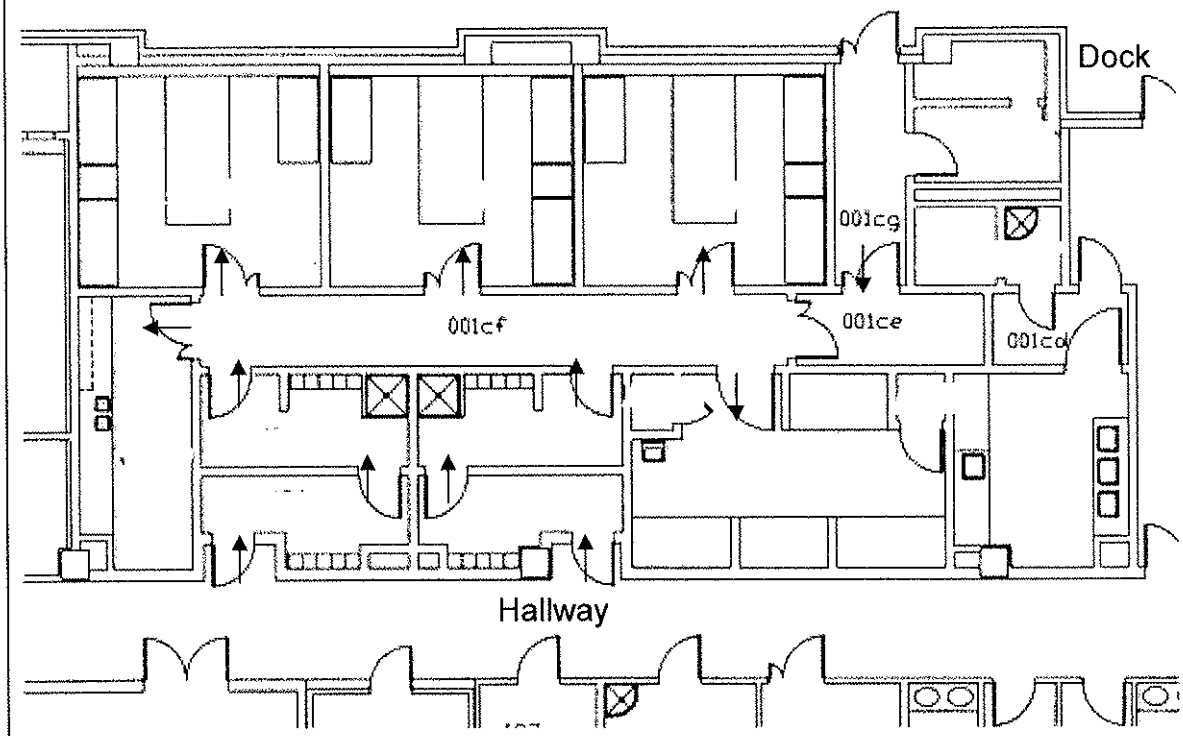
✔ 13. An eyewash facility is readily available inside the laboratory.

✔ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

✔ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

✔ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

Veterinary Research Building /



2005 Inspection Report

(Inspections conducted 01/05)

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator Dr. L.G. Adams
Lab Contact Person Doris Hunter
Department VTPB
Office Phone Number 845-9814
Lab Phone Number 845-9814
Lab Location - Bldg _____ Room 1

Biological agents used:
✔ Recombinant DNA
✔ Human pathogens - list: *Brucella abortus, Brucella melitensis, Mycobacterium bovis*

✔ Animal pathogens- list: *Brucella abortus, Brucella melitensis, Mycobacterium bovis*

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: BL3

Results: ✔ Meets criteria at appropriate biosafety level
_____ Does not meet criteria

Comments:

Date of Inspection: 01/12/05

Environmental Health & Safety Inspector: Nancy Eaker

NIH BIOSAFETY LEVEL 3 CRITERIA

A. Standard Microbiological Practices

✔ 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

✔ 2. Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

✔ 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

✔ 4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

✔ 5. Policies for the safe handling of sharps are instituted.

✔ 6. All procedures are performed carefully to minimize the creation of aerosols.

✔ 7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

✔ 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

✔ 9. Persons under 16 years of age are not allowed to enter a BL3 laboratory.

✔ 10. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

✔ 11. An insect and rodent control program is in effect.

B. Special Practices

✔ 1. Laboratory doors are kept closed when experiments are in progress.

✔ 2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

✔ 3. The laboratory director establishes 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.

✔ 4. When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

✓ 5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled.

✓ 6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

✓ 7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

✓ 8. Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

✓ 9. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

✓ 10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.

b. 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

c. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.

d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

✓ 11. All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

✓ 12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.

b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

✓ 13. Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

✓ 14. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms

are decontaminated before disposal or reuse.

✔ 15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.
Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

✔ 16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

✔ 17. Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

C. Safety Equipment (Primary Barriers)

✔ 1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

✔ 2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

✔ 3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

✔ 4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

✔ 5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

✔ 6. Respiratory and face protection are used when in rooms containing infected animals.

D. Laboratory Facilities (Secondary Barriers)

✔ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

✔ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

✔ 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are contructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

✔ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

✔ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

✔ 6. Windows in the laboratory are closed and sealed.

✔ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

✔ 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✔ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

✔ 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

✔ 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

✔ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

✔ 13. An eyewash facility is readily available inside the laboratory.

✔ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

✔ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

✔ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator Dr. Thomas Ficht
Lab Contact Person Carol Turse
Department VTPB
Office Phone Number 845-4185 or 845-4118
Lab Phone Number 845-4185
Lab Location - Bldg _____ Room _____

Biological agents used:
✔ Recombinant DNA
✔ Human pathogens - list: *Brucella melitensis*

✔ Animal pathogens- list: *Brucella abortus, Brucella melitensis, Brucella suis*

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: BL3

Results: ✔ Meets criteria at appropriate biosafety level
_____ Does not meet criteria

Comments:

Date of Inspection: 01/12/05

Environmental Health & Safety Inspector: Nancy Eaker

NIH BIOSAFETY LEVEL 3 CRITERIA

A. Standard Microbiological Practices

✓ 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

✓ 2. Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

✓ 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

✓ 4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

✓ 5. Policies for the safe handling of sharps are instituted.

✓ 6. All procedures are performed carefully to minimize the creation of aerosols.

✓ 7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

✓ 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

✓ 9. Persons under 16 years of age are not allowed to enter a BL3 laboratory.

✓ 10. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

✓ 11. An insect and rodent control program is in effect.

B. Special Practices

✓ 1. Laboratory doors are kept closed when experiments are in progress.

✓ 2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

✓ 3. The laboratory director establishes 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.

✓ 4. When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

✓ 5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled.

✓ 6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

✓ 7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

✓ 8. Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

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✓ 10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.
   a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
   b. 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
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✓ 12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.
   a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
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those chemicals used to decontaminate the work surfaces and equipment.

✔ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

N/A 6. Windows in the laboratory are closed and sealed.

✔ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

✔ 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✔ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

✔ 10.HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

✔ 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

✔ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

✔ 13. An eyewash facility is readily available inside the laboratory.

✔ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

✔ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

✔ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

TEXAS A&M UNIVERSITY

ANIMAL FACILITY INSPECTION / CERTIFICATION

Principal Investigator Dr. L.G. Adams / Dr. Thomas Ficht
Lab Contact Person Doris Hunter / Carol Turse
Department VTPB
Office Phone Number 845-4185
Lab Phone Number 845-4185
Lab Location - Bldg Room

Biological agents used:
Recombinant DNA
✔ Human pathogens - list: *Brucella abortus, Brucella melitensis, Mycobacterium bovis*

✔ Animal pathogens- list: *Brucella abortus, Brucella melitensis, Mycobacterium bovis*

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: ABL3

Results: ✔ Meets criteria at appropriate biosafety level
_____ Does not meet criteria

Comments:

Date of Inspection: 01/12/05

Environmental Health & Safety Inspector: Nancy Eaker

ANIMAL BIOSAFETY LEVEL 3

A. Standard Practices

✔ 1. Aside from the standard policies, procedures, and protocols for emergency situations established by the facility director, appropriate special policies and procedures should be developed as needed and approved by the Institutional Animal Care and Use Committee (IACUC) and the Institutional Biosafety Committee (IBC).

✔ 2. The laboratory or animal facility director limits access to the animal room to the fewest number of individuals possible. Personnel who must enter the room for program or service purposes when work is in progress are advised of the potential hazard.

✔ 3. An appropriate medical surveillance program is in place. All personnel receive appropriate immunizations or tests for the agents handled or potentially present (e.g., hepatitis B vaccine, TB skin testing). When appropriate, a serum surveillance system should be implemented. In general, persons who may be at increased risk of acquiring infection, or for whom infection might have serious consequences, are not allowed in the animal facility unless special procedures can eliminate the extra risk. Assessment should be made by the occupational health physician.

✔ 4. A biosafety manual is prepared or adopted. Personnel are advised of special hazards, and are required to read and to follow instructions on practices and procedures.

✔ 5. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use should be done only in designated areas and are not permitted in animal or procedure rooms.

✔ 6. All procedures are carefully performed to minimize the creation of aerosols or splatters.

✔ 7. Equipment and work surfaces in the room are routinely decontaminated with an effective disinfectant after work with the infectious agent, and especially after overt spills, splashes, or other contamination by infectious materials.

✔ 8. All wastes from the animal room (including animal tissues, carcasses, contaminated bedding, unused feed, sharps, and other refuse animal tissues) are transported from the animal room in leak-proof, covered containers for appropriate disposal in compliance with applicable institutional or local requirements. Incineration is recommended. The outer surface of the containers is disinfected prior to moving the material.

✔ 9. Policies for the safe handling of sharps are instituted.
   a. Needles and syringes or other sharp instruments are restricted in the animal facility for use only when there is no alternative, such as for parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.
   b. Syringes that re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
   c. Plasticware should be substituted for glassware whenever possible.

✔ 10. Personnel wash their hands after handling cultures and animals, after removing gloves, and before leaving the animal facility.

✔ 11. A biohazard sign must be posted on the entrance to the animal room whenever infectious agents are present. The hazard warning sign identifies the infectious agent(s) in use, lists the name and telephone number of the responsible person(s), and indicates the special

requirements for entering the animal room (e.g., the need for immunizations and respirators).

✓ 12. All infectious samples are collected, labeled, transported, and processed in a manner that contains and prevents transmission of the agent(s).

✓ 13. Laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. As necessary, personnel receive updates and/or additional training on procedural or policy changes. Records of all training provided are maintained.

✓ 14. An insect and rodent control program is in effect.

B. Special Practices

✓ 1. Cages are autoclaved or thoroughly decontaminated before bedding is removed and before they are cleaned and washed. Equipment must be decontaminated according to any local, state, or federal regulations before being packaged for transport or removal from the facility for repair or maintenance.

✓ 2. A spill procedure is developed and posted. Only personnel properly trained and equipped to work with infectious materials are to clean up spills. Spills and accidents that result in overt exposures to infectious materials must be immediately reported to the facility director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

✓ 3. All wastes from the animal room must be autoclaved prior to incineration or other appropriate terminal treatment.

✓ 4. Materials not related to the experiment (e.g., plants, animals) are not permitted in the animal room.

C. Safety Equipment (Primary Barriers)

✓ 1. Uniforms or scrub suits are worn by personnel entering the animal room. Wrap-around or solid-front gowns or uniforms should be worn over this clothing. Front-button laboratory coats are unsuitable. The gown must be removed and left in the animal room. Before leaving the animal facility, scrub suits and uniforms are removed and appropriately contained and decontaminated prior to laundering or disposal.

✓ 2. Personal protective equipment used is based on risk assessment determinations.
   a. Personal protective equipment is used for all activities involving manipulations of infectious material or infected animals.
   b. Personnel wear gloves when handling infected animals. Gloves are removed aseptically and autoclaved with other animal room wastes before disposal.
   c. Appropriate face/eye and respiratory protection (e.g., respirators and face shields) is worn by all personnel entering animal rooms.
   d. Boots, shoe covers, or other protective footwear, and disinfectant foot baths are available and used where indicated.

✓ 3. The risk of infectious aerosols from infected animals or their bedding also can be reduced if animals are housed in containment caging systems, such as open cages placed in inward flow ventilated enclosures (e.g., laminar flow cabinets), solid wall and bottom cages covered with filter bonnets, or other equivalent primary containment systems.

✓ 4. Biological safety cabinets and other physical containment devices are used whenever conducting procedures with a potential for creating aerosols. These include necropsy of infected animals, harvesting of tissues or fluids from infected animals or eggs, or intranasal inoculation of animals. At BSL-3, all work should be done in a primary barrier; otherwise respirators should be worn by personnel in the room.

D. Facilities (Secondary Barriers)

✓ 1. The animal facility is separated from areas that are open to unrestricted personnel traffic within the building.

✓ 2. Access to the facility is limited by a self-closing and self-locking door. This exterior entry door may be controlled by a key lock, card key, or proximity reader. Entry into the animal room is via a double-door entry which includes a change room and shower(s). An additional double-door access (air-lock) or double-doored autoclave may be provided for movement of supplies and wastes into and out of the facility, respectively. Doors to animal rooms open inward and are self-closing. Doors to cubicles inside an animal room may open outward or slide horizontally or vertically.

✓ 3. The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (walls, floors, and ceilings) are water-resistant. Penetrations in floor, walls and ceiling surfaces are sealed and openings around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

✓ 4. A hands-free or automatically operated hand washing sink is provided in each animal room near the exit door. The sink trap is filled with an appropriate disinfectant after each use.

✓ 5. Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize horizontal surface areas.

N/A 6. Any windows must be resistant to breakage. Where possible, windows should be sealed. If the animal facility has windows that open, they are fitted with fly screens.

✓ 7. If floor drains are provided, they are always filled with an appropriate disinfectant.

✓ 8. Ventilation should be provided in accordance with criteria from the *Guide for Care and Use of Laboratory Animals*, latest edition. 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 recirculated to any other area of the building. Filtration and other treatments of the exhaust air may not be required, but should be considered based on site requirements, and specific agent manipulations and use conditions. The exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Personnel must verify that the direction of the airflow (into the animal areas) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the animal room entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the animal spaces. Audible alarms should be considered to notify personnel of HVAC system failure.

✓ 9. The HEPA filtered exhaust air from a Class II biological safety cabinet can be recirculated into the animal room if the cabinet is tested and certified at least annually. When exhaust air from Class II safety cabinets is to be discharged directly to the outside through the

building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used, they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

✓ 10. Cages are washed in a cage washer. The mechanical cage washer has a final rinse temperature of at least 180 ° F.

✓ 11. An autoclave is available which is convenient to the animal rooms where the biohazard is contained. The autoclave is utilized to decontaminate infectious waste before moving it to other areas of the facility.

N/A 12. If vacuum service (i.e., central or local) is provided, each service connection should be fitted with liquid disinfectant traps and an in-line HEPA filter, placed as near as practicable to each use point or service cock. Filters are installed to permit in-place decontamination and replacement.

✓ 13. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

✓ 14. The completed Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified at least annually against these procedures as modified by operational experience.

✓ 15. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services, and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment of the site conditions, or other applicable federal, state, or local regulations.

2007 Inspection Report

(Inspections conducted 02/07-~~05~~06/07) 06/07 corrected date ad 9/22/07

TEXAS A&M UNIVERSITY

VICE PRESIDENT FOR RESEARCH - OFFICE OF RESEARCH COMPLIANCE

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College Station, TX 77843-1186
1500 Research Parkway, Suite B-150

979.458.1467
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Institutional Biosafety Committee | Institutional Animal Care and Use Committee | Institutional Review Board

MEMORANDUM

TO: Dr. Franklin Stein, Director
Veterinary Medical Park (VMP)
MS 4458

FROM: Tiffany M. Agnew, Program Coordinator
Institutional Bio-Safety Program (IBSP)

DATE: June 29, 2007

REG.: Annual IBC Inspection of Select Agent Facilities- Buildings '

On February 22, 2007, the following individuals completed the Annual IBC Inspection of the Select Agent Facilities- Building

Dr. Thomas Ficht- IBC Member (Chair)
Dr. Vernon Tesh- IBC Member
Mr. Brent Mattox- IBC Member/BSO
Ms. Nancy Eaker- EHS
Ms. Tiffany Agnew- IBSP Coordinator

The aforementioned team utilized the combined checklist from Environmental Health and Safety and the Office of Research Compliance to complete the inspection of the facilities. The use of this combined checklist marks the combined inspection by both offices, to reduce duplicated efforts for identical information. In accordance with CFR 42 § 73.9, inspection of Select Agent Facilities at Texas A&M University were due to be conducted in January. However, due to inclement weather, the inspection of this facility was rescheduled to take place on February 22, 2007.

Due to renovations taking place specifically in Building ' ancy Eaker completed an additional inspection on March 30, 2007 and April 3, 2007. The aforementioned individual utilized the Environmental Health and Safety checklist to complete the inspection of the facilities. During these inspection, the following deficiencies were noted by the inspection team:

1. As a result of the **Facility Assessment** of the *Laboratory Facilities (Secondary Barriers)*, the following was noted in respect of the interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination:

    a. The interior of the facility is being altered.
    b. There is not a sink for hand washing; the "sink" is located in the shower and the faucet is in the containment area.
    c. The shower area is the closet thing to an eyewash.

2. As a result of the **Program Assessment**, the inspection team noted that there was **NO SBAT work** taking place in these buildings at the time of the inspection. The team also noted that before SBAT work can be performed in these buildings, there must be IBC and CDC approval documentation.

The IBC requests these deficiencies are rectified before: **July 26, 2007.** Before the next inspection of this facility, it must be documented that these deficiencies have been rectified. Upon receipt of this

correspondence, please provide written indication that you have indeed received this document, and that you agree to complete all necessary corrections.

If you have any additional questions or concerns, please feel free to contact our office.

cc: Dr. Thomas Ficht
Dr. Melanie Ihrig
Dr. Richard Ewing
SBAT files
Dr. L. Garry Adams
Dr. Betsy Browder
IBC files

*Revised to reflect EHS notes. (jma)

IBC INSPECTION REPORT
BSL3/ABSL3 SBAT FACILITIES & Entity Program

Date: February 22, 2007
Principal Investigator/Lab Director: Dr. Frank Stein
Location: Building Number – _____ Room (s): ABSL & BSL3

Inspection Team:
Tom Ficht, Vernon Tesh,
Brent Mattox, Nancy Eaker,
Tiffany Agnew

Section I - Facility Assessment (PI)

A. Safety Equipment (Primary Barriers)

☐ Yes ☐ No Protective laboratory clothing, such as solid-front or wrap-around gowns, scrub suits, or coveralls, are worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

☐ Yes ☐ No Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

☐ Yes ☐ No Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

☐ Yes ☐ No All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

☐ Yes ☐ No When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

☐Yes ☐ No Respiratory and face protection are used when in rooms containing infected animals.

B. Laboratory Facilities (Secondary Barriers)

☑ Yes ☐ No The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

☐ Yes ☑ No Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

Sink is located in the shower; the faucet is in the containment area.

☐ Yes ☑ No The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are

constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

☑ Yes ☐ No Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

☑ Yes ☐ No Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

☐Yes ☐ No Windows in the laboratory are closed and sealed.

N/A

☑ Yes ☐ No A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

☑ Yes ☐ No Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

☑ Yes ☐ No A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

Interior of facility is being altered.

☑ Yes ☐ No HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

☐ Yes ☐ No 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

N/A

☐ Yes ☐ No Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

N/A

☐ Yes ☑ No An eyewash facility is readily available inside the laboratory.

The shower is the closet thing to an eyewash.

☐ Yes ☑ No Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

☑ Yes ☐ No The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

- Floor plan(s) include:
  - Sink location
    ☐ Yes ☐ No
  - Eyewash locations
    ☐ Yes ☐ No
  - Biosafety cabinet (BSC) locations
    ☐ Yes ☐ No
  - Fume hood locations
    ☐ Yes ☐ No
  - HVAC supply and exhaust locations
    ☐ Yes ☐ No
  - Freezer/refrigerator locations
    ☐ Yes ☐ No
  - Other large equipment locations (incubators, centrifuges, etc)
    ☐ Yes ☐ No
- Provide a description of the HVAC system (check all that are appropriate):
  - ☐ Single-pass ☐ Re-circulated
  - ☐ Dedicated exhaust ☐ Shared exhaust
  - ☐ Constant air volume ☐ Variable air volume
  - ☐ Redundant exhaust fans
  - ☐ Emergency power back-up
- Provide information on the biosafety cabinets in use (attach additional sheets if needed):
  - Class of cabinet:
  - ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3)
  - ☐ II, B1 ☐ II, B2 ☐ III
  - Biosafety cabinet connection to the HVAC system:
  - ☐ Hard duct ☐ Thimble ☐ Re-circulating
  - Define certification period:
  - ☐ Annual ☐ Biannual ☐ Other (explain): _____
  - Does user verify air flow during BSC use?
    ☐ Yes ☐ No
  - If floor drains are provided, the traps are always filled with an appropriate disinfectant:
    ☐ Yes ☐ No

☑ Yes ☐ No Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

C. Standard Microbiological Practices

☐ Yes ☐ No Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

☐Yes ☐ No Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave

the laboratory.

☐ Yes ☐ No Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

☐ Yes ☐ No Mechanical pipetting devices are used; mouth pipetting is prohibited.

☐ Yes ☐ No Policies for the safe handling of sharps are instituted.

☐ Yes ☐ No All procedures are performed carefully to minimize the creation of aerosols.

☐ Yes ☐ No Work surfaces are decontaminated at least once a day and after any spill of viable material.

☐ Yes ☐ No All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

☐ Yes ☐ No Persons under 16 years of age are not allowed to enter a BL3 laboratory.

☐ Yes ☐ No If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

☐ Yes ☐ No An insect and rodent control program is in effect.

D: Special Practices

☐ Yes ☐ No Laboratory doors are kept closed when experiments are in progress.

☐ Yes ☐ No The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

☐ Yes ☐ No The laboratory director establishes 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.

☐ Yes ☐ No When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

☐ Yes ☐ No Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled.

☐ Yes ☐ No Baseline serum samples are collected as appropriate and stored for all laboratories and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

☐ Yes ☐ No A Biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and Biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

☐ Yes ☐ No Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

☐ Yes ☐ No The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

☐ Yes ☐ No A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

- Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic ware should be substituted for glassware whenever possible.
- 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
- Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
- Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

☐ Yes ☐ No All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

☐ Yes ☐ No Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

- Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
- Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

☐ Yes ☐ No Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

☐ Yes ☐ No All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories

and animal rooms are decontaminated before disposal or reuse.

☐ Yes ☐ No Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained. Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

☐ Yes ☐ No Animals and plants not related to the work being conducted are not permitted in the laboratory.

☐ Yes ☐ No Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

Section II - Program Assessment (PI and/or Institutional BioSafety Program- IBSP)

☑ Yes ☐ No 1. An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with Select Agents at this facility: ***IBC approval is handled by the PI; work currently approved for PI Ficht and PI Adams. Approved AUP must be in place before work can begin. A copy of the approved AUP must be provided to Dr. Stein. Signage, noting the use of Biohazards, will then be placed on the building. Buildings assigned by Dr. Stein; list maintained by Melissa Horseman. Signage remains on building until decontaminated.***

If yes: IBC approved the work proposed for this facility on: _____ (date).

☑ Yes ☐ No 2. **Training**: Site specific and safety training is provided to individuals with access to areas where Select Agents are handled or stored:

a. Is provided prior to individuals beginning to work with Select Agents: ☑ Yes ☐ No
Training provided through CMP and the PI
b. Is provided: ☐ Annually ☐ Biannually ☑ Other (specify frequency):
When work is being performed in buildings.
c. Written records of individuals are kept: ☑ Yes ☐ No
d. Personnel demonstrate proficiency in laboratory procedures prior to working with Select Agents: ☑ Yes ☐ No
e. Unannounced visits by EH&S and follow up by supervisory personnel: ☑ Yes ☐ No
Point of contact: William Skirvanek

3. Provide a brief explanation of the system in place to detect loss or theft of select agent(s):
Located within the Incident Response Plan

4. **Inventory**: Individual responsible for inventory of select agent(s): ***No agent stored in buildings.***
a. How often is the inventory record reconciled? ***Determined by the PI***
b. How is access to the inventory log limited? ***Determined by the PI***
c. Inventory tracking includes the following information (list): ***Wellness Counts (health checks) completed by CMP and PI personnel; numbers recorded on cage cards. Daily animal census conducted for SBAT animals; physically counted before and after change out.***

5. **Security**: There is a site-specific Security Plan for this laboratory: ☑ Yes ☐ No
a. Building with Select Agent has self-closing doors: ☑ Yes ☐ No
b. Means to limit access to buildings with laboratories with Select Agent:
Guard station at the facility entrance: ☐ Yes ☑ No
Card access system or locks: ☑ Yes ☐ No
Gates at entrance with a key punch pad.
Security alarm system in the laboratory building: ☐ Yes ☑ No
Other (describe):
f. Means to limit access to laboratories with Select Agent once inside the building:
Door to laboratory is locked: ☑ Yes ☐ No
Card access system or locks: ☑ Yes ☐ No
Other (describe): **No additional monitoring of buildings. Doors are always kept locked when occupied. Keys are issued by Dr. Stein's personnel for each project.**
g. Means to limit access to select agents once inside the laboratory:
Locked incubators, refrigerators, freezers, etc.: ☑ Yes ☐ No
Security alarm system that directly monitors the laboratory: ☐ Yes ☑ No
Other (describe): ***No agents are stored in the facility***
h. Means to limit access to select agents in storage: ***N/A*** **(see previous question)**
Storage area door locked: ☐ Yes ☐ No
Lock boxes: ☐ Yes ☐ No
Security alarm system that directly monitors the laboratory: ☐ Yes ☐ No
Other (describe): _____

i. Means to monitor unauthorized entry into the laboratory where select agents are used or stored: ***N/A*** (see question "g")
Electronic logs of card access system entries are reviewed for unusual activity: ☐ Yes ☐ No
Manual sign in and out logs are kept and monitored: ☐ Yes ☐ No
Video camera surveillance: ☐ Yes ☐ No
Other (describe): _____

j. The laboratory is secured when no one is present during regular working hours: ☑ Yes ☐ No

k. Number of people with access: ***Those whom are listed on the 4B table for the facility.***

l. Individuals not directly involved in research activities have access to Select Agent: ☐ Yes ☑ No
If yes, please explain: _____

m. Non-laboratory personnel (visitors, including janitorial and facility maintenance personnel) have access to the laboratory with select agents: ☐ Yes ☑ No
No access for janitorial staff; all janitorial work completed by DOJ approved PI personnel.
If yes, are they allowed into the laboratory unescorted? ☐ Yes ☐ No

6. **Decontamination**: All cultures, stock and other regulated wastes are decontaminated before disposal by an approved decontamination method: ☑ Yes ☐ No
If yes, describe method: ***Autoclave***

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **RECOMBINANT DNA**

☐ Yes ☐ No 1. The facility has an Institutional Biosafety Committee that has approved work with recombinant DNA or has approval pending:

☐ Yes ☐ No 2. The Biosafety level listed in the *Application for IBC Permit* for this laboratory meets NIH Guidelines:

3. Will you be possessing, using, or transferring the following:
   a. Select Agent nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that are capable of infection and/or replication: ☐ Yes ☐ No
   b. Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids are in a vector or host chromosome and/or are expressed *in vivo* or *in vitro:* ☐ Yes ☐ No
   c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. ☐ Yes ☐ No

4. Are you intending to conduct the following experiments:
   a. Experiments utilizing recombinant DNA techniques that involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture: ☐ Yes ☐ No
   b. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxin molecules lethal for vertebrates at an LD50<100 ng/kg body weight: ☐ Yes ☐ No
   c. Provide a brief description of the recombinant constructs and any associated expression control of elements, including what the recombinant DNA encodes for, if known:

   d. Give an estimate of range of length of recombinant DNA to be used:

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **SMALL ANIMALS**

1. List species of small animals that will be used:

2. Describe route of infection:

3. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No
   If yes, describe method:
4. The facility requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this facility? ☐ Yes ☐ No
   If yes, the proposed work with Select Agents has been approved by the IBC: ☐Yes ☐ No

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **LARGE ANIMALS**

1. List species of large animals that will be used: _____

2. Describe route of infection:

3. Carcass of animals are disposed of to avoid their use as food for human beings or animals: ☐Yes ☐ No

4. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐Yes ☐ No
   If yes, give method: _____

5. Carcass of animals are disposed of on site: ☐ Yes ☐ No

6. The facility requires that in an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at his facility: ☐ Yes ☐ No
   If yes, the proposed work has been approved by the IACUC: ☐ Yes ☐ No

Optional - TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR

1. A Chemical hygiene plan is available for the facility using toxins: ☐ Yes ☐ No

2. Maximum quantity of each toxin under the control of the Principal Investigator at a give time:

3. Form of toxins used: ☐ Liquid ☐ Lyophilized
   a. The toxin is produced by live agent at the facility: ☐ Yes ☐ No
      If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____
   b. Dilution procedures and other manipulations of the concentrated toxins are:
      Conducted in ☐ Fume hood ☐ Biosafety cabinet
      If a fume hood is used, certification of the hood is conducted:
      ☐ Annually ☐ Biannually ☐ Other (describe): _____
      Conducted with two knowledgeable people present: ☐ Yes ☐ No

4. A hazard sign on the door when toxins are present: ☐ Yes ☐ No

5. Floor plan(s) include:
   Sink location: ☐ Yes ☐ No
   Eyewash locations: ☐ Yes ☐ No
   Biosafety cabinet (BSC) locations: ☐ Yes ☐ No
   Fume hood locations: ☐ Yes ☐ No
   HVAC supply and exhaust locations: ☐ Yes ☐ No
   Freezer/refrigerator locations: ☐ Yes ☐ No
   Other large equipment locations (incubators, centrifuges, etc): ☐ Yes ☐ No

6. Plan provides a description of the HVAC system (check all that are appropriate):
   ☐ Single-pass ☐ Re-circulated ☐ Dedicated exhaust ☐ Shared exhaust

☐ Constant air volume ☐ Variable air volume ☐ Redundant exhaust fans ☐ Emergency power back-up

7. Plan provides information on the biosafety cabinets in use (attach additional sheets if needed):
   Class of cabinet:
   ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III
   Biosafety cabinet connection to the HVAC system:
   ☐ Hard duct ☐ Thimble ☐ Re-circulating
   Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain): _____
   Does user verify air flow during BSC use? ☐ Yes ☐ No

Section III – Entity Program (IBSP)

☐ Yes ☐ No Entity Program documents IBC approvals which include Select Agent required information.

☐ Yes ☐ No Entity documents registrations.

☐ Yes ☐ No Entity documents (IBC) are current and up to date.

☐ Yes ☐ No Entity documents changes to the registration and does not allow access until amendments have been approved.

☐ Yes ☐ No Entity has a current Incident Response Plan

☐ Yes ☐ No Entity emergency response drill and evaluation is documented annually

☐ Yes ☐ No Entity Security Plan is reviewed and documented annually.

☐ Yes ☐ No Entity documents annual inspections and follow up requirements

Section IV – Inspection Summary

1. As a result of the **Facility Assessment** of the *Laboratory Facilities (Secondary Barriers)*, the following was noted in respect of the interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination:

    a. The interior of the facility is being altered.
    b. There is not a sink for hand washing; the "sink" is located in the shower and the faucet is in the containment area.
    c. The shower area is the closet thing to an eyewash.

2. As a result of the **Program Assessment**, the inspection team noted that there was **NO SBAT work** taking place in these buildings at the time of the inspection. The team also noted that before SBAT work can be performed in these buildings, there must be IBC and CDC approval documentation.

IBC INSPECTION REPORT
BSL3/ABSL3 SBAT FACILITIES & Entity Program

Date: 2-22-07

Principal Investigator/Lab Director: Dr. Stein ~~Roberta Zhang~~, Director

Location: Building Number - BL3 Hots Room (s) _____

Inspection Team:

Dr. Stein, Brent Mattox (EHS)
Debra Turner (VTPB), Nancy Baker (EHS),
Tiffany (IBC), _____,
Dr. Fight (IBC), _____,
Dr. Tesh (IBC), _____

Section I - Facility Assessment (PI)

A. Safety Equipment (Primary Barriers)

☐ Yes ☐ No Protective laboratory clothing, such as solid-front or wrap-around gowns, scrub suits, or coveralls, are worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

☐ Yes ☐ No Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

☐ Yes ☐ No Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

☐ Yes ☐ No All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

☐ Yes ☐ No When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

☐ Yes ☐ No Respiratory and face protection are used when in rooms containing infected animals.

B. Laboratory Facilities (Secondary Barriers)

☐ Yes ☐ No The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

☐ Yes ☐ No Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

☐ Yes ☐ No The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls,

prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

- Floor plan(s) include:
  - Sink location
    ☐ Yes ☐ No
  - Eyewash locations
    ☐ Yes ☐ No
  - Biosafety cabinet (BSC) locations
    ☐ Yes ☐ No
  - Fume hood locations
    ☐ Yes ☐ No
  - HVAC supply and exhaust locations
    ☐ Yes ☐ No
  - Freezer/refrigerator locations
    ☐ Yes ☐ No
  - Other large equipment locations (incubators, centrifuges, etc)
    ☐ Yes ☐ No
- Provide a description of the HVAC system (check all that are appropriate):
  - ☐ Single-pass ☐ Re-circulated
  - ☐ Dedicated exhaust ☐ Shared exhaust
  - ☐ Constant air volume ☐ Variable air volume
  - ☐ Redundant exhaust fans
  - ☐ Emergency power back-up
- Provide information on the biosafety cabinets in use (attach additional sheets if needed):
  - Class of cabinet:
  - ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3)
  - ☐ II, B1 ☐ II, B2 ☐ III
  - Biosafety cabinet connection to the HVAC system:
  - ☐ Hard duct ☐ Thimble ☐ Re-circulating
  - Define certification period:_____
  - ☐ Annual ☐ Biannual ☐ Other (explain): _____
  - Does user verify air flow during BSC use?
    ☐ Yes ☐ No
  - If floor drains are provided, the traps are always filled with an appropriate disinfectant:
    ☐ Yes ☐ No

☐ Yes ☐ No Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

C. Standard Microbiological Practices

☐ Yes ☐ No Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

☐ Yes ☐ No Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

☐ Yes ☐ No Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

☐ Yes ☐ No Mechanical pipetting devices are used; mouth pipetting is prohibited.

evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

☐ Yes ☐ No

The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

☐ Yes ☐ No

A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

- Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic ware should be substituted for glassware whenever possible.
- 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
- Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
- Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

☐ Yes ☐ No

All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

☐ Yes ☐ No

Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

- Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
- Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

☐ Yes ☐ No

Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

☐ Yes ☐ No

All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

☐ Yes ☐ No

Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained. Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are

Section II - Program Assessment (PI and/or Institutional BioSafety Program- IBSP)

☐ Yes ☐ No An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with Select Agents at this facility:

If yes: IBC approved the work proposed for this facility on: _____ (date).

☐ Yes ☐ No Training: Site specific and safety training is provided to individuals with access to areas where Select Agents are handled or stored:

Is provided prior to individuals beginning to work with Select Agents:
Is provided: ☐ Annually ☐ Biannually ☐ Other (specify frequency):
Written records of individuals are kept: ☐ Yes ☐ No
Personnel demonstrate proficiency in laboratory procedures prior to working with Select Agents: Unannounced visits by EH&S and follow up by supervisory personnel:
☐ Yes ☐ No
Provide a brief explanation of the system in place to detect loss or theft of select agent(s):
Individual responsible for inventory of select agent(s):
How often is the inventory record reconciled?
How is access to the inventory log limited?
Inventory tracking includes the following information (list):
There is a site-specific Security Plan for each of the laboratories listed above (number 2):
☐ Yes ☐ No
Building with select agents has self-closing doors: ☐ Yes ☐ No
Means to limit access to buildings with laboratories with select agents:
Guard station at the facility entrance
Card access system or locks
Security alarm system in the laboratory building
Other (describe): _____
Means to limit access to laboratories with select agents once inside the building:
Door to laboratory is locked:
Card access system or locks
Other (describe): _____
Means to limit access to select agents once inside the laboratory:
Locked incubators, refrigerators, freezers, etc.
Security alarm system that directly monitors the laboratory
Other (describe): _____
Means to limit access to select agents in storage:
Storage area door locked
Lock boxes
Security alarm system that directly monitors the laboratory
Other (describe): _____
Means to monitor unauthorized entry into the laboratory where select agents are used or stored:
Electronic logs of card access system entries are reviewed for unusual activity
Manual sign in and out logs are kept and monitored
Video camera surveillance
Other (describe): _____

13. List species of large animals that will be used: _____
14. Describe route of infection:
15. Carcass of animals are disposed of to avoid their use as food for human beings or animals: ☐Yes ☐ No
16. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐Yes ☐ No
    a. If yes, give method: _____
17. Carcass of animals are disposed of on site: ☐ Yes ☐ No
18. The facility requires that in an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at his facility: ☐ Yes ☐ No
    a. If yes, the proposed work has been approved by the IACUC ☐ Yes ☐ No

Optional - TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR

19. A Chemical hygiene plan is available for the facility using toxins: ☐ Yes ☐ No
20. Maximum quantity of each toxin under the control of the principal investigator at a give time:
21. Form of toxins used: ☐ Liquid ☐ Lyophilized
22. The toxin is produced by live agent at the facility: ☐ Yes ☐ No
    a. If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____
23. Dilution procedures and other manipulations of the concentrated toxins are:
    a. Conducted in ☐ Fume hood ☐ Biosafety cabinet
        i. If a fume hood is used, certification of the hood is conducted:
        ☐ Annually ☐ Biannually ☐ Other (describe): _____
    b. Conducted with two knowledgeable people present: ☐ Yes ☐ No
    c. A hazard sign on the door when toxins are present: ☐ Yes ☐ No

24. Floor plan(s) include:
    a. Sink location ☐ Yes ☐ No
    b. Eyewash locations ☐ Yes ☐ No
    c. Biosafety cabinet (BSC) locations ☐ Yes ☐ No
    d. Fume hood locations ☐ Yes ☐ No
    e. HVAC supply and exhaust locations ☐ Yes ☐ No
    f. Freezer/refrigerator locations ☐ Yes ☐ No
    g. Other large equipment locations (incubators, centrifuges, etc) ☐ Yes ☐ No
25. Plan provides a description of the HVAC system (check all that are appropriate):
    a. ☐ Single-pass ☐ Re-circulated
    b. ☐ Dedicated exhaust ☐ Shared exhaust
    c. ☐ Constant air volume ☐ Variable air volume
    d. ☐ Redundant exhaust fans
    e. ☐ Emergency power back-up
26. Plan provide information on the biosafety cabinets in use (attach additional sheets if needed):
    a. Class of cabinet:
    ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3)
    ☐ II, B1 ☐ II, B2 ☐ III
    b. Biosafety cabinet connection to the HVAC system:
    ☐ Hard duct ☐ Thimble ☐ Re-circulating
    c. Define certification period:
    ☐ Annual ☐ Biannual ☐ Other (explain): _____
    d. Does user verify air flow during BSC use? ☐ Yes ☐ No

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator Dr. Tom Ficht
Lab Contact Person Melissa Kahl-McDonagh
Department VTPB
Office Phone Number 845-4118
Lab Phone Number 845-4185
Lab Location - Bldg ___ Room _____

Biological agents used:
__ Recombinant DNA
__ Human pathogens - list: *B. abortus, B. melitensis, B. suis*

__ Animal pathogens- list: *B. abortus, B. melitensis, B. suis*

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: __ BL2 X BL3

Results: X Meets criteria at appropriate biosafety level
_____ Does not meet criteria

Comments:

Facility inspection only. Item D.15. should be verified by the Office of Research Compliance.

Date of Inspection: 05/01/07

Environmental Health & Safety Inspector: B. Mattox & N. Eaker

NIH BIOSAFETY LEVEL 3 CRITERIA

A. Standard Microbiological Practices

____ 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

____ 2. Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

____ 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

____ 4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

____ 5. Policies for the safe handling of sharps are instituted.

____ 6. All procedures are performed carefully to minimize the creation of aerosols.

____ 7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

____ 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

____ 9. Persons under 16 years of age are not allowed to enter a BL3 laboratory.

____10. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

____11. An insect and rodent control program is in effect.

B. Special Practices

____ 1. Laboratory doors are kept closed when experiments are in progress.

____ 2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

____ 3. The laboratory director establishes 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.

____ 4. When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

____ 5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for

the agent being handled.

____ 6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

____ 7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

____ 8. Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

____ 9. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

___10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
b. 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
c. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

___11. All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

___12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

___13. Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

___14. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

___ 15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

___ 16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

___ 17 Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

C. Safety Equipment (Primary Barriers)

___1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

___ 2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

___ 3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

___ 4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

___ 5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

___ 6. Respiratory and face protection are used when in rooms containing infected animals.

D. Laboratory Facilities (Secondary Barriers)

Y__ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

Y__ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

Y__3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are contructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

Y__4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

Y__5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

Y__6. Windows in the laboratory are closed and sealed.

Y__7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the

laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

Y 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

Y 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

Y 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

N/A 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

N/A 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

Y 13. An eyewash facility is readily available inside the laboratory.

Y 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

___ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

Y 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator Dr. Tom Ficht
Lab Contact Person Melissa Kahl-McDonagh
Department VTPB
Office Phone Number 845-4118
Lab Phone Number 845-4185
Lab Location - Bldg ____ Room ____

Biological agents used:
__ Recombinant DNA
__ Human pathogens - list: *B. abortus, B. melitensis, B. suis*

__ Animal pathogens- list: *B. abortus, B. melitensis, B. suis*

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: __ BL2 X BL3

Results: X Meets criteria at appropriate biosafety level
____ Does not meet criteria

Comments:

Facility inspection only. Item D.15. should be verified by the Office of Research Compliance.

Date of Inspection: 05/01/07

Environmental Health & Safety Inspector: B. Mattox & N. Eaker

NIH BIOSAFETY LEVEL 3 CRITERIA

A. Standard Microbiological Practices

____ 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

____ 2. Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

____ 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

____ 4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

____ 5. Policies for the safe handling of sharps are instituted.

____ 6. All procedures are performed carefully to minimize the creation of aerosols.

____ 7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

____ 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

____ 9. Persons under 16 years of age are not allowed to enter a BL3 laboratory.

____10. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

____11. An insect and rodent control program is in effect.

B. Special Practices

____ 1. Laboratory doors are kept closed when experiments are in progress.

____ 2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

____ 3. The laboratory director establishes 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.

____ 4. When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

____ 5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for

the agent being handled.

____ 6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

____ 7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

____ 8. Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

____ 9. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

___10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
b. 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
c. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

___11. All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

___12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

___13. Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

___14. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

___ 15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

___ 16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

___ 17 Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

C. Safety Equipment (Primary Barriers)

___1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

___ 2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

___ 3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

___ 4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

___ 5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

___ 6. Respiratory and face protection are used when in rooms containing infected animals.

D. Laboratory Facilities (Secondary Barriers)

Y__ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

Y__ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

Y__3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are contructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

Y__4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

Y__5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

Y__6. Windows in the laboratory are closed and sealed.

Y__7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the

laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

Y 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

Y 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

Y 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

N/A 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

N/A 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

Y 13. An eyewash facility is readily available inside the laboratory.

Y 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

___ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

Y 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

5/1/07 Re-Inspection of...

- Sink installed

...(Lab Room)
- Door closure installed
- Eyewash solution available

...(Animal Room)
- Door closure installed
- BSC re-positioned & rechecked 4/30/07; waiting on report from PAT.

TEXAS A&M UNIVERSITY

ANIMAL FACILITY INSPECTION / CERTIFICATION

Principal Investigator: Dr. Thomas Ficht
Lab Contact Person: Melissa Kahl-McDonagh or Gabby Kapp
Department: VTPB / CMP
Office Phone Number: Dr. Ficht – 845-4118
Lab Phone Number: Ms. Kahl-McDonagh – 845-4185; Ms. Kapp - 845-7433
Lab Location – Bldg: _____ Room: _____

Biological agents used:
__ Recombinant DNA
X Human pathogens - list: *B. abortus, B. melitensis, B. suis*

X Animal pathogens- list: *B. abortus, B. melitensis, B. suis*

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: __ ABL2 X ABL3

Results: X Meets criteria at appropriate biosafety level
_____ Does not meet criteria

Comments:

Facilities inspection only. Item D.14. should be verified by the Office of Research Compliance.

Date of Inspection: 05/01/07

Environmental Health & Safety Inspector: B. Mattox & N. Eaker

ANIMAL BIOSAFETY LEVEL 3

A. Standard Practices

___ 1. Aside from the standard policies, procedures, and protocols for emergency situations established by the facility director, appropriate special policies and procedures should be developed as needed and approved by the Institutional Animal Care and Use Committee (IACUC) and the Institutional Biosafety Committee (IBC).

___ 2. The laboratory or animal facility director limits access to the animal room to the fewest number of individuals possible. Personnel who must enter the room for program or service purposes when work is in progress are advised of the potential hazard.

___ 3. An appropriate medical surveillance program is in place. All personnel receive appropriate immunizations or tests for the agents handled or potentially present (e.g., hepatitis B vaccine, TB skin testing). When appropriate, a serum surveillance system should be implemented. In general, persons who may be at increased risk of acquiring infection, or for whom infection might have serious consequences, are not allowed in the animal facility unless special procedures can eliminate the extra risk. Assessment should be made by the occupational health physician.

___ 4. A biosafety manual is prepared or adopted. Personnel are advised of special hazards, and are required to read and to follow instructions on practices and procedures.

___ 5. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use should be done only in designated areas and are not permitted in animal or procedure rooms.

___ 6. All procedures are carefully performed to minimize the creation of aerosols or splatters.

___ 7. Equipment and work surfaces in the room are routinely decontaminated with an effective disinfectant after work with the infectious agent, and especially after overt spills, splashes, or other contamination by infectious materials.

___ 8. All wastes from the animal room (including animal tissues, carcasses, contaminated bedding, unused feed, sharps, and other refuse animal tissues) are transported from the animal room in leak-proof, covered containers for appropriate disposal in compliance with applicable institutional or local requirements. Incineration is recommended. The outer surface of the containers is disinfected prior to moving the material.

___ 9. Policies for the safe handling of sharps are instituted.
   a. Needles and syringes or other sharp instruments are restricted in the animal facility for use only when there is no alternative, such as for parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.
   b. Syringes that re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
   c. Plasticware should be substituted for glassware whenever possible.

___10. Personnel wash their hands after handling cultures and animals, after removing gloves, and before leaving the animal facility.

___ 11. A biohazard sign must be posted on the entrance to the animal room whenever infectious agents are present. The hazard warning sign identifies the infectious agent(s) in use, lists the name and telephone number of the responsible person(s), and indicates the special

requirements for entering the animal room (e.g., the need for immunizations and respirators).

___ 12. All infectious samples are collected, labeled, transported, and processed in a manner that contains and prevents transmission of the agent(s).

___13. Laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. As necessary, personnel receive updates and/or additional training on procedural or policy changes. Records of all training provided are maintained.

___14. An insect and rodent control program is in effect.

B. Special Practices

___1. Cages are autoclaved or thoroughly decontaminated before bedding is removed and before they are cleaned and washed. Equipment must be decontaminated according to any local, state, or federal regulations before being packaged for transport or removal from the facility for repair or maintenance.

___ 2. A spill procedure is developed and posted. Only personnel properly trained and equipped to work with infectious materials are to clean up spills. Spills and accidents that result in overt exposures to infectious materials must be immediately reported to the facility director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

___ 3. All wastes from the animal room must be autoclaved prior to incineration or other appropriate terminal treatment.

___ 4. Materials not related to the experiment (e.g., plants, animals) are not permitted in the animal room.

C. Safety Equipment (Primary Barriers)

___ 1. Uniforms or scrub suits are worn by personnel entering the animal room. Wrap-around or solid-front gowns or uniforms should be worn over this clothing. Front-button laboratory coats are unsuitable. The gown must be removed and left in the animal room. Before leaving the animal facility, scrub suits and uniforms are removed and appropriately contained and decontaminated prior to laundering or disposal.

___ 2. Personal protective equipment used is based on risk assessment determinations.
   a. Personal protective equipment is used for all activities involving manipulations of infectious material or infected animals.
   b. Personnel wear gloves when handling infected animals. Gloves are removed aseptically and autoclaved with other animal room wastes before disposal.
   c. Appropriate face/eye and respiratory protection (e.g., respirators and face shields) is worn by all personnel entering animal rooms.
   d. Boots, shoe covers, or other protective footwear, and disinfectant foot baths are available and used where indicated.

___ 3. The risk of infectious aerosols from infected animals or their bedding also can be reduced if animals are housed in containment caging systems, such as open cages placed in inward flow ventilated enclosures (e.g., laminar flow cabinets), solid wall and bottom cages covered with filter bonnets, or other equivalent primary containment systems.

___ 4. Biological safety cabinets and other physical containment devices are used whenever conducting procedures with a potential for creating aerosols. These include necropsy of infected animals, harvesting of tissues or fluids from infected animals or eggs, or intranasal inoculation of animals. At BSL-3, all work should be done in a primary barrier; otherwise respirators should be worn by personnel in the room.

D. Facilities (Secondary Barriers)

Y__ 1. The animal facility is separated from areas that are open to unrestricted personnel traffic within the building.

Y__ 2. Access to the facility is limited by a self-closing and self-locking door. This exterior entry door may be controlled by a key lock, card key, or proximity reader. Entry into the animal room is via a double-door entry which includes a change room and shower(s). An additional double-door access (air-lock) or double-doored autoclave may be provided for movement of supplies and wastes into and out of the facility, respectively. Doors to animal rooms open inward and are self-closing. Doors to cubicles inside an animal room may open outward or slide horizontally or vertically.

Y__3. The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (walls, floors, and ceilings) are water-resistant. Penetrations in floor, walls and ceiling surfaces are sealed and openings around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

Y__4. A hands-free or automatically operated hand washing sink is provided in each animal room near the exit door. The sink trap is filled with an appropriate disinfectant after each use.

Y__5. Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize horizontal surface areas.

Y__6. Any windows must be resistant to breakage. Where possible, windows should be sealed. If the animal facility has windows that open, they are fitted with fly screens.

Y__7. If floor drains are provided, they are always filled with an appropriate disinfectant.

Y__8. Ventilation should be provided in accordance with criteria from the *Guide for Care and Use of Laboratory Animals*, latest edition. 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 recirculated to any other area of the building. Filtration and other treatments of the exhaust air may not be required, but should be considered based on site requirements, and specific agent manipulations and use conditions. The exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Personnel must verify that the direction of the airflow (into the animal areas) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the animal room entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the animal spaces. Audible alarms should be considered to notify personnel of HVAC system failure.

Y__9. The HEPA filtered exhaust air from a Class II biological safety cabinet can be recirculated into the animal room if the cabinet is tested and certified at least annually. When exhaust air from Class II safety cabinets is to be discharged directly to the outside through the

building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used, they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

Y 10. Cages are washed in a cage washer. The mechanical cage washer has a final rinse temperature of at least 180 ° F.

Y 11. An autoclave is available which is convenient to the animal rooms where the biohazard is contained. The autoclave is utilized to decontaminate infectious waste before moving it to other areas of the facility.
NOTE: Material to be transported to CMP for autoclaving.

N/A 12. If vacuum service (i.e., central or local) is provided, each service connection should be fitted with liquid disinfectant traps and an in-line HEPA filter, placed as near as practicable to each use point or service cock. Filters are installed to permit in-place decontamination and replacement.

Y 13. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

___14. The completed Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified at least annually against these procedures as modified by operational experience.

Y 15. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services, and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment of the site conditions, or other applicable federal, state, or local regulations.

TEXAS A&M UNIVERSITY

ANIMAL FACILITY INSPECTION / CERTIFICATION

Principal Investigator: Dr. Thomas Ficht
Lab Contact Person: Melissa Kahl-McDonagh or Gabby Kapp
Department: VTPB / CMP
Office Phone Number: Dr. Ficht – 845-4118
Lab Phone Number: Ms. Kahl-McDonagh – 845-4185; Ms. Kapp - 845-7433
Lab Location – Bldg: _____ Room: _____

Biological agents used:
__ Recombinant DNA
X Human pathogens - list: *B. abortus, B. melitensis, B. suis*

X Animal pathogens- list: *B. abortus, B. melitensis, B. suis*

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: __ ABL2 X ABL3

Results: X Meets criteria at appropriate biosafety level
_____ Does not meet criteria

Comments:

Facilities inspection only. Item D.14. should be verified by the Office of Research Compliance.

Date of Inspection: 05/01/07

Environmental Health & Safety Inspector: B. Mattox & N. Eaker

ANIMAL BIOSAFETY LEVEL 3

A. Standard Practices

___ 1. Aside from the standard policies, procedures, and protocols for emergency situations established by the facility director, appropriate special policies and procedures should be developed as needed and approved by the Institutional Animal Care and Use Committee (IACUC) and the Institutional Biosafety Committee (IBC).

___ 2. The laboratory or animal facility director limits access to the animal room to the fewest number of individuals possible. Personnel who must enter the room for program or service purposes when work is in progress are advised of the potential hazard.

___ 3. An appropriate medical surveillance program is in place. All personnel receive appropriate immunizations or tests for the agents handled or potentially present (e.g., hepatitis B vaccine, TB skin testing). When appropriate, a serum surveillance system should be implemented. In general, persons who may be at increased risk of acquiring infection, or for whom infection might have serious consequences, are not allowed in the animal facility unless special procedures can eliminate the extra risk. Assessment should be made by the occupational health physician.

___ 4. A biosafety manual is prepared or adopted. Personnel are advised of special hazards, and are required to read and to follow instructions on practices and procedures.

___ 5. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use should be done only in designated areas and are not permitted in animal or procedure rooms.

___ 6. All procedures are carefully performed to minimize the creation of aerosols or splatters.

___ 7. Equipment and work surfaces in the room are routinely decontaminated with an effective disinfectant after work with the infectious agent, and especially after overt spills, splashes, or other contamination by infectious materials.

___ 8. All wastes from the animal room (including animal tissues, carcasses, contaminated bedding, unused feed, sharps, and other refuse animal tissues) are transported from the animal room in leak-proof, covered containers for appropriate disposal in compliance with applicable institutional or local requirements. Incineration is recommended. The outer surface of the containers is disinfected prior to moving the material.

___ 9. Policies for the safe handling of sharps are instituted.
   a. Needles and syringes or other sharp instruments are restricted in the animal facility for use only when there is no alternative, such as for parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.
   b. Syringes that re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
   c. Plasticware should be substituted for glassware whenever possible.

___10. Personnel wash their hands after handling cultures and animals, after removing gloves, and before leaving the animal facility.

___ 11. A biohazard sign must be posted on the entrance to the animal room whenever infectious agents are present. The hazard warning sign identifies the infectious agent(s) in use, lists the name and telephone number of the responsible person(s), and indicates the special

requirements for entering the animal room (e.g., the need for immunizations and respirators).

___ 12. All infectious samples are collected, labeled, transported, and processed in a manner that contains and prevents transmission of the agent(s).

___13. Laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. As necessary, personnel receive updates and/or additional training on procedural or policy changes. Records of all training provided are maintained.

___14. An insect and rodent control program is in effect.

B. Special Practices

___1. Cages are autoclaved or thoroughly decontaminated before bedding is removed and before they are cleaned and washed. Equipment must be decontaminated according to any local, state, or federal regulations before being packaged for transport or removal from the facility for repair or maintenance.

___ 2. A spill procedure is developed and posted. Only personnel properly trained and equipped to work with infectious materials are to clean up spills. Spills and accidents that result in overt exposures to infectious materials must be immediately reported to the facility director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

___ 3. All wastes from the animal room must be autoclaved prior to incineration or other appropriate terminal treatment.

___ 4. Materials not related to the experiment (e.g., plants, animals) are not permitted in the animal room.

C. Safety Equipment (Primary Barriers)

___ 1. Uniforms or scrub suits are worn by personnel entering the animal room. Wrap-around or solid-front gowns or uniforms should be worn over this clothing. Front-button laboratory coats are unsuitable. The gown must be removed and left in the animal room. Before leaving the animal facility, scrub suits and uniforms are removed and appropriately contained and decontaminated prior to laundering or disposal.

___ 2. Personal protective equipment used is based on risk assessment determinations.
   a. Personal protective equipment is used for all activities involving manipulations of infectious material or infected animals.
   b. Personnel wear gloves when handling infected animals. Gloves are removed aseptically and autoclaved with other animal room wastes before disposal.
   c. Appropriate face/eye and respiratory protection (e.g., respirators and face shields) is worn by all personnel entering animal rooms.
   d. Boots, shoe covers, or other protective footwear, and disinfectant foot baths are available and used where indicated.

___ 3. The risk of infectious aerosols from infected animals or their bedding also can be reduced if animals are housed in containment caging systems, such as open cages placed in inward flow ventilated enclosures (e.g., laminar flow cabinets), solid wall and bottom cages covered with filter bonnets, or other equivalent primary containment systems.

___ 4. Biological safety cabinets and other physical containment devices are used whenever conducting procedures with a potential for creating aerosols. These include necropsy of infected animals, harvesting of tissues or fluids from infected animals or eggs, or intranasal inoculation of animals. At BSL-3, all work should be done in a primary barrier; otherwise respirators should be worn by personnel in the room.

D. Facilities (Secondary Barriers)

Y 1. The animal facility is separated from areas that are open to unrestricted personnel traffic within the building.

Y 2. Access to the facility is limited by a self-closing and self-locking door. This exterior entry door may be controlled by a key lock, card key, or proximity reader. Entry into the animal room is via a double-door entry which includes a change room and shower(s). An additional double-door access (air-lock) or double-doored autoclave may be provided for movement of supplies and wastes into and out of the facility, respectively. Doors to animal rooms open inward and are self-closing. Doors to cubicles inside an animal room may open outward or slide horizontally or vertically.

Y 3. The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (walls, floors, and ceilings) are water-resistant. Penetrations in floor, walls and ceiling surfaces are sealed and openings around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

Y 4. A hands-free or automatically operated hand washing sink is provided in each animal room near the exit door. The sink trap is filled with an appropriate disinfectant after each use.

Y 5. Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize horizontal surface areas.

Y 6. Any windows must be resistant to breakage. Where possible, windows should be sealed. If the animal facility has windows that open, they are fitted with fly screens.

Y 7. If floor drains are provided, they are always filled with an appropriate disinfectant.

Y 8. Ventilation should be provided in accordance with criteria from the *Guide for Care and Use of Laboratory Animals*, latest edition. 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 recirculated to any other area of the building. Filtration and other treatments of the exhaust air may not be required, but should be considered based on site requirements, and specific agent manipulations and use conditions. The exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Personnel must verify that the direction of the airflow (into the animal areas) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the animal room entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the animal spaces. Audible alarms should be considered to notify personnel of HVAC system failure.

Y 9. The HEPA filtered exhaust air from a Class II biological safety cabinet can be recirculated into the animal room if the cabinet is tested and certified at least annually. When exhaust air from Class II safety cabinets is to be discharged directly to the outside through the

building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used, they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

Y 10. Cages are washed in a cage washer. The mechanical cage washer has a final rinse temperature of at least 180 ° F.

Y 11. An autoclave is available which is convenient to the animal rooms where the biohazard is contained. The autoclave is utilized to decontaminate infectious waste before moving it to other areas of the facility.
NOTE: Material to be transported to CMP for autoclaving.

N/A 12. If vacuum service (i.e., central or local) is provided, each service connection should be fitted with liquid disinfectant traps and an in-line HEPA filter, placed as near as practicable to each use point or service cock. Filters are installed to permit in-place decontamination and replacement.

Y 13. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

___14. The completed Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified at least annually against these procedures as modified by operational experience.

Y 15. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services, and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment of the site conditions, or other applicable federal, state, or local regulations.

Re-inspected 4/9/07

To: Brent Mattox

From: Nancy L. Eaker

Date: April 3, 2007

Subject: Inspection of BL3 Hut

I visited BL3 Hut Bldg 1 on Friday, March 30, 2007, and again this morning. CMP has constructed four rooms in the containment area: an airlock for bringing equipment in, a lab room, an animal room and a corridor. My notes on the facility are below:

Outer Locker Room:

- The light was a long time in coming on. In fact, I was not aware it came on until I was leaving the facility. In when I entered.
- The door frame (for the door leading outside) is rusted at the bottom, and there are gaps between the floor and the door frame.

Inner Locker Room:

- Air filter is missing and needs to be replaced. (CMP personnel said it would be replaced when construction was completed.)
- Cracks in paint (in far corner and in wall above lockers) need to be sealed/re-painted. Still there
- The door between the inner locker and the containment area does not close completely on its own.

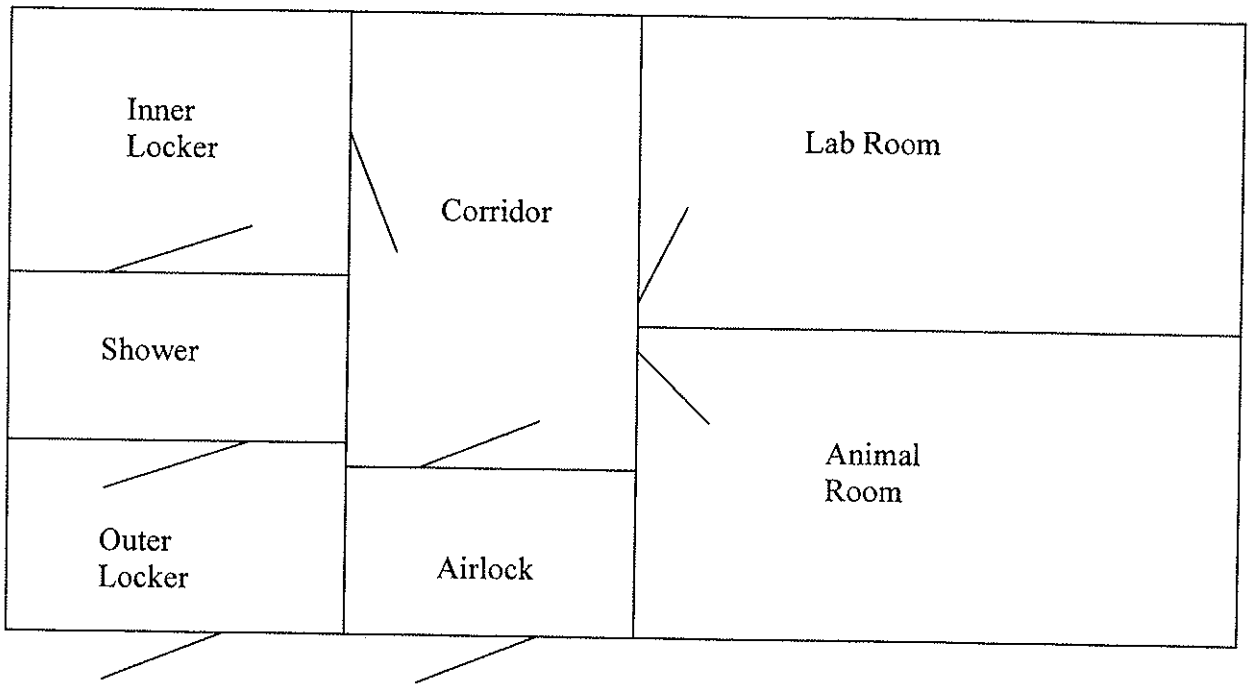
Containment Areas:

- The exhaust vent for the building is in the animal room, which is highly negative to the rest of the facility. Louvered vents allow air to travel from the corridor and the lab room into the animal room.
- The drainage trough runs between the lab room and the animal room. This needs to be sealed to prevent a potential escape route for loose animals.
- The newly constructed walls are not sealed at the floor, ceiling or walls. There is a large gap (light is visible) between the new wall and the permanent wall between the corridor and the lab room. Door frames still need to be sealed
- There is no seal around the light fixtures where they come through the walls.
- CMP personnel said they have a plug for the floor drain.
- Paint on permanent walls is chipped or flaking in places.
- Caulking should be checked for small holes or gaps.
- Air filter in animal room is very dirty and should be replaced.
- Nail hole in animal room door needs to be filled in. both rooms
- Door seals around doors to lab, animal room, and airlock have gaps in the corners.

Still need to caulk along floor at constructed walls & along wall between ~~BSC~~ rooms at BSC (lab side)

- ~~Door knob fixtures should be sealed.~~
- Seal on outer door of air lock needs to be repaired at the top where it has come loose. Also, foam-like seal on bottom of door appears to be coming off.
- Lighting in airlock is inadequate. A minimum of 20 foot candles is required. Better ??
- Wooden door jam (to airlock) needs to be painted.
- Verify that all screw holes are sealed/painted.
- Foam padding covers the faucet in corridor. No sink is available in either the animal room or the lab room. There is no eyewash in the lab room.

A rough diagram of the new construction is below.



4/9/07 Re-inspection

✓ Along floors @ constructed wall

✓ B/w Permanent & constructed wall
b/w Lab & animal rms (Lab side)

✓ Along door frames

4/13 ✓ Door seals

✓ Holes in pipes

✓ Seal crack above coving next to exit door
(in airlock)

To: Brent Mattox
Biological Safety Officer

From: Nancy L. Eaker
Environmental Safety Supervisor

Date: April 3, 2007

Subject: Inspection of BL3 Hut

I visited BL3 Hut Bldg ` on Friday, March 30, 2007, and again this morning. CMP has constructed four rooms in the containment area: an airlock for bringing equipment in, a lab room, an animal room and a corridor. My notes on the facility are below:

Outer Locker Room:

- The light was a long time in coming on. In fact, I was not aware it came on until I was leaving the facility.
- The door frame (for the door leading outside) is rusted at the bottom, and there are gaps between the floor and the door frame.

Inner Locker Room:

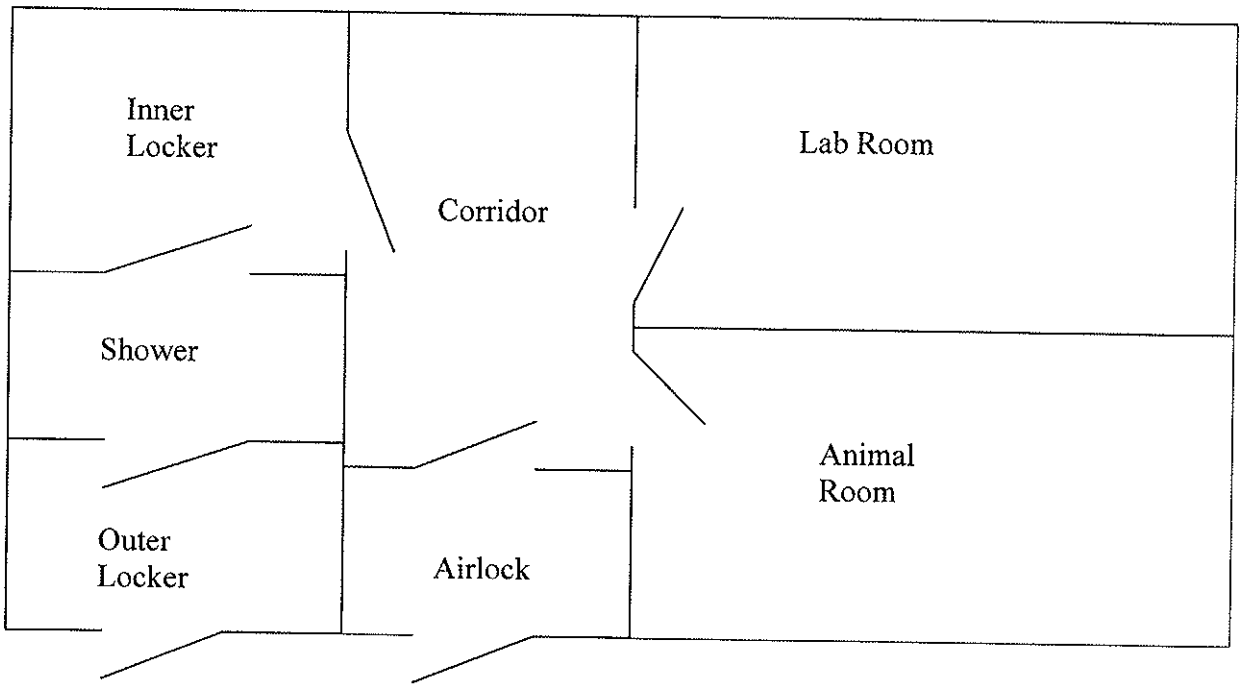
- Air filter is missing and needs to be replaced. (CMP personnel said it would be replaced when construction was completed.)
- Cracks in paint (in far corner and in wall above lockers) need to be sealed/re-painted.
- The door between the inner locker and the containment area does not close completely on its own.

Containment Areas:

- The exhaust vent for the building is in the animal room, which is highly negative to the rest of the facility. Louvered vents allow air to travel from the corridor and the lab room into the animal room.
- The drainage trough runs between the lab room and the animal room. This needs to be sealed to prevent a potential escape route for loose animals.
- The newly constructed walls are not sealed at the floor, ceiling or permanent walls. There is a large gap (light is visible) between the new wall and the permanent wall between the corridor and the lab room.
- There is no seal around the light fixtures where they come through the walls.
- Doors to new areas are not self-closing.
- CMP personnel said they have a plug for the floor drain.
- Paint on permanent walls is chipped or flaking in places.
- Caulking should be checked for small holes or gaps.
- Air filter in animal room is very dirty and should be replaced.

- Nail hole in animal room door needs to be filled in.
- Door seals around doors to lab, animal room, and airlock have gaps in the corners.
- Seal on outer door of air lock needs to be repaired at the top where it has come loose. Also, foam-like seal on bottom of door appears to be coming off.
- Lighting in airlock is inadequate. A minimum of 20 foot candles is required.
- Wooden door jam (to airlock) needs to be painted.
- Verify that all screw holes are sealed/painted.
- Foam padding covers the faucet in corridor. No sink is available in either the animal room or the lab room. There is no eyewash in the lab room.
- In both lab and animal rooms, there is a large hole in the pipe structures. These need to be sealed.

A rough diagram of the new construction is below.



TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator Ficht
Lab Contact Person Gabby / Melissa Kahl
Department VTPB/CMP
Office Phone Number
Lab Phone Number
Lab Location - Bldg _____ Room Lab Room

Biological agents used:
__ Recombinant DNA
__ Human pathogens - list:

__ Animal pathogens- list:

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: __ BL2 ✓ BL3

Results:
____ Meets criteria at appropriate biosafety level
✓ Does not meet criteria

Comments:

Date of Inspection: 3/30/07 & 4/3/07

Environmental Health & Safety Inspector: MEaker

NIH BIOSAFETY LEVEL 3 CRITERIA

A. Standard Microbiological Practices

____ 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

____ 2. Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

____ 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

____ 4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

____ 5. Policies for the safe handling of sharps are instituted.

____ 6. All procedures are performed carefully to minimize the creation of aerosols.

____ 7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

____ 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

____ 9. Persons under 16 years of age are not allowed to enter a BL3 laboratory.

____10. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

____11. An insect and rodent control program is in effect.

B. Special Practices

____ 1. Laboratory doors are kept closed when experiments are in progress.

____ 2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

____ 3. The laboratory director establishes 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.

____ 4. When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

____ 5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for

the agent being handled.

____ 6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

____ 7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

____ 8. Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

____ 9. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

___10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.

b. 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

c. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.

d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

___11. All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

___12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.

b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

___13. Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

___14. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

___ 15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

___ 16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

___ 17 Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

C. Safety Equipment (Primary Barriers)

___1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

___2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

___3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

___4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

___5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

___6. Respiratory and face protection are used when in rooms containing infected animals.

D. Laboratory Facilities (Secondary Barriers)

✓ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

No 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door. sink located in shower; faucet in containment area

No 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are contructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

✓ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

✓ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

N/A 6. Windows in the laboratory are closed and sealed.

✓ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the

laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

✓ 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas. ?

✓ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

But interior ~~structure~~ bldg of altered

✓ 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

? N/A 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

? N/A 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

at time of inspection

~~N/A~~ or No 13. An eyewash facility is readily available inside the laboratory.

at time of inspection

Shower area closest thing to eyewash

No 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

→ Airlock

✓ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

? ✓ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

To: Brent Mattox
Biological Safety Officer

From: Nancy L. Eaker
Environmental Safety Supervisor

Date: April 3, 2007

Subject: Inspection of BL3 Hut '

I visited BL3 Hut Bldg ' on Friday, March 30, 2007, and again this morning. CMP has constructed four rooms in the containment area: an airlock for bringing equipment in, a lab room, an animal room and a corridor. My notes on the facility are below:

Outer Locker Room:

- The light was a long time in coming on. In fact, I was not aware it came on until I was leaving the facility.
- The door frame (for the door leading outside) is rusted at the bottom, and there are gaps between the floor and the door frame.

Inner Locker Room:

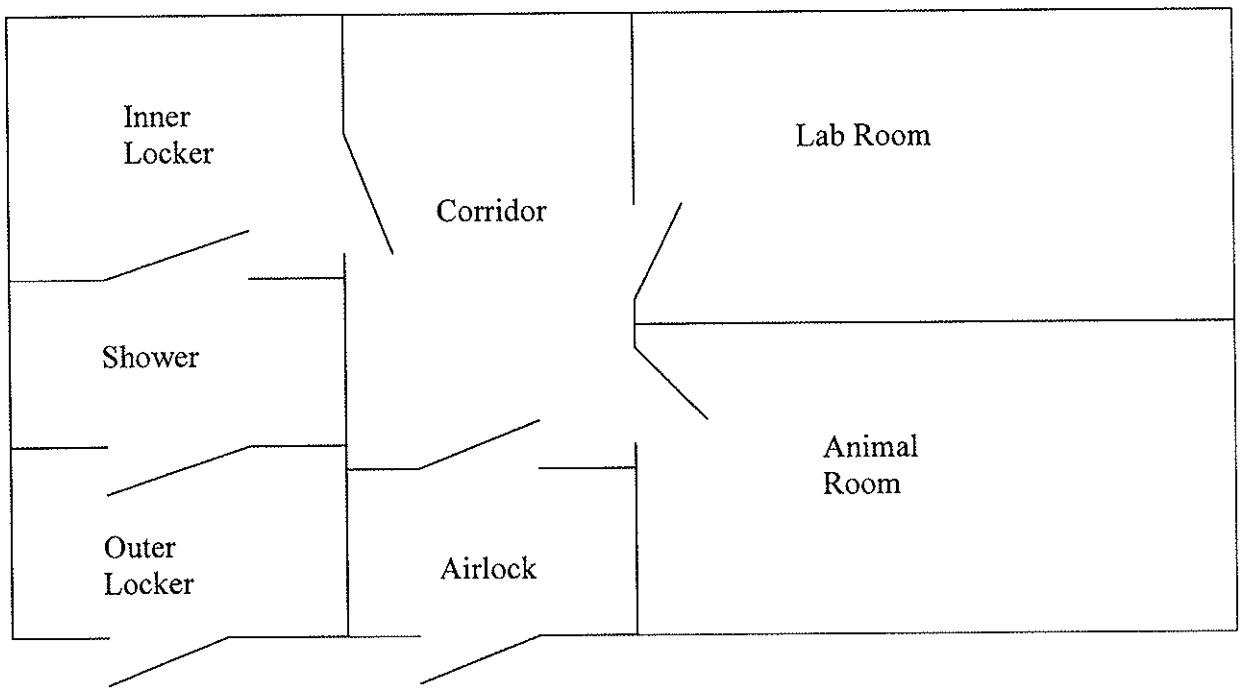
- Air filter is missing and needs to be replaced. (CMP personnel said it would be replaced when construction was completed.)
- Cracks in paint (in far corner and in wall above lockers) need to be sealed/re-painted.
- The door between the inner locker and the containment area does not close completely on its own.

Containment Areas:

- The exhaust vent for the building is in the animal room, which is highly negative to the rest of the facility. Louvered vents allow air to travel from the corridor and the lab room into the animal room.
- The drainage trough runs between the lab room and the animal room. This needs to be sealed to prevent a potential escape route for loose animals.
- The newly constructed walls are not sealed at the floor, ceiling or permanent walls. There is a large gap (light is visible) between the new wall and the permanent wall between the corridor and the lab room.
- There is no seal around the light fixtures where they come through the walls.
- Doors to new areas are not self-closing.
- CMP personnel said they have a plug for the floor drain.
- Paint on permanent walls is chipped or flaking in places.
- Caulking should be checked for small holes or gaps.
- Air filter in animal room is very dirty and should be replaced.

- Nail hole in animal room door needs to be filled in.
- Door seals around doors to lab, animal room, and airlock have gaps in the corners.
- Seal on outer door of air lock needs to be repaired at the top where it has come loose. Also, foam-like seal on bottom of door appears to be coming off.
- Lighting in airlock is inadequate. A minimum of 20 foot candles is required.
- Wooden door jam (to airlock) needs to be painted.
- Verify that all screw holes are sealed/painted.
- Foam padding covers the faucet in corridor. No sink is available in either the animal room or the lab room. There is no eyewash in the lab room.
- In both lab and animal rooms, there is a large hole in the pipe structures. These need to be sealed.

A rough diagram of the new construction is below.



TEXAS A&M UNIVERSITY

ANIMAL FACILITY INSPECTION / CERTIFICATION

Principal Investigator: Fahl
Lab Contact Person: Melissa / Gabby (CMP)
Department: VTPB / CMP
Office Phone Number
Lab Phone Number
Lab Location – Bldg: _____ Room: Animal Room

Biological agents used:
__ Recombinant DNA
__ Human pathogens - list:

__ Animal pathogens- list:

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: __ ABL2 ✓ ABL3

Results: ____ Meets criteria at appropriate biosafety level
✓ Does not meet criteria

Comments:

Date of Inspection: 3/30/07 + 4/3/07

Environmental Health & Safety Inspector: LLEaker

ANIMAL BIOSAFETY LEVEL 3

A. Standard Practices

___ 1. Aside from the standard policies, procedures, and protocols for emergency situations established by the facility director, appropriate special policies and procedures should be developed as needed and approved by the Institutional Animal Care and Use Committee (IACUC) and the Institutional Biosafety Committee (IBC).

___ 2. The laboratory or animal facility director limits access to the animal room to the fewest number of individuals possible. Personnel who must enter the room for program or service purposes when work is in progress are advised of the potential hazard.

___ 3. An appropriate medical surveillance program is in place. All personnel receive appropriate immunizations or tests for the agents handled or potentially present (e.g., hepatitis B vaccine, TB skin testing). When appropriate, a serum surveillance system should be implemented. In general, persons who may be at increased risk of acquiring infection, or for whom infection might have serious consequences, are not allowed in the animal facility unless special procedures can eliminate the extra risk. Assessment should be made by the occupational health physician.

___ 4. A biosafety manual is prepared or adopted. Personnel are advised of special hazards, and are required to read and to follow instructions on practices and procedures.

___ 5. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use should be done only in designated areas and are not permitted in animal or procedure rooms.

___ 6. All procedures are carefully performed to minimize the creation of aerosols or splatters.

___ 7. Equipment and work surfaces in the room are routinely decontaminated with an effective disinfectant after work with the infectious agent, and especially after overt spills, splashes, or other contamination by infectious materials.

___ 8. All wastes from the animal room (including animal tissues, carcasses, contaminated bedding, unused feed, sharps, and other refuse animal tissues) are transported from the animal room in leak-proof, covered containers for appropriate disposal in compliance with applicable institutional or local requirements. Incineration is recommended. The outer surface of the containers is disinfected prior to moving the material.

___ 9. Policies for the safe handling of sharps are instituted.
   a. Needles and syringes or other sharp instruments are restricted in the animal facility for use only when there is no alternative, such as for parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.
   b. Syringes that re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
   c. Plasticware should be substituted for glassware whenever possible.

___ 10. Personnel wash their hands after handling cultures and animals, after removing gloves, and before leaving the animal facility.

___ 11. A biohazard sign must be posted on the entrance to the animal room whenever infectious agents are present. The hazard warning sign identifies the infectious agent(s) in use, lists the name and telephone number of the responsible person(s), and indicates the special

requirements for entering the animal room (e.g., the need for immunizations and respirators).

___ 12. All infectious samples are collected, labeled, transported, and processed in a manner that contains and prevents transmission of the agent(s).

___13. Laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. As necessary, personnel receive updates and/or additional training on procedural or policy changes. Records of all training provided are maintained.

___14. An insect and rodent control program is in effect.

B. Special Practices

___1. Cages are autoclaved or thoroughly decontaminated before bedding is removed and before they are cleaned and washed. Equipment must be decontaminated according to any local, state, or federal regulations before being packaged for transport or removal from the facility for repair or maintenance.

___ 2. A spill procedure is developed and posted. Only personnel properly trained and equipped to work with infectious materials are to clean up spills. Spills and accidents that result in overt exposures to infectious materials must be immediately reported to the facility director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

___ 3. All wastes from the animal room must be autoclaved prior to incineration or other appropriate terminal treatment.

___ 4. Materials not related to the experiment (e.g., plants, animals) are not permitted in the animal room.

C. Safety Equipment (Primary Barriers)

___ 1. Uniforms or scrub suits are worn by personnel entering the animal room. Wrap-around or solid-front gowns or uniforms should be worn over this clothing. Front-button laboratory coats are unsuitable. The gown must be removed and left in the animal room. Before leaving the animal facility, scrub suits and uniforms are removed and appropriately contained and decontaminated prior to laundering or disposal.

___ 2. Personal protective equipment used is based on risk assessment determinations.
   a. Personal protective equipment is used for all activities involving manipulations of infectious material or infected animals.
   b. Personnel wear gloves when handling infected animals. Gloves are removed aseptically and autoclaved with other animal room wastes before disposal.
   c. Appropriate face/eye and respiratory protection (e.g., respirators and face shields) is worn by all personnel entering animal rooms.
   d. Boots, shoe covers, or other protective footwear, and disinfectant foot baths are available and used where indicated.

___ 3. The risk of infectious aerosols from infected animals or their bedding also can be reduced if animals are housed in containment caging systems, such as open cages placed in inward flow ventilated enclosures (e.g., laminar flow cabinets), solid wall and bottom cages covered with filter bonnets, or other equivalent primary containment systems.

___ 4. Biological safety cabinets and other physical containment devices are used whenever conducting procedures with a potential for creating aerosols. These include necropsy of infected animals, harvesting of tissues or fluids from infected animals or eggs, or intranasal inoculation of animals. At BSL-3, all work should be done in a primary barrier; otherwise respirators should be worn by personnel in the room.

D. Facilities (Secondary Barriers)

✓ 1. The animal facility is separated from areas that are open to unrestricted personnel traffic within the building.

✓ 2. Access to the facility is limited by a self-closing and self-locking door. This exterior entry door may be controlled by a key lock, card key, or proximity reader. Entry into the animal room is via a double-door entry which includes a change room and shower(s). An additional double-door access (air-lock) or double-doored autoclave may be provided for movement of supplies and wastes into and out of the facility, respectively. Doors to animal rooms open inward and are self-closing. Doors to cubicles inside an animal room may open outward or slide horizontally or vertically.

NO 3. The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (walls, floors, and ceilings) are water-resistant. Penetrations in floor, walls and ceiling surfaces are sealed and openings around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

NO 4. A hands-free or automatically operated hand washing sink is provided in each animal room near the exit door. The sink trap is filled with an appropriate disinfectant after each use.
faucet in "corridor";

✓ 5. Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize horizontal surface areas.

✓ 6. Any windows must be resistant to breakage. Where possible, windows should be sealed. If the animal facility has windows that open, they are fitted with fly screens.

✓ 7. If floor drains are provided, they are always filled with an appropriate disinfectant.

✓ 8. Ventilation should be provided in accordance with criteria from the *Guide for Care and Use of Laboratory Animals*, latest edition. 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 recirculated to any other area of the building. Filtration and other treatments of the exhaust air may not be required, but should be considered based on site requirements, and specific agent manipulations and use conditions. The exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Personnel must verify that the direction of the airflow (into the animal areas) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the animal room entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the animal spaces. Audible alarms should be considered to notify personnel of HVAC system failure.

Interior of structure has been altered

✓ 9. The HEPA filtered exhaust air from a Class II biological safety cabinet can be recirculated into the animal room if the cabinet is tested and certified at least annually. When exhaust air from Class II safety cabinets is to be discharged directly to the outside through the

building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used, they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

N/A 10. Cages are washed in a cage washer. The mechanical cage washer has a final rinse temperature of at least 180 ° F. N/A at time of inspection

No 11. An autoclave is available which is convenient to the animal rooms where the biohazard is contained. The autoclave is utilized to decontaminate infectious waste before moving it to other areas of the facility. O/S site

N/A 12. If vacuum service (i.e., central or local) is provided, each service connection should be fitted with liquid disinfectant traps and an in-line HEPA filter, placed as near as practicable to each use point or service cock. Filters are installed to permit in-place decontamination and replacement.

No 13. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision. In Airlock

? 14. The completed Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified at least annually against these procedures as modified by operational experience.

✓ 15. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services, and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment of the site conditions, or other applicable federal, state, or local regulations.

2006 Inspection Report

(Inspections conducted 02/06)

Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

___ 16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

___ 17 Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

C. Safety Equipment (Primary Barriers)

___1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

___ 2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

___ 3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

___ 4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

___ 5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

___ 6. Respiratory and face protection are used when in rooms containing infected animals.

D. Laboratory Facilities (Secondary Barriers)

✓ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway. **See notes.**

✓ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

✗ 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are contructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination. **See notes.**

✓ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

✓ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

N/A 6. Windows in the laboratory are closed and sealed.

✓ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the

laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

N/A 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✓ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

N/A 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

N/A 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

✓ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

✓ 13. An eyewash facility is readily available inside the laboratory.

✓ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

✓ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

✓ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

NOTES: Magnahelic gauge reading: 0.46.

Noted standing water in outer locker room.

Door to animal room from inner locker room does not close completely on its own.

Noted corrosion around door frames (at floor) in outer locker room and in animal room. Also noted corrosion on metal frame work in animal room.

Noted cracked and/or chipped paint in inner locker room and in animal room (around opening in wall for sensor wire, walls, ceiling, etc.). Noted large chip in paint above door to shower in inner locker room. Noted small holes and/or cracks in sealant, especially in corners and around door frames.

No biological hazard sign on outer door. No emergency contact information on outer door.

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator
Lab Contact Person
Department
Office Phone Number
Lab Phone Number
Lab Location - Bldg _____ Room

Biological agents used:
__ Recombinant DNA
__ Human pathogens - list:

__ Animal pathogens- list:

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: __ BL2 ✓ BL3

Results: _____ Meets criteria at appropriate biosafety level
_____ Does not meet criteria

Comments:

Date of Inspection: 02/27/06 Entered 2/27/06 NB

Environmental Health & Safety Inspector: NB Baker

Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

___ 16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

___ 17 Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

C. Safety Equipment (Primary Barriers)

___1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

___ 2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

___ 3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

___ 4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

___ 5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

___ 6. Respiratory and face protection are used when in rooms containing infected animals.

D. Laboratory Facilities (Secondary Barriers)

✓ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

✓ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

See Note 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are contructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

✓ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and ✓ those chemicals used to decontaminate the work surfaces and equipment.

___ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

N/A 6. Windows in the laboratory are closed and sealed.

✓ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the

magnahelic @ 0.44 ✓

laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

N/A 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✓ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

N/A 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

N/A 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

✓ ? 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

✓ 13. An eyewash facility is readily available inside the laboratory. Shower

✓ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

✓ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

✓ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

✓ No seal around light switch in outer locker. ?
✓ Corrosion where door frame meets floor in outer locker area & in animal room. On metal framework.
✓ Standing water in outer locker area
✓ Possible crack in seam along ceiling in inner locker area – but could be cob-web, instead.
✓ Door to animal room doesn't close all the way on its own. ✓ Inner locker seams also around wire coming through wall. (sensor)
✓ Crack/chips in paint in animal room - where wire comes through wall (above light switch); along column & in corners. Around door frames; (Better than it ~~was~~ ?)

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Meets criteria**

Comments:

Date of Inspection: **2/1/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

D. Laboratory Facilities (Secondary Barriers)

✓ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

✓ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

✓ 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

✓ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

✓ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

✓ 6. Windows in the laboratory are closed and sealed.

✓ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

✓ 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✓ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

✓ 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

✓ 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

✓ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

✓ 13. An eyewash facility is readily available inside the laboratory.

✓ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

✓ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

✓ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator
Lab Contact Person
Department
Office Phone Number
Lab Phone Number
Lab Location - Bldg _____ Room

Biological agents used:
__ Recombinant DNA
__ Human pathogens - list:

__ Animal pathogens- list:

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: __ BL2 ✓ BL3

Results: _____ Meets criteria at appropriate biosafety level
_____ Does not meet criteria

Comments:

Date of Inspection: 02/27/06

Environmental Health & Safety Inspector: MEaker

Contacted ✓ 2/27/06

Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

___ 16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

___ 17 Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

C. Safety Equipment (Primary Barriers)

___1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

___ 2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

___ 3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

___ 4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

___ 5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

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N/A or ✓ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

Seal - light switch in autoclave locker ?

✓ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

N/A ___ 6. Windows in the laboratory are closed and sealed.

✓ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the

✓ Magnahelic @ 0.08

laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

N/A 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

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✓ 13. An eyewash facility is readily available inside the laboratory. shower

✓ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision. ~~shower~~

✓ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

✓ corrosion where door frame meets floor in outer locker area & animal room.
✓ Cracks/chips in paint: outer locker (around door frame) (ceiling); Inner locker area; animal room (better than previous)
Door to animal room cracked open.
✓ Corrosion of metal frame work in animal room
~~RV Exposure~~

(Noted access log & SOP in outer locker room)

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator
Lab Contact Person
Department
Office Phone Number
Lab Phone Number
Lab Location - Bldg _____

Biological agents used:
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__ Animal pathogens- list:

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: __ BL2 _X_ BL3

Results: _____ Meets criteria at appropriate biosafety level
_____ Does not meet criteria

Comments:

Date of Inspection: 02/27/2006

Environmental Health & Safety Inspector: Nancy L. Eaker

NIH BIOSAFETY LEVEL 3 CRITERIA

A. Standard Microbiological Practices

____ 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

____ 2. Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

____ 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

____ 4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

____ 5. Policies for the safe handling of sharps are instituted.

____ 6. All procedures are performed carefully to minimize the creation of aerosols.

____ 7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

____ 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

____ 9. Persons under 16 years of age are not allowed to enter a BL3 laboratory.

____10. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

____11. An insect and rodent control program is in effect.

B. Special Practices

____ 1. Laboratory doors are kept closed when experiments are in progress.

____ 2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

____ 3. The laboratory director establishes 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.

____ 4. When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

____ 5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for

the agent being handled.

____ 6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

____ 7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

____ 8. Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

____ 9. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

___10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
b. 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
c. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

___11. All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

___12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

___13. Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

___14. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

___ 15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

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N/A 6. Windows in the laboratory are closed and sealed.

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laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

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NOTES: Magnahelic gauge reading: 0.08.

Outer door to animal room was left cracked open.

Noted corrosion around door frames (at floor) in outer locker room and in animal room. Also noted corrosion on metal frame work in animal room.

Noted cracked and/or chipped paint throughout facility (walls, ceiling, etc.). Noted small holes and/or cracks in sealant, especially in corners and around door frames.

No biological hazard sign on outer door. No emergency contact information on outer door.

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Principal Investigator
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Department
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Evidenced ✓ 2/27/04

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N/A

Some wear on table (worn paint, rust).

___ 6. Windows in the laboratory are closed and sealed.

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* Magnahelic gauge at 0.70. Must really pull/push to open

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N/A 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✓ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

N/A 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

✓ 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

✓ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

✓ 13. An eyewash facility is readily available inside the laboratory. shower

X 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.
✓ light in outer changing area long-time coming on & dim

✓ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

✓ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations. light switch in outer locker - no seal?

✓ Cracks / chips in paint - inner locker area (walls & ceiling); also at seam in ceiling / wall joint in the corner).

In animal room: ✓ door closes but does not latch

✓ Corrosion around outer doors' door frames (where meets floor. Also around metal frame (chipping paint)

✓ Crack(s) in seam along door frame in animal room.

✓ Drain cover on floor alone trough grating (not over drain); 1 piece of grating missing

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator
Lab Contact Person
Department
Office Phone Number
Lab Phone Number
Lab Location - Bldg _____

Biological agents used:
__ Recombinant DNA
__ Human pathogens - list:

__ Animal pathogens- list:

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: __ BL2 _X_ BL3

Results: _____ Meets criteria at appropriate biosafety level
_____ Does not meet criteria

Comments:

Date of Inspection: 02/27/2006

Environmental Health & Safety Inspector: Nancy L. Eaker

NIH BIOSAFETY LEVEL 3 CRITERIA

A. Standard Microbiological Practices

____ 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

____ 2. Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

____ 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

____ 4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

____ 5. Policies for the safe handling of sharps are instituted.

____ 6. All procedures are performed carefully to minimize the creation of aerosols.

____ 7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

____ 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

____ 9. Persons under 16 years of age are not allowed to enter a BL3 laboratory.

____10. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

____11. An insect and rodent control program is in effect.

B. Special Practices

____ 1. Laboratory doors are kept closed when experiments are in progress.

____ 2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

____ 3. The laboratory director establishes 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.

____ 4. When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

____ 5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for

the agent being handled.

____ 6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

____ 7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

____ 8. Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

____ 9. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

___10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
b. 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
c. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

___11. All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

___12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

___13. Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

___14. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

___ 15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

___ 16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

___ 17 Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

C. Safety Equipment (Primary Barriers)

___1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

___ 2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

___ 3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

___ 4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

___ 5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

___ 6. Respiratory and face protection are used when in rooms containing infected animals.

D. Laboratory Facilities (Secondary Barriers)

_✓_ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway. **See notes.**

_✓_ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

_x_ 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are contructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination. **See notes.**

_✓_ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

_✓_ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

N/A 6. Windows in the laboratory are closed and sealed.

_✓_ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the

laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

N/A 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✓ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

N/A 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

N/A 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

✓ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

✓ 13. An eyewash facility is readily available inside the laboratory.

✱ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision. **See notes.**

✓ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

✓ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

NOTES: Magnahelic gauge reading: 0.7. Door is difficult to open.
Door between animal room and inner locker room closes but does not latch.
Noted corrosion around door frames (at floor) in outer locker room and in animal room. Also noted corrosion on metal frame work in animal room.
Noted cracked and/or chipped paint in inner locker room and in animal/surgical room (walls, ceiling, etc.). Noted small holes and/or cracks in the sealant, especially in corners and around door frames.
One piece of grating over drainage trough is missing. Drain cover is on floor, not over drain.
Light in outer locker room takes a long time to come on, and when it does, it is dim.
No biological hazard sign on outer door. No emergency contact information on outer door.

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator
Lab Contact Person
Department
Office Phone Number
Lab Phone Number
Lab Location - Bldg _____

Biological agents used:
__ Recombinant DNA
__ Human pathogens - list:

__ Animal pathogens- list:

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: __ BL2 _X_ BL3

Results: _____ Meets criteria at appropriate biosafety level
_____ Does not meet criteria

Comments:

Date of Inspection: 02/27/2006

Environmental Health & Safety Inspector: Nancy L. Eaker

NIH BIOSAFETY LEVEL 3 CRITERIA

A. Standard Microbiological Practices

____ 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

____ 2. Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

____ 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

____ 4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

____ 5. Policies for the safe handling of sharps are instituted.

____ 6. All procedures are performed carefully to minimize the creation of aerosols.

____ 7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

____ 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

____ 9. Persons under 16 years of age are not allowed to enter a BL3 laboratory.

____10. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

____11. An insect and rodent control program is in effect.

B. Special Practices

____ 1. Laboratory doors are kept closed when experiments are in progress.

____ 2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

____ 3. The laboratory director establishes 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.

____ 4. When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

____ 5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for

the agent being handled.

____ 6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

____ 7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

____ 8. Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

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___10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
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c. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
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___11. All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

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a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
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___13. Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

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___ 17 Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

C. Safety Equipment (Primary Barriers)

___1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

___ 2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

___ 3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

___ 4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

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___ 6. Respiratory and face protection are used when in rooms containing infected animals.

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✓ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

✓ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

× 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are contructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination. **See notes.**

✓ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

✓ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

N/A 6. Windows in the laboratory are closed and sealed.

✓ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the

laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

N/A 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✓ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

N/A 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

N/A 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

✓ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

✓ 13. An eyewash facility is readily available inside the laboratory.

✓ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision. **See notes.**

✓ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

✓ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

NOTES: Noted standing water in outer locker room.
Magnahelic gauge reading: 0.36
Noted corrosion around door frames (at floor) in outer locker room and in animal room. Also noted corrosion on metal frame work in animal room.
Noted cracked and/or chipped paint throughout facility (walls, ceiling, etc.). Noted small holes or cracks in the sealant, especially in corners and around door frames. Need to seal the gap around the air filter in the inner locker room.
Noted cracks in flooring next to frame of outside door. Also noted that a large portion of the flooring is chipped next to the drainage trough (area is approximately 3' long x 3" wide).
Grating over drainage trough is in place, but drain cover itself is missing.
Light in shower room is somewhat dim due to discolored light cover.
No biological hazard sign on outer door. No emergency contact information on outer door.

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator
Lab Contact Person
Department
Office Phone Number
Lab Phone Number
Lab Location - Bldg _____ ___ Room

Biological agents used:
__ Recombinant DNA
__ Human pathogens - list:

__ Animal pathogens- list:

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: __ BL2 __ BL3

Results: _____ Meets criteria at appropriate biosafety level
_____ Does not meet criteria

Comments:

Date of Inspection: 02/27/04

Environmental Health & Safety Inspector: MLeake Entered 2/27/04

Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

___ 16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

___ 17 Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

C. Safety Equipment (Primary Barriers)

___1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

___ 2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

___ 3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

___ 4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

___ 5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

___ 6. Respiratory and face protection are used when in rooms containing infected animals.

D. Laboratory Facilities (Secondary Barriers)

✓ Standing water in outer locker

✓ ___1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

✓ ___ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

See Note ___ 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are contructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

N/A ___ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

Seal - light switches in outer locker ?

N/A ✓ ___ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

N/A ___ 6. Windows in the laboratory are closed and sealed. ✓ magnahelic gauge 0.36

✓ ___ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the

✓ Corrosion around door frame (at floor) in

✓ Grating over trough in place but drain cover missing

laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

N/A 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✓ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

N/A 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

N/A 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

✓ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

13. An eyewash facility is readily available inside the laboratory. (shower)

✓ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.
✓ light dim in shower - light cover discolored

✓ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

✓ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

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✓ Chipped paint in shower near sink; ✓ floor chipped near trough ✓ crack in paint in inner locker area (ceiling) ✓ small holes in seams around ✓ seams in corners and at door frames ~~where~~ along floor in inner locker area ✓ Chips in paint in inner locker area & 1 locker affected. In seal in corner of inner locker area ✓ crack in paint beneath outlet in inner locker area & above door - Animal room ✓ crack in floor covering at ~~near~~ outside door frame ✓ some corrosion on frame. ✓ Cracks & chips in paint along frame & walls & ceiling.

- ~~Remove cardboard above lockers in inner locker area.~~

2007 Inspection

(inspections conducted 02/07)

TEXAS A&M UNIVERSITY

VICE PRESIDENT FOR RESEARCH - OFFICE OF RESEARCH COMPLIANCE

1186 TAMU
College Station, TX 77843-1186
1500 Research Parkway, Suite B-150

979.458.1467
FAX 979.862.3176
http://researchcompliance.tamu.edu

Institutional Biosafety Committee | Institutional Animal Care and Use Committee | Institutional Review Board

MEMORANDUM

TO: Vernon L. Tesh
Microbial and Molecular Pathogenesis
1114

FROM: Tiffany M. Agnew, Program Coordinator
Institutional Bio-Safety Program

DATE: February 2, 2007

REG.: Annual IBC Inspection of Select Agent Facilities-

At 8:00 am (CST) on January 10, 2007, the following individuals completed the Annual IBC Inspection of the Select Agent Facilities-

Dr. Thomas Ficht, IBC Member (Chair)
Mr. Brent Mattox- IBC Member/EHS; BSO
Ms. Nancy Eaker- EHS
Ms. Angelia Raines- IBC Member/Director, ORC
Ms. Tiffany Agnew- IBSP Coordinator

The aforementioned team utilized the combined checklist from Environmental Health and Safety and the Office of Research Compliance to complete the inspection of the facilities. The use of this combined checklist marks the combined inspection by both offices, to reduce duplicated efforts for identical information. In accordance with CFR 42 § 73.9, inspection of Select Agent Facilities at Texas A&M University should have been conducted in December 2006. However, in an attempt to give the Select Agent investigators and laboratory directors an opportunity to review the combined checklist, the inspections of all Select Agent Facilities were scheduled to be completed in January 2007. The inspection of Building was originally scheduled to take place on Wednesday, January 10, 2007; however, due to inclement weather, the University was closed on this day. The inspection was rescheduled for the aforementioned date.

During this inspection, the following deficiencies were noted by the inspection team:

1. As a result of the **Facility Assessment** of the *Laboratory Facilities (Secondary Barriers)*, the following was noted in respect of the floor plans:

    a. The floor plans were not reviewed during this inspection.

2. As a result of the Program Assessment, the PI Tesh noted that due to a misunderstanding in the manner in which the inventory was to be kept, he indicated there may be a discrepancy found. PI notes there will be seven (7) vials of the agent found.
Note: Biosafety Officer did not indicate this to be an inspection finding.

3. In the **Optional** section of the inspection report, the team noted that although the PI Tesh has a Chemical Hygiene Plan is in place, he never keeps the aggregate level of the recombinant Shiga toxin, only the vials or rDNA that produce the Shiga toxin. In addition, it was noted that the PI

only maintains the plasmid that could create the toxin. Therefore, this section was not completed by the inspection team.

4. It is important to note that PI only enters the BSL3 suite in Building .o retrieve the agent that is kept in a locked freezer in the BSL3 suite. When PI will manipulate the agent, he does so in his laboratory, which is BSL2 containment.

The IBC found there to be no deficiencies found during this inspection. Notification of the next IBC/EHS joint inspection will be sent to you at least 30 days before the actual inspection date.

If you have any additional questions or concerns, please contact our office as soon as possible.

Thank you for your patience and cooperation in this matter.

cc: IBC
Department head
IBC Files

IBC INSPECTION REPORT
BSL3/ABSL3 SBAT FACILITIES & Entity Program

Date: January 10, 2007
Principal Investigator/Lab Director: Dr. Vernon L. Tesh
Location: Building Number -____ Room (s) ____(lab- BSL2)

Inspection Team:
Brent Mattox, Tom Ficht,
Angelia Raines, Nancy Eaker,
Tiffany Agnew

Section I - Facility Assessment (PI)

A. Safety Equipment (Primary Barriers)

☑ Yes ☐ No Protective laboratory clothing, such as solid-front or wrap-around gowns, scrub suits, or coveralls, are worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

☑ Yes ☐ No Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

☑ Yes ☐ No Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

☑ Yes ☐ No All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

☐ Yes ☐ No When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

☐ Yes ☐ No Respiratory and face protection are used when in rooms containing infected animals.

B. Laboratory Facilities (Secondary Barriers)

☑ Yes ☐ No The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

☑ Yes ☐ No Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

☑ Yes ☐ No The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant.

Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

☑ Yes ☐ No Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

☑ Yes ☐ No Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

☑ Yes ☐ No Windows in the laboratory are closed and sealed.

☑ Yes ☐ No A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

☑ Yes ☐ No Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

☑ Yes ☐ No A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

☑ Yes ☐ No HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

☑ Yes ☐ No 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

☑ Yes ☐ No Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

☑ Yes ☐ No An eyewash facility is readily available inside the laboratory.

☑ Yes ☐ No Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

☑ Yes ☐ No The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

- Floor plan(s) include:
  - Sink location
    ☐ Yes ☐ No
  - Eyewash locations
    ☐ Yes ☐ No
  - Biosafety cabinet (BSC) locations
    ☐ Yes ☐ No
  - Fume hood locations
    ☐ Yes ☐ No
  - HVAC supply and exhaust locations
    ☐ Yes ☐ No
  - Freezer/refrigerator locations
    ☐ Yes ☐ No
  - Other large equipment locations (incubators, centrifuges, etc)
    ☐ Yes ☐ No
- Provide a description of the HVAC system (check all that are appropriate):
  - ☑ Single-pass ☐ Re-circulated
  - ☐ Dedicated exhaust ☐ Shared exhaust
  - ☐ Constant air volume ☐ Variable air volume
  - ☐ Redundant exhaust fans
  - ☐ Emergency power back-up
- Provide information on the biosafety cabinets in use (attach additional sheets if needed):
  - Class of cabinet:
  - ☐ I ☐ II, Type A1 ☑ II, Type A2 (formerly II, B3)
  - ☑ II, B1 ☐ II, B2 ☐ III
  - Biosafety cabinet connection to the HVAC system:
  - ☐ Hard duct ☐ Thimble ☐ Re-circulating
  - Define certification period:_____
  - ☑ Annual ☐ Biannual ☐ Other (explain): _____
  - Does user verify air flow during BSC use?
    ☐ Yes ☐ No
  - If floor drains are provided, the traps are always filled with an appropriate disinfectant:
    ☐ Yes ☐ No

☐ Yes ☐ No Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

C. Standard Microbiological Practices

☑ Yes ☐ No Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

☑ Yes ☐ No Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

☑ Yes ☐ No Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

☑ Yes ☐ No Mechanical pipetting devices are used; mouth pipetting is prohibited.

☑ Yes ☐ No Policies for the safe handling of sharps are instituted.

☑ Yes ☐ No All procedures are performed carefully to minimize the creation of aerosols.

☑ Yes ☐ No Work surfaces are decontaminated at least once a day and after any spill of viable material.

☑ Yes ☐ No All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

☑ Yes ☐ No Persons under 16 years of age are not allowed to enter a BL3 laboratory.

☑ Yes ☐ No If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

☑ Yes ☐ No An insect and rodent control program is in effect.

D: Special Practices

☑ Yes ☐ No Laboratory doors are kept closed when experiments are in progress.

☑ Yes ☐ No The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

☑ Yes ☐ No The laboratory director establishes 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.

☑ Yes ☐ No When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

☑ Yes ☐ No Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled.

☑ Yes ☐ No Baseline serum samples are collected as appropriate and stored for all laboratories and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

☑ Yes ☐ No A Biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and Biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

☑ Yes ☐ No Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

☑ Yes ☐ No

The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

☑ Yes ☐ No

A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

- Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic ware should be substituted for glassware whenever possible.
- 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
- Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
- Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

☑ Yes ☐ No

All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

☑ Yes ☐ No

Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

- Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
- Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

☑ Yes ☐ No

Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

☑ Yes ☐ No

All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

☑ Yes ☐ No

Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained. Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities,

National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

☑ Yes ☐ No Animals and plants not related to the work being conducted are not permitted in the laboratory.

☑ Yes ☐ No Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

Section II - Program Assessment (PI and/or Institutional BioSafety Program- IBSP)

☑ Yes ☐ No 1. An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with Select Agents at this facility:

If yes: IBC approved the work proposed for this facility on: **1/8/2004** (date).
(Renewal in process.)

☑ Yes ☐ No 2. **Training**: Site specific and safety training is provided to individuals with access to areas where Select Agents are handled or stored:

a. Is provided prior to individuals beginning to work with Select Agents: ☑ Yes ☐ No
b. Is provided: ☑ Annually ☐ Biannually ☐ Other (specify frequency):
c. Written records of individuals are kept: ☑ Yes ☐ No
d. Personnel demonstrate proficiency in laboratory procedures prior to working with Select Agents: ☑ Yes ☐ No
e. Unannounced visits by EH&S and follow up by supervisory personnel: ☑ Yes ☐ No

3. Provide a brief explanation of the system in place to detect loss or theft of select agent(s):
Incident Response Plan provides information regarding this item.

4. **Inventory**: Individual responsible for inventory of select agent(s): **Dr. Vernon Tesh**
a. How often is the inventory record reconciled? **Annually- 11/21/05; Confusion in logs**
b. How is access to the inventory log limited? **Information found in Security Plan**
c. Inventory tracking includes the following information (list): **Dr. Tesh reconciles inventory; BSO confirms during annual inventory check**

5. **Security**: There is a site-specific Security Plan for this laboratory: ☑ Yes ☐ No
a. Building with Select Agent has self-closing doors: ☑ Yes ☐ No
b. Means to limit access to buildings with laboratories with Select Agent:
Guard station at the facility entrance: ☐ Yes ☑ No
Card access system or locks: ☑ Yes ☐ No
6:00 a.m. – 6:00 p.m. Monday - Friday, 24 hours on weekends
Security alarm system in the laboratory building: ☑ Yes ☐ No
Other (describe): **Alarm will sound if door to is held open too long.**
f. Means to limit access to laboratories with Select Agent once inside the building:
Door to laboratory is locked: ☑ Yes ☐ No
Card access system or locks: ☐ Yes ☐ No
Other (describe): **Thumb print reader**
g. Means to limit access to select agents once inside the laboratory:
Locked incubators, refrigerators, freezers, etc.: ☑ Yes ☐ No
Security alarm system that directly monitors the laboratory: ☐ Yes ☐ No
Other (describe):_____
h. Means to limit access to select agents in storage:
Storage area door locked: ☑ Yes ☐ No
Lock boxes: ☑ Yes ☐ No
Security alarm system that directly monitors the laboratory: ☐ Yes ☐ No
Other (describe): **Locked freezer; agent in a locked box within freezer; PI Samuel has the key to the freezer, but cannot access locked box. When PI Tesh is using the agent, all non-DOJ approved personnel are not allowed in the laboratory.**
i. Means to monitor unauthorized entry into the laboratory where select agents are used or stored:
Electronic logs of card access system entries are reviewed for unusual activity: ☑ Yes ☐ No
Manual sign in and out logs are kept and monitored: ☑ Yes ☐ No
Video camera surveillance: ☐ Yes ☑ No
Other (describe): _____

j. The laboratory is secured when no one is present during regular working hours: ☑ Yes ☐ No

k. Number of people with access: **2**

l. Individuals not directly involved in research activities have access to Select Agent: ☐ Yes ☑ No

If yes, please explain: _____

m. Non-laboratory personnel (visitors, including janitorial and facility maintenance personnel) have access to the laboratory with select agents: ☑ Yes ☐ No
If yes, are they allowed into the laboratory unescorted? ☐ Yes ☑ No

6. Decontamination: All cultures, stock and other regulated wastes are decontaminated before disposal by an approved decontamination method: ☑ Yes ☐ No
If yes, describe method: **Autoclave**

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **RECOMBINANT DNA**

☑ Yes ☐ No 1. The facility has an Institutional Biosafety Committee that has approved work with recombinant DNA or has approval pending.

☑ Yes ☐ No 2. The Biosafety level listed in the *Application for IBC Permit* for this laboratory meets NIH Guidelines:

3. Will you be possessing, using, or transferring the following:
   a. Select Agent nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that are capable of infection and/or replication: ☐ Yes ☑ No
   b. Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids are in a vector or host chromosome and/or are expressed *in vivo* or *in vitro:* ☐ Yes ☑ No
   c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. ☑ Yes ☐ No

4. Are you intending to conduct the following experiments:
   a. Experiments utilizing recombinant DNA techniques that involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture: ☐ Yes ☑ No
   b. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxin molecules lethal for vertebrates at an LD50<100 ng/kg body weight: ☐ Yes ☑ No
   c. Provide a brief description of the recombinant constructs and any associated expression control of elements, including what the recombinant DNA encodes for, if known:

   d. Give an estimate of range of length of recombinant DNA to be used:

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **SMALL ANIMALS**

1. List species of small animals that will be used: _____

2. Describe route of infection:

3. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No
If yes, describe method: _____

4. The facility requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this facility? ☐ Yes ☐ No
If yes, the proposed work with Select Agents has been approved by the IACUC: ☐Yes ☐ No

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **LARGE ANIMALS**

1. List species of large animals that will be used: _____

2. Describe route of infection:

3. Carcass of animals are disposed of to avoid their use as food for human beings or animals: ☐Yes ☐ No

4. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐Yes ☐ No
   If yes, give method: _____

5. Carcass of animals are disposed of on site: ☐ Yes ☐ No

6. The facility requires that in an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at his facility: ☐ Yes ☐ No
   If yes, the proposed work has been approved by the IACUC: ☐ Yes ☐ No

Optional - TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR

1. A Chemical hygiene plan is available for the facility using toxins: ☑ Yes ☐ No

2. Maximum quantity of each toxin under the control of the Principal Investigator at a give time:

3. Form of toxins used: ☐ Liquid ☐ Lyophilized
   a. The toxin is produced by live agent at the facility: ☐ Yes ☐ No
      If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____
   b. Dilution procedures and other manipulations of the concentrated toxins are:
      Conducted in ☐ Fume hood ☐ Biosafety cabinet
      If a fume hood is used, certification of the hood is conducted:
      ☐ Annually ☐ Biannually ☐ Other (describe): _____
      Conducted with two knowledgeable people present: ☐ Yes ☐ No

4. A hazard sign on the door when toxins are present: ☐ Yes ☐ No

5. Floor plan(s) include:
   Sink location: ☐ Yes ☐ No
   Eyewash locations: ☐ Yes ☐ No
   Biosafety cabinet (BSC) locations: ☐ Yes ☐ No
   Fume hood locations: ☐ Yes ☐ No
   HVAC supply and exhaust locations: ☐ Yes ☐ No
   Freezer/refrigerator locations: ☐ Yes ☐ No
   Other large equipment locations (incubators, centrifuges, etc): ☐ Yes ☐ No

6. Plan provides a description of the HVAC system (check all that are appropriate):
   ☐ Single-pass ☐ Re-circulated ☐ Dedicated exhaust ☐ Shared exhaust
   ☐ Constant air volume ☐ Variable air volume ☐ Redundant exhaust fans ☐ Emergency power back-up

7. Plan provides information on the biosafety cabinets in use (attach additional sheets if needed):
   Class of cabinet:
   ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III
   Biosafety cabinet connection to the HVAC system:
   ☐ Hard duct ☐ Thimble ☐ Re-circulating
   Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain): _____
   Does user verify air flow during BSC use? ☐ Yes ☐ No

Section III – Entity Program (IBSP)

☐ Yes ☐ No Entity Program documents IBC approvals which include Select Agent required information.

☐ Yes ☐ No Entity documents registrations.

☐ Yes ☐ No Entity documents (IBC) are current and up to date.

☐ Yes ☐ No Entity documents changes to the registration and does not allow access until amendments have been approved.

☐ Yes ☐ No Entity has a current Incident Response Plan

☐ Yes ☐ No Entity emergency response drill and evaluation is documented annually

☐ Yes ☐ No Entity Security Plan is reviewed and documented annually.

☐ Yes ☐ No Entity documents annual inspections and follow up requirements

Section IV – Inspection Summary

1. As a result of the **Facility Assessment** of the *Laboratory Facilities (Secondary Barriers)*, the following was noted in respect of the floor plans:

    a. The floor plans were not reviewed during this inspection.

2. As a result of the Program Assessment, the PI Tesh noted that due to a misunderstanding in the manner in which the inventory was to be kept, he indicated there may be a discrepancy found. PI notes there will be seven (7) vials of the agent found.
Note: Biosafety Officer did not indicate this to be an inspection finding.

3. In the **Optional** section of the inspection report, the team noted that although the PI Tesh has a Chemical Hygiene Plan is in place, he never keeps the aggregate level of the recombinant Shiga toxin, only the vials or rDNA that produce the Shiga toxin. In addition, it was noted that the PI only maintains the plasmid that could create the toxin. Therefore, this section was not completed by the inspection team.

4. It is important to note that PI only enters the BSL3 suite in Building to retrieve the agent that is kept in a locked freezer in the BSL3 suite. When PI will manipulate the agent, he does so in his laboratory, which is BSL2 containment.

mistakenly gave PI version with "DRAFT" printed, however PI understands this is not draft, but official doc. (mo)

TEXAS A&M UNIVERSITY

VICE PRESIDENT FOR RESEARCH - OFFICE OF RESEARCH COMPLIANCE
1186 TAMU
College Station, TX 77843-1186
1500 Research Parkway, Suite B-150
979.458.1467
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http://researchcompliance.tamu.edu

Institutional Biosafety Committee | Institutional Animal Care and Use Committee | Institutional Review Board

MEMORANDUM

TO: Dr. James Samuel
Medical Microbiology and Immunology
MS 1114

FROM: Tiffany M. Agnew, Program Coordinator
Institutional Bio-Safety Program

DATE: February 2, 2007

REG.: Annual IBC Inspection of Select Agent Facilities- Building Samuel)

At 10:15 a.m. (CST) on January 10, 2007. the following individuals completed the Annual IBC Inspection of the Select Agent Facilities- Building Samuel):

Ms. Angelia Raines- IBC Member/Director, ORC
Dr. Thomas Ficht- IBC Member (Chair)
Mr. Brent Mattox- IBC Member/EHS
Ms. Nancy Eaker- EHS
Ms. Tiffany Agnew- IBSP Coordinator

The aforementioned team utilized the combined checklist from Environmental Health and Safety and the Office of Research Compliance to complete the inspection of the facilities. The use of this combined checklist marks the combined inspection by both offices, to reduce duplicated efforts for identical information. In accordance with CFR 42 § 73.9, inspection of Select Agent Facilities at Texas A&M University have been conducted in December. However, in an attempt to give the Select Agent investigators an opportunity to review the combined checklist, the inspections of all Select Agent Facilities were scheduled to be completed in January. The inspection for Building was originally scheduled to take place on Wednesday, January 10, 2007; however, due to inclement weather, the University was closed on this day. The inspection was rescheduled for the aforementioned date.

During this inspection, the following deficiencies were noted by the inspection team:

1. As a result of the **Facility Assessment** of the *Laboratory Facilities (Secondary Barriers)*, the following was noted in respect of the interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination:
   a. Room
      i. Penetration(s) in wall(s) next to the autoclave unit
      ii. Cracks in the paint

   b. Room
      i. Airflow alarm sounding (Air balance was verified to be good, but the sensor was inoperable.)
      ii. Fire extinguisher has not been serviced since 2004 (Others in suite should be serviced/checked as well.)
      iii. Cracks in paint
      iv. Hole in wall near door needs to be filled
      v. Coving where it meets the wall needs to be sealed; gaps noted
      vi. No door sweep on the door

c. Room
   i. No door sweep on the door
   ii. Cracks in paint
   iii. Hole in wall near door needs to be filled
   iv. Coving where it meets the wall needs to be sealed

d. Room
   i. UV light on Biosafety Cabinet (BSC) needs to be repaired. (EHS will notify contractor.)
   ii. Cracks in paint
   iii. Coving where it meets the wall needs to be sealed
   iv. Glass containers noted on the floor

2. As a result of the **Program Assessment** in regards to *Training*, the following was noted:
   a. Several training certificates were not signed.

3. As a result of the **Program Assessment** in regards to *records*, the following was noted:
   a. There was no updated Emergency Contact list in records. (Records reflect investigator who is no longer at institution.)

4. As a result of the **Program Assessment** in regards to the *Agent Access Log*, the following was noted:
   a. Improper use of the Agent Access Log; entries were not complete and there were many inconsistencies.
   b. Members of the team suggested PI provide additional training to personnel in the correct usage of the log.

The IBC requests these deficiencies are rectified before the next inspection of this facility, which is scheduled to take place: **March 2007**. Upon receipt of this correspondence, please provide written indication that you have indeed received this document, and that you agree to complete all necessary corrections.

If you have any additional questions or concerns, please contact our office as soon as possible.

check in : Fri., Feb, 23, 2007

Note: Dr. Samuel will take care of corrections (considered "minor" - per Angelia)
- Brent will take care of UV light in BSC - ^_^

cc: IBC
Department head
IBC files

* hes will get someone to contact Dr. Samuel to assist w/corrections

IBC INSPECTION REPORT
BSL3/ABSL3 SBAT FACILITIES & Entity Program

Date: January 10, 2007
Principal Investigator/Lab Director: Dr. James Samuel
Location: Building Number ____ Room (s) _____

Inspection Team:

Angelia Raines, Tom Ficht
Brent Mattox, Nancy Eaker

Section I - Facility Assessment (PI)

A. Safety Equipment (Primary Barriers)

☑ Yes ☐ No Protective laboratory clothing, such as solid-front or wrap-around gowns, scrub suits, or coveralls, are worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

☑ Yes ☐ No Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

☑ Yes ☐ No Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

☑ Yes ☐ No All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

☑ Yes ☐ No When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

☑ Yes ☐ No Respiratory and face protection are used when in rooms containing infected animals.

B. Laboratory Facilities (Secondary Barriers)

☑ Yes ☐ No The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

☑ Yes ☐ No Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

☐ Yes ☑ No The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and

disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

☑Yes ☐ No Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

☑ Yes ☐ No Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

☑ Yes ☐ No Windows in the laboratory are closed and sealed.

☑ Yes ☐ No A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

☑ Yes ☐ No Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

☐ Yes ☑ No A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

☑ Yes ☐ No HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

☑ Yes ☐ No 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

☑ Yes ☐ No Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

☑ Yes ☐ No An eyewash facility is readily available inside the laboratory.

☑ Yes ☐ No Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

☑ Yes ☐ No The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as

modified by operational experience.

- Floor plan(s) include:
  - Sink location
    ☐ Yes ☐ No
  - Eyewash locations
    ☐ Yes ☐ No
  - Biosafety cabinet (BSC) locations
    ☐ Yes ☐ No
  - Fume hood locations
    ☐ Yes ☐ No
  - HVAC supply and exhaust locations
    ☐ Yes ☐ No
  - Freezer/refrigerator locations
    ☐ Yes ☐ No
  - Other large equipment locations (incubators, centrifuges, etc)
    ☐ Yes ☐ No
- Provide a description of the HVAC system (check all that are appropriate):
  - ☑ Single-pass ☐ Re-circulated
  - ☐ Dedicated exhaust ☑ Shared exhaust
  - ☐ Constant air volume ☐ Variable air volume
  - ☐ Redundant exhaust fans
  - ☐ Emergency power back-up
- Provide information on the biosafety cabinets in use (attach additional sheets if needed):
  - Class of cabinet:
  - ☐ I ☐ II, Type A1 ☑ II, Type A2 (formerly II, B3)
  - ☑ II, B1 ☐ II, B2 ☐ III
  - Biosafety cabinet connection to the HVAC system:
  - ☐ Hard duct ☐ Thimble ☐ Re-circulating
  - Define certification period:_____
  - ☐ Annual ☐ Biannual ☐ Other (explain): _____
  - Does user verify air flow during BSC use?
    ☐ Yes ☐ No
  - If floor drains are provided, the traps are always filled with an appropriate disinfectant:
    ☐ Yes ☐ No

☐ Yes ☐ No Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

C. Standard Microbiological Practices

☑ Yes ☐ No Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

☑ Yes ☐ No Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

☑ Yes ☐ No Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

☑ Yes ☐ No Mechanical pipetting devices are used; mouth pipetting is prohibited.

☑ Yes ☐ No Policies for the safe handling of sharps are instituted.

☑ Yes ☐ No All procedures are performed carefully to minimize the creation of aerosols.

☑ Yes ☐ No Work surfaces are decontaminated at least once a day and after any spill of viable material.

☑ Yes ☐ No All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

☑ Yes ☐ No Persons under 16 years of age are not allowed to enter a BL3 laboratory.

☑ Yes ☐ No If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

☑ Yes ☐ No An insect and rodent control program is in effect.

D: Special Practices

☑ Yes ☐ No Laboratory doors are kept closed when experiments are in progress.

☑ Yes ☐ No The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

☑ Yes ☐ No The laboratory director establishes 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.

☑ Yes ☐ No When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

☑ Yes ☐ No Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled.

☑ Yes ☐ No Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

☑ Yes ☐ No A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

☑ Yes ☐ No Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure

evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

☑ Yes ☐ No

The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

☑ Yes ☐ No

A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

- Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic ware should be substituted for glassware whenever possible.
- 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
- Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
- Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

☑ Yes ☐ No

All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

☑ Yes ☐ No

Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.

- Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
- Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

☑ Yes ☐ No

Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

☑ Yes ☐ No

All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

☑ Yes ☐ No

Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained. Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are

immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

☑ Yes ☐ No Animals and plants not related to the work being conducted are not permitted in the laboratory.

☑ Yes ☐ No Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

Section II - Program Assessment (PI and/or Institutional BioSafety Program- IBSP)

☑ Yes ☐ No An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with Select Agents at this facility:
If yes: IBC approved the work proposed for this facility on: **4/21/04** (date).

☑ Yes ☐ No 2. **Training**: Site specific and safety training is provided to individuals with access to areas where Select Agents are handled or stored:
   a. Is provided prior to individuals beginning to work with Select Agents: ☑ Yes ☐ No
   b. Is provided: ☑ Annually ☐ Biannually ☐ Other (specify frequency):
   Records indicate training completed May 2, 2006 (reflected changes in facility entry).
   c. Written records of individuals are kept: ☑ Yes ☐ No
   d. Personnel demonstrate proficiency in laboratory procedures prior to working with Select Agents: ☑ Yes ☐ No
   e. Unannounced visits by EH&S and follow up by supervisory personnel: ☐ Yes ☐ No

3. Provide a brief explanation of the system in place to detect loss or theft of select agent(s):
within the Incident Response Plan

4. **Inventory**: Individual responsible for inventory of select agent(s): **Dr. Samuel Eunhee Lee (designee)**
   a. How often is the inventory record reconciled? **12/09/05 (Indicated in SOP as Annually)**
   b. How is access to the inventory log limited? **In locked cabinet and on secure file on computer; PI and designee only have access keys and password**
   c. Inventory tracking includes the following information (list):

5. **Security**: There is a site-specific Security Plan for this laboratory: ☑ Yes ☐ No
   a. Building with Select Agent has self-closing doors: ☑ Yes ☐ No
   b. Means to limit access to buildings with laboratories with Select Agent:
   Guard station at the facility entrance: ☐ Yes ☑ No
   Card access system or locks: ☑ Yes ☐ No
   6:00 a.m.-6:00 p.m. Monday-Friday, 24 hours on weekends
   Security alarm system in the laboratory building: ☑ Yes ☐ No
   Other (describe): **Alarm will sound if door is held open too long.**
   f. Means to limit access to laboratories with Select Agent once inside the building:
   Door to laboratory is locked: ☑ Yes ☐ No
   Doors to BSL3 locked 24 hours. These doors are magnetic on both sides of the door, with dual key card and fingerprint ID system.
   Card access system or locks: ☑ Yes ☐ No
   Other (describe): _____
   g. Means to limit access to select agents once inside the laboratory:
   Locked incubators, refrigerators, freezers, etc.: ☑ Yes ☐ No
   Locked freezers only; locks are only on inventory items. .
   Security alarm system that directly monitors the laboratory: ☑ Yes ☐ No
   Other (describe): **Hawkeye System used; reports filter into the radio room on campus. Only DOJ approved personnel have access to BSL3 Suite.**
   h. Means to limit access to select agents in storage:
   Storage area door locked: ☑ Yes ☐ No
   Lock boxes: ☑ Yes ☐ No
   Freezer has padlock. Lock box within freezer that only Dr. Tesh has key an authorization to access.
   Security alarm system that directly monitors the laboratory: ☐ Yes ☑ No
   Other (describe): _____
   i. Means to monitor unauthorized entry into the laboratory where select agents are used or stored: **Facility Access Log**
   Electronic logs of card access system entries are reviewed for unusual activity: ☑ Yes ☐ No
   Manual sign in and out logs are kept and monitored: ☑ Yes ☐ No
   Video camera surveillance: ☐ Yes ☑ No

j. The laboratory is secured when no one is present during regular working hours: ☑ Yes ☐ No

k. Number of people with access: **all those listed on 4B table**

l. Individuals not directly involved in research activities have access to Select Agent: ☑ Yes ☐ No
If yes, please explain: **George Martin (building manager- DOJ approved)**

m. Non-laboratory personnel (visitors, including janitorial and facility maintenance personnel) have access to the laboratory with select agents: ☑ Yes ☐ No
If yes, are they allowed into the laboratory unescorted? ☐ Yes ☑ No

6. Decontamination: All cultures, stock and other regulated wastes are decontaminated before disposal by an approved decontamination method: ☑ Yes ☐ No
If yes, describe method: **Noted in Standard Operational Procedures (Biosafety Plan)**

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **RECOMBINANT DNA**

☑ Yes ☐ No 1. The facility has an Institutional Biosafety Committee that has approved work with recombinant DNA or has approval pending.
New submission will need to be before: April 21, 2007

☑ Yes ☐ No 2. The biosafety level listed in the *Application for IBC Permit* for this laboratory meets NIH Guidelines.

3. Will you be possessing, using, or transferring the following:
   a. Select Agent nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that are capable of infection and/or replication: ☐ Yes ☑ No
   b. Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids are in a vector or host chromosome and/or are expressed *in vivo* or *in vitro*: ☐ Yes ☑ No
   c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. ☑ Yes ☐ No

4. Are you intending to conduct the following experiments:
   a. Experiments utilizing recombinant DNA techniques that involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture: ☐ Yes ☑ No
   b. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxin molecules lethal for vertebrates at an LD50<100 ng/kg body weight: ☐ Yes ☑ No
   c. Provide a brief description of the recombinant constructs and any associated expression control elements, including what the recombinant DNA encodes for, if known:
   Noted in *Application for IBC Permit*
   d. Give an estimate of range of length of recombinant DNA to be used:
   Less than 20

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **SMALL ANIMALS**

1. List species of small animals that are used: **mice, and guinea pigs**

2. Describe route of infection: **oral, nasal, aerosolization, and i.p.**

3. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☑ Yes ☐ No
If yes, describe method: **autoclave**

4. The facility requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this facility? ☑ Yes ☐ No
If yes, the proposed work with Select Agents has been approved by the IACUC: ☑Yes ☐ No

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH **LARGE ANIMALS**

1. List species of large animals that will be used: _____

2. Describe route of infection:

3. Carcass of animals are disposed of to avoid their use as food for human beings or animals: ☐Yes ☐ No

4. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐Yes ☐ No
   If yes, give method: _____

5. Carcass of animals are disposed of on site: ☐ Yes ☐ No

6. The facility requires that in an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at his facility: ☐ Yes ☐ No
   If yes, the proposed work has been approved by the IACUC: ☐ Yes ☐ No

Optional - TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR

1. A Chemical hygiene plan is available for the facility using toxins: ☐ Yes ☐ No

2. Maximum quantity of each toxin under the control of the Principal Investigator at a give time:

3. Form of toxins used: ☐ Liquid ☐ Lyophilized
   a. The toxin is produced by live agent at the facility: ☐ Yes ☐ No
      If yes, provide a brief description of procedures used (Include an estimate of the maximum quantities grown at a given time): _____
   b. Dilution procedures and other manipulations of the concentrated toxins are:
      Conducted in ☐ Fume hood ☐ Biosafety cabinet
      If a fume hood is used, certification of the hood is conducted:
      ☐ Annually ☐ Biannually ☐ Other (describe): _____
      Conducted with two knowledgeable people present: ☐ Yes ☐ No

4. A hazard sign on the door when toxins are present: ☐ Yes ☐ No

5. Floor plan(s) include:
   Sink location: ☐ Yes ☐ No
   Eyewash locations: ☐ Yes ☐ No
   Biosafety cabinet (BSC) locations: ☐ Yes ☐ No
   Fume hood locations: ☐ Yes ☐ No
   HVAC supply and exhaust locations: ☐ Yes ☐ No
   Freezer/refrigerator locations: ☐ Yes ☐ No
   Other large equipment locations (incubators, centrifuges, etc): ☐ Yes ☐ No

6. Plan provides a description of the HVAC system (check all that are appropriate):
   ☐ Single-pass ☐ Re-circulated ☐ Dedicated exhaust ☐ Shared exhaust
   ☐ Constant air volume ☐ Variable air volume ☐ Redundant exhaust fans ☐ Emergency power back-up

7. Plan provides information on the biosafety cabinets in use (attach additional sheets if needed):
   Class of cabinet:
   ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III
   Biosafety cabinet connection to the HVAC system:
   ☐ Hard duct ☐ Thimble ☐ Re-circulating
   Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain): _____
   Does user verify air flow during BSC use? ☐ Yes ☐ No

Section III – Entity Program (IBSP)

☐ Yes ☐ No Entity Program documents IBC approvals which include Select Agent required information.

☐ Yes ☐ No Entity documents registrations.

☐ Yes ☐ No Entity documents (IBC) are current and up to date.

☐ Yes ☐ No Entity documents changes to the registration and does not allow access until amendments have been approved.

☐ Yes ☐ No Entity has a current Incident Response Plan

☐ Yes ☐ No Entity emergency response drill and evaluation is documented annually

☐ Yes ☐ No Entity Security Plan is reviewed and documented annually.

☐ Yes ☐ No Entity documents annual inspections and follow up requirements

Section IV – Inspection Summary

1. As a result of the **Facility Assessment** of the *Laboratory Facilities (Secondary Barriers)*, the following was noted in respect of the interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination:
    a. Room
        i. Penetration(s) in wall(s) next to the autoclave unit
        ii. Cracks in the paint

    b. Room
        i. Airflow alarm sounding (Air balance was verified to be good, but the sensor was inoperable.)
        ii. Fire extinguisher has not been serviced since 2004 (Others in suite should be serviced/checked as well.)
        iii. Cracks in paint
        iv. Hole in wall near door needs to be filled
        v. Coving where it meets the wall needs to be sealed; gaps noted
        vi. No door sweep on the door

    c. Room
        i. No door sweep on the door
        ii. Cracks in paint
        iii. Hole in wall near door needs to be filled
        iv. Coving where it meets the wall needs to be sealed

    d. Room
        i. UV light on Biosafety Cabinet (BSC) needs to be repaired. (EHS will notify contractor.)
        ii. Cracks in paint
        iii. Coving where it meets the wall needs to be sealed
        iv. Glass containers noted on the floor

2. As a result of the **Program Assessment** in regards to *Training*, the following was noted:
    a. Several training certificates were not signed.

3. As a result of the **Program Assessment** in regards to *records*, the following was noted:
    a. There was no updated Emergency Contact list in records. (Records reflect investigator who is no longer at institution.)

4. As a result of the **Program Assessment** in regards to the Agent Access Log, the following was noted:
    a. Improper use of the Agent Access Log; entries were not complete and there were many inconsistencies.
    b. Members of the team suggested PI provide additional training to personnel in the correct usage of the log.

2006 Inspection Report

(Inspections conducted 01/06)

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator
Lab Contact Person
Department
Office Phone Number
Lab Phone Number
Lab Location - Bldg Room

Biological agents used:
__ Recombinant DNA
__ Human pathogens - list: Coxiella burnetti
Brucella abortus
__ Animal pathogens- list:

__ Human tissues or body fluids
__ Non-pathogenic biological materials

Biosafety Level: __ BL2 __ BL3

Results: ____ Meets criteria at appropriate biosafety level
____ Does not meet criteria

Comments:

Too much clutter in shower area!
Everything else looks good.

Date of Inspection: 1-9-06

Environmental Health & Safety Inspector:

NIH BIOSAFETY LEVEL 3 CRITERIA

A. Standard Microbiological Practices

✓ 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

✓ 2. Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

✓ 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

✓ 4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

✓ 5. Policies for the safe handling of sharps are instituted.

✓ 6. All procedures are performed carefully to minimize the creation of aerosols.

✓ 7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

✓ 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

✓ 9. Persons under 16 years of age are not allowed to enter a BL3 laboratory.

✓ 10. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

✓ 11. An insect and rodent control program is in effect.

B. Special Practices

✓ 1. Laboratory doors are kept closed when experiments are in progress.

✓ 2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

✓ 3. The laboratory director establishes 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.

✓ 4. When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

✓ 5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for

the agent being handled.

6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

8. Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

9. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.
    a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
    b. 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
    c. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
    d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

11. All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.
    a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
    b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

13. Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

14. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

✓ 16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

17 Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

Animals housed in separate room

C. Safety Equipment (Primary Barriers)

✓ 1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

✓ 2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

✓ 3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

✓ 4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

✓ 5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

✓ 6. Respiratory and face protection are used when in rooms containing infected animals.

D. Laboratory Facilities (Secondary Barriers)

✓ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

✓ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

✓ 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are contructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

✓ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

✓ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

NA 6. Windows in the laboratory are closed and sealed.

✓ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the

laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors. (Except cages - transported to Lab)

___ 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas. As much as possible

___ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

___ 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

___ 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

___ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

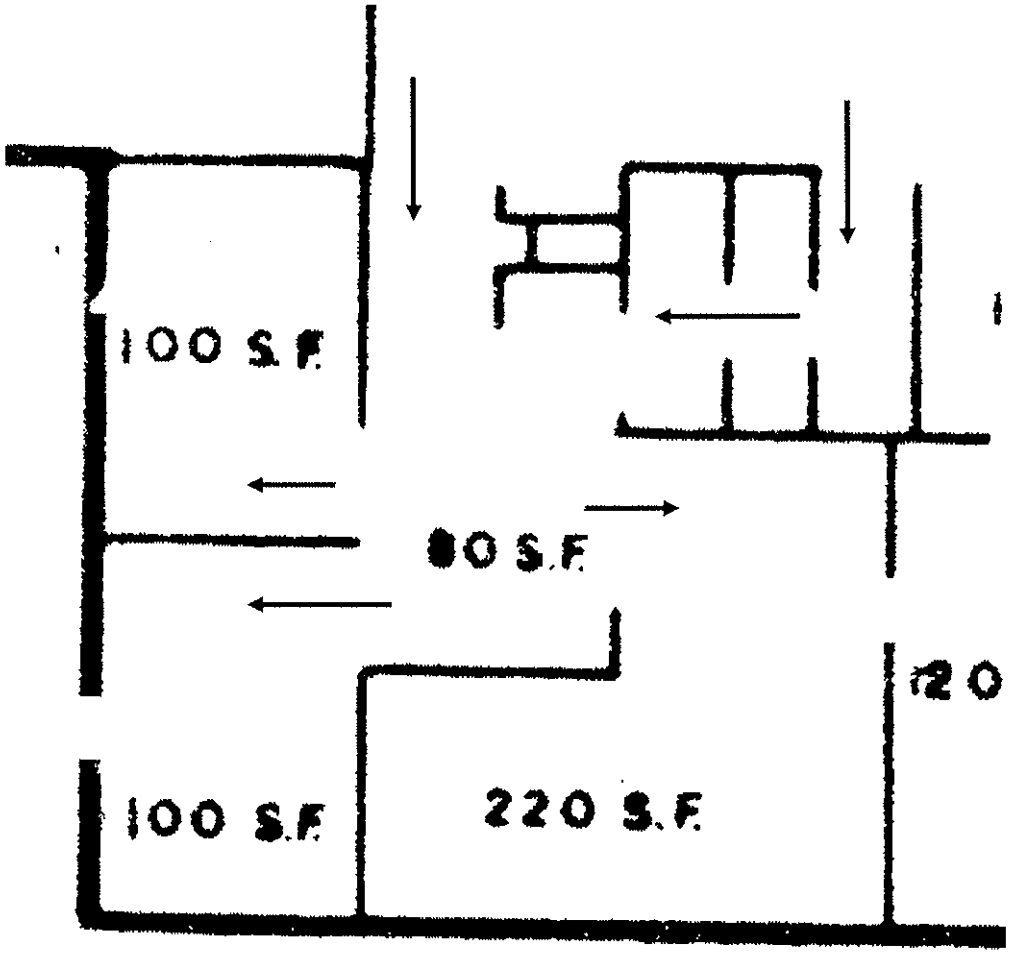
___ 13. An eyewash facility is readily available inside the laboratory.

___ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

___ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

___ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

Reynolds Medical Science Center /



2005 Inspection Report

(Inspections conducted 01/05)

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator: Dr. James Samuel / Dr. Renee Tsolis
Lab Contact Person: Dr. James Samuel / Dr. Renee Tsolis
Department: MMIM
Office Phone Number: 862-1684 / 458-0778
Lab Phone Number: _____
Lab Location - Bldg _____ Room _____

Biological agents used:

✔ Recombinant DNA

✔ Human pathogens - list: *Coxiella burnetii, Rickettsia prowazekii, Brucella abortus, Brucella melitensis, Brucella suis*

✔ Animal pathogens- list: *Coxiella burnetii, Rickettsia prowazekii, Brucella abortus, Brucella melitensis, Brucella suis*

✔ Toxins- list: *Shigatoxin*

__ Human tissues or body fluids

__ Non-pathogenic biological materials

Biosafety Level: BL3

Results: ✔ Meets criteria at appropriate biosafety level

_____ Does not meet criteria

Comments:

Date of Inspection: 01/12/05

Environmental Health & Safety Inspector: Jeffrey C. Truss

NIH BIOSAFETY LEVEL 3 CRITERIA

A. Standard Microbiological Practices

__✔__ 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

__✔__ 2. Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.

__✔__ 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.

__✔__ 4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

__✔__ 5. Policies for the safe handling of sharps are instituted.

__✔__ 6. All procedures are performed carefully to minimize the creation of aerosols.

__✔__ 7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

__✔__ 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

__✔__ 9. Persons under 16 years of age are not allowed to enter a BL3 laboratory.

__✔__ 10. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

__✔__ 11. An insect and rodent control program is in effect.

B. Special Practices

__✔__ 1. Laboratory doors are kept closed when experiments are in progress.

__✔__ 2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

__✔__ 3. The laboratory director establishes 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.

__✔__ 4. When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

__✔__ 5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially

present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled.

✔ 6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

✔ 7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

✔ 8. Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

✔ 9. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

✔ 10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.
   a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
   b. 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 or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
   c. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
   d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

✔ 11. All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

✔ 12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.
   a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
   b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

✔ 13. Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

✔ 14. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.

✔ 15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written

records are maintained.
Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and the NIH/OBA. Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9838 or (301) 496-9839 (fax).

✔ 16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

✔ 17 Laboratory animals held in a BL3 area shall be housed in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, solid-wall and bottom cages covered by filter bonnets, or solid-wall and bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

C. Safety Equipment (Primary Barriers)

✔ 1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.

✔ 2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

✔ 3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

✔ 4. All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.

✔ 5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

✔ 6. Respiratory and face protection are used when in rooms containing infected animals.

D. Laboratory Facilities (Secondary Barriers)

✔ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

✔ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

✔ 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are contructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

✔ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

✔ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

N/A 6. Windows in the laboratory are closed and sealed.

✔ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

✔ 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✔ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

✔ 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

✔ 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

✔ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

✔ 13. An eyewash facility is readily available inside the laboratory.

✔ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

✔ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

✔ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

2005 Inspection Report

(Inspections conducted 1/05-2/05)

CORRECTED 2/1/05

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Does not meet criteria**

Comments:

- **Check air balance**

Date of Inspection: **1/14/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

D. Laboratory Facilities (Secondary Barriers)

✓ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

✓ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

✓ 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

✓ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

✓ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

✓ 6. Windows in the laboratory are closed and sealed.

✓ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

✓ 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✓ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

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× 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

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TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Meets criteria**

Comments:

Date of Inspection: **2/1/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

D. Laboratory Facilities (Secondary Barriers)

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with a non-fabric material that can be easily decontaminated.

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CORRECTED 2/1/05

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Does not meet criteria**

Comments:

- **Check air balance**

Date of Inspection: **1/14/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

D. Laboratory Facilities (Secondary Barriers)

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✓ 6. Windows in the laboratory are closed and sealed.

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TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Meets criteria**

Comments:

Date of Inspection: **2/1/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

D. Laboratory Facilities (Secondary Barriers)

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CORRECTED 2/1/05

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Does not meet criteria**

Comments:

- **Air balance should be checked**

Date of Inspection: **1/14/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

D. Laboratory Facilities (Secondary Barriers)

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CORRECTED 2/1/05

✓ 6. Windows in the laboratory are closed and sealed.

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TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Meets criteria**

Comments:

Date of Inspection: **2/1/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

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✓ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

✓ 6. Windows in the laboratory are closed and sealed.

✓ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

✓ 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✓ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

✓ 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

✓ 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

✓ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

✓ 13. An eyewash facility is readily available inside the laboratory.

✓ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

✓ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

✓ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

Brad Mattox
Sara R Jordan

IBC INSPECTION REPORT
BSL3/ABSL3 SBAT FACILITIES

Date: 12/02/05

Notes:

1. Inspection Team: Mattox, Jordan, Kretzschmar, Raines (Samuel, Tesh)
2. Location: Bldg

3. Floor plan(s) include: (Refer to January 2005 EH&S Inspection of these facilities)
   a. Sink location ☑ Yes ☐ No
   b. Eyewash locations ☑ Yes ☐ No
   c. Biosafety cabinet (BSC) locations ☑ Yes ☐ No
   d. Fume hood locations ☑ Yes ☐ No
   e. HVAC supply and exhaust locations ☑ Yes ☐ No
   f. Freezer/refrigerator locations ☑ Yes ☐ No
   g. Other large equipment locations (incubators, centrifuges, etc) ☑ Yes ☐ No
4. Provide a description of the HVAC system (check all that are appropriate): (Refer to January 2005 EH&S Inspection Report)
   a. ☑ Single-pass ☐ Re-circulated
   b. ☑ Dedicated exhaust ☐ Shared exhaust
   c. ☐ Constant air volume ☐ Variable air volume
   d. ☑ Redundant exhaust fans
   e. ☐ Emergency power back-up
5. Provide information on the biosafety cabinets in use (attach additional sheets if needed):
   a. Class of cabinet:
      ☐ I ☑ II, Type A1 ☐ II, Type A2 (formerly II, B3)
      ☐ II, B1 ☐ II, B2 ☐ III
   b. Biosafety cabinet connection to the HVAC system:
      ☐ Hard duct ☑ Thimble ☑ Re-circulating
   c. Define certification period:
      ☑ Annual ☐ Biannual ☐ Other (explain): _____
   d. Does user verify air flow during BSC use? ☐ Yes ☐ No
6. BSL-3 laboratory registration must answer the following:
   a. Entry into the lab is through a double set of lockable self-closing doors: ☑ Yes ☐ No
   b. Each laboratory room has a hands-free sink: ☑ Yes ☐ No
   c. An eyewash station is readily available inside the laboratory: ☑ Yes ☐ No
   d. There is an autoclave or other verified or approved method for decontamination within the laboratory: ☑ Yes ☐ No
   e. If no autoclave in the BSL-3 laboratory, describe waste handling protocols to be used by the laboratory personnel: Project Specific
   f. Laboratory exhaust is re-circulated to other areas of the facility: ☐ Yes ☑ No
   g. The laboratory is maintained at negative air pressure to provide directional air into the laboratory: ☑ Yes ☐ No
   h. A visual system is provided for laboratory personnel to monitor directional air before entry and during use of the laboratory: Not in Lab ☐ Yes ☑ No
   i. An alarm system is provided to warn laboratory personnel of exhaust system failure:

☑ Yes ☐ No

7. ABSL-3 laboratory registration must include the following:
   a. Animal laboratories are separated from open and unrestricted areas: ☑ Yes ☐ No
   b. Entry into the animal lab is through a double set of lockable, self-closing doors: ☑ Yes ☐ No
   c. External doors are self-closing, self-locking, and open inward: ☑ Yes ☐ No
   d. Each animal room contains a hands-free hand washing sink: ☑ Yes ☐ No
   e. Animal laboratory exhaust is re-circulated to other areas of the facility: ☐ Yes ☑ No
   f. The animal laboratory is maintained at negative air pressure to provide directional air into the animal laboratory: ☑ Yes ☐ No
   g. A visual system is provided for laboratory personnel to monitor directional air before entry and during use of the animal laboratory: ☐ Yes ☑ No
   h. An alarm system is provided to warn laboratory personnel of exhaust system failure: ☑ Yes ☐ No
   i. HEPA filtration of all exhaust air is present: ☑ Yes ☐ No
   j. There is an autoclave in the laboratory: Autoclave in suite ☑ Yes ☐ No
   k. Cage washing is with a mechanical cage washer: Cage Washer @ ☑ Yes ☐ No
   l. Cage washing area is shown on the floor plans: ☐ Yes ☐ No
   m. Animal waste is treated (carcasses, sewage, bedding, etc) before disposal: ☑ Yes ☐ No
      If yes, describe treatment method: _____
   n. If floor drains are provided, the traps are always filled with an appropriate disinfectant: ☑ Yes ☐ No

8. Appropriate personal protective equipment is used: ☑ Yes ☐ No
9. Vacuum lines contain HEPA filters: ☐ Yes ☐ No ☐ Vacuum lines are not used
10. Each laboratory using select agents has an agent-specific, site-specific biosafety manual: ☑ Yes ☐ No
11. A medical surveillance system is in place for laboratory personnel using select agents: ☑ Yes ☐ No
12. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director: ☑ Yes ☐ No
13. A sharps policy is in place for this laboratory (or laboratories): ☑ Yes ☐ No
14. A site-specific emergency operations plan is available for this laboratory: ☑ Yes ☐ No
15. An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with select agents at this facility: ☐ Yes ☐ No ☐ Application submitted, but pending
    a. If yes, has IBC approved the work proposed for this facility: (Project Specific) ☑ Yes ☐ No
    b. The facility has been inspected by USDA, FDA, CLIA, DoE, DoD or others: ☐ Yes ☑ No
    c. If yes, then give agency and date of last inspection(s): _____
16. Training:
    a. Site specific and safety training is provided to individuals with access to areas where select agents are handled or stored: ☑ Yes ☐ No
    b. Is provided prior to individuals beginning to work with select agents: ☑ Yes ☐ No
    c. Is provided: ☐ Annually ☐ Biannually ☐ Other (specify frequency): (Project Specific)
    d. Written records of individuals are kept: ☑ Yes ☐ No
    e. Personnel demonstrate proficiency in laboratory procedures prior to working with select agents: (Personnel are required to pass knowledge assessment/test) ☑ Yes ☐ No
17. Provide a brief explanation of the system in place to detect loss or theft of select agent(s): (As noted in PI's SOP)
    a. Individual responsible for inventory of select agent(s): (PI or designee)
    b. How often is the inventory record reconciled? (At least annually)

c. How is access to the inventory log limited? (Locked in freezer and records are locked in PI's desk)

d. Inventory tracking includes the following information (list): (See Inventory Access Log)

18. There is a site-specific security plan for each of the laboratories listed above (number 2): ☑ Yes ☐ No

a. Building with select agents has self-closing doors: ☑ Yes ☐ No

b. Means to limit access to buildings with laboratories with select agents:
- ☐ Guard station at the facility entrance
- ☑ Card access system or locks 6pm – 7Am
- ☑ Security alarm system in the laboratory building
- ☐ Other (describe):

c. Means to limit access to laboratories with select agents once inside the building:
- ☑ Door to laboratory is locked:
- ☑ Card access system or locks + ↓
- ☑ Other (describe): finger print I.D. system for access.

d. Means to limit access to select agents once inside the laboratory:
- ☑ Locked incubators, refrigerators, freezers, etc. Inventoried freezers are Locked
- ☑ Security alarm system that directly monitors the laboratory Hawkeye
- ☐ Other (describe): _____

e. Means to limit access to select agents in storage:
- ☑ Storage area door locked freezer – key + Tumbler
- ☑ Lock boxes – DNA Tech inside of freezer.
- ☑ Security alarm system that directly monitors the laboratory
- ☐ Other (describe): _____

f. Means to monitor unauthorized entry into the laboratory where select agents are used or stored:
- ☑ Electronic logs of card access system entries are reviewed for unusual activity – Google Maps, facility mang
- ☑ Manual sign in and out logs are kept and monitored
- ☐ Video camera surveillance
- ☑ Other (describe): finger print I.D. system on exterior door.

g. The laboratory is secured when no one is present during regular working hours: ☑ Yes ☐ No

h. Number of people with access: (See DOJ listing for each PI and CMP)

i. Individuals not directly involved in research activities have access to select agents: ☐ Yes ☑ No

If yes, please explain: _____

j. Non-laboratory personnel (visitors, including janitorial and facility maintenance personnel) have access to the laboratory with select agents: (need escorts) ☐ Yes ☑ No

If yes, are they allowed into the laboratory unescorted? ☐ Yes ☐ No

19. All cultures, stock and other regulated wastes are decontaminated before disposal by an approved decontamination method: ☐ Yes ☐ No

a. If yes, describe method: (Project Specific)

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH RECOMBINANT DNA

20. The facility has an Institutional Biosafety Committee that has approved work with recombinant DNA or has approval pending: ☐ Yes ☐ No

21. The biosafety level listed in Section 4A for this laboratory meets NIH guidelines: ☐ Yes ☐ No

22. Will you be possessing, using, or transferring the following:

a. Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that are capable of infection and/or replication. ☐ Yes ☒ No

b. Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids are in a vector or host chromosome and/or are expressed *in vivo* or *in vitro*. ☐ Yes ☒ No

c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. ☐ Yes ☒ No

23. Are you intending to conduct the following experiments:
    a. Experiments utilizing recombinant DNA techniques that involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture. (Project/Lab Specific) ☐ Yes ☒ No
    b. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxin molecules lethal for vertebrates at an LD50<100 ng/kg body weight. ☐ Yes ☒ No
24. Provide a brief description of the recombinant constructs and any associated expression control of elements, including what the recombinant DNA encodes for, if known: (As noted in IBC permit)
25. Give an estimate of range of length of recombinant DNA to be used:

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH SMALL ANIMALS –

26. List species of small animals that will be used: (As noted in IBC permit) mouse
27. Describe route of infection: (Project Specific)
28. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No
    If yes, describe method: (Bagged, decontaminated, moved to facility, autoclaved, incinerator or biodigester)
29. The facility requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this facility: ☐ Yes ☐ No
    a. If yes, the proposed work with select agents in small animals has been approved by the IACUC: (Project Specific) ☐ Yes ☐ No
30. The laboratory space is accredited by AAALAC: ☐ Yes ☐ No
    a. If yes, give inspection date: (Summer 2005)

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH LARGE ANIMALS – N/A

31. List species of large animals that will be used:
32. Describe route of infection: Project Specific ip
33. Carcass of animals are disposed of to avoid their use as food for human beings or animals: ☒ Yes ☐ No
34. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☒ Yes ☐ No
    a. If yes, give method: Biodigester, Incinerator
35. Carcass of animals are disposed of on site: ☐ Yes ☐ No
36. The facility requires that in an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at his facility: ☐ Yes ☐ No
    a. If yes, the proposed work with select agents in large animals has been approved by the IACUC: (Project Specific) ☐ Yes ☐ No
37. The laboratory space is accredited by AAALAC: ☐ Yes ☐ No

a. If yes, give inspection date:

TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR **(NOTE: N/A FOR THESE FACILITIES)**

38. A Chemical hygiene plan is available for the facility using toxins: ☑ Yes ☐ No
39. Maximum quantity of each toxin under the control of the principal investigator at a give time:
40. Form of toxins used: ☑ Liquid ☑ Lyophilized
41. The toxin is produced by live agent at the facility: ☑ Yes ☐ No
    a. If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): 100 mL
42. Dilution procedures and other manipulations of the concentrated toxins are:
    a. Conducted in ☐ Fume hood ☑ Biosafety cabinet
        i. If a fume hood is used, certification of the hood is conducted:
        ☐ Annually ☐ Biannually ☑ Other (describe): _____
    b. Conducted with two knowledgeable people present: ☑ Yes ☐ No
    c. A hazard sign on the door when toxins are present: ☑ Yes ☐ No

CORRECTED 2/1/05

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Does not meet criteria**

Comments:

- **Light out in entrance**
- **Check air balance (Locker room is negative to the animal room).**

Date of Inspection: **1/14/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

D. Laboratory Facilities (Secondary Barriers)

✓ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

✓ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

✓ 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

✓ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

✓ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

✓ 6. Windows in the laboratory are closed and sealed.

✓ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

✓ 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✓ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

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✓ 13. An eyewash facility is readily available inside the laboratory.

✓ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

x 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

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TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Meets criteria**

Comments:

Date of Inspection: **2/1/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

D. Laboratory Facilities (Secondary Barriers)

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and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

✓ 6. Windows in the laboratory are closed and sealed.

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CORRECTED 2/1/05

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Does not meet criteria**

Comments:

- **Check air balance.**

Date of Inspection: **1/14/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

D. Laboratory Facilities (Secondary Barriers)

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CORRECTED 2/1/05

✓ 6. Windows in the laboratory are closed and sealed.

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✓ 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

✓ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

✓ 13. An eyewash facility is readily available inside the laboratory.

✓ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

x 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

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TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Meets criteria**

Comments:

Date of Inspection: **2/1/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

D. Laboratory Facilities (Secondary Barriers)

✓ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

✓ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

✓ 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

✓ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

✓ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets,

and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

✓ 6. Windows in the laboratory are closed and sealed.

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CORRECTED 2/1/05

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Does not meet criteria**

Comments:

- **Check air balance**
- **Pressure in locker room is negative to animal room**

Date of Inspection: **1/14/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

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TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Meets criteria**

Comments:

Date of Inspection: **2/1/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

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CORRECTED 2/1/05

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Does not meet criteria**

Comments:

- **Check air balance.**

Date of Inspection: **1/14/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

D. Laboratory Facilities (Secondary Barriers)

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TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Meets criteria**

Comments:

Date of Inspection: **2/1/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

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CORRECTED 2/1/05

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Does not meet criteria**

Comments:

- **Check air balance.**

Date of Inspection: **1/14/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

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✓ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

x 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

✓ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Meets criteria**

Comments:

Date of Inspection: **2/1/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

D. Laboratory Facilities (Secondary Barriers)

✓ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

✓ 2. Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

✓ 3. The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

✓ 4. Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

✓ 5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

✓ 6. Windows in the laboratory are closed and sealed.

✓ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

✓ 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

✓ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

✓ 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

✓ 11. 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. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

✓ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

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CORRECTED 2/1/05

TEXAS A&M UNIVERSITY

LABORATORY INSPECTION / CERTIFICATION FOR RESEARCH INVOLVING INFECTIOUS AGENTS and/or RECOMBINANT DNA

Lab Location - Bldg

Biosafety Level: **BL3**

Results: **Does not meet criteria**

Comments:

- **Check air balance.**

Date of Inspection: **1/14/05**

Environmental Health & Safety Inspector: **Jeffrey C. Truss**

NIH BIOSAFETY LEVEL 3 CRITERIA

D. Laboratory Facilities (Secondary Barriers)

✓ 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

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CORRECTED 2/1/05

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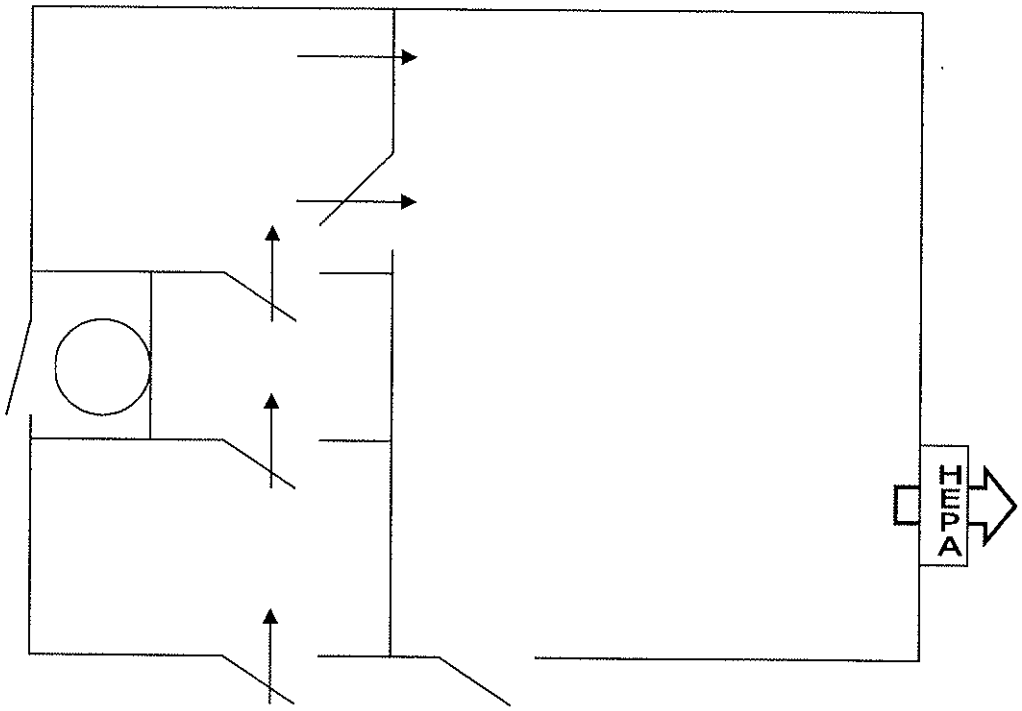
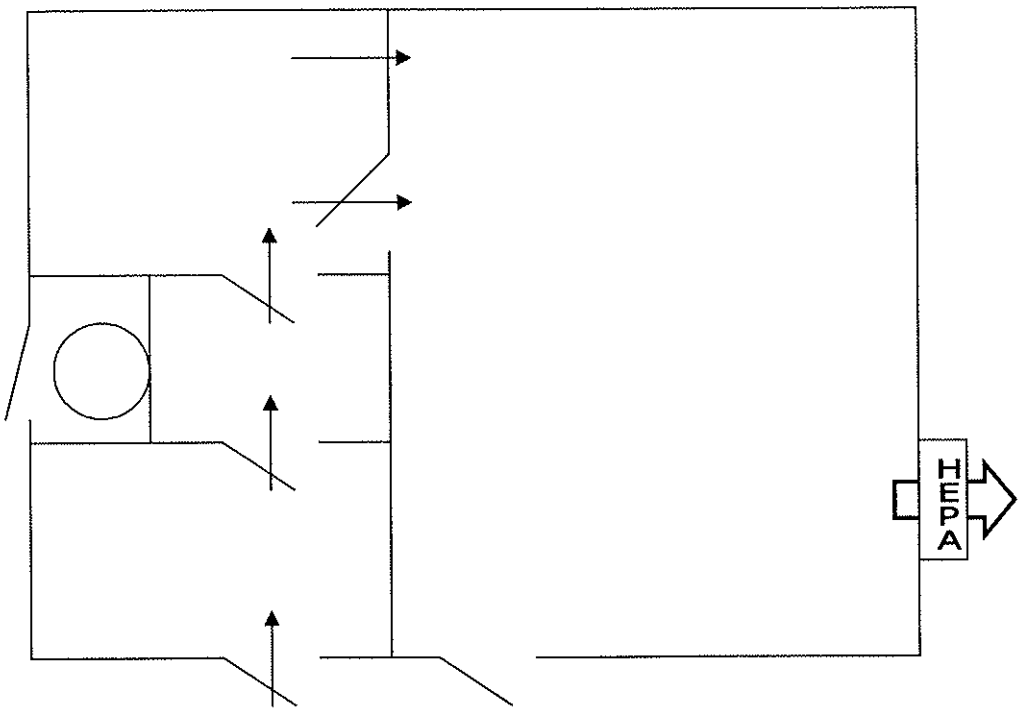
Isolation Facility



Isolation Facility



Entry Logs (Manual and Electronic)

Week of Thanksgiving 2006
April 2007
July 2007

Entry Logs (Manual and Electronic)

Week of Thanksgiving 2006
April 2007
July 2007

Main Biohazard Entry Log

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
7/10/07	C. McFarland	C. McFarland	MMP	845	11:00	necropsy (-20 spigs)
"	L. Ly		↓	↓	↓	↓
"	D. Bonilla		↓	~~8:46~~	1143	MAINT.
7-10-07	German Hernandez		CMP	850	11:27	MAINT
7-10-07	B. Richards		MMP	8:50	11:00	necropsy.
"	A. Jeevan		CMP	900	~~11:00~~	D & H
7-10-07	Gordon Draper					Autoclave
7-10-07	Gordon Draper		CMP	115		
7-10-07	Lionel Gallardo		LMS	1:16		Maintenance
7-10-07	Donald Johnson		LMS	1:17		Maintenance
7-10-07	B. Richards		CMP	1:20		MAINT
7-10-07	B. Richards					

Main Biohazard Entry Log

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
7-3-07	Gordon Draper		CMP	325	412	Escort
7-3-07	Freddie Wilhelm	Freddie Wilhelm	CMP	10:30	11:50	Maint.
7-3-07	GRAND HAUS MAINTENANCE		CMP	10:35	11:58	Maint.
7-3-07	WILLIAM RICHARDS	William Richard	CMP	10:40	12:05	Maint.
7-3-07	Sean Knox		CMP	2:04	5:00	
07/04/07	Stacie Brown		CMP	8:25	11:48	
07/05/07	Stacie Brown		CMP	8:47	11:43	HV
07-05-07	GRAND HAUS MAINTENANCE		CMP	9:10	9:49	CHANGE LIGHT BULB
7-5-07	Sean Knox		CMP	4:07	4:35	Unload autoclave
7-6-07	Sean Knox		CMP	9:32	11:25	
07/06/07	Stacie Brown		CMP	9:50	11:32	[redacted]
07/06/07	Stacie Brown		CMP	12:55	2:10	
7/6/07	Sean Knox		CMP	3:45	4:17	Autoclave
07/07/07	Stacie Brown		CMP	8:13	9:20	HV
07/08/07	Stacie Brown		CMP	8:18	9:40	HV
7-9-07	GRAND HAUS MAINTENANCE		CMP	8:41	[redacted]	MAINT
7-9-07	Bo Richards		CMP	8:45	10:37	MAINT
7-9-07	Gordon Draper		CMP	1041	1204	major work on Autoc
7-9-07	Gordon Draper		CMP	1315	[redacted]07	Cont Autoclave
7-9-07	Sean Knox		CMP	200	5:12	HV / A
7-10-07	Darold Johnson		[redacted]/LMS	8:38	11:16	MAINT
7-10-07	Richard Cyrus		LMS	8:34	11:17	MAINT

Main Biohazard Entry Log

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
6/26	L Ly		MMP	9:20	10:40	Chall
06/26/07	Stacie Brown		CMP	2:45	3:00	Clean & tran. room
06/26/07	Stacie Brown		CMP	3:23	4:37	Mouse cannula in
6/27	L. Ly		MMP	8:40	9:45	Necropsy
	C. McFarland		↓	↓	↓	↓
↓	T. Yamamoto		↓	↓	↓	↓
06/27/07	Stacie Brown		CMP	8:49	11:24	Δ
6/27/07	Sean Knox		CMP	1:13	3:40	H-V
06/27/07	Stacie Brown		CMP	1:32	2:55	Δ
06/28/07	Stacie Brown		CMP	9:05	12:30	H-V
6/28/07	J Flannagan		MMP	3:30	9:15	Weekly
6/29/07	Sean Knox		CMP	9:0950 (SK)	12:05	Δ
06/29/07	Stacie Brown		CMP	1:39	4:19	Δ
6-30-07	Gordon Draper		CMP	838	934	H-TV
6/30/07	Sean Knox		CMP	10:52	11:11	Inspect lab
7-1-07	Gordon Draper		CMP	836	1007	H-V
07-02-07	Stacie Brown		CMP	9:03	11:40	
7-0-07	Freddie Wilhelm		CMP	1:45	2:45	cabinet removal
7-2-07	[illegible]		CMP	1:16	3:20	"
7-2-07	Bo Richards		CMP	1:17	3:05	
7-2-07	Sean Knox		CMP	1:31	5:04	Δ
7-2-07	Melissa Kahl-McDonald		UPR	3:25	4:10	

Main Biohazard Entry Log

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
7/10/07	C. McFarland	C. McFarland	MMP	845	11:00	necropsy (~20 spigs)
"	L. Ly		↓	↓	↓	↓
"	D. Bonilla		↓	↓	↓	↓
7-10-07	[illegible]	[illegible]	CMP	[illegible]	1143	MAINT.
7-10-07	B. RICHARDS	[illegible]	CMP	8:50	11:27	MAINT
"	A. Jeevan	[illegible]	MMP	8:50	11:00	necropsy.
7-10-07	Gordon Draper	[illegible]	CMP	900	[illegible]	D
						Autoclave
7-10-07	Gordon Draper	[illegible]	CMP	115		
7-10-07	Lionel [illegible]	[illegible]	LMS	1:16		Maintenance
7-10-07	Donald Johnson	[illegible]	LMS	1:17		Maintenance
7-10-07	B. RICHARDS	[illegible]	CMP	1:20		MAINT

Main Biohazard Entry Log

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
7-3-07	Gordon Draper		CMP	325	412	Escort
7-3-07	Freddie Wilhelm	Freddie Wilhelm	CMP	10:30	11:50	Maint.
7-3-07	GERALD HALL MAINTENANCE		CMP	10:35	11:58	Maint.
7-3-07	WILLIAM RICHARDS	William Richard	CMP	10:40	12:05	Maint.
7-3-07	Sean Knox		CMP	2:04	5:00	
07/04/07	Stacie Brown		CMP	8:25	11:48	
07/05/07	Stacie Brown		CMP	8:47	11:43	
07-05-07	GERALD HALL MAINTENANCE		CMP	9:10	9:44	CHAMBER CKGT B+B 5th
7-5-07	Sean Knox		CMP	4:07	4:35	Unload autoclave
7-6-07	Sean Knox		CMP	9:32	11:25	
07/06/07	Stacie Brown		CMP	9:50	11:32	
07/06/07	Stacie Brown		CMP	12:55	2:10	
7/6/07	Sean Knox		CMP	3:45	4:17	Autoclave
07/07/07	Stacie Brown		CMP	8:13	9:20	
07/08/07	Stacie Brown		CMP	8:18	9:40	
7-9-07	GERALD HALL MAINTENANCE		CMP	8:41	10:10	MAINT
7-9-07	BO RICHARDS		CMP	8:45	10:37	MAINT
7-9-07	Gordon Draper		CMP	1041	1204	Maint. Autoclave
7-9-07	Gordon Draper		CMP	1315	1501	Cont Autoclave
7-9-07	Sean Knox		CMP	2:00	5:12	MAINT / A
7-10-07	Darold Johnson		CMP / LMS	8:38	11:16	MAINT
7-10-07	Richard Cyrus		LMS	8:39	11:17	MAINT

Main Biohazard Entry Log

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
6/26	L Ly		MMP	9:2[illegible]	10:40	chall
06/26/07	Stacie Brown		CMP	2:45	3:00	clean & tran. room
06/26/07	Stacie Brown		CMP	3:23	4:37	house animals
6/27	L. Ly		MMP	8:40	9:45	Necropsy
	C. McFarland		↓	↓	↓	↓
↓	T. Yamamoto		↓	↓	↓	↓
06/27/07	Stacie Brown		CMP	8:49	11:24	
6/27/07	Sean Knox		CMP	1:13	3:40	
06/27/07	Stacie Brown		CMP	1:32	2:55	
06/28/07	Stacie Brown		CMP	9:05	12:30	
6/28/07	JD Jamagne		MMP	3:30	9:15	Weigh
6/29/07	Sean Knox		CMP	9:0950 (SK)	12:05	Δ
06/29/07	Stacie Brown		CMP	1:39	4:19	Δ
6-30-07	Gordon Draper		CMP	838	934	H-TV
6/30/07	Sean Knox		CMP	10:52	11:11	Inspect lab
7-1-07	Gordon Draper		CMP	836	1007	HV
07/02/07	Stacie Brown		CMP	9:03	11:46	[illegible] Start
7-0-07	Freddie Wilhelm		CMP	1:45	2:45	cabinet removed
7-2-07	[illegible]		CMP	1:16	3:20	
7-2-07	Bo Richards		CMP	1:17	3:05	
7-2-07	Sean Knox		CMP	1:31	5:04	
7-2-07	Melissa Kahl-McDonald		UPR	3:25	4:10	

Main Biohazard Entry Log

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
3.29.07	[illegible]	[signature]	MMP/Samuel	10:40	11:25	HV [illegible]
3-29-07	Suat Cirillo	[signature]	MMP	11:01	3:18	Necropsy
3-29-07	John D. Delaney	[signature]	CMP	2:15	3:57	HV
3/30/07	Melissa Kahl-McDonald	[signature]	UTPB	3:20	4:30	Euthanize 5 r
3/30/07	[illegible]	[signature]	UTPB	3:2	4:30	[illegible] mice
3/30/07	John D. Delaney	[signature]	CMP	8:45	11:58	Δ
3/30/07	John D. Delaney	[signature]	CMP	3:32	4:47	Δ
3/31/07	Amy Henson	[signature]	CMP	8:53	10:20	hv
4/1/07	Amy Henson	[signature]	CMP	8:49	10:15	hv
4/2/07	Amy Henson	[signature]	CMP	8:17	12:00	Δ
4/3/07	Amy Henson	[signature]	CMP	8:55	12:00	Δ
4/3/07	De Lacharros	[signature]	CMP	9:00	12:00	
4/3/07	Sean Knox	[signature]	CMP	1:50	2:03	Showers
4/3/07	Sean Knox	[signature]	CMP	3:29	4:15	House Animals in
4/3/07	T. Yamamoto	[signature]	MMP	4:25	5:25	Observation
4/3/07	S. Yamamoto	[signature]	MMP	4:35	5:25	Observation
4/4/07	Amy Henson	[signature]	CMP	8:08	12:00	
4/4/07	L. McFarland	[signature]	CMP	10:15	12:45	Challenge
11	T. Yamamoto	Jestika	↓	↓	↓	↓
11	S. Yamamoto	[signature]	↓	↓	↓	↓
4-4-07	Sarah Draper	[signature]	CMP	421	434	Lecture Room ✓
4/5/07	Amy Henson	[signature]	CMP	845	9:11	Δ

Main Biohazard Entry Log

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
04/05/07	Stacie Brown	Stacie Brown	CMP	4:33	4:47	clean & tran. room
4/6/07	Amy Henson	Amy Henson	CMP	830	1230	
4/6/07	[illegible]	[illegible]	MMIDA	1050	100	Challenge
	T. Yamamoto	Toshiko	"	"		"
"	S. Yamamoto	Saburo	"	"		"
4-6-07	Sean Knox	[illegible]	CMP	1:31	2:06	load autoclave, put animals [illegible]
4-7-07	Gordon Draper	[illegible]	CMP	952	1124	Mu TV
4-7-07	Kosi Russell-Lodrigue	[illegible]	MMP/Samuel	1:34	1:45	VRr
4-8-07	Gordon Draper	[illegible]	CMP	926	[illegible]	[illegible]
4/9/07	Melissa Kahl-McDonagh	[illegible]	VTPB	11:00	[illegible]	[illegible] mice
4/9/07	Sean Knox	[illegible]	CMP	12:55	5:15	
4/9/07	S. Velakumar	[illegible]	MMP	2:20 pm	5:45	[illegible]
"	Manireath K.	[illegible]	"		5:45	
4/9/07	Melissa Kahl-McDonagh	[illegible]	VTPB	320	330	mice
4/10/07	Melissa Kahl-McDonagh	[illegible]	VTPB	155	[illegible]	[illegible] mice
4/10/07	Amy Henson	Amy Henson	CMP	1:15	3:00	[illegible]
4/10/07	Melissa Kahl-McDonagh	[illegible]	VTPB	2:50	[illegible]	[illegible] mice
4/10/07	S. Holster	[illegible]	CMP	3:45	5:50	Shower
4/11/07	Amy Henson	Amy Henson	CMP	816	10:39	
4/11/07	Melissa Kahl McDonagh	[illegible]	VTPB	1050	1140	
4/11/07	Manireath K.	[illegible]	MMP	1:10	1:30 pm	[illegible] check out [illegible] mice
[illegible]/13/07	David McMurray	[illegible]	MMP	3:25	1:40	infection

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
4/12/07	Ian Ly	[illegible]	MMP	8:25	9:53	Infection
4/12/07	Sean Knox	[illegible]	CMP	8:30	1:33	Check Locker Rms
4/12/07	Amy Henson	[illegible]	CMP	8:46	12:33	
4/12/07	McFarland	[illegible]	MMP	9:00	11:3[illegible]	
4/12	[illegible]	[illegible]	"	"	11:30	"
4/13	Amy Henson	[illegible]	Cmp	824	1:[illegible]	
4/13	C. McFarland	[illegible]	MMP	8:45	10:15	necropsy
"	L. Ly	[illegible]	"	"	↓	"
"	K. Sawant		"	"		"
"	A. Jeevan	[illegible]	"	"		"
4/13/07	Sean Knox	[illegible]	CMP	9:17	12:06	Δ
4/13/07	Amy Henson	[illegible]	Cmp	4:49	4:58	f locker rm
4/14/07	Amy Henson	[illegible]	Cmp	834	"	hv
4/15/07	Amy Henson	[illegible]	Cmp	9:00	1045	hv
4/16/07	[illegible]	[illegible]	UTRS	8:30	9:45	cm
4/16/07	Nancy Ecker	[illegible]	FASA	9:32	[illegible]	Inspection
4/16/07	[illegible]	[illegible]	LARR	9:32	[illegible]	Inspection
4/16	L. Ly	[illegible]	MMP	10:00	11:[illegible]	infect (pleurisy)
4/16/07	Sean Knox	[illegible]	CMP	1:22	4:15	Δ
4/17/07	Amy Henson	[illegible]	Cmp	9:02	12:38	Δ
4/17/07	Sean Knox	[illegible]	CMP	10:46	11:30	Inspect

[illegible]	Ken Gillenwater	[illegible]	CMP	3:50	4:30	CDC inspection
4/17/07	Diane Martin	[illegible]	CDC	3:30	4:30	CDC inspection
4/17/07	Richmond Henkel	RD Henkel	CDC	3:30	4:30	CDC inspection
4/18/07	Amy Henson	[illegible]	CMP	1023	1207	[illegible]
4/18/07	Amy Henson	[illegible]	CMP	1.10	4:30	[illegible]
4/18/07	Jean Knox	[illegible]	CMP	1:43	3:59	[illegible] "H"
4/19/07	L. Ly	[illegible]	MMP	7:00	8:30	Necropsy
4/19/07	Amy Henson	[illegible]	CMP	9:07	12:16	[illegible]
4/19/07	Christine McFarland	[illegible]	MMP	9:20	10:45	weigh + health ck.
4/19/07	JV Domingues	[illegible]	"	9:35	"	" "
4/19/07	John Dehmy	[illegible]	CMP	1:15		Shower
4/19/07	Amy Henson	[illegible]	CMP	1:33	3:07	[illegible]
4/20/07	Amy Henson	[illegible]	CMP	9:00	12:00	[illegible]
4/20/07	Amy Henson	[illegible]	CMP	1:20	3:30	[illegible]

Main Biohazard Entry Log

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
4/9/07	Gaylan Draper		CMP	PM	153	Clean ↗ Trays Runs
4-21-07	Gaylan Draper		CMP	903	1023	H+V
4/22/07	Gaylan Draper		CMP	859	1026	H+V
4/23/07	Amy Henson		CMP	9:30	210	↓
4/23/07	Sean Knox		CMP			
4/23/07	Amy Henson		CMP	1.30	3 05	Δ
4/23/07	Sean Knox		CMP	1:35	3:49	Δ
4/24/07	John Delaney		CMP	2:45	5:05	Δ
4/25/07	John D. Delaney		CMP	1:30	1:40	Shower
4/25/07	Sean Knox		CMP	1:53	4:35	H+
4/26/07	Christine McFarland		MMPA	8:30	950	health check, weigh
4/26/07	JDamingver		MMP	8:35	950	" "
4/26/07	Amy Henson		CMP	8.41	[redacted] 217	↓
4/26/07	Selvakumar		MMP	10:10 Am	12:00	mice. infection
"	Manivath		"	"	"	"
04/26/07	Stacie Brown		CMP	10:35	12:41	spot
4/26/07	John D. Delaney		CMP	1:35	1:45	Shower
4/26/07	Amy Henson		CMP	1:59	3:00	Clean cages
4/26/07	Ken Gillenwater		CMP	2:02	5:05	Clean cages
4/26/07	Sean Knox		CMP	2:51	4:55	clean cages
4/27/07	Selvakumar		MMP	7:45 AM	10:15 Am	mice - Necropsy
"	Manivath		"	"	"	"

Main Biohazard Entry Log

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
4/27/07	Amy Henson		CMP	9:28	12:05	
4/27/07	Nancy Eaker		EHS	11:05	1:04	Inspection
4/27/07	Jeff Hay		Physical Plant	11:05	1:02	Inspection
4/27	Mike Garcia		P. Plant	11:05	12:54	Inspection
4-27	Bo Richards		ARD	11:05	1:40	
4/27	Amy Henson		CMP	1:20	3:20	Δ
4-27-08	Gordon Draper		CMP	405	417	Clean Trans Runs
4/28/07	Amy Henson		CMP	9:05	10:10	hv
4/29/07	Amy Henson		CMP	928	1045	hv
4/30/07	Sean Knox		CMP	9:31	12:39	Δ
4/30/07	Amy Henson		CMP	11:15	12:15	Δ
4/30/07	Amy Henson		CMP	1:20	4:10	ABC
5-1-07	Gordon Draper		CMP	857	1254	Hc
5/1	L. Ly		MMP	10:00	10:45	challenge
5/1	D. McMurray		MMP	↓	↑	↓
5/1	D Dominguez		MMP	11:05	1:10	Challenge
5/1	T Yamamoto		MMP	"	↓	"
5/1	C McFarland		MMP	"	↓	"
5/1-07	Gordon Draper		CMP	235	310	Load Autoclave
5/02/07	L. Ly		MMPA	8.40	11:10	NECROPSY
↓	T. YAMAMOTO		↓	↓	↓	↓
	K. STUART					
	D. BONILLA					

Main Biohazard Entry Log

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
3.29.07	[illegible]	[signature]	MMP/Samuel	10:40	11:25	HV/Fx
3-29-07	Suat Cirillo	[signature]	MMP	11:01	3:18	Necropsy
3-29-07	John D. Delaney	[signature]	CMP	2:15	3:57	HV
3/30/07	Melissa Kahl-McDonald	[signature]	UTPB	3:20	4:30	Euthanize 5 ln
3/30/07	[illegible]	[signature]	UTPB	3:2	4:30	[illegible]
3/30/07	John D. Delaney	[signature]	CMP	8:45	11:58	Δ
3/30/07	John D. Delaney	[signature]	CMP	3:32	4:47	Δ
3/31/07	Amy Henson	[signature]	CMP	853	1020	hv
4/1/07	Amy Henson	[signature]	CMP	849	1015	hv
4/2/07	Amy Henson	[signature]	CMP	817	1200	Δ
4/3/07	Amy Henson	[signature]	CMP	835	1200	Δ
4/3/07	[illegible]	[signature]	[illegible]	[illegible]	[illegible]	
4/3/07	Sean Knox	[signature]	CMP	1:50	2:03	Shower
4/3/07	[illegible]	[signature]	MMP	3:29	4:15	House Animals in
4/3/07	S. Yamamoto	[signature]	MMP	4:25	5:25	observation
4/4/07	Amy Henson	[signature]	CMP	4:35	5:25	Observation
4/4/07	[illegible] McFarland	[signature]	CMP	8:08	1200	Δ
11	T Yamamoto	[signature]	CMP	10:15	12[illegible]	Challenge
11	S Yamamoto	[signature]	↓	↓	↓	↓
4-4-07	[illegible]	[signature]	CMP	421	434	Lecture . . /
4/5/07	Amy Henson	[signature]	CMP	845	1117	

Main Biohazard Entry Log

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
04/05/07	Stacie Brown	[signature]	CMP	4:33	4:47	clean & tran. room
4/6/07	Amy Henson	[signature]	Cmp	830	1230	Δ
4/6/07	[illegible]	[signature]	MMPA	1050	100	Challenge
"	T. Yamamoto	Toshihiko	"	"	↓	"
"	S. Yamamoto	Saburo	"	"	↓	"
4-6-07	Sean Knox	[signature]	CMP	1:31	2:06	load autoclave, put animal cage
4-7-07	Gordon Draper	[signature]	Cmp	952	1124	Hu TV
4-7-07	Kosi Russell-Lodrigue	[signature]	MMP/Samuel	1:34	1:45	
4-8-07	Gordon Draper	[signature]	Cmp	926	[illegible]	HTV "
4/[illegible]/07	Melissa Kahl-McDonagh	[signature]	VPB	11:00	[illegible]	Cultivate mice
4/9/07	Sean Knox	[signature]	CMP	12:55	5:15	Δ
4/9/07	S. Natkumar	[signature]	MMP	2:20pm	5:45	Sp/mice Necropsy
"	Manirath K.	[signature]	"		5:45	"
4/9/07	Melissa Kahl-McDonagh	[signature]	VPB	320	350	mice
4/10/07	Melissa Kahl-McDonagh	[signature]	VPB	955	[illegible]	Euth mice
4/10/07	Amy Henson	[signature]	Cmp	1:15	5:00	AL
4/10/07	Melissa Kahl-McDonagh	[signature]	VPB	2:50	3:05	vaccinate mice
4/10/07	Sx Holster	[signature]	CMP	3:45	3:50	Shower
4/11/07	Amy Henson	[signature]	Cmp	816	12:59	Δ
4/11/07	Melissa Kahl McDonagh	[signature]	VPB	1030	11:40	
4/11/07	Manirath K.	[signature]	MMP	2:10	2:55 pm	check out on mice
4/13/07	Devi McMillin	[signature]	MMP	5:25	7:50	[illegible]

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
4/12/07	Lan Ly		MMP	8:25	9:50	Infection
4/12/07	Sean Knox		CMP	8:30	1:23	Check Lutter Rms
4/12/07	Amy Henson		CMP	8:46	12:53	
4/12/07	[illegible]		MMP	9:00	11:30	Weights + Measures
4/13	Amy Henson		CMP	8:24	1:51	
4/13	C. McFarland		MMP	8:45	1:15	Necropsy
"	L. Ly		"	"		"
"	K. Sawicki		"	"		"
"	A. Jeevan		"	"	↓	"
4/13/07	Sean Knox		CMP	9:17	2:01	
4/13/07	Amy Henson		CMP	4:49	4:58	f. Locker rm
4/14/07	Amy Henson		CMP	8:34	"	h.
4/15/07	Amy Henson		CMP	9:00	10:48	
4/16/07	[illegible]		LITR	8:30	5:45	LM
4/16/07	Kelsey Eckert		FASD	9:52	[illegible]	Inspection
4/16/07	S. Hinkens		LARK	9:52	[illegible]	Inspection
4/16	L Ly		MMP	10:00	11:[illegible]	Infect (pleurisy)
4/16/07	Sean Knox		CMP	1:22	4:15	Δ
4/17/07	Amy Henson		CMP	9:02	12:38	Δ
4/17/07	Sean Knox		CMP	10:46	11:30	Inspect

	Ken Gillenwater		CMP	3:50	4:30	CDC inspection
4/17/07	Diane Martin		CDC	3:30	4:30	CDC inspection
4/17/07	Richmond Henkel	RD Henkel	CDC	3:30	4:30	CDC inspection
4/18/07	Amy Henson		CMP	10:23	12:07	
4/18/07	Amy Henson		CMP	1:10	4:30	
4/18/07	Sean Knox		CMP	1:43	3:59	
4/19/07	L. Ly		MMP	7:00	8:30	Necropsy
4/19/07	Amy Henson		CMP	9:07	12:16	
4/19/07	Christine McFarland	C. McF	MMP	9:20	10:45	weigh + health ck.
4/19/07	J Dominguez		"	9:35	"	" "
4/19/07	John Dehmey		CMP	1:15		Shower
4/19/07	Amy Henson		CMP	1:33	3:07	
4/20/07	Amy Henson		CMP	9:00	12:00	
4/20/07	Amy Henson		CMP	1:20	3:30	

Main Biohazard Entry Log

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
4/19/07	Gordon Draper		CMP	PM	153	Clean Trays Rm
4-21-07	Gordon Draper		CMP	903	1023	H-TV
4/22/07	Gordon Draper		CMP	859	1026	H-TV
4/23/07	Amy Henson		CMP	9:20	1210	Δ
4/23/07	Sean Knox		CMP			
4/23/07	Amy Henson		CMP	1:30	3:05	Δ
4/23/07	Sean Knox		CMP	1:35	3:49	Δ
4/24/07	John Delaney		CMP	2:45	5:05	Δ
4/25/07	John D. Delaney		CMP	1:30	1:40	Shower
4/25/07	Sean Knox		CMP	1:53	4:35	H-
4/26/07	Christine McFarland		MMPA	8:30	950	health check, weigh
4/26/07	J Demingver		MMP	8:36	950	" "
4/26/07	Amy Henson		CMP	8:41	[illegible]217	Δ
4/26/07	Selvakumar		MMP	10:10 Am	12:00	mice - infection
"	Manivath		"	"	"	"
04/26/07	Stacie Brown		CMP	10:35	12:41	spot Δ
4/26/07	John D. Delaney		CMP	1:35	1:45	Shower
4/26/07	Amy Henson		CMP	1:59	3:00	Clean cages
4/26/07	Ken Gillenwater		CMP	2:02	5:05	clean cages
4/26/07	Sean Knox		CMP	2:51	4:55	clean cages
4/27/07	Selvakumar		MMP	7:45 AM	10:15 Am	mice - Necropsy
"	Manivath		"	"	"	"

Main Biohazard Entry Log

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
4/27/07	Amy Henson		CMP	9:28	12:05	Δ
4/27/07	Nancy Eaker		EH&S	11:05	1:04	Inspection
4/27/07	Jeff Hay		Physical Plant	11:05	1:02	Inspection
4-27	Mike Garcia		P. Plant	11:05	12:54	INSPECTION
4-27	Liz Richards		LARC	11:05	1:40	
4/27	Amy Henson		CMP	1:20	3:20	Δ
4-27-08	Gordon Draper		CMP	405	417	clean trans lens
4/28/07	Amy Henson		CMP	9:05	10:10	h
4/29/07	Amy Henson		CMP	928	1045	h/B
4/30/07	Sean Knox		CMP	9:31	12:39	Δ
4/30/07	Amy Henson		CMP	11:15	12:15	Δ
4/30/07	Amy Henson		CMP	1:20	4:10	ABS
5/1	Gordon Draper		CMP	857	1254	#
5/1	L. Ly		MMP	10:00	10:45	challenge
5/1	D. McMurray		MMP	↓	↓	↓
5/1	JDominguez		MMP	11:05	1:10	Challenge
5/1	T Yamamoto		MMP	"	↓	"
5/1	C McFarland		MMP	"		"
5/1-07	Gordon Draper		CMP	235	310	Load Auto clave
5/02/07	L. Ly		MMPA	8:40	11:10	NECROPSY
	T. YAMAMOTO			↓	↓	↓
	F. STARR					
↓	D. BONILLA		↓			

	Ken Gillenwater		CMP	3:30	4:30	CDC inspection
4/17/07	Diane Martin		CDC	3:30	4:30	
4/17/07	Richard Henkel	RD Henkel				
4/18/07	Amy Henson					
4/18/07	Amy Henson					
4/18/07	Jean Knox					
4/19/07	L. Ly					
4/19/07	Amy Henson					
4/19/07	Christine McFarland	C. McF				
4/19/07	J Dominguez					
4/19/07	John Dehmey					
4/19/07	Amy Henson					
4/20/07	Amy Henson					
4/20/07	Amy Henson					

PLEASE NOTE:

WE ARE REQUESTING THAT CMP PROVIDES US ANOTHER COPY OF THIS PAGE TO ENSURE NO ENTRY INFORMATION IS LOST IN THIS POOR COPY.

WE WILL HAVE THE COPY TOMORROW (7-26-07)

Main Biohazard Entry Log

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
11/19/06	Katie Evans		MMP	11:55	3:15	Necropsy
11/20/06	Sean Knox		CMP	10:33	12:10	
11/20/06	Stacie Brown		CMP	1:35	4:15	2
11/21/06	Amy Henson		CMP	8:45	11:40	Δ
11/21/06	Sean Knox		CMP	2:00	3:33	H"
11/22/06	Sean Knox		CMP	8:53	11:57	Δ
11-22-06	Pei Jianwu		VTPB	9:10	11:20	challenge mice
11-22-06	Dins Xicheng		VTPB	9:10	11:20	challeny mice
11-22-06	Chen Chen		mmp	9:50	11:25	bleeding
11-22-06	Kasi Russell-Lodrigue		mmp	9:50	11:25	bleeding
11/23/06	Amy Henson		CMP	8:50	11:05	Δ
11/24/06	Amy Henson		CMP	9:10	11:58	Δ
11-25-06	Chris Knowlton		CMP	9:20	10:23	H&T/all, antibiotic
11-26-06	Gordon Draper		CMP	843	933	H&T
11/27/06	Sean Knox		CMP	10:40	12:25	Δ
11/27/06	Stacie Brown		CMP	11:55	12:05	shower
11/27/06	D. Sargent	D. Sargent	CMP	1:15	1:25	Shower
11/27/06	John D. Delaney		CMP	1:38	4:45	Δ
11/28/06	John D. Delaney		CMP	9:35	12:37	Δ
11/28	C. McFarland		MMPA	11:15	12:15	Skin testing
11	A Deeon		11	11	11	cotton rats
11/28/06	Amy Henson		CMP	3:24	4:50	hr

Main Biohazard Entry Log

Date	Name (printed)	Signature	Dept./Inv.	Time In	Time Out	Purpose
11/19/06	Katie Evans	[signature]	mmp	11:55	3:15	Necropsy
11/20/06	Sean Knox	[signature]	CMP	10:33	12:40	H
11/20/06	Stacie Brown	[signature]	CMP	1:35	4:15	x
11/21/06	Amy Henson	[signature]	Cmp	8:45	11:40	Δ
11/21/06	Sean Knox	[signature]	CMP	2:00	3:33	H
11/22/06	Sean Knox	[signature]	CMP	8:53	11:57	Δ
11-22-06	Pei Jianwu	[signature]	VTPB	9:10	11:20	Challenge mice
11-22-06	Ding Xicheng	[signature]	VTPB	9:10	11:20	challenge mice
11-22-06	Chen Chen	[signature]	mmp	9:50	11:25	bleeding
11-22-06	Kasi Russell-Lodrigue	[signature]	mmp	9:50	11:25	bleeding
11/23/06	Amy Henson	[signature]	Cmp	8:50	11:05	Λ
11/24/06	Amy Henson	[signature]	Cmp	9:10	11:58	Δ
11-25-06	Chris Knowlton	[signature]	CMP	9:20	10:23	HUT wall, autoclave
11-26-06	Gordon Draper	[signature]	CMP	843	933	HUT
11/27/06	Sean Knox	[signature]	CMP	10:40	12:25	Δ
11/27/06	Stacie Brown	[signature]	CMP	11:55	12:05	Shower
11/27/06	D. Sargent	D. Sargent	cmp	1:15	1:25	Shower
11/27/06	John D. Delaney	[signature]	CMP	1:38	4:45	Δ
11/28/06	John D. Delaney	[signature]	CMP	9:35	12:37	Δ
11/28	C. McFarland	[signature]	MMDA	11:15	12:15	Skin testing
11	A Devan	[signature]	11	11	11	cotton rats
11/28/06	Amy Henson	[signature]	CMP	3:24	4:50	hv

FACILITY ACCESS LOG

ROOM #_____ BUILDING #_____ PI NAME Fichet

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial)
				In / Out			Number		Yes
7/3/07	Sean Knox		CMP	2:00 / 5:00	SK				
7/6/07	Stacie Brown		CMP	8:25 / 11:45	SB				
7/6/07	Stacie Brown		CMP	3:47 / 11:45	SB				
7/6/07	Sean Knox		CMP	9:36 / 11:35	SK				
7/9/07	Stacie Brown		CMP	8:12 / 4:20	SB				
7/9/07	Stacie Brown		CMP	8:18 / 9:40	SB				
7/9/07	Sean Knox		CMP	2:00 / 5:12	SK				
7/10/07	Gordon Dreyer		CMP	9:00 / 11:49	GD				
				/					
				/					
				/					

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #** 1 **BUILDING #** _____ **PI NAME** Tight

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial)
6/26/07	Stacie Brown		CMP	8:43 / 11:46	SB				
6/26/07	Sean Knox		CMP	1:18 / 3:55	SK				
6/26/07	Stacie Brown		CMP	9:45 / 11:01	SB				
6/27/07	Sean Knox		CMP	1:13 / 3:40	SK				
6/28/07	Stacie Brown		Cmp	9:05 / 12:??	SB				
6/29/07	Sean Knox		CMP	9:?? / 12:05	SK				
6/30	Gordy Dupr		CMP	8?? / 434	GD				
7/1	Gordy Dupr		CMP	8?? / 1007	GD				
7/2/07	Stacie Brown		CMP	9:02 / 11:40	SB				
7/2/07	Melissa Kahl-McDonagh		UTPB	3:?? / 4:10	MKM	T	VIN		CM MKM CM
7/2/07	Gordy Dupre		CMP	32? / 412	GD				

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #** _ **BUILDING #** ___ **PI NAME** Fitch

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial)
4/24	John D. Dehmy		CMP	2:45 / 5:00	JD				
4/25/07	Sean Knox		CMP	1:52 / 4:35	SK				
4/26/07	Amy Henson		CMP	8:41 / 12:17	AH				
4/27/07	Amy Henson		CMP	1:20 / 3:30	AH				
4/28/07	Amy Henson		CMP	9:03 / 10:10	AH				
4/29/07	Amy Henson		CMP	9:28 / 10:45	AH				
4/30/07	Sean Knox		CMP	9:31 / 12:39	SK				
5/1/07	Gordon Dapp		CMP	8:57 / 11:54	GD				
5/2/07	Sean Knox		CMP	9:05 / 2:24	SK				
5/3	Gordon Dapp		CMP	1:16 / 2:50	GD				
5/3	Gordon Dapp		CMP	9:06 / 2:00	GD				

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #** ____ **BUILDING #** ____ **PI NAME** Fitch

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY							THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)		[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial)
4/17/07	Amy Henson	Amy Henson	CMP	9:01 / 11:58	AH					
4/17/07	Sean Knox	Sean Knox	CMP	10:46 / 11:30	SK					
4/17/07	Ken Gilkenwater	Ken Gilkenwater	CMP	11:30	KG			✓		
4/17/07	Diane Martin	Diane Martin	CDC	3:30	✓	DM ✓	I	3192I G12	KG	already trained
4/17/07	RD Hankel	RD Hankel	CDC	3:30 / 4:30	✓	✓	I	3,304 014	KG	already trained
4/18/07	Sean Knox	Sean Knox	CMP	1:43 / 3:59	SK					
4/19	Amy Henson	Amy Henson	CMP	9:07 / 12:16	AH					
4/20	Amy Henson	Amy Henson	CMP	12:00	AH					
4-21-07	Gordon Draper	Gordon Draper	CMP	9:07 / 10:23	GD					
4-22	Gordon Draper	Gordon Draper	CMP	8:59 / 10:06	GD					
4/23	Amy Henson	Amy Henson	CMP	1:30 / 3:05	AH					

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #** _____ **BUILDING #** _____ **PI NAME** Ficht

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY							THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)		[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initital)	Received Hazard Training (Initial)
4/10/07	Amy Henson	Amy Henson	CMP	1:15 / 5:05	AH					
4/11/07	Melissa Kahl-McDonagh	MKahl	VTPB	2:30 / 5:00	MKM					
4/11/07	Amy Henson	Amy Henson	CMP	8:16 / 12:59	AH					
4/11/07	Melissa Kahl-McDonagh	MKahl	VTPB	10:30 / 16:40	MKM					
4/12/07	Amy Henson	Amy Henson	CMP	8:46 / 13:33	AH					
4/13/07	Amy Henson	Amy Henson	CMP	8:24 / 12:51	AH					
4/13/07	Sean Knox	SK	CMP	9:17 / 12:06	SK					
4/14/07	Amy Henson	Amy Henson	CMP	8:34 / 10:14	AH					
4/15	Amy Henson	Amy Henson	CMP	9:00 / 10:48	AH					
4/16/07	angela aiena	aiena	VTPB	8:30 / 9:45	AA					
4/16/07	Sean Knox	SK	CMP	11:32 / 4:15						

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG ROOM # BUILDING # PI NAME Fick

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial)
4/3/07	Amy Henson		CMP	855 1300	AH				
4/3/07	Sean Knox		CMP	3:29 4:15	SK				
4/4/07	Amy Henson		CMP	8:08 1200	AH				
4/5/07	Amy Henson		CMP	8:45 1217	AH				
4/6/07	Amy Henson		CMP	8:09 1230	AH				
4/7/07	Gordon Draper		CMP	952 1124	GD				
4/7/07	Gordon Draper		CMP	926 1047	GD				
4/9/07	Melissa Kahl-McDonald		VTPS	11:03 1230	MKM				
4/9/07	Sean Knox		CMP	2:55 5:5	SK				
4/9/07	Melissa Kahl-McDonald		VTPS	310 530	MKM				
4/11/07	Melissa Kahl-McDonald		VTPS	415 130	MKM				

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #** **BUILDING #** **NAME** Ficht

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial)
3/27/07	John D. Delaney		CMP	10:52 / 1:30	JD				
3/27/07	John D. Delaney		CMP	2:30 / 4:45	JD				
3/28/07	John D. Delaney		CMP	8:57 / 12:35	JD				
3/29/07	John D. Delaney		CMP	8:55 / 12:05	JD				
3/29/07	Melissa Cahl-McDonagh		UTPB	320 / 430	MKM				
3/24/07	ANGELO ALEXIS		UTPB	3:20 / 4:30	ACA				
3/30/07	John D. Delaney		CMP	8:45 / 11:50	JD				
3/30/07	John D. Delaney		CMP	3:32 / 4:47	JD				
2/22/07	Amy Henson		CMP	853 / 1020	AH				
4/11/07	Amy Henson		CMP	847 / 10:15	AH				
4/12/07	Amy Henson		CMP	817 / 1230	AH				

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG

ROOM #_____ BUILDING _____

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initital)	Received Hazard Training (Initial)
							Number		
7/3/07	Sean Knox		CMP	2:02 / 5:06	SK				
7/6/07	Stacie Brown		CMP	8:25 / 11:48	SB				
7/6/07	Stacie Brown		CMP	3:42 / 11:43	SB				
7/6/07	Stacie Brown		CMP	9:36 / 11:35	SB				
7/6/07	Sean Knox		CMP	8:43 / 4:20	SK				
07/9/07	Stacie Brown		CMP	8:18 / 9:40	SB				
07/9/07	Stacie Brown		CMP	2:00 / 5:12	SB				
7/9/07	Sean Knox		CMP	9:00 / 11:49	SK				
7/10/07	Gordon Draper		CMP						

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #** 1 **BUILDING #** _____ **PI NAME** Tight

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial)
6/6/07	Stacie Brown	[signature]	CMP	8:43 / 11:46	SB				
6/26/07	Sean Knox	[signature]	CMP	1:18 / 3:55	SK				
6/6/07	Stacie Brown	[signature]	CMP	9:15 / 11:00	SB				
6/27/07	Sean Knox	[signature]	CMP	1:13 / 3:40	SK				
6/8/07	Stacie Brown	[signature]	Cmp	9:05 / 12:2[illegible]	SB				
6/29/07	Sean Knox	[signature]	CMP	9:[illegible] / 2:05	SK				
6-30	Gordy Dupe	[signature]	CMP	8[illegible] / 934	GD				
7-1	Gordy Dupe	[signature]	CMP	8[illegible] / 1007	GD				
7/2/07	Stacie Brown	[signature]	CMP	9:03 / 11:40	SB				
7/2/07	Melissa Kahl-McDonagh	[signature]	UTB	3:2[illegible] / 4:10	MKM	T	UIN	[signature]	MKM CH
7-2-07	Gordy Dupe	[signature]	CMP	32[illegible] / 412	GD				

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #** _ **BUILDING #** ___ **PI NAME** Fitch

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THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY							THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)		[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial)
4/24	John D. Dabney	John D. Dabney	CMP	2:45 / 5:05	JD					
4/25/07	Sean Knox	Sean Knox	CMP	1:52 / 4:35	SK					
4/26/07	Amy Henson	Amy Henson	CMP	8:41 / 12:17	AH					
4/27/07	Amy Henson	Amy Henson	CMP	1:20 / 3:30	AH					
4/28/07	Amy Henson	Amy Henson	CMP	9:03 / 10:10	AH					
4/29/07	Amy Henson	Amy Henson	CMP	9:28 / 10:45	AH					
4/30/07	Sean Knox	Sean Knox	CMP	9:31 / 12:39	SK					
5/1/07	Gordon Dapp	Gordon Dapp	CMP	8:57 / 12:54	GD					
5/2/07	Sean Knox	Sean Knox	CMP	9:05 / 2:24	SK					
5/2	Gordon Dapp	Gordon Dapp	CMP	1:16 / 2:50	GD					
5/3/07	Gordon Dapp	Gordon Dapp	CMP	9:06 / 2:00	GD					

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #** _____ **BUILDING** _____ **PI NAME** Fitch

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Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)		[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initital)	Received Hazard Training (Initial)
4/17/07	Amy Henson	Amy Henson	CMP	9:01 / 1:58	AH					
4/17/07	Sean Knox	Sean Knox	CMP	1:46 / 11:30	SK					
4/17/07	Ken Gilkenwater	Ken Gilkenwater	CMP	3:30	KG			✓		
4/17/07	Diane Martin	Diane Martin	CDC	3:30	✓	DM ✓	I	31921 / 012	KG	already trained
4/17/07	RD Hewitt	RD Hewitt	CDC	3:30 / 4:30	✓	✓	I	36304 / 014	KG	already trained
4/18/07	Sean Knox	Sean Knox	CMP	1:43 / 3:59	SK					
4/19	Amy Henson	Amy Henson	CMP	9:07 / 12:14	AH					
4/20	Amy Henson	Amy Henson	CMP	[illegible] / 12:00	[illegible] AH					
4-21-07	Gordon Draper	Gordon Draper	CMP	9:07 / 10:23	GD					
4-22	Gordon Draper	Gordon Draper	CMP	8:59 / 10:26	GD					
4/23	Amy Henson	Amy Henson	CMP	1:30 / 3:05	AH					

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #** _____ **BUILDING #** _____ **PI NAME** Ficht

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THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial)
4/10/07	Amy Henson	Amy Henson	CMP	1:15 / 505	AH				
4/11/07	Melissa Kahl-McDonagh	MKahl	VTPB	230 / 500	MKM				
4/11/07	Amy Henson	Amy Henson	CMP	816 / 1259	AH				
4/11/07	Melissa Kahl-McDonagh	MKahl	VTPB	1050 / 1640	MKM				
4/12/07	Amy Henson	Amy Henson	CMP	946 / 1933	AH				
4/13/07	Amy Henson	Amy Henson	CMP	824 / 1251	AH				
4/13/07	Sean Knox	SK	CMP	917 / 206	SK				
4/14/07	Amy Henson	Amy Henson	CMP	834 / 104	AH				
4/15	Amy Henson	Amy Henson	CMP	9:00 / 10:48	AH				
4/16/07	emergency	emergency	VTPB	8:30 / 9:45	AC				
4/16/07	Sean Knox	SK	CMP	11:20 / 4:15					

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #** _ **BUILDING #** _____ **PI NAME** Fick

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THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY							THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)		[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial)
4/3/07	Amy Henson	Amy Henson	CMP	855 1300	AH					
4/3/07	Sean Knox	Sean Knox	CMP	3:29 4:15	SK					
4/4/07	Amy Henson	Amy Henson	CMP	8:08 1200	AH					
4/5/07	Amy Henson	Amy Henson	CMP	8:45 1217	AH					
4/6/07	Amy Henson	Amy Henson	CMP	8:00 1230	AH					
4/7/07	Linda Draper	Linda Draper	CMP	952 1124	LD					
4/8/07	Linda Draper	Linda Draper	CMP	926 1047	LD					
4/9/07	Melissa Kahl-McDonald	Melissa Kahl-McDonald	VTPS	11:05 1230	MKM					
4/9/07	Sean Knox	Sean Knox	CMP	12:55 5:5	SK					
4/9/07	Melissa Kahl-McDonald	Melissa Kahl-McDonald	VTPS	310 550	MKM					
4/10/07	Melissa Kahl-McDonald	Melissa Kahl-McDonald	VTPS	415 130	MKM					

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #** _ **BUILDING #** _ **PI NAME** Ficht

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial)
3/27/07	John D. Delaney	John D. Delaney	CMP	10:52 11:00	JD				
3/27/07	John D. Delaney	John D. Delaney	CMP	2:30 4:45	JD				
3/28/07	John D. Delaney	John D. Delaney	CMP	8:57 12:05	JD				
3/29/07	John D. Delaney	John D. Delaney	CMP	8:55 12:05	JD				
3/29/07	Melissa Cahl-McDonagh	Melissa Cahl-McDonagh	UTPB	320 430	MKM				
3/24/07	ANGELO ALCINO	Angelo Alcino	UTPB	3:20 4:30	AA				
3/30/07	John D. Delaney	John D. Delaney	CMP	8:45 11:50	JD				
3/30/07	John D. Delaney	John D. Delaney	CMP	3:32 4:47	JD				
3/31/07	Amy Henson	Amy Henson	CMP	853 1020	AH				
4/1/07	Amy Henson	Amy Henson	CMP	845 1015	AH				
4/2/07	Amy Henson	Amy Henson	CMP	817 1020	AH				

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #** **BUILDING #** **PI NAME** Research

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time In / Out	Status (Initial One) Authorized / Escorted	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below) Type / Number	Verified/ Escorted By (Initial)	Received Hazard Training (Initial) To
6-30	Gordon Draper		CMP	834 / 934	MD				
7-1	Gordon Draper		CMP	836 / 1007	MD				
07/02/07	Stacie Brown		CMP	9:03 / 11:40	SB				
7/3/07	Sean Knox		CMP	2:04 / 5:00	SK				
07/04/07	Stacie Brown		CMP	8:25 / 11:45	SB				
07/05/07	Stacie Brown		CMP	8:14 / 11:43	SB				
7/6/07	Sean Knox		CMP	9:36 / 11:25	SK				
07/07/07	Stacie Brown		CMP	8:15 / 9:20	SB				
07/08/07	Stacie Brown		CMP	8:18 / 9:40	SB				
7/9/07	Sean Knox		CMP	2:00 / 5:12	SK				
7-10	Gordon Draper		CMP	900 / 1149	MD				

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM** **BUILDING #** **PI NAME** Wunsch

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initital)	Receive Hazard Trainin (Initial)
04/26/07	Stacie Brown	Stacie Brown	CMP	10:35 / 2:41	SB				
4/27/07	Amy Henson	Amy Henson	CMP	1:20 / 3:20	AH				
4/28/07	Amy Henson	Amy Henson	CMP	9:05 / 10:10	AH				
4/29/07	Amy Henson	Amy Henson	CMP	9:28 / 10:45	AH				
4/30/07	Sean Knox	Sean Knox	CMP	9:31 / 12:39	SK				
5/1/07	Gordon Draper	Gordon Draper	CMP	8:57 / 12:54	GD				
5/6/07	Sean Knox	Sean Knox	CMP	9:05 / 2:24	SK				
5/2/07	Gordon Draper	Gordon Draper	CMP	11:16 / 2:50	GD				
5/3/07	Gordon Draper	Gordon Draper	CMP	9:06 / 2:00	GD				
5/4/07	Gordon Draper	Gordon Draper	CMP	8:47 / 3:15	GD				
5/5	Gordon Draper	Gordon Draper	CMP	9:01 / 1:07	GD				

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #** _____ **BUILDING #**_____ **PI NAME** Russell-Ladbe

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY							THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)		[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initital)	Received Hazard Training (Initial)
4/17/07	Richard Henkel	RDHenkel	CDC	3:30 / 4:30	✓	✓	I Inspection	CDC Badge 36304	KG	yes SK
4/18/07	Sean Knox	S Knox	CMP	1:43 / 3:59	SK					
4/19/07	L.									
4/19	Amy Henson	Amy Henson	CMP	9:07 / 12:10	AH					
4/20	Amy Henson	Amy Henson	CMP	9:00 / 12:00	AH					
4-21	Gordon Draper	Gordon Draper	CMP	9:03 / 10:23	GD					
4-22	Gordon Draper	Gordon Draper	CMP	8:59 / 10:26	GD					
4/23	Amy Henson	Amy Henson	CMP	9:20 / 3:05	AH					
4/24/07	John D. Delaney	John D. Delaney	CMP	2:45 / 5:05	JD					
4/25/07	Sean Knox	S Knox	CMP	1:53 / 4:38	SK					
4/26/07	Sean Knox	S Knox	CMP	2:51 / 4:55	SK					

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM** ___ **BUILDING #** ___ **PI NAME** Russell - Lodge

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initital)	Received Hazard Training (Initial)
4/11/07	Amy Henson		CMP	8:16 / 12:59	AH				
4/12/07	Amy Henson		CMP	8:46 / 12:33	AH				
4/13/07	Amy Henson		CMP	8:24 / 12:51	AH				
4/13/07	Sean Knox		CMP	9:17 / 12:06	SK				
4/14	Amy Henson		CMP	8:31 / 10:14	AH				
4/15	Amy Henson		CMP	9:30 / 10:48	AH				
4/16	Sean Knox		CMP	11:22 / 4:15	SK				
4/17/07	Amy Henson		CMP	9:01 / 12:38	AH				
4/17/07	Sean Knox		CMP	10:46 / 11:30	SK				
4/17/07	Ken Gallenwater		CMP	3:30	KG				
4/17/07	Diane Martz		CDC	3:30 / 4:30	DM ✓	✓ I Inspect	CDC Badge 31921	KG	✓ CDC

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #____ __ BUILDING # ___ PI NAME** Rissel

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initital)	Received Hazard Training (Initial)
4/1/07	Amy Henson		CMP	849 / 10:15	AH				
4/2/07	Amy Henson		CMP	847 / 2:30	AH				
4/3/07	Amy Henson		CMP	835 / 500	AH				
4/4/07	Amy Henson		CMP	8:08 / 500	AH				
4/5/07	Amy Henson		CMP	845 / 11:17	AH				
4/6/07	Amy Henson		CMP	830 / 1230	AH				
4/7/07	Gaden Draper		CMP	95 / 1124	GD				
4/7/07	Kaori Russell-Lodrigue		CMP	1:34 / 145	KR				
4/8/07	Gaden Draper		CMP	926 / 1047	GD				
4/9/07	Sean Knox		CMP	12:55 / 5:15	SK				
4/10/07	Amy Henson		CMP	1.15 / 500	AH				

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #** 7 **BUILDING #** **PI NAME** [redacted]

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY							THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time In / Out	Status (Initial One)		[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below) Type / Number	Verified/ Escorted By (Initital)	Received Hazard Training (Initial) Yes
6/30	Gordon Draper	[redacted]	CMP	838 / 934	MD					
7/1	Gordon Draper	[redacted]	CMP	836 / 1007	MD					
7/2/07	Stacie Brown	[redacted]	CMP	9:03 / 11:40	SB					
7/3/07	Sean Knox	[redacted]	CMP	2:54 / 5:00	SK					
7/5/07	Stacie Brown	[redacted]	CMP	8:25 / 11:45	SB					
7/6/07	Stacie Brown	[redacted]	CMP	8:14 / 11:43	SB					
7/9/07	Sean Knox	[redacted]	CMP	9:36 / 11:25	SK					
7/10/07	Stacie Brown	[redacted]	CMP	8:15 / 9:20	SB					
7/10/07	Stacie Brown	[redacted]	CMP	8:18 / 9:40	SB					
7/9/07	Sean Knox	[redacted]	CMP	2:00 / 5:12	SK					
7/10	Gordon Draper	[redacted]	CMP	900 / 1149	MD					

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

ACCESS LOG ROOM # _____ BUILDING # _____ PI NAME Uranell

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED F ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Receiv Hazar Traini (Initia
04/26/07	Stacie Brown	Stacie Brown	CMP	10:35 / 2:41	SB				
4/27/07	Amy Henson	Amy Henson	CMP	1:20 / 3:20	AH				
4/30/07	Amy Henson	Amy Henson	CMP	9:05 / 10:10	AH				
4/30/07	Amy Henson	Amy Henson	CMP	9:28 / 10:45	AH				
4/30/07	Sean Knox	Sean Knox	CMP	9:31 / 12:39	SK				
5/1/07	Gordon Draper	Gordon Draper	CMP	8:57 / 12:54	GD				
5/6/07	Sean Knox	Sean Knox	CMP	9:05 / 2:24	SK				
5/2/07	Gordon Draper	Gordon Draper	CMP	11:16 / 2:50	GD				
5/3/07	Gordon Draper	Gordon Draper	CMP	9:06 / 2:00	GD				
5/4/07	Gordon Draper	Gordon Draper	CMP	8:57 / 3:15	GD				
5/5	Gordon Draper	Gordon Draper	CMP	9:01 / 1:07	GD				

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #____** **BUILDING #____** **PI NAME** Russell-Lodge

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initital)	Received Hazard Training (Initial)
4/17/07	Richard Henkel	RDHenkel	CDC	3:30 / 4:30	✓	✓	I	Inspection	CDC Badge 36304	KG	yes
4/18/07	Sean Knox	S Knox	CMP	1:43 / 3:59	SK						CDC
4/19	L.										
4/19	Amy Henson	Amy Henson	CMP	9:07 / 12:10	AH						
4/20	Amy Henson	Amy Henson	CMP	9:00 / 12:00	AH						
4-21	Gordon Draper	Gordon Draper	CMP	9:03 / 10:23	GD						
4-22	Gordon Draper	Gordon Draper	CMP	8:59 / 12:26	GD						
4/23	Amy Henson	Amy Henson	CMP	9:30 / 3:05	AH						
4/24/07	John D. Delany	John D. Delany	CMP	2:45 / 5:05	JD						
4/25/07	Sean Knox	S Knox	CMP	1:53 / 4:38	SK						
4/26/07	Sean Knox	S Knox	CMP	2:51 / 4:55	SK						

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #_____** **BUILDING #_____** **PI NAME** Russell - Lodge

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY							THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)		[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initital)	Received Hazard Training (Initial)
4/11/07	Amy Henson		CMP	8:16 / 12:59	AH					
4/12/07	Amy Henson		CMP	8:46 / 12:33	AH					
4/13/07	Amy Henson		CMP	8:24 / 12:51	AH					
4/13/07	Sean Knox		CMP	9:17 / 12:06	SK					
4/14	Amy Henson		CMP	8:34 / 10:14	AH					
4/15	Amy Henson		CMP	9:00 / 10:48	AH					
4/16	Sean Knox		CMP	11:22 / 4:15	SK					
4/17/07	Amy Henson		CMP	9:01 / 12:38	AH					
4/17/07	Sean Knox		CMP	10:46 / 11:30	SK					
4/17/07	Ken Gallemore		CMP	3:30	KG					
4/17/07	Diane Martin		CDC	3:30 / 4:30	DM	✓	I Inspect	CDC Badge 31921	KG	CDC

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #** — **BUILDING #** — **PI NAME** Russell

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial)
4/1/07	Amy Henson		CMP	849 / 10:15	AH				
4/2/07	Amy Henson		CMP	847 / 330	AH				
4/3/07	Amy Henson		CMP	835 / 300	AH				
4/4/07	Amy Henson		CMP	8:08 / 300	AH				
4/5/07	Amy Henson		CMP	845 / 1211	AH				
4/6/07	Amy Henson		CMP	830 / 1230	AH				
4/7/07	Caden Draper		CMP	95 / 1124	CD				
4/7/07	Kari Russell-Lodrigue		MMP	1:34 / 145	KR				
4/8/07	Caden Draper		CMP	926 / 1047	CD				
4/9/07	Sean Knox		CMP	12:55 / 5:15	SK				
4/10/07	Amy Henson		CMP	1:15 / 500	AH				

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

Report Selection Criteria

Date Time Format:	Local
Start Date Time:	7/1/2007 12:00:00AM
End Date Time:	7/25/2007 3:15:35PM
Badge Number:	[All]
Badgeholder Name:	[All]
Event Description:	[All]
Event Reason Type:	[All]
Door Name:	Biohazard
Sort by:	Datetime
Print Shading:	Yes

Badge Events Report

Date	Time	Event Description	Event Reason Type	Door Name	Badge Number / Name	Archive/ Minutes	Egress/ Duress
7/1/2007	8:35:24AM	Accept	>>None<<	Biohazard Entry -	6016429723558409 - DRAPER, GORDON B.		In
7/2/2007	1:13:22PM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/2/2007	1:20:06PM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/2/2007	1:22:44PM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/2/2007	1:35:22PM	Accept	>>None<<	Biohazard Entry -	6016427725338549 - KNOX, SEAN		In
7/2/2007	3:29:32PM	Accept	>>None<<	Biohazard Entry -	6016429723558409 - DRAPER, GORDON B.		In
7/3/2007	10:28:24AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/3/2007	10:33:02AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/3/2007	10:35:28AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/3/2007	1:38:28PM	Accept	>>None<<	Biohazard Entry -	6016427725338549 - KNOX, SEAN		In
7/3/2007	2:11:48PM	Accept	>>None<<	Biohazard Entry -	6016427725338549 - KNOX, SEAN		In
7/5/2007	9:01:44AM	Accept	>>None<<	Biohazard Entry -	6016422118706980 - KNOWLTON, CHRISTOPHER		In
7/5/2007	4:10:08PM	Accept	>>None<<	Biohazard Entry -	6016427725338549 - KNOX, SEAN		In
7/6/2007	9:20:34AM	Accept	>>None<<	Biohazard Entry -	6016427725338549 - KNOX, SEAN		In
7/6/2007	9:38:40AM	Accept	>>None<<	Biohazard Entry -	6016427725338549 - KNOX, SEAN		In
7/6/2007	3:45:38PM	Accept	>>None<<	Biohazard Entry -	6016427725338549 - KNOX, SEAN		In

Badge Events Report

Date	Time	Event Description	Event Reason Type	Door Name	Badge Number / Name	Archive/ Minutes	Egress/ Duress
7/9/2007	8:40:50AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/9/2007	8:41:00AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/9/2007	8:47:04AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/9/2007	10:41:20AM	Accept	>>None<<	Biohazard Entry -	6016429723558409 - DRAPER, GORDON B.		In
7/9/2007	1:15:28PM	Accept	>>None<<	Biohazard Entry -	6016429723558409 - DRAPER, GORDON B.		In
7/9/2007	2:05:16PM	Accept	>>None<<	Biohazard Entry -	6016427725338549 - KNOX, SEAN		In
7/10/2007	8:40:08AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/10/2007	8:44:40AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/10/2007	8:49:48AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/10/2007	8:54:54AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/10/2007	9:00:48AM	Accept	>>None<<	Biohazard Entry -	6016429723558409 - DRAPER, GORDON B.		In
7/10/2007	9:00:50AM	Accept	>>None<<	Biohazard Entry -	6016429723558409 - DRAPER, GORDON B.		In
7/10/2007	9:07:58AM	Accept	>>None<<	Biohazard Entry -	6016429723558409 - DRAPER, GORDON B.		In
7/10/2007	1:14:16PM	Accept	>>None<<	Biohazard Entry -	6016429723558409 - DRAPER, GORDON B.		In
7/10/2007	2:02:36PM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/10/2007	2:08:44PM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/10/2007	2:12:02PM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/10/2007	2:15:18PM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/11/2007	8:29:46AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/11/2007	8:34:32AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/11/2007	9:59:56AM	Accept	>>None<<	Biohazard Entry -	6016427725338549 - KNOX, SEAN		In
7/11/2007	10:03:34AM	Accept	>>None<<	Biohazard Entry -	6016427725338549 - KNOX, SEAN		In

Badge Events Report

Date	Time	Event Description	Event Reason Type	Door Name	Badge Number / Name	Archive/ Minutes	Egress/ Duress
7/11/2007	1:50:50PM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/11/2007	1:53:10PM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/11/2007	2:02:22PM	Accept	>>None<<	Biohazard Entry -	6016429723558409 - DRAPER, GORDON B.		In
7/12/2007	9:59:44AM	Accept - Msg Displayed	>>None<<	Biohazard Entry -	6016428149356265 - DOMINGUEZ, JUSTIN		In
7/12/2007	12:47:38PM	Accept	>>None<<	Biohazard Entry -	6016429723558409 - DRAPER, GORDON B.		In
7/12/2007	1:49:46PM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/12/2007	1:51:52PM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/13/2007	9:50:06AM	Accept	>>None<<	Biohazard Entry -	6016427725338549 - KNOX, SEAN		In
7/13/2007	2:02:42PM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/13/2007	2:04:42PM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/13/2007	2:48:16PM	Accept	>>None<<	Biohazard Entry -	6016429723558409 - DRAPER, GORDON B.		In
7/13/2007	4:32:10PM	Accept	>>None<<	Biohazard Entry -	6016429612635227 - HOLSTER, SCOT		In
7/14/2007	9:24:50AM	Accept	>>None<<	Biohazard Entry -	6016429723558409 - DRAPER, GORDON B.		In
7/15/2007	9:06:48AM	Accept	>>None<<	Biohazard Entry -	6016429723558409 - DRAPER, GORDON B.		In
7/16/2007	8:35:04AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/16/2007	8:39:14AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/16/2007	10:02:14AM	Accept	>>None<<	Biohazard Entry -	6016427725338549 - KNOX, SEAN		In
7/16/2007	1:30:54PM	Accept	>>None<<	Biohazard Entry -	6016429723558409 - DRAPER, GORDON B.		In
7/17/2007	10:26:30AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/17/2007	10:27:54AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/17/2007	10:30:56AM	Accept	>>None<<	Biohazard Entry -	6016429597146638 - RICHARDS, WILLIAM		In
7/17/2007	1:23:56PM	Accept	>>None<<	Biohazard Entry -	6016427725338549 - KNOX, SEAN		In