

APPENDIX “A”

**Standard Operating Procedures
Physical and Personnel Security, Access
Control, Incident Reporting and Breaches in
Security**

RESPONSIBILITY:

All personnel given access to ABSL-3 areas are responsible for maintaining security and reporting security concerns when working in the ABSL-3 areas. **NOTE: In accordance to Title 42, CFR, Part 73, only staff with Department of Justice (DOJ) clearance for access to Select Biological Agents and Toxins may work with projects involving the use of select agents/toxins.**

GENERAL INFORMATION:

1. All ABSL-3 locations require an individual security access card to enter the ABSL-3 area.
2. CMP Individual access cards and keys required to gain access to the ABSL-3 area and the ABSL-3 area are stored in the Main facility supervisor's office in a double lock box. Individual access cards and keys are signed out/in daily to personnel assigned to each area by an area supervisor. The lock box access log is stored inside on the first door of the double lock box and is checked at the end of the day by an area supervisor to ensure that all cards and keys have been returned.
3. Access cards are only to be used by the individual assigned to that card (never shared).
4. All individuals entering ABSL-3 areas containing select agents must sign-in and out of the area on the proper select agent facility access log.
5. Always make sure each secured door that you enter/exit secures before leaving the area.
6. All individuals escorting non DOJ approved individuals into an ABSL-3 area containing select agents must verify the individuals identification, sign the individual in as a visitor (record ID type and #) and stay with the individual at all times when in the ABSL-3 select agent area.
7. The University Police Department (UPD) must be notified before transporting Select Agents on public roadways so that a police escort can be provided. **Note: many of the roads on campus are considered to be public roadways.**

ABSL-3 Access Control:

1. Access is secured by way of individual security card access readers located at Vivarium entry doors.
2. The ABSL-3 area located inside of the Vivarium is also secured by way of individual security card access readers. Each animal room and lab room inside of the ABSL-3 area is secured by coded key pad locks.
3. ABSL-3 Security access cards are assigned by the Area Coordinator only to individuals who have been approved to enter the ABSL-3 area. Codes to access key pad controlled rooms containing Select Agents in the ABSL-3 area are only provided to individuals that have been cleared to work with select agents by the DOJ.
4. All individuals entering the ABSL-3 area must sign in and out on the Main ABSL-3 area log. All individuals entering a room containing animals exposed to a select agent must sign in and out on the specific select agent access log.

5. Actual agents (outside of animals) are not stored in the ABSL-3 area.

ABSL-3 Access Control:

1. The ABSL-3 area located inside of the Vivarium is secured by way of individual security card access readers as well as a finger print scan reader.
2. RMB ABSL-3 Security access cards are assigned by the Facility Coordinator only to individuals who have been cleared to work with select agents by the DOJ. The Facility Coordinator will also take an electronic finger scan of the cleared individual.
3. Individuals must use both access card and finger scan before they are granted access to the ABSL-3 area.

ABSL-3 Access Control:

1. The ABSL-3 area located inside of the _____ building is secured by way of individual security card access readers as well as an entry door key lock.
2. _____ ABSL-3 security access cards are assigned only to individuals who have been cleared to work with select agents by the DOJ.
3. Individuals must use both access card and a key before they can gain access to the ABSL-3 area.
4. Always ensure that the locks on access doors remain locked behind you after entering and exiting.

Incident Reporting & Breaches in Security

The University Police Department (9-911 emergency, 845-2345 non-emergency), the Responsible Official or designee (Brent Mattox, 862-2062 or 450-0662), and Environmental Health and Safety (845-2132) must be notified in the event of:

1. Any loss or compromise of keys, passwords, combinations, etc.;
2. Any suspicious persons or activities;
3. Suspicious packages;
4. Any loss or theft of Select Agents or toxins;
5. Missing chemicals;
6. Any release of Select Agents or toxins;
7. Any sign that inventory and use records of Select Agents or toxins have been altered or otherwise compromised;
8. Cyber security breach;
9. Non-biological incident such as violence against person;

10. Unusual or threatening phone calls;
11. Undocumented visitors;
12. Severe weather and natural disasters.

Breaches in security and detection of unauthorized or suspicious persons must be immediately reported to the University Police Department at 9-911. UPD will direct your actions once notified and have the authority to forcefully remove any unauthorized or suspicious persons.

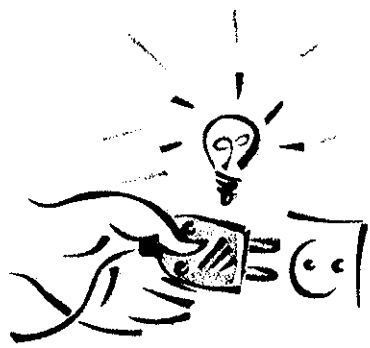
APPENDIX “B”

Deemed Export Requirements

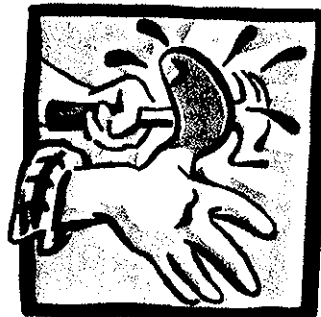
**Document to
be provided
by PI.**

APPENDIX “C”

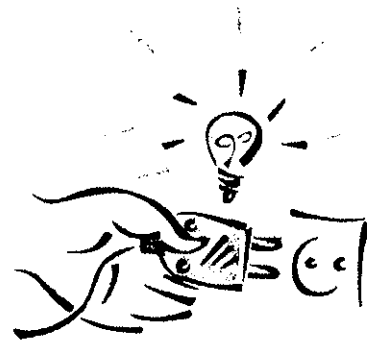
Emergency Contact Information & Response Procedures



ABSL3 Emergency Response Plan



POWER OUTAGES



All personnel given access to ABSL-3 areas are responsible for maintaining security and reporting security concerns when working in the ABSL-3 areas. **NOTE: In accordance to Title 42, CFR, Part 73, only staff with Department of Justice (DOJ) clearance for access to Select Biological Agents and Toxins may work with projects involving the use of select agents/toxins**

Contact Numbers:

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

1. In the event of a power outage, the Physical Plant Radio Room is notified through the Hawkeye system and has been instructed to notify CMP personnel. If you are called, you must respond to the radio room call & remain at the facility until the problem has been resolved.

The duty supervisor should keep a written log of all events: recording times communications, contacts, time of resolution and determined problem.
2. The emergency power generator will engage within seconds after the power outage and will sustain:
 - lights
 - security system
 - air handlers
 - select power plugs in the Biohazard & Surgery area.Fuel & function of the generator is the responsibility of Physical Plant.
3. Communication with the Radio Room during the outage is essential (845-4311). They should be able to find out how serious the problem is and give an approximate time that the power will be off.
4. For all outages, contact the CMP Facilities Coordinator (777-0258) or their representative (218- 8598) to inform him/her of the problem.
5. CMP personnel should check:

- All ventilated housing racks/blowers. In the event of an extended power outage, emergency power outlets are located in the O.R. Training Room.
- All animal rooms to make sure the emergency backup lights and air handlers have engaged.
- Room temperatures to insure a temperature problem does not develop.

6. Once power is restored:
 - CMP personnel should check the alarm panels and reset if necessary.
 - Physical plant personnel and/or CMP building maintenance personnel should check the building ventilation/air conditioning systems (including chilled & hot water pumps) and animal room light timers to ensure proper operation.
 - Employee time clocks must be reset.

NOTE: If you do not know how to reset the time clock and cannot reach someone that does, employees should be instructed to sign in and sign out until a reset can be performed.

7. Check all other animal care facilities to determine if power problems are widespread or limited to Main.

Contact Numbers:

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

1. In the event of a power outage the Radio Room should contact George Martin (Cell 228-3380, Home and personnel. COM personnel are responsible for responding and following up with Physical Plant personnel, if needed. CMP is notified as an FYI. COM personnel may contact CMP personnel if assistance is needed. If the Radio room is unable to contact George Martin or his designate, CMP personnel must respond.
2. The lights and the air handlers will all run off the emergency generators (fuel & function of these generators are the responsibility of the Physical Plant).
3. Each room must be checked to make sure that the lights and air are working appropriately.
4. Contact the Radio Room and make sure they are aware of the problem (845-4311).
5. Remain in close contact with Physical Plant and the repair personnel until the situation is resolved.
6. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty veterinarian.
7. Check all other animal care facilities to determine if power problems are widespread.

Contact Numbers:

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

1. In the event of a power outage the Radio Room should contact Noberto Espitia (Cell ... Home
and CMP personnel. CVM personnel are responsible for responding and following up with
Physical Plant personnel, if needed. CMP is notified as an FYI. CVM personnel may contact CMP
personnel if assistance is needed. If the Radio room is unable to contact Noberto Espitia or his
designate, CMP personnel must respond.
2. The lights & air handlers are all run off the emergency generators (fuel and function of these generators
are the responsibility of the Physical Plant).
3. Each room must be checked to make sure that the lights and air are working appropriately.
4. Contact the Radio Room and make sure they are aware of the problem (845-4311).
5. Remain in close contact with Physical plant and the repair personnel until situation is resolved.
6. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty
veterinarian.
7. Check all other animal care facilities to determine if power problems are widespread.

TEMPERATURE PROBLEMS



All personnel given access to ABSL-3 areas are responsible for maintaining security and reporting security concerns when working in the ABSL-3 areas. **NOTE: In accordance to Title 42, CFR, Part 73, only staff with Department of Justice (DOJ) clearance for access to Select Biological Agents and Toxins may work with projects involving the use of select agents/toxins.**

Contact Numbers:

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

This facility has both high-low temp alarms.

1. If an alarm is activated, the temperature alarm panel will beep and the room(s) involved will light up on the panel. The panel is located on the back wall of the _____ ↓ supervisor office.
PLEASE NOTE: The panel will not function again until it has been reset. Therefore when the alarm has signaled, you must respond, resolve the problem & reset the temperature alarm panel.
2. The Radio room is automatically notified (Hawkeye) after hours and on weekends /holidays. The Radio room will then contact CMP personnel.
3. Check the thermometer readings in all room(s) that have been identified by the control panel. Ensure the thermostat is working properly.
4. If the temperature is too high (>85) in the room, the animal room doors may be propped open until the problem is corrected (even cubicles). If the temperature is too low, space heaters (located in the tool room) should be put in the critical rooms until the problem is corrected.
5. Contact the CMP Facilities Coordinator (777-0258) or their representative (218-8598) and inform him/her of the problem.
6. Contact the Radio Room and request a repair technician, if needed (845-4311).

7. The on-call supervisor or other responsible CMP personnel must remain at the facility until each room(s) has reached normal temperatures. Once normal temps have been achieved:
 - Push the Reset button on the panel.
 - Close any animal room doors that had been opened due to high temps.
 - Turn off any supplemental heat sources.
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Contact Numbers:

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

This facility is equipped with high-low temp alarms.

1. In the event of a temp alarm, an automatic phone dialing system will attempt to contact George Martin (Cell 228-3380, Home 775-3215) or his designate. If the event that COM personnel fail to respond, the dialing system will attempt to contact the CMP On-Call Supervisor.
2. Once an alarm notification has been received, you can remotely identify the room/area in alarm and determine what the current temperature is by calling 862-7399. Once the system answers:
 - Press "0" when the system answers your call.
 - Once prompted, enter "10" (pass-number) followed by the "#" key.
 - Listen to the entire message and then press "1" followed by the "#" key.
 - To check room temps, enter each room's probe no. (list below) followed by the # key.NOTE: You can only check one probe at a time. To check additional probes, repeat instruction above.

Rm 420C - 62
Rm 420D - 63

NOTE: *Be patient and listen to each entire message. Enter all numbers firmly.*

3. Once the room in alarm has been identified:
 - Call the Radio Room and request a technician to respond (845-4311).
 - Give the Radio Room operator the building name/number, room number(s) involved.
4. You will need to stay in close contact with the repair technician until the situation has been resolved and the temperature(s) has been stabilized.
5. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty vet.

Contact Numbers:

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

There are no temperature alarms at this facility.

1. Once a temperature problem has been identified:
 - Call the Radio Room and request a technician to respond (845-4311).
 - Give the Radio Room operator the building name/number, room number(s) involved.
2. You will need to stay in close contact with the repair technician until the situation has been resolved and the temperature(s) has been stabilized.
3. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty vet.

WATER PROBLEMS



All personnel given access to ABSL-3 areas are responsible for maintaining security and reporting security concerns when working in the ABSL-3 areas. **NOTE: In accordance to Title 42, CFR, Part 73, only staff with Department of Justice (DOJ) clearance for access to Select Biological Agents and Toxins may work with projects involving the use of select agents/toxins.**

Contact Numbers:

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

1. Contact the CMP Facilities Coordinator (777-0258) or their representative (218-8598).
2. A CMP employee should be designated to oversee the problem. This person must remain at the facility and in close contact with the repair personnel until the water problem is resolved.
3. The CMP On-Call Supervisor is responsible for ensuring all animals have access to water.
4. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty vet.
NOTE: There are no automated watering systems in use.

Contact Numbers:

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

1. Contact George Martin (Cell _____, Home _____) or his designate.
2. The CMP On-Call Supervisor is responsible for ensuring all animals have access to water.
3. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty vet.
NOTE: There are no automated watering systems in use.

Contact Numbers:

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

1. Contact Noberto Espitia (Cell _____, Home _____) or his designate.
2. The CMP On-Call Supervisor is responsible for ensuring all animals have access to water.
3. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty vet.
NOTE: There are no automated watering systems in use.

INTRUDER/SECURITY ALARM



All personnel given access to ABSL-3 areas are responsible for maintaining security and reporting security concerns when working in the ABSL-3 areas. **NOTE: In accordance to Title 42, CFR, Part 73, only staff with Department of Justice (DOJ) clearance for access to Select Biological Agents and Toxins may work with projects involving the use of select agents/toxins. Breaches in security and detection of unauthorized or suspicious persons must be immediately reported to the University Police Department at 9-911. UPD will direct your actions once notified and have the authority to forcefully remove any unauthorized or suspicious persons.**

LARR

Contact Numbers:

University Police Department (UPD)
Emergency 9-911 Non-Emergency 845-2345

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home

Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home

INTRUDER ALARM

1. The LARR security system is controlled through a computer that keeps the entry doors continuously locked. When doors are locked, the security alarm is engaged.
2. Locked doors that are forced opened will trigger the alarm immediately. Doors equipped with a card scanner will trigger the alarm if held open for more than >15 seconds.
3. The alarm is NOT audible and will automatically notify the Radio Room and UPD when it is activated.
5. The Facility Coordinator (On-Call Supervisor on weekends and holidays) will be contacted by UPD if the intruder alarm has been triggered.

6. The Facility Coordinator or On-Call Supervisor must respond to the call and meet the UPD officer at .. complete a security check of the facility.

FACILITY BREAK-INS

1. DO NOT enter the building any further than you already have. DO NOT touch anything located inside or outside of the building.
2. Use a cellular phone or go to another facility to use a telephone.
3. Call UPD (9-911 from campus; 911 from off-campus).
4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.

Contact Numbers:

University Police Department (UPD)
Emergency 9-911 Non-Emergency 845-2345

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home

Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home

INTRUDER ALARMS

The intruder alarm at the College of Medicine is not an audible alarm and CMP will **NOT** be notified.

FACILITY BREAK-INS

1. DO NOT enter the building any further than you already have. DO NOT touch anything located inside or outside of the building.
2. Use a cellular phone or go to another facility to use a telephone.
3. Call UPD (9-911 from campus; 911 from off-campus).
4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.

5. Call George Martin (Cell 228-3380, Home

Contact Numbers:

University Police Department (UPD)
Emergency 9-911 Non-Emergency 845-2345

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home

Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home

INTRUDER ALARM

The intruder alarm at the Vet Research Tower is an audible alarm. CMP will **NOT** be notified. In the event you discover an intruder alarm, notify Noberto Espitia (Cell Home '). All follow up information will be obtained through Noberto.

FACILITY BREAK-INS

1. DO NOT enter the building any further than you already have. DO NOT touch anything located inside or outside of the building.
2. Use a cellular phone or go to another facility to use a telephone.
3. Call UPD (9-911 from campus; 911 from off-campus).
4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.
5. Call Noberto Espitia.

FIRE ALARMS/FIRES



All personnel given access to ABSL-3 areas are responsible for maintaining security and reporting security concerns when working in the ABSL-3 areas. **NOTE: In accordance to Title 42, CFR, Part 73, only staff with Department of Justice (DOJ) clearance for access to Select Biological Agents and Toxins may work with projects involving the use of select agents/toxins**

Contact Numbers:

College Station Fire Department
Emergency 9-911 Non-Emergency 764-3700

Physical Plant Radio Room (Non-Emergency)
24hr 845-4311

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home 777-0132

Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home 229-2696

1. The fire alarm panel is located in the men's ABSL3 entryway. There are six zones labeled on the panel and a schematic of the building labeled with corresponding zones highlighted. All Supervisors are to meet in the main Supervisor's office or front desk if a fire exists in the area of the supervisor's office. All other personnel must EXIT the building immediately and congregate in the vet school parking lot (PA 36), at least 100 feet from the bldg. Weekend/Holiday crews will meet at the supervisor's office and consult the supervisor in charge for instructions
2. The first supervisor to the office will silence (push silence button) the audible alarm at the fire panel. Allow the alarm to sound for at least 30 seconds before silencing.
3. Use the intercom (overhead page code 89) to announce the fire alarm and request evacuation of the building.

4. Retrieve the "FIRE ALARM SOP" binder located on the shelf of the supervisor's office or on the receptionist desk. One supervisor or designated person should remain at the office to coordinate assignments.
5. If a fire exists:

Small fires: Working in pairs, attempt to contain with an extinguisher. If fire cannot be contained, exit area immediately. Close all doors while exiting the facility.

Large fires: Close all doors in immediate area of building and exit building immediately.
4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.
5. If the fire presents an animal health related issue, (or you need assistance) contact the on-duty veterinarian.
4. Re-entry to the building is at the discretion of the Fire Dept and/or the Director of CMP.

Contact Numbers:

College Station Fire Department
Emergency 9-911 Non-Emergency 764-3700

Physical Plant Radio Room (Non-Emergency)
24hr 845-4311

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home

Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home

1. If a fire alarm occurs exit the building by the closest exit. Upper floors use stairwells ONLY.
2. CMP personnel should meet at the end bldg entrance to the Wehner Bldg (end adjacent to the COM dock) until all are accounted for.
3. If a fire exists:

Small fires: If a small fire occurs, use the fire extinguishers and hoses found at various locations throughout the hallways to extinguish the fire. If fire cannot be contained, exit area immediately. Close all doors while exiting the facility.

Large fires: Pull any fire alarm located in the hallways (usually near the service elevator stairwell). Close all doors in immediate area of building and exit building immediately. Upper floors use stairwells ONLY.

4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.
5. If the fire presents an animal health related issue, (or you need assistance) contact the on-duty veterinarian.
6. Re-entry to the building is at the discretion of the Fire Dept. and/or the COM Building Proctor.

Contact Numbers:

**College Station Fire Department
Emergency 9-911 Non-Emergency 764-3700**

**Physical Plant Radio Room (Non-Emergency)
24hr 845-4311**

**CMP On-Call Supervisor
Cell 777-7014**

**On-Call Veterinarian
24hr 845-7433**

**Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home**

**Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home**

1. If a fire alarm occurs exit the building by the closest exit. Upper floors use stairwells ONLY.
2. CMP personnel should meet at the parking area located directly across from the service vehicle parking area until all are accounted for.

3. If a fire exists:

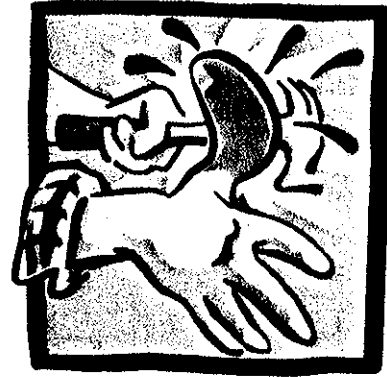
Small fires: If a small fire occurs, use the fire extinguishers and hoses found at various locations throughout the hallways to extinguish the fire. If fire cannot be contained, exit area immediately. Close all doors while exiting the facility.

Large fires: Pull any fire alarm located in the hallways. Close all doors in immediate area of building and exit building immediately. Upper floors use stairwells ONLY.

4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.
5. If the fire presents an animal health related issue, (or you need assistance) contact the on-duty veterinarian.

6. Re-entry to the building is at the discretion of the Fire Dept. and/or the CVM Building Proctor.

PERSONNEL INJURIES/ EMERGENCY SERVICES



All personnel given access to ABSL-3 areas are responsible for maintaining security and reporting security concerns when working in the ABSL-3 areas. **NOTE: In accordance to Title 42, CFR, Part 73, only staff with Department of Justice (DOJ) clearance for access to Select Biological Agents and Toxins may work with projects involving the use of select agents/toxins**

Contact Numbers:

TAMU EMS/Ambulance
Emergency 9-911 Non-Emergency 845-1525

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Scott & White Occupational Medicine
691-3458

St. Joseph Hospital
776-3777

College Station Medical Center
764-5100

ALL FACILITIES

1. When employees are injured on the job or have an illness that requires medical assistance, it is imperative that proper treatment be obtained. It is also important that the employee's supervisor is notified. If the injury/emergency presents an animal health related issue, (or you need veterinary assistance) contact the on-duty veterinarian.
2. For on the job injuries, it is important to complete the procedures described below to ensure documentation is available to provide medical benefits for the injured employee and to comply with applicable reporting requirements of the state and TAMU.
 - The employee sustains an on-the-job injury and informs the supervisor of the incident.
 - The employee's supervisor or designee completes a **First Report of Injury (TWCC-1)** form immediately or as soon as possible.

- The employee's supervisor or the departmental representative responsible for overseeing Workers' Compensation Insurance (WCI) documentation faxes the completed **First Report of Injury (TWCC-1)** form to the WCO at 847-8546.
 - The employee's department retains a copy of the First Report of Injury.
3. All correspondence regarding the injury or illness should be maintained in a confidential medical file in the employee's department and retained in accordance to the Retention Schedule for Texas A&M University System.
 4. For more information regarding the TAMU WCI Program, please visit their website <http://hr.tamu.edu/relations/wrkscomp.html>

ANIMAL EMERGENCIES & EUTHANASIA



All personnel given access to ABSL-3 areas are responsible for maintaining security and reporting security concerns when working in the ABSL-3 areas. **NOTE: In accordance to Title 42, CFR, Part 73, only staff with Department of Justice (DOJ) clearance for access to Select Biological Agents and Toxins may work with projects involving the use of select agents/toxins**

Contact Numbers:

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

ALL FACILITIES

1. Remember for all animal emergencies:
 - Keep yourself and the animal SAFE from harm.
 - SECURE the animal (isolate if it is housed with other animals).
 - SEEK assistance.
2. Observe the animal personally so you can:
 - Render the animal safe and secure
 - Render immediate first aid if needed (short of giving an animal medications or drugs)
 - Answer questions on a first hand basis.
3. Contact the investigator & inform them of the animal health problem (follow procedures outlined in *SOP: A-I. G.4.: Investigator Contact Log Documentation*).
4. Investigator phone numbers can be found on the weekend/holiday notes in the folder on the Main Supervisor's desk.
5. Call the vet and inform them of all animal health problems and how they are being resolved.
NOTE: Be sure you have observed the animal yourself before contacting the duty veterinarian.
6. If a health problem cannot be resolved to your satisfaction with an investigator, contact the duty veterinarian again.

7. Keep the duty Veterinarian informed of all animal health problems and their resolutions

NOTE:

Animals are to be euthanized by CMP animal care staff only following written approval or request of the principal investigator, his/her designated representative, or a CMP veterinarian.

In emergency situations permission from the investigator (document all pertinent information in the Investigator Contact Log as described in SOP A-I.G.4.) or a CMP veterinarian may be given over the phone, but should be followed up in writing in a timely manner.

APPENDIX “D”

Facility Access Log

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	Departmental/ 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)	
							Person	Registered	By	

(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)

APPENDIX “E”

Security and Training Certificate

Texas A&M University
Security and Safety Training Certificate
For
Authorized Persons who have Access to Areas or Facilities and Research Laboratories
Working with Select Agents or Toxins

I. INTRODUCTION

Texas A&M University (University) places great importance on the laboratory safety, including work practices, appropriate containment equipment, well-designed facilities, and administrative controls that reduce the risk of infection or injury for laboratory workers, the contamination of the external environment and the general safety and welfare of the University and the surrounding communities. Due to the heightened concerns about the use of biological, chemical, and radioactive materials for terrorism and criminal activity, the University is taking action to strengthen laboratory and data security to meet the requirement of the CDC and USDA Select Agent Regulations (43 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121). The following procedures are a necessary part of these security policies.

II. VISITOR CLASSIFICATIONS

Select Agent Area Visitor: A person who has not undergone a security assessment by the Department of Justice nor been approved for access to Select Agents pursuant to Title 42, CFR, Part 73. Select Agent Area Visitors must fit within the classes listed below:

- Maintenance Visitor – A University employee or University approved contractor who has been authorized as an accompanied-person with a business need to perform routine cleaning, maintenance or repairs within a secured area or laboratory containing Select Agents or Toxins.
- Delivery Visitor - University employee or University approved contractor who has been authorized as an accompanied-person with a business need to deliver or receive Packages within a secured area or laboratory containing Select Agents or Toxins.
- Research Visitor - University employee, student or University approved collaborator who has been authorized as an accompanied-person with a business need to conduct or witness research, train or tour within a secured area or laboratory containing Select Agents or Toxins.
- General Visitor - University employee or University approved visitor (e.g. CDC/FDA/USDA or other inspectors) who has been authorized as an accompanied-person with a business need within a secured area or laboratory containing Select Agents or Toxins.

III. COMPLIANCE REQUIREMENTS

The information contained within this form meets the requirements for training authorized persons with access to a Select Agent Area within a secured facility at the University. All authorized persons accessing areas with select agents or toxins or visiting facilities with select agents or toxins will adhere to the safety and security standards set forth herein. Non-compliance will result in disciplinary action and potential criminal and/or civil penalties as provided by federal and state law. Authorized Persons shall also have the appropriate training and vaccinations as required by the Principal Investigator's Laboratory Security and Safety Plan for Laboratories Working with Select Agents and Toxins. A copy of the Principal Investigator's Laboratory Security and Safety Plan for Laboratories Working with Select Agents and Toxins is available from the Principal Investigator or the Research Compliance Office (979/458-1467).

IV. CRIMINAL LIABILITY

Under the USA Patriot Act, it is a crime (fines and/or imprisonment) for "restricted persons" to possess (which can mean merely being nearby or having access to) any biological agent or toxin listed as a select agent in Title 42, CFR Part 73 and not exempted therein. A list of Select Agents and Toxins can be located at <http://researchcompliance.tamu.edu/IBC> or by contacting the Research Compliance Office (979/458-1467).

A "Restricted Person" is an individual who

- is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;
- has been convicted in any court or received deferred adjudication for a crime punishable by imprisonment for a term exceeding 1 year;
- is a fugitive from justice;
- is an unlawful user of any controlled substance (as defined by § 102 of the Controlled Substances Act (21 U.S.C. § 802));
- is an alien illegally or unlawfully in the United States;
- has been adjudicated as a mental defective or been committed to any mental institution;
- has been discharged dishonorably from the United States Armed Services; or
- has the status of a non-permanent resident of the U.S. and a citizen of a country determined by the Secretary of State to repeatedly provide support for acts of international terrorism (currently Iran, Iraq, Syria, Cuba, North Korea, Sudan, and Libya)

V. ENTRANCE REGISTRATION

All visitors (both Facility Visitors and Select Agent Area Visitors) must register by signing the Facility Access Log upon entry and exit to the facility. Visitors must provide picture identification with name, organization affiliation, employee id (if University employee), reason for visit, location of visit, escort name, entry time, and exit time.

Select Agent Area Visitors within the secured areas or laboratories containing Select Agents must be accompanied at all times by an Authorized Person. Authorized Persons must maintain visual contact with the Select Agent Area Visitor(s) at all times. At no point, may a Select Agent Area Visitor(s) be left unattended while in secured areas or laboratories containing Select Agents.

VI. INSPECTION

When you request access to any secured facility, you are hereby volunteering to be searched. University security personnel have the right to inspect all items upon entry to and exit from the area where Select Agents and Toxins are stored or used.

VII. REPORTING

Campus Police

To report a loss, crime or emergency on campus, call the University Police Department at 9-911 (emergency) or 845-2345 (non-emergency/off campus) or extension 5-2345 (non-emergency/on campus). This number is answered 24 hours a day by certified telecommunications personnel who maintain two way radio communications with University Police Department officers on duty throughout the campus.

Security breach alarms reported by the access control security system will result in an immediate response by the University Police Department. The University Police Department will respond to any threatening situation or suspicious person reported or observed at the facility.

Environmental Health and Safety

To report accidents, spills, physical hazards or other laboratory issues, call Environmental Health and Safety immediately at 845-2132. After hours, dial 845-4311 and ask for the Environmental Health and Safety Services person on-call.

Research Compliance

Any other events or questions may be directed to the Responsible Official or the Research Compliance Office at 979/458-4167.

VIII. UNIVERISTY EMERGENCY RESPONSE PROCEDURES

Please refer to:

- University Crisis Management Plan: <http://finance.tamu.edu/ehsd/resources/generalsafety/crisismgmt.pdf>

CERTIFICATION

I have read and understood the above policies on admittance as an Authorized Person into a secured area or laboratory containing Select Agents and Toxins. By signing this form, I certify that I do not meet the criteria of a **Restricted Person** as outlined above in Section IV, Criminal Liability.

Additionally, by signing this form, I certify that I have read and understand the laboratory security and emergency policies and procedures for working with *Coxiella burnetii*, *Rickettsia prowazekii*, and *Brucella* spp. in Laboratory Animal Resources and Research Building animal holding rooms 135, 136, 137, 140, 141, and 142 under the direction of James Samuel.

I further certify that I understand the hazards of working with *Coxiella burnetii*, *Rickettsia prowazekii*, and *Brucella* spp.; the indications of infection or intoxication by this agent; the reporting system for potential exposure and accidents; how to seek evaluation and therapy; the standard microbiological practices for this laboratory; the special Biosafety practices required for Biosafety Level 3 work according to the Biosafety in Microbiological and Biomedical Laboratories guidebook; the safety and security standards set forth above; and the standard operating safety and security procedures for this laboratory.

Finally, I certify that any transfer of this select agent will be done in accordance with CDC/USDA regulations; that any theft, loss, or release of this agent will be reported to the University Police Department and the Office of the Vice President for Research; and that the detailed records of information necessary to account for all activities related to this agent will be maintained.

Signature of Person Receiving Training

Date

Printed name of Person Receiving Training

Supervisor/Authorized Person Signature

Date

Printed Name of Authorized Person Providing Training

(Reproduce this document as needed to cover all personnel)

APPENDIX “F”

Standard Operating Procedures Inventory Control

RESPONSIBILITY:

All personnel given access to ABSL-3 areas are responsible for maintaining security and reporting security concerns when working in the ABSL-3 areas. **NOTE: In accordance to Title 42, CFR, Part 73, only staff with Department of Justice (DOJ) clearance for access to Select Biological Agents and Toxins may work with projects involving the use of select agents/toxins.**

GENERAL INFORMATION:

1. All ABSL-3 locations require an individual security access card to enter the ABSL-3 area.
2. CMP Individual access cards and keys required to gain access to the ABSL-3 area and the ABSL-3 area are stored in the Main facility supervisor's office in a double lock box. Individual access cards and keys are signed out/in daily to personnel assigned to each area by an area supervisor. The lock box access log is stored inside on the first door of the double lock box and is checked at the end of the day by an area supervisor to ensure that all cards and keys have been returned.
3. Access cards are only to be used by the individual assigned to that card (never shared).
4. All individuals entering ABSL-3 areas containing select agents must sign-in and out of the area on the proper select agent facility access log.
5. Always make sure each secured door that you enter/exit secures before leaving the area.
6. All individuals escorting non DOJ approved individuals into an ABSL-3 area containing select agents must verify the individuals identification, sign the individual in as a visitor (record ID type and #) and stay with the individual at all times when in the ABSL-3 select agent area.
7. The University Police Department (UPD) must be notified before transporting Select Agents on public roadways so that a police escort can be provided. **Note: many of the roads on campus are considered to be public roadways.**

LARR ABSL-3 Animal Inventory Control Procedures:**Guinea Pig/Rabbit**

Each animal will be individually housed in the ABSL-3 and identified with a CMP generated cage card and USDA number (when applicable). Each animal transferred into the ABSL-3 will be recorded on a log to include CMP cage card number, identification number assigned by the PI and date transferred to the ABSL-3. When animals are euthanized or die, that date will be recorded in the log corresponding with the animal's ID. This log will be kept in the supervisors office. A physical animal census will be taken and recorded daily for each animal room. All animal inventories will be reconciled the first of each month to verify inventory counts are accurate. These counts will be shared with the Primary investigator

Mouse/Rat

A record of the number of animals (with the cage card numbers and number of animals per cage) will be recorded in an animal inventory control log book for each PI, Specie, Select Agent, and AUP. The number of animals in each cage will be recorded on the cage card in the lower left hand corner. Any addition or deletion of animal(s) from that cage will need to be recorded on the cage card by crossing out the previous number and writing the correct number to the right of the previous. The addition/deletion will need to be recorded (along with an explanation of the activity)

on the Animal Inventory Control Log located behind the posted room log. A visual animal census will be taken and recorded daily for each room. The number of animals in each cage will be physically counted and verified against the cage card during each cage change. All animal inventories will be reconciled the first of each month to verify inventory counts are accurate. These counts will be shared with the Primary investigator

Storage of SBAT Infected Animal Carcasses:

SBAT Freezer storage space is provided and will be coordinated by the _____/Main Supervisor. The freezer is kept locked (when not in use) and will only be accessed by trained SBAT approved CMP personnel. Investigators will leave animal carcasses (bagged) in their animal rooms and CMP personnel will remove the carcasses and place them into the SBAT freezer daily. An SBAT freezer inventory log will be in place to record all SBAT carcasses entering the freezer. **Storage of actual agents is not permitted in the _____ facility ABSL-3 area**

ABSL3 Select Agent Inventory Control Log

PI: _____

Select Agent: _____

Room: _____

Initials	Date	Event	(+/-) # of		Total Balance	
			Cages	Animals	#cages	#Animals

Sample

APPENDIX “G”

Agent Access Log

**Document to
be provided
by PI.**

APPENDIX “H”

**Standard Operating Procedures
Shipping, Receiving and Transferring Select
Agents**

**Document to
be provided
by PI.**

SECURITY PLAN:
SELECT BIOLOGICAL AGENTS AND TOXINS
BUILDING ABSL3, ROOMS
TEXAS A&M UNIVERSITY

Dr. Thomas A Ficht
Dr. James E Samuel
Principal Investigators

The Security Plan for this facility has been developed by Dr. Thomas A. Ficht and Dr. James Samuel on July 18, 2007. This Security Plan has been prepared with the intent of being in compliance with the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* and 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73. This plan is based on the conclusions reached in *Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents*, published in *Morbidity and Mortality Weekly Report* (December 6, 2002; 51:RR-19:1-6), which is attached to this plan. This Security Plan is required to be reviewed annually or whenever changes occur.

Richard E. Ewing, Ph.D.
Vice President for Research - Texas A&M University
Responsible Official

Date

ANNUAL REVIEW VERIFICATION	
VERIFICATION DATE	SIGNATURE
/ / 2007	
/ / 2008	
/ / 2009	

Security Plan for Texas A&M University:

Title 42 CFR Part 73 requires that an individual or entity required to register, must develop and implement a written security plan. The security plan must be sufficient to safeguard the Select Agent or toxin against unauthorized access, theft, loss, or release. The plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the Select Agent or toxin.

All DOJ Authorized Persons accessing areas with Select Agents or visiting facilities with Select Agents will adhere to the safety and security standards set forth in this plan so as to ensure that the requirements of Title 42 CFR Part 73 are met. Additionally, all DOJ Authorized Persons will complete the required training and certifications prior to entering areas with Select Agents. Each individual with DOJ authorized access to a Select Agent will be familiar with security and emergency procedures. Their knowledge and understanding will be documented.

All DOJ Authorized Persons must understand and comply with the security procedures. Each individual with access to a Select Agent will adhere to this plan to minimize opportunities for accidental or intentional unauthorized removal of any Select Agent.

This security plan will be reviewed by faculty and laboratory directors at least annually and revised as necessary to ensure that it is adequate for current conditions and consistent with other facility-wide policies and procedures. This could involve a check of keys, locks and alarms.

Drills or exercises will be conducted at least annually to test and evaluate the effectiveness of this security plan. This plan will be reviewed and revised, as necessary, after any drill or exercise and after any incident.

Principal investigators and laboratory supervisors responsible for laboratories and other facilities where select agents are used or stored must adopt these procedures and develop a security plan that is facility-specific. Both safety and security experts should be consulted in the evaluations and development of individual facility-specific recommendations.

Risk Assessment for

Agent-Specific Risk Assessment:

Dr. Thomas Ficht and Dr. James Samuel have reviewed the APHIS/CDC Security Information Document. Using the definitions specified by APHIS/CDC, the overall agent-specific risk for LARR Rooms is Low, Moderate, High, Highest based on Insert rationale for risk assessment.

Threat Assessment:

Dr. Thomas Ficht and Dr. James Samuel have reviewed the APHIS/CDC Security Information Document and considering all the threats listed, the probability of their occurrence is:

Man	Nature	Incident
<input type="checkbox"/> Low	<input type="checkbox"/> Low	<input type="checkbox"/> Low
<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate
<input type="checkbox"/> High	<input type="checkbox"/> High	<input type="checkbox"/> High

The consequences should they occur are:

Man	Nature	Incident
<input type="checkbox"/> Low	<input type="checkbox"/> Low	<input type="checkbox"/> Low
<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate
<input type="checkbox"/> High	<input type="checkbox"/> High	<input type="checkbox"/> High

This risk assessment is based on Insert rationale for risk assessment.

Vulnerability Assessment:

Based on a review of the APHIS/CDC Security Information Document, the security weaknesses and deficiencies at this facility, and the corrective measures considered, the overall vulnerability at the 143 is Low, Moderate, High.

Protective Measures:

Discuss measures that are in place to mitigate the risks, threats, and overall vulnerability

Security Consensus Meeting:

List of relevant personnel (PI, RO, ARO, etc) have met and concluded that based upon the agent, threat, and vulnerability assessments the following security measures are necessary to prevent the theft, loss, and release of select agents and toxins:

List recommended measures

Physical Security:

At Rooms rooms where select agents and toxins are possessed, used, stored or transferred are separate from public access areas.

The physical security systems have been tailored to address site-specific characteristics and requirements, ongoing programs, operational needs, and to achieve acceptable protection levels using current technology. Standard Operating Procedures establishing the following requirements, at minimum, have been included in the **Appendix A**. Safety and security experts must be involve in any evaluations and development of security recommendations.

- Each BSL-3 laboratory shall post entry requirement procedures. All visitors shall follow the facility's entry requirements.
- A background check and/or security risk assessment (SRA) is required before new employees are assigned to the facility or laboratory area. Guests must be escorted or cleared for entry using the same procedures as for regular workers.
- Before entering the laboratories, check the reading of the room pressure monitor. Do not enter the laboratory if the monitor indicates a red light. If the monitor indicates a red light (negative room pressure), the laboratory director must be contacted immediately. Laboratory personnel must verify that the direction of the airflow is going into the BSL-3 laboratory. Read and follow all entry procedures. Biohazard door signs, entry requirements and procedures must be posted.
- Entry into the facility is restricted to DOJ Authorized Personnel. All persons entering the BSL-3 facility must be advised of the potential biohazards and informed of laboratory procedures.
- Keep facility and laboratory doors closed at all times to prevent unauthorized entry. The following procedures will be used to secure the laboratory, room, or area when approved individuals (under HHS 42 CFR part 73.8) under are not present: the facility is secured using individual access cards, the ABSL3 area is secured with individual access cards and cipher locks. Access cards and codes are assigned only individuals who are DOJ approved to work with select agents.
- Proper training of all staff (including students) that uses the BSL3 suite will be provided by the Comparative Medicine Program under the guidance of Dr. Thomas Ficht, Dr. James Samuel, and/or the Office of Research Compliance.
- Select Agents and toxins requiring freezers, refrigerators, cabinets, and other containers where they are stored will be secured against unauthorized access. These storage procedures are outlined in Appendix F. Storage of select agents is not permitted at building
- Laboratories, storage areas, and equipment (e.g. freezers, refrigerators, cabinets, etc.) will be locked when the Select Agents (stocks of biological agents, hazardous chemicals or radioactive materials) are not in direct view of authorized staff (e.g. when located in unattended storage areas).
- Emergency contact signs will be placed on facility and laboratory doors, including 24-hour contact numbers. Emergency contact signs include the names and contact information such as work telephone and alternate telephone numbers of the Principal Investigator, Biosafety Officer, and the person(s) responsible for the building or facility. Also, included are telephone numbers for the University Police

Department and College Station Fire Department. (Emergency contact information is found in the Appendix A.)

Information Systems Control:

The facility will systematically integrate cyber security into management and work practices at all levels so that missions are accomplished while protecting electronic information and electronic information systems. This is to be accomplished through effective integration of cyber security management into all facets of work planning and execution. The overall management of cyber security functions and activities will become an integral part of mission accomplishment. If sensitive electronic data are present in the facility or laboratory, information technology specialists should assess the security of hardware and software products in addition to the security of local area networks. Hard copies of security sensitive records (e.g., inventory records, etc.) will be properly secured and accessed only by individuals with authorized access approval (under HHS 42 CFR part 73.8). Information Services will be used as a resource for data security.

Inventory Control and Records Retention:

The Responsible Official and/or Responsible Official's designee will maintain records created in pursuance to Title 42, CFR, Part 73, Title 7, CFR Part 331 and Title 9, CFR, Part 121 and will implement a system to ensure that such records are accurate and that the authenticity of records may be verified. Records will be maintained for a period of three (3) years in accordance with Title 42, CFR, Part 73, Title 7, CFR Part 331 and Title 9, CFR, Part 121. If the select agent is also registered with USDA, the following will be referenced: "USDA Security Policies and Procedures for Biosafety Level-3 Facilities", <http://www.usda.gov/ocio/directives/DM/DM9610-001.htm>.

At minimum, records should include:

- 1) The name of the agent (scientific and common name and strain where applicable);
- 2) Amount (number of vials or contains inventoried);
- 3) Biosafety Level, agent type;
- 4) Storage location;
- 5) Site of usage (building and room numbers);
- 6) Storage methods and conditions (refrigerator, freezer type, etc.);
- 7) Date of change of status (i.e. removal, change of custody, transfers, etc.);
- 8) Disposition (including shipping) when removed from inventory;
- 9) Method, amount, and date of destruction (when applicable);
- 10) Scientist with contact information (telephone number and address of researcher or diagnostician).

Access to Select Agent inventory will be limited to Dr. Thomas Ficht, Dr. James Samuel, and a designated alternate. Both Dr. Thomas Ficht, Dr. James Samuel, and the designated alternate must be a DOJ Authorized Person. An Authorized Person will then record removal, placement and/or access data into the inventory record in accordance with Title 42, CFR, Part 73, Title 7, CFR Part 331 and Title 9, CFR, Part 121. The Principal Investigator and/or the designated alternate will maintain and document the current and accurate inventory of each Select Agent held on the Agent Verification Log, which shall be secured at all times and viewed only by DOJ approved personnel.

- Any working cultures that become new repository stocks must be added to the inventory. New pathogens (not already in inventory) identified in diagnostic or experimental samples or generated through recombinant technologies must be added to the repository and inventory database.

- Scientists are responsible for the accuracy of databases and laboratory records, which are subject to review by their supervisor, director, and authorized personnel.

Access Control:

- Only DOJ Authorized Persons (cleared by the US Department of Justice as indicated in HHS 42 CFR Part 73.8) will have access to Select Agents. These policies are required for compliance with the HHS/CDC and USDA regulations for Select Agents. All personnel working with select agents and toxins must be approved by the APHIS Administrator or HHS Secretary and must be listed on APHIS/CDC Form 1, Section 4B.
- All visitors shall be escorted in the BSL-3 facility by a DOJ Authorized Person. Visitors must sign in and out in the Facility Access Log. DOJ Authorized Persons must maintain visual contact with the visitor(s) at all times. At no point, may a visitor(s) be left unattended while in secured areas or laboratories containing Select Agents.
- DOJ Authorized Persons will receive laboratory safety and security training when initial DOJ Select Agent access approval is granted; annually thereafter and when new requirements are implemented. Visitors will receive laboratory safety and security training prior to the first entry to a secured area or laboratory containing Select Agents; annually thereafter and when new requirements are implemented. Additionally, Dr. Thomas Ficht and Dr. James Samuel will mentor and assess scientific/lab skills with persons working within their labs on an ongoing basis. All training should be documented on the Security and Safety Training Certificate.
- All other individuals, including maintenance workers and visitors, understand security requirements will be trained and equipped to follow established procedures.
- All DOJ Authorized Persons, as well as workers and new employees, will be known to facility and laboratory personnel.
- All DOJ Authorized Persons approved for access to Select Agents (including students) will wear a visible identification badge that includes, at a minimum, a photograph, the wearer's name, and an expiration date.
- Visitors should be issued an identification badge including their name and an expiration date.
- Visitors will be escorted at all times when in an area where Select Agents are present.
- DOJ Authorized Persons are always required to swipe their ID card when entering and leaving the suite, even if the door has already been opened by another user. DOJ Authorized Persons are also responsible for making sure that non-authorized persons do not enter the laboratory after an authorized person has opened the door with a card key. **SHARING OF CARD ACCESS AND/OR ENTRY CONTROLS BY ANY INDIVIDUAL IS NOT PERMITTED.**
- It is best to use the "buddy system" when working with hazardous materials in a facility or laboratory. However, if it is necessary to work in the facility or laboratory alone during non-routine hours, let someone know where you will be and how long you expect to be in the facility or laboratory. Arrange for someone to check on you at least hourly.

- Access during non-routine work hours should be limited to authorized personnel. Allow individuals not approved for access (HHS 42 CFR Part 73.8) from the HHS Secretary or Administrator to conduct routine cleaning, maintenance, repairs, and other activities not related to Select Agents or toxins only when continually escorted and monitored by approved individuals (Part 73.8). At no point, may a visitor(s) be left unattended while in secured areas or laboratories containing Select Agents.
- Access to BSL 3 labs to those who do not have written authorization to enter the suite is not permitted. Visitors must sign in and out in the lab log book and must be escorted at all times by an authorized individual. DOJ Authorized Persons must maintain visual contact with the visitor(s) at all times. At no point, may a visitor(s) be left unattended while in secured areas or laboratories containing Select Agents. Visitors who are not United States citizens are required to have written authorization before entering labs.
- Maintain a logbook to record entries of all visitors, maintenance workers, repairmen, and others needing one-time or occasional entry into an area where Select Agents are present. The means of identification should include a current valid picture driver's license or state identification card or passport. This information should be documented on the Facility Access Log.
- Access to containers where Select Agents (stocks of biological agents, hazardous chemicals or radioactive materials) are stored is controlled by procedures listed in **Appendix F**. Storage of select agents is not permitted at building.
- Maintain a current list of authorized persons who possess door keys or those who have knowledge regarding the keypad access numbers or the security entry system.
- If an Access Card is lost or compromised, the University Police Department will be notified and the card will be deactivated. If Investigators change room assignments, then the access code for their particular rooms will be changed.

Unauthorized or Suspicious Persons

DOJ Authorized Persons are required to remove all unauthorized and suspicious person in and around the select agent area immediately and report them to the Responsible Official, Alternate Responsible Official, and the University Police Department.

Approach any visitors that appear wandering in the facility or laboratory areas and ask if you can help direct them. Suspicious or unexplained behavior will be reported immediately to the University Police Department (emergency 9-911; non-emergency 845-2345) and Responsible Official or designee as described in the **Incident Response Plan**.

Shipping, Receiving, & Transferring Select Agents:

All shipping, receiving, transfers (internal & external) of Select Agents will meet the provisions set forth in HHS 42 CFR Part 72 and Part 73.14. If the Select Agent is also registered with USDA, reference “USDA Security Policies and Procedures for Biosafety Level-3 Facilities.” Standard Operating Procedures establishing the following requirements, at minimum, are listed below:

Note: *Shipments must be packed by a DOT/IATA trained and certified person. Environmental Health and Safety Department (EHS, 845-2132) will be contacted for assistance before arranging shipments in or out of campus.*

Only persons trained and certified for dangerous goods shipping will pack or ship infectious materials. Certificates of completion of DOT/IATA training must be made available upon request.

Infectious substances affecting humans and animals will be stored in locked freezers. The agents will be packaged for shipment according to DOT/IATA regulations and shipped by freight handlers under supervision of their dangerous goods specialists and under computerized shipping surveillance.

- The Environmental Health & Safety Department (EH&S), with the assistance of the University Police Department (UPD), will inspect all suspicious packages before they are brought into or removed from the area where Select Agents or toxins are used or stored. The recipient or receiving facility should be known to the sender and the sender should make an effort to ensure the materials are shipped to a facility or laboratory equipped to handle those materials safely. Contaminated or possibly contaminated materials should be decontaminated before they leave the facility or laboratory areas. All unexpected or suspicious packages will be inspected by visual or noninvasive techniques before they are brought into, or removed from, the area where Select Agents or toxins are used or stored. Guidelines for recognizing suspicious packages have been provided by the U.S. Postal Service and can be found at: http://www.usps.com/news/2001/press/pr01_1010tips.htm. If unexpected or suspicious Packages are received, then the sender should be contacted to verify that the package is legitimate. If any individual observes suspicious packages being transported out of the laboratory (for example, packages that have an unusual weight or size), then they should immediately notify UPD and wait for an officer to respond.
- All intra-facility transfers or external shipments (send/receive) of Select Agents must be documented and reported to the Responsible Official or designee (contact the Office of Research Compliance, 458-3624, and the Environmental Health and Safety Department, 845-2132). Transfers will remain under the supervision of a DOJ Authorized Person, including chain-of-custody documents and will remain in the possession of the Authorized person in order to safeguard against theft, loss, or release.
- The DOJ authorized person will inspect all packages upon entry to and exit from the area. All packages will be screened (visual and/or x-ray) before being brought into the laboratory area. If a suspicious or unexpected package is delivered to the facility or laboratory, **do not open it**. Contact the University Police Department (emergency 9-911; non-emergency 845-2345).

The following protocol will be used to receive all Select Agents or toxins based in HHS 42 CFR 73.8:

- Dr. Thomas Ficht or Dr. James Samuel will request the receipt of a Select Agent, by completing Section A-Recipient (REQUESTOR) Information of the **Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2)**. *(Electronic copies of the form may be found at: <http://www.selectagents.gov/resources/APHIS-CDC%20Form%202.pdf>).*
- Dr. Thomas Ficht or Dr. James Samuel will inform EH&S of request to receive Select Agents or toxins.
- Dr. Thomas Ficht or Dr. James Samuel will complete all necessary blocks of Section A and submit the completed form to the Office of Research Compliance (ORC) for the signature of the Responsible Official/Alternate Responsible Official (RO/ARO).
- Upon receipt of the **Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2)**, the ORC will confirm that Dr. Thomas Ficht or Dr. James Samuel has the appropriate Institutional Biosafety Committee (IBC) approvals in place and is listed on the University's registration for the Select Agent or toxin.
- When the signature of the RO/ARO has been obtained, the ORC will return the document to Dr. Thomas Ficht or Dr. James Samuel.
- Dr. Thomas Ficht or Dr. James Samuel will send the document to the Sender for them to complete Section B of the form.
- Once the form is complete, it is the responsibility of the Sender (Transferor) to then fax the document to the CDC.
- The CDC will fax an approval to the (RO) of both the Sender and Receiver. The approval will then be forwarded to the ORC.
- Upon receipt, the ORC will contact EH&S, who will contact the transferring (RO) and Principal Investigator to verify shipping date and confirm shipping address.
- EH&S will notify Dr. Thomas Ficht or Dr. James Samuel of shipment arrival and arrange transfer of package to user laboratory.
- Packages will be opened in the laboratory in the presence of EH&S.

The following protocol will be used to send all Select Agents or toxins based in HHS 42 CFR 73.8:

- Dr. Thomas Ficht or Dr. James Samuel will complete Section B- Sender (TRANSFEROR) Information of the **Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2)** upon receipt of form from the Recipient.
- Dr. Thomas Ficht or Dr. James Samuel will send the completed form to the ORC to obtain the RO/ARO signature.
- Dr. Thomas Ficht or Dr. James Samuel will inform EH&S. EH&S and Dr. Thomas Ficht or Dr. James Samuel will coordinate to arrange the shipment of the package. EH&S will contact the transferring RO and Principal Investigator to verify shipping date and confirm shipping address.
- Once the signature has been obtained, the ORC will fax the completed form to the CDC for approval.
- The CDC will fax an approval to the RO of both the Sender and Receiver. The approval will then be forwarded to the ORC.
- Notification of approval will be sent to the ORC, and the ORC will inform Dr. Thomas Ficht or Dr. James Samuel and EH&S of the approval.
- EH&S will assist Dr. Thomas Ficht or Dr. James Samuel with the shipment and arrange transfer of

package to user laboratory.

- EH&S will complete blocks 38-40 of Section D- Shipping Information of the form, and return completed form to the ORC.
- A copy of the Dangerous Goods manifest and air bill is maintained by EH&S.
- EHS/Principal Investigator notifies the receiving institution that the package has been shipped.

EHS and laboratory staff will validate contents of shipment against EA-101 form.

- APHIS/CDC Form 2 is dated (Section D) and signed by EH&S staff to confirm volume and number of vials shipped against the inventory.
- A copy of the completed APHIS/CDC Form 2 is faxed to CDC Select Agent Program and to the transferring RO and Principal Investigator.
- Destruction of Select Agent is recorded on the APHIS/CDC Form 2 and is faxed to CDC.
- Hardcopy of file is retained in archive files for a minimum of 3 years.

Incident Reporting and Breaches in Security:

Standard Operating Procedures regarding this particular area have been developed and are located in the **Incident Response Plan** to include:

The University Police Department, Environmental Health and Safety, and the Responsible Official or designee will be notified in the event of:

- 1) Any loss or compromise of keys, passwords, combinations, etc.;
 - 2) Any suspicious persons or activities;
 - 3) Suspicious packages;
 - 4) Any loss or theft of Select Agents or toxins;
 - 5) Missing chemicals;
 - 6) Any release of Select Agents or toxins;
 - 7) Any sign that inventory and use records of Select Agents or toxins have been altered or otherwise compromised;
 - 8) Cyber security breach;
 - 9) Non-biological incident such as violence against person;
 - 10) Unusual or threatening phone calls;
 - 11) Undocumented visitors;
 - 12) Severe weather and natural disasters.
- Report suspicious or unexplained behavior immediately to the University Police Department (emergency 9-911; non-emergency 845-2345) and the Responsible Official.
 - If possible, program speed dial of emergency contacts (e.g., 9-911, facility or laboratory director, University Police 845-2345, etc.) on the phones in the facility or laboratory.

Incident Response:

The emergency response plan must be coordinated with any entity-wide plans. The plan must address such events as bomb threats, severe weather (hurricanes, floods), earthquakes, power outages, and other natural disasters or emergencies.

Reference: http://finance.tamu.edu/ehsd/resources/gensafety/Emergency_Ref.asp.

Involve facility administrators, laboratory directors, principal investigators, laboratory workers, facility safety office, and facility law enforcement officials in emergency planning. Control of access to facility and laboratory areas can make an emergency response more difficult.

- Police, fire, and other emergency responders should be informed as to the types of biological materials that are in use in the laboratory areas and special access control devices that are in use (e.g. card-key, etc.).
- Police, fire, and other emergency responders should assist in planning their responses to emergencies in the laboratory areas.
- The emergency response plan includes provisions for immediate notification of (and response by) laboratory directors, laboratory workers, safety office personnel, or other knowledgeable individuals when an emergency occurs.

The emergency response plan must address the following:

- 1) The hazards associated with the use of the Select Agents and toxins;
- 2) Any hazards associated with response actions that could lead to a spread of a Select Agent or toxin;
- 3) Planning and coordination with outside parties;
- 4) Personnel roles, lines of authority, training, and communication;
- 5) Emergency recognition and prevention;
- 6) Safe distances and places of refuge;
- 7) Site security and control;
- 8) Evacuation routes and procedures;
- 9) Decontamination;
- 10) Personal protective and emergency equipment; and
- 11) Special procedures needed to address the hazards of specific agents.

In the event that a Select Agent must be relocated, Dr. Thomas Ficht or Dr. James Samuel will relocate agents to their other BSL3 approved areas. In the event of an emergency, with the approval of CDC and assistance from EHS, the agent will be moved using proper transport/shipping requirements.

Understanding and Complying with Security Procedures

All persons authorized to work with select agents and toxins shall review and be familiar with this site-specific security plan.

CMP Meeting/Training Attendance Record

Event: PAPR Air-Mate HEPA filter Use

Date: 2/28/2007

Event Trainer: Chris Knowlton

Name (Print)	UIN
Allison R. Ficht	
Xicheng Ding	
Thomas Ficht	
SANGEETA KHARE	
Elihu Aranday	
JOCCELYNE MAYOR (BRAY)	
LEO M. NJONGMETA	
Wattika Mwangi	
Michael Reams	
Travis Kincannon	
Lionel GALT	
David B. Johnson	
TRAM PHAM	
Deedee Hartmanguler	
Freddie Wilhelm	

ⓐ 3-9-07

ⓐ 3-9-07

ⓐ 4-13-07

ⓐ 4-13-07

ⓐ 4-13-07

ⓐ 6-4-07

ⓐ 6-4-07

ⓐ 6-4-07

ⓐ 6-4-07

6/28/07

7-2-07

7-2-07

Laboratory
Mechanics
Services

TRAINING RECORD

EVENT TITLE: (PAPR) Air-Mate HEPA filter USE

EVENT TRAINER: Ken Gillenwater

EVENT DATE: 5/16/06

NAME: (Please Print)

UIN #

Toshiko Yamamoto

Christine McFarland

Justin Dominguez

Hyosun Cho

Dana McMurray

Lan Ly

Ammikutty Jeevan

SIANA BONUA

Kirti Sawant

SABURO YAMAMOTO

Guest

Rebecca Coulter

Joseph Kwanglok Hsu

Jianwu Pei

ALFREDO WONG - GONZALEZ

Melissa Kahl-McDonagh

Angela Owen

8

KG 5/18/06

KG 5/18/06

6/6/06

6/6/06

6/6/06

6/6/06

8/31/06

9/12/06

2-21-07

2-21-07

2/21/07

2/21/07

5/18/06

3/1-06

4/12/06

2/1/07

Protocols provided

2004-153 Ficht

2006-249 Samuel

2006-27 Ficht

2007-6 Samuel

2005-79 Ficht

2006-23 Samuel

2007-66 Adams

2006-11 Ficht

IBC 2007008 Ficht

IBC 2003213 Samuel

minimum of 20 minutes fan operation to establish laminar flow conditions.)

- 2.3 Take off the outer pair of gloves and discard in waste in bio-safety cabinet.
- 2.4 Take off the Tyvek sleeves and discard in waste in bio-safety cabinet.
- 2.5 Take off the lab coat.
- 2.6 Disinfect the inner pair of gloves.
- 2.7 Take off the facemask.

9.3 In the Changing Rooms

- 1.2 Remove the inner pair of latex gloves.
- 1.3 Remove scrub suit
- 1.4 Hands will be washed in with foam antibacterial soap
- 1.5 Hands will then be washed with soap and water in Rm 414 after exit

10. Decontamination Procedures

10.1 All waste material leaving the BSL3 facility must first be autoclaved for at least an hour except for the liquids decontaminated with bleach as noted above.

10.2 A double-door autoclave is located in the laboratory next to the anteroom.

10.3 Do not autoclave materials containing chlorine bleach, volatile chemicals or radioactive materials.

10.4 Monthly Wex-cide 128 (1 gal) poured down floor drains to ensure periodic decontamination. Log of activity maintained by facilities manager.

11. Special Protocols: AEROSOL CHALLENGES

11.1 Intra-entity transfer forms must be filled out prior to any transfer between buildings.

11.2 *Coxiella* suspensions used for inoculations are prepared and loaded into conical tubes in rooms of building in the biological safety cabinets.

11.3 Inoculum containing viable organisms is transported from the facility in generalized "triple" packaging (primary receptacle, water tight secondary packaging, durable outer packaging) required for a biological agent of human disease.

3.1 The outer packaging is left in the locker room and the inner packaging is brought into room

- 3.2 This packaging requires the "Infectious Substance" label on the outside of the package. This packaging must be certified to meet rigorous performance tests as outlined in the DOT, USPS, PHS, and IATA regulations.
 - 3.3 Such samples are transported through the men's or women's locker rooms at the CMP facility under constant supervision from approved persons.
- 11.4 At the CMP facility, personnel will change from street clothes into appropriate wardrobe
- 4.1 In the outer locker room, street clothes are removed and scrubs put on.
 - 4.2 In the inner changing room, two pairs of gloves, facemask, tyvek suits and powered air-purifying respirators (PAPRs) are put on before entry into the main hallway.
- 11.5 At the CMP facility, animals will be transported to _____ in microisolater cages.
- 5.1 Make certain that the room airflow indicator is working and that the air is flowing from outside the room to inside at a safe level.
- 11.6 Madison Chamber preparation and use (building _____)
- 6.1 Plug cord from control box into the wall socket. Check the light on the control box. Connect the source of compressed air (e.g., building; tank) through the small flow meter to the nebulizer. Make sure that the compressed air regulator reads at least 30 psig. When the main switch is on, the vacuum pump, fans, and timer should be operating.
 - 6.2 Carefully unscrew the glass jar from the nebulizer and place about 10 ml of challenge suspension in the jar or 2ml in a precious fluid chamber. Nebulizer jars are filled with inoculum under the safety cabinet. Attach the jar to the nebulizer unit and adjust the vertical stainless steel tube so that the lower (intake) end is about half an inch below the level of fluid in the jar.
 - 6.3 Load the animal basket into the chamber, being careful to center it so that it doesn't touch the fan blades. Close the door and turn on the main switch, activating the vacuum pump, fans, and timer.
 - 6.4 Check the main (room) air flow meter (the larger meter on the right). The center of the float (ball) should run about "21".
 - 6.5 Turn on the compressed air and simultaneously start the timer. The air flow rate through the compressed air flow meter should read about 5 psig.
Check visually to be certain that the challenge inoculum is being

nebulized.

6.6 After exactly 300 seconds (5 min), the compressed air supply to the nebulizer should be shut off and the nebulization process will stop. Flow through the small meter will drop to zero, and visual inspection of the nebulizer will show no activity. The timer should continue to run.

6.7 After an additional 600 seconds (10 min) or 900 seconds (15 min)

total on the timer, turn off the main switch, stopping the vacuum pump, fans, and timer.

6.8 Open the chamber door and remove the animal basket.

9.1 Personnel handling the animals need to take extreme care and spray their gloves with Wexcide. After the transfer is complete, the outer pair of gloves are removed and immediately replaced.

6.9 Remove the glass nebulizer jar, and decant the challenge suspension

back into the original tube for transfer back to the originating lab.

The jar is decontaminated with bleach and is either reloaded with a different strain or thoroughly decontaminated and loaded with 70% ethanol for decontamination cycle.

11.7 Post run decontamination

7.1 Place each individual housing cage back in the rack, then place the rack back into the chamber. Seal chamber door using the attached latching system.

7.2 Place 15ml of 70% ethanol into the nebulizer reservoir, and re-attach the jar to the chamber and run the chamber for 15 min.

7.3 Once the cycle has been completed (green light turns on), open the chamber, and spray all external surfaces of the cage, rack and internal housing cages with Wexcide, covering all surfaces.

7.4 The cages/ rack should then be extensively rinsed out with water to remove Wexcide residue, wipe dry.

7.5 Spray internal surfaces of the chamber with Wexcide and soak for 10 minutes. Wipe dry, and spray with 70% ethanol to remove disinfectant residue. **WARNING: Be sure to spray ethanol after the Wexcide treatment as the residue may damage the chamber.**

7.6 All personnel decontaminate each other in room using disinfectant prior to leaving the lab, wexcide, diluted according to manufacturer's instructions are used for this purpose. Animal cages are similarly disinfected as is the rack that may be used to transport them into room

7.7 The animal rack is transported back to the animal holding room. The tyvek suits are removed in the hall outside room and placed in approved containers to be autoclaved by CMP personnel.

7.8 Full-face respirators are removed last and surface decontaminated with 70% ethanol.

11.8 The inoculums and extracted tissues are returned to building in approved containers

8.1 Animals may either be sacrificed at CMP (building or moved back to animal holding facilities by CMP personnel.

2.1 Animal carcasses are autoclaved and sent to the incinerator by CMP personnel.

8.3 After thorough decontamination of container containing inoculums, containers are placed inside approved durable (leak-proof) transport container that is then closed, sealed, and disinfected as well.

8.4 Scrubs are removed in inner changing rooms and placed in containers to be autoclaved by CMP personnel. Facemasks and gloves are thrown away.

8.5 All personnel shower before entering the outer changing room.

8.6 Street clothes and personal belongings are collected before exiting BL-3 suite.

(Browder Copy)

July 27, 2007

TAMU BLD ---

Mechanical
email

Richard Henkel	CDC/DSAT	BEE3@CDC.GOV
DWAYNE LASKY	CDC/OHS	RDL1@CDC.GOV
DAVID CALHOON	PHYSICAL PLANT AM-5	DCALHOON@PPFSH.TAMU.EDU
Calvin Schoonover	MAN-Physical Plant	CSchoonover@tamu.edu
DAVID L. CARLTON	TAMU/CALP	dearhton@tamu.edu
MIKE GARON	PHYSICAL PLANT	MGARON@TAMU.EDU
BO RICHARDS	TAMU/CMP	brichards@TAMU.EDU
Eric Brewer	Physical Plant	ebrewer@ppqu.tamu.edu
Paul Watson	PHPL	pwatson@tamu.edu
GABRIELLE KAPP	CMP	gkapp@tamu.edu
Stephen Starle	CMP	sstarle@tamu.edu
Olivia Ash		

Employee Work Area Table

Revised 7/23/2007

Main and Ancillary

Support

Kapp, Gabby M21366	Pro. Manager (5/9 - 8/7/06)	Noey, Christy M27341	LAT (1/19-11/20/00)	Sterle, Stephen M09520	ARS (2/7 - 5/14/98)
Gillenwater, Ken M28802	ARS (5/4 - 7/2/01)	Blazek, Frank M23818	ALAT (11/30 - 4/14/97)	Lopez, Mary M23989	LATG (2/27 - 4/25/05)
Abatie, Kim M28960	LATG (9/13 - 11/26/01)	Korthus, Kim M30542	LAC (9/14 - 4/5/07)	Singletonary, Nancy M29440	LAT (7/26-7/23/01)
Knox, Sean M23950	LATG (9/29 - 6/19/97)	Haywood, James M29982	LAC (4/18 - 5/19/05)	Vacant M29378	LAT
Holster, Scot M23776	LATG (6/15 - 3/1/05)	Vacant M33054	LAC	Payne, Sarah M28915	LAC (6/1/2007)
Sargent, Deborah M03089	ALAT (9/5-1/22/02)	Wolter, Jacob M32982	LAC (10/25 - 2/9/06)	Vacant M27146	ALAT

Knowlton, Chris M23956	LATG (1/13 - 5/26/05)	Facilities		Hejl, Kristen M29940	LAC (7/20/07 - 3/26)
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Draper, Gordon M28954	ALAT (9/9 - 11/16/00)	Carlton, Dave M14317	Fac. Coordinator (2/29 - 2/15/93)		
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Brown, Stacie M28956	ALAT (3/1 - 10/18/04)	Richards, William M23770	Lab Mech II (10/4 - 10/13/94)		Gem
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Vacant M21501	ALAT	Wilhelm, Freddie M28282	Lab Mech I (7/3-1/24/00)	Galaviz, Stacy M26074	CMP AHSC (4/11 - /18/00)
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Shawhan, Zac M28917	LAC (7/20/07 - 7/18)	Bohn, Diane M32971	LAC (4/7 - 2/9/2006)	Vacant M32862	Res Spec
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Cowan, Tressie M29027	LAC (8/5 - 9/18/06)	Hartmangruber, Gerald M28920	LAC (2/18 - 4/19/05)	Kovar, Jean M32816	Res Assoc (6/14 - 10/17/05)
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Alanis, Sergio M33053	LAC (1/18 - 2/8/07)	Training & Lab/Dr. Gresham		Vacant M32784	Res Assoc
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Lopez, Raymond M29969	LAC (3/21 - 3/23/07)	VACANT M04529	ARS	Bridges, Brooke M33812	Tech II (5/27 - 2/19/07)
--------------------------	-------------------------	------------------	-----	---------------------------	-----------------------------

Vacant LAT M21500		Byrd, Ryan M32186	CMP TSS (10/20 - 3/24/05)	Dr. Callicott	Asst Lecturer (2/26)
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		Vacant M28953	LATG	Dr. Lamon	Asst Lecturer
--	--	------------------	------	-----------	---------------

McKown, Lisa M09638	Admin Asst (11/15 - 10/24/06)	Taylor, Andrea M26344	TSS (9/8 - 11/14/00)	Dr. Suvila	Asst Lecturer
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King, Ruby M17401	Acct Asst II (11/5 - 7/9/98)	Vacant M33028	CMP TT		
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Sands, Anita M06464	Sr. Off Asst (8/12 - 2/20/06)	Pierson, Krystle M33927	CMP ATSS (11/16 - 5/16/2007)		
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Eliminated /2 years to reactivate

Administration



full copy to
Powell + Tate

TEXAS A&M UNIVERSITY

**Office of the Vice President for Research
Texas A&M University
1186TAMU
College Station, Texas 77843-1186**

Telephone: (979) 458-1467

Facsimile: (979) 862-3176

Date: July 23, 2007

To: CMP - Betsy Browder/Melanie Ihrig

Facsimile: 845-6706

From: Tiffany

Per Olivia, I am faxing Dr. Samuel's approved IBC application/permit (2003213-Samuel).

His new application is still pending IBC approval.

Thanks!

Pages Sent (Including Cover Page): 43

**SHOULD YOU EXPERIENCE ANY DIFFICULTIES IN RECEIVING THIS
FACSIMILE, PLEASE CALL THE OFFICE AT (979) 458-1467**

The information contained in this facsimile message is legally privileged and confidential information intended only for the use of the individual or entity named above. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution, or copy of this telecopy is strictly prohibited. If you have received this telecopy in error, please immediately notify us by telephone. Thank you.

Current/New Incident Response Plans Followed by Crisis Management Plan for Texas A&M

_____ Adams/Fich'

_____ Adams/Ficht

_____ Ficht /Ihrig/Samuels

_____ Samuels -

File in Numerical Order (building number) with the supporting documentation.

Place a divider (yellow sheet) between each Plan

INCIDENT RESPONSE PLAN

Building 3SL3 Suite

PI – Ficht

PI - Adams

Texas A&M University, College Station, TX 77843

to ensure compliance with

42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

- 1.1 General. This is the incident response plan for the possession and use of *Brucella abortus*, *Brucella suis* and *Brucella melitensis* at Texas A&M University main campus (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121. This plan covers the use of these select agents when used in buildings 3.
- 1.2. This plan describes the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

- 2.1 Principal Investigator (PI). The Principal Investigator, Dr. Thomas A. Ficht, has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to Dr. Ficht. The PI is responsible for ensuring all incidents regarding theft, loss or release are immediately reported to the proper institutional officials. This document outlines response actions concerning any theft, loss, or release from select biological agents and toxins (SBAT) facilities, including illness of personnel or visitors in SBAT facilities. Certain actions outlined below are performed in parallel rather than sequentially (see attached flowchart).
- 2.2 All lab personnel (including the PI) are responsible for immediately reporting an incident to the University Police Department (UPD) for theft or loss or to the Institutional Biosafety Officer (BSO) for release (including occupational exposure).
- 2.3 UPD – Responsible for immediately contacting the Alternate Responsible Official (ARO) and beginning an investigation of the incident. A written investigation report will be submitted to the Institutional Biosafety Committee (IBC), the PI and the ARO within 5 days of the incident. UPD will also work with the PI to conduct a security assessment following any incident involving loss or theft.
- 2.3 BSO - Responsible for immediately contacting the Alternate Responsible Official and beginning an investigation of the incident. A written investigation report will be submitted to the IBC, the PI and the ARO within 5 days of the incident. The BSO will also work with the PI to conduct a safety assessment following any incident involving a release (including occupational exposure).
- 2.4 ARO - Responsible for immediately contacting the Responsible Official, CDC, NIH (if rDNA) and other key institutional contacts regarding the incident. The ARO will work with the BSO, UPD and the PI to insure that the written report is correct and that the report will be submitted to CDC, NIH (if rDNA) and other key institutional contacts.

- 2.5 Responsible Official – Is responsible for compliance to the Select Agent regulations and insuring requirements (registration, investigations, etc) are properly carried out.
- 2.6 Contact information is found on the Emergency contact list. The list is attached to this document and is posted throughout the lab.
- 2.7 Annual Program Review. The Responsible Official or Alternate Responsible Official will audit the incident response program on an annual basis. This review will include drills and exercises to ensure the effectiveness of the incident response plan. Based on the outcome of drills, exercises or reported incidents, this incident response plan will be reviewed and updated as necessary.

3. Description of Work

This plan covers all work being performed at TAMU. Each lab will be responsible for providing information specific to the work being performed as follows:

Lab	Work description	Unique features of Agent	Biological Use Authorization	Biosafety Level
	Storage of <i>Brucella abortus</i> , <i>B. suis</i> , <i>B. melintensis</i>	Locked freezer	0741	3
	Work with <i>Brucella abortus</i> , <i>B. suis</i> , <i>B. melintensis</i>	BSC	0741	3
	Storage of <i>Brucella</i> -infected animal carcasses	Locked freezer	0741	3
	Inoculation of mice with <i>Brucella</i> spp. And necropsy of infected animals	BSC	0741	3

Additional information concerning the laboratories and the select agent use is contained in the facility's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or Environmental Health and Safety Office.

4. Response to theft:

- 4.1 Determination of Loss or Theft – The following are examples of events that may be considered a loss or theft. Possible loss or theft of the select agent will be reported initially to the Principal Investigator if any of the following have occurred:
 - 4.1.1 The lock on the Select Agent storage area has been found open or appears to have been tampered with;
 - 4.1.2 Evidence of forced entry into the laboratory or storage areas has been found;
 - 4.1.3 A discrepancy in the Select Agent inventory that can not be reconciled;
 - 4.1.4 An employee reports cultures or samples missing;
 - 4.1.5 A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2;
 - 4.1.6 An infected animal is missing from its microisolator cage.

4.2 Report/Investigation Process:

Theft (unauthorized removal) or **Loss** (failure to account for) a select agent or toxin

- 4.2.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected theft or loss of SBATS to

UPD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345). Based on circumstances, UPD will notify EHSD.

If the release is discovered and UPD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the person shall then notify the LD/PI.

After notification to UPD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact ORC.

- 4.2.1.1 Upon notification of discovery of a theft or loss, UPD will immediately notify ORC.
- 4.2.1.2 Upon notification from UPD, ORC will immediately notify the Responsible Official (RO) and Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, and UPD.
- 4.2.1.3 UPD (and ESHD, based on circumstances) will immediately investigate the incident. The investigation will include coordination with the LD/PI and others approved with access or visiting SBAT facilities. UPD will submit a written report to ORC within 5 days of being notified about the discovery of the theft or loss. If the investigation provides evidence that a theft or loss did not occur, circumstances will be documented in UPD's investigation report.
- 4.2.1.4 Based on the UPD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss or Release of Select Agents and Toxins) with CDC. ORC will maintain an official copy of information submitted to CDC and will provide a copy of the submission to the RO, UPD/EHSD, and LD/PI.
- 4.2.1.5 UPD will notify the appropriate Federal, State, or local law enforcement agencies.
- 4.2.1.6 The LD/PI will ensure notification to the funding agency
- 4.2.2 A risk assessment will be conducted immediately upon discovery of a loss or theft. The risk assessment will be a part of the investigation report.
 - 4.2.2.1 In addition to the investigation, upon notification of a theft or loss, UPD (with input from EHSD and the LD/PI) will conduct a risk assessment to determine if the laboratory is operating in a safe and secure manner and to attempt to determine the cause of the theft. This risk assessment shall include, but not be limited to a comprehensive laboratory survey, review of access logs, review of inventory records, and verification that all equipment is operating within normal parameters (e. g. biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of theft will also be reviewed and modified, as warranted. If deficiencies in safe and secure practices are discovered, all work in the laboratory will cease until corrective actions have been taken.

- 4.1.2.2 If deemed necessary, the EHSD/UPD will contact Biosafety Program Coordinator to convene a special meeting of the Institutional BioSafety Committee (IBC).
- 4.1.2.3 Documentation of the risk assessment will be maintained by UPD with a copy sent to the LD/PI, EHSD and ORC.
- 4.1.2.4 Security Risk Assessments will be completed by UPD, with input from the LD/PI (and EHSD, based on circumstances). The results of the risk assessment and findings, including any requirements for post theft procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI, EHSD, and ORC.
- 4.1.2.5 The ORC will contact CDC, and if needed, a copy of the assessment will be submitted. ORC will also update the RO.

- 4.2.3 UPD will establish and maintain a specific file for each theft or loss incident, with all pertinent information.
- 4.2.4 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected loss or theft to UPD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

5. Investigation

- 5.1 The Investigation Committee for all releases will be headed by the EHSD's Institutional Biosafety Officer (BSO) with input from UPD and the PI. UPD will lead investigations involving theft or loss, with input from the BSO and PI.
 - 5.1.1 The BSO/UPD will investigate the event as quickly as possible, but no later than 24 hours of the initial report or the incident.
 - 5.1.2 The investigation should include a review of all materials related to the research, including access logs, inventory logs, laboratory notes and laboratory plans (security, safety and incident response)
 - 5.1.3 Once the investigation is complete, the BSO or UPD will submit an investigation report to the IBB and RO.
 - 5.1.4 Once the Committee has determined the response and informed the RO and IBC (through the Office of Research Compliance), the IBC will review the report and make a recommendation to the RO of any additional actions that they believe are needed.
 - 5.1.5 After the RO has approved of the recommended actions, the PI will receive a written response from the IBC.

6. Reporting

- 6.1 All incident reports are included in the IBC agenda minutes for review by the full board at the next convened meeting. Serious events should be specifically presented to the IBC by the BSO/UPD or IBC Chair at the next convened meeting.
 - 6.1.1 The investigation report, at a minimum, shall include the following information:
 - 6.1.1.1 A detailed description of the incident.
 - 6.1.1.2 A list of all personnel involved in the incident.
 - 6.1.1.3 A description of what occurred and what has or needs to be done to prevent any future incident.
 - 6.1.1.4 An assessment of the safety or security risk of continuing the research.

6.1.1.5 A recommendation of any changes that need to be made to the plans (safety, security or incident response), medical surveillance or laboratory procedures to reduce the risk of a reoccurrence.

6.1.1.6 A recommendation for training, if needed.

6.1.2 Incidents involving SBAT will be immediately reported to the CDC with a written report (Form 3) submitted within seven (7) days.

6.1.3 Events involving rDNA must be reported to the NIH immediately in writing but no later than 30 days of the incident.

7. **Release of a Select Agent or Toxin.**

Examples of a possible release (including occupational exposures of the agent or toxin include but are not limited to the following:

7.1 A package containing the Select Agent or toxin that has been received, which has been damaged in transit, such that the primary containment vessel appears to have been compromised;

7.2 Simultaneous complete power failure of the Biosafety cabinet and loss of negative pressure in the BSL-3 suite during work in the Biosafety cabinet with open cultures;

7.3 Simultaneous spill of cultures outside the Biosafety cabinet and failure of negative pressure in the Biosafety Level 3 suite. In case of a spill, a spill kit containing absorbent material and disinfectant will be located in a designated lab for each Principal Investigator;

7.3.1 Personnel are advised to immediately leave the lab after removing any contaminated clothing and to return in Tyvek suits with Powered Air Purifying Respirator (PAPR) after the air has been scrubbed clean by air handlers (approx. one hour).

7.4 In case release of the Select Agent or toxin outside the BSL-3 laboratory is suspected, the Principal Investigator will notify the BSO and ARO as well as the Responsible Official, and the building manager.

7.5 Exposure of laboratory personnel to cultures. The following incidents may result in unintentional exposure to the Select Agent that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to BSO who will immediately contact the Scott & White Occupational Health office, where they will be evaluated for possible post-exposure prophylaxis. The exposure will be reported by the Principal Investigator to the BSO who reports immediately to the ARO, who will notify CDC of the exposure. The following are examples of unintentional exposure:

7.5.1 A spill of live culture outside the Biosafety cabinet;

7.5.2 Failure of the Biosafety cabinet during work with *Brucella*;

7.5.3 Needle stick or cut with sharps contaminated with *Brucella*;

7.5.4 If a bite from a *Brucella*-infected animal penetrates the double gloves and breaks the skin;

7.5.5 A centrifuge accident that results in aerosolization of *Brucella*.

8. **Process of reporting and investigating a Release:**

Release – Occupational exposure (clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been release outside of the primary bio-containment barrier), or release of an agent or toxin outside of the primary barriers of the biocontainment area.

- 8.1 All individuals approved for access or visiting SBAT facilities must upon discovery immediately report any actual or suspected release to the BSO of the Environment Health and Safety Department (EHSD). Based on circumstances, EHSD will notify the University Police Department (UPD). During normal business hours, call EHSD at 845-2132. If it is outside of normal business hours, call UPD who will notify EHSD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345).

If the release is discovered and the BSO is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the individual must then notify the LD/PI.

After notification to the BSO by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact the Office of Research Compliance (ORC).

- 8.1.1 Upon notification of discovery of a release, EHSD will immediately notify Scott & White Occupational Health office and ORC.
- 8.1.2 Upon notification from EHSD, ORC will immediately notify the ARO, the RO and the Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, EHSD, and UPD.
- 8.1.3 EHSD (and UPD, based on circumstances) will immediately investigate the incident. The investigation will include the coordination with the LD/PI and others approved with access or visiting SBAT facilities. EHSD will submit a written report to ORC within 5 days of being notified about discovery of the release. If the investigation provides evidence that a release did not occur, circumstances will be documented in EHSD's investigation report.
- 8.1.4 Based on the EHSD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss, or Release of Select Agents and Toxins) with the CDC within seven calendar days of the discovery of the release. ORC will maintain an official copy of information submitted to the CDC and will provide a copy of the submission to the RO, EHSD, and LD/PI.
- 8.1.5 EHSD will obtain confirmation from health care providers that reports to other state or federal health agencies have been submitted. The LD/PI will ensure notification to the funding agency.
- 8.2 A risk assessment will be conducted immediately upon discovery regarding any release.
- 8.2.1 In addition to the investigation, upon notification of a release, EHSD (under the direction of the Biological Safety Officer (BSO)) will conduct a risk assessment to determine if the laboratory is operating in a safe manner and attempt to determine the cause or most likely route of the release. This risk assessment shall include but not be limited to a comprehensive laboratory survey, review of access logs to determine potential occupational exposures, review of inventory records, and verification that all equipment is operating within normal parameters (e.g., biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of the release will also be reviewed by EHSD and modified, as warranted, in consultation with the LD/PI. If deficiencies in safe practices are discovered, all work in the laboratory will cease until corrective actions have been taken.

- 8.2.2 If deemed necessary based on the risk assessment, the BSO will contact ORC to convene a special meeting of the Institutional BioSafety Committee.
- 8.2.3 Documentation of the risk assessment will be maintained by EHSD with a copy sent to the LD/PI and the ORC.
- 8.2.4 Risk assessments will be completed with input from the LD/PI. The results of the risk assessment and findings, including any requirements for post decontamination procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI and ORC.
- 8.2.5 ORC will contact CDC, and if needed, a copy of the risk assessment will be submitted. ORC will also update the RO.
- 8.3 The following additional steps will also be taken immediately upon discovery regarding an actual or suspected occupational exposure:
 - 8.3.1 EHSD will direct the LD/PI to notify laboratory personnel and visitors that a potential exposure has occurred and refer them to Scott & White Occupational Health for consultation. EHSD will obtain access logs and other information to determine a complete list of potentially exposed personnel. EHSD will then follow-up with potentially exposed personnel to ensure notification.
 - 8.3.2 Individuals will be encouraged to contact Occupational Health at Scott & White Clinic, or to immediately identify to medical personnel, the agent they were potentially exposed to if treatment is sought. Scott & White Occupational Health Clinic or the attending physician will test for the organism (e. g. *Brucella* species), and begin prophylaxis as deemed appropriate by the attending physician.
 - 8.3.3 If an occupational exposure is confirmed through appropriate medical tests or as determined by a physician, all personnel and potentially exposed individuals will be immediately referred to Scott & White for screening, testing, or preventive prophylaxis as determined by the attending physician. If personnel or visitors are at remote locations (other university facilities, traveling), they should immediately report to a physician of choice and explain that a positive occupational exposure to a specific organism has occurred and specific treatment or screening is desired. Personal physicians should be encouraged to contact either EHSD or Scott and White Occupational Health if they have any questions.
 - 8.3.4 EHSD, in consultation with Scott & White, will perform periodic follow-up with the group of exposed or potentially exposed personnel for a period of time as appropriate for the organism.
- 8.4 EHSD will establish and maintain a specific file for each release incident, with all pertinent information.
- 8.5 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected release to EHSD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

9. Security Breach:

A security breach will be determined to have occurred if any of the following are observed:

- 9.1 The access control system has failed, leaving the BSL-3 suite accessible to unauthorized persons;
- 9.2 An unauthorized person is observed unaccompanied in the BSL-3 suite;
- 9.3 A lost or stolen card was used to access the BSL-3 suite;
- 9.4 An unauthorized person has accessed the computer used to control entry to the BSL-3 suite;
- 9.5 An unexpected or suspicious package arrives in the laboratory.

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the UPD and the ARO of the security breach and take steps to correct the problem. Corrective procedures will be secured immediately, but no later than 24 hours; an inventory will be performed of all samples and animals in the laboratory and in Select Agent storage. Any missing Select Agent samples or animals will be reported to ARO, RO and CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator, the ARO and the UPD will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

10. Severe weather or natural disasters.

The most likely occurrences in this area are severe thunderstorms, floods or tornadoes.

- 10.1 If severe weather (thunderstorms or flooding) is predicted, experiments with Select Agents should be suspended until the severe weather has passed to avoid power outages during the work. All samples should be secured inside the locked -80°C freezer or the locked +4°C storage.
- 10.2 If an earthquake is felt, workers should immediately leave the suite-if possible, shedding gloves and lab coat on the way out of the BSL-3 suite. Cleanup, if necessary, can be performed once it is safe to re-enter the building.
- 10.3 Power to the BSL-3 suite may be affected if the emergency generator is flooded. In this case, all samples should be secured inside the -80°C freezer. If the vivarium is threatened by flooding, animal cages should be fastened shut, put into secondary containers (biohazard bag or large Tupperware) and transported (CMP) for secure holding until the threat of flooding has passed. If it becomes necessary to evacuate the College Station area, all animal experiments will be terminated before evacuation by euthanizing the animals and storing the carcasses in the secure select agent storage in room.
- 10.4 In case of a power outage, if there is no immediate danger to the building, secure all infectious samples inside a -80°C freezer, the +4°C refrigerator, or the incubators. The Biosafety cabinets and air handling system of the BSL-3 suite are on emergency backup power, which will prevent exposure to infectious samples in case of a power outage. Follow standard procedures for leaving the laboratory and return once the power has been restored to resume work.

11. Fire, Gas leak, Steam leak, Explosion, Bomb threat:

- 11.1 If work is being performed in the Biosafety cabinet, cap all samples, dispose of gloves and outer laboratory coat, and leave the laboratory immediately. If the fire is within the BSL 3 laboratory, and the worker feels (s)he can safely extinguish the fire, then the fire extinguisher located in the interior hall may be used. If a worker feels his or her safety threatened, (s)he should leave the laboratory immediately without stopping to decontaminate or secure any work, using the designated escape routes (through the locker rooms or the exterior "airlock" door on the west side of the building). Upon leaving the building, personnel should assemble outside the in the assigned spot (southern corner of corner of and report to the Lab Safety Officer for attendance.

- 11.2 Notify the appropriate emergency responders: Fire 9-911 or 911 from mobile phones, the Principal Investigator and the Biosafety Officer. For steam and gas leaks, notify TAMU Operations and Maintenance.
- 11.3 In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police immediately by calling the emergency number, 9-911, 911, 845-8900, or 845-2345. Also inform the Principal Investigator and Responsible Official. Always be sure to give the number and location of the building and your name and telephone extension number.
 - 11.3.1 The University Police Department will assign personnel to investigate the call and take whatever police action they may deem necessary and reasonable for the safety of the campus community. The University Police will conduct a search of the building, or of specific locations in or around the building. When judged prudent and feasible to do so, the search will be conducted with the assistance and cooperation of the Principal Investigator and/or Responsible Official. After an evaluation/assessment of the content of the bomb threat, the decision to evacuate or close building shall be made jointly, whenever possible, by the Police and the Principal Investigator and/or Responsible Official.
 - 11.3.2 Any unusual or suspicious object should be reported immediately to the University Police or to any immediate supervisor or administrative officer. Suspected objects or materials should NOT be touched or disturbed. Every bomb threat or incident of a suspected explosive device should be considered valid until all reasonable precautions for public safety have been taken or until the danger to life and property is terminated.

12. Failure of Select Agent Storage Freezer:

- 12.2 If the -80°C freezer in _____ at is used to store *Brucella* strains fails, the strains will be moved to a temporary backup location, which is either the other -80°C Revco freezer located in room 127, or in secure freezer in a locked BSL-2 laboratory. This freezer will be locked in order to limit access to personnel authorized to work with select agents.

13. Workplace violence:

- 13.1 Incidents of disruptive or threatening behavior on the part of an employee, student or visitor should be reported immediately to the Principal Investigator, who will report the incident to the Department Head, UPD, ARO and the Workplace Violence Response Team, as proscribed by the TAMU Personnel and Procedures manual section 290-09. If the individual accused of disruptive or threatening behavior is authorized for access to select agents, this person's access will be suspended pending the results of an investigation by the Workplace Violence Response Team. If an act of violence or a physical assault has occurred, or the threatening activity occurs within the BSL-3 laboratory, the person feeling threatened should call the police immediately to report the incident. If the person accused of violence has access to select agents, the person's access will be suspended pending the outcome of the investigation. Suspension of select agent access will be reported to the UPD, and ARO and a suspended individual's access will be inactivated within 24 hours.

14. Entry of emergency responders into the BSL-3 laboratory.

- 14.1 In a case in which a life-threatening injury or medical condition (i.e. heart attack) occurs inside the BSL-3 laboratory, emergency responders will be allowed to enter the laboratory. If possible, upon feeling ill the laboratory worker should immediately exit the suite to facilitate treatment by emergency responders. Personnel protective equipment, including Tyvek suits, PAPRs and gloves, are located inside the entries (locker rooms) to the BSL-3 suite. A spill kit containing absorbent materials and disinfectant is located under the bench in each of the labs. A First Aid kit is located inside the lab. If responders

are required to enter an area where a spill has occurred, they will be referred to Scott and White Clinic and offered post-exposure prophylaxis.

- 14.1.1 Entry procedure for the BSL-3 laboratory: Dress yourself in a Tyvek suit, gloves, shoe covers and PAPRs before entering the laboratories.
- 14.1.2 Providing first aid and emergency medical treatment in the BSL-3 laboratory: A person working inside the Biosafety hood is not considered to be contagious unless a spill has occurred. The person's gloves may be contaminated, and may be removed to facilitate treatment. If there is no space within the labs to put the person on the floor, move the person to the interior hallway to administer treatment.
- 14.1.3 Exit procedure from the BSL-3 laboratory: Emergency responders should remove Tyvek suit, PAPR, shoe covers and gloves before exiting and leave them behind in the BSL-3 laboratory. Hands should be washed immediately upon exit from the BSL-3 laboratory.
- 14.1.4 Decontamination procedures for medical equipment and clothing: Emergency responders should decontaminate equipment before leaving the laboratory by one of the following methods:
 - 14.1.4.1 Autoclaving. Autoclaves are located within the BSL3 suite or on the
 - 14.1.5 Wiping surfaces with 10% bleach followed by 1% Virkon-S.

15. Incident Response Plan Testing (Drills)

- 15.1 Drills or tabletop exercises will be conducted annually to test the effectiveness of the Biosafety plan. The drills or exercises will be coordinated with the TAMU Police Department and will include, but not be limited to, the Principal Investigator or designee, BSO, TAMU Fire Department representative and the Campus Emergency Planner.
- 15.2 The drill or exercise will include, but not be limited to, accessibility to restricted space, attempted or unauthorized entry into restricted spaces challenge, animal room security, staff knowledge of hazard/emergency protocols for their work location(s) and other situations that are deemed appropriate for each work location.
- 15.3 Following the drill or exercise, which will test the various components of the incident response plan for completeness, those involved will critique their findings for each drill/exercise location. The Principal Investigator working with the Responsible Official and Biosafety Officer will implement changes as necessary changes to the plan. Results of the drill or exercise will be reviewed by the Biological Safety Administrative Advisory Committee (Institutional Biosafety Committee).

16. Texas A&M University Crisis Management Plan

- 16.1 The entity crisis management plan is contained in a separate document and is referenced in the individual laboratory emergency response plan.
- 16.2 Additional information concerning the laboratory emergency response plan is contained in the laboratory's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or the Environmental Health & Safety Department.
- 16.3 The Alternate Responsible Official and Biosafety Officer should be contacted immediately in the case of any emergency in a select agent lab. The Alternate

Responsible Official will coordinate access and information issues with campus police, fire, and emergency responders.

- 16.4 If necessary, the Responsible Official will coordinate the emergency relocation of select agents to another secure location.
17. **Site security and control are described in detail in the Select Agent Security Plan**
 - 17.1 The buildings are secured by a keyed lock. Sharing of keys with other personnel is not permitted.
 - 17.2 Individuals not authorized for access to Select Agents must be accompanied by approved personnel at all times while in the buildings.
 - 17.3 Data that could enable access to select agents by unauthorized personnel should be located on password-protected computers.
 - 17.4 If approved personnel are observed violating security or Biosafety procedures, this observation should be reported immediately to the Principal Investigator. The Principal investigator will report the violation to the UPD who will investigate the allegation and determine whether the violator should have his/her Select Agent access suspended or revoked. Suspension of Select Agent access will be reported to the Alternate Responsible Official, the RO and the individual's key card access will be terminated within 24 hours.
18. **Inventory Discrepancies:**
 - 18.1 Inventory discrepancies will be documented on the agent access form.
 - 18.2 All discrepancies will be immediately reported to the Principal Investigator.
 - 18.3 If the discrepancy is believed to be a result of loss or theft, the incident response procedures for loss or theft and release will be followed.
 - 18.4 If the discrepancy is a result of a transfer, the transfer form will be documented.
19. **References**
 - 19.1 42 CFR Part 73
 - 19.2 7 CFR Part 331
 - 19.3 9 CFR Part 121
 - 19.4 Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention, National Institutes of Health, Fourth Edition, May 1999
 - 19.5 Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents (Revised BMBL, Appendix F), published in Morbidity and Mortality Weekly Report, December 6, 2002.

SBAT Incident Response
Emergency Contact Numbers

PI Information			
PI Ficht			
Office – 979 845-4118			
Mobile – 979 574-9466			
Home – (979) 633-3333			
Building Manager			
Lorten Skow			
979-845-3194			
Department Head			
Gerald Bratton			
979-845-5941			
Incidents involving Theft or Loss University Police Department (UPD) contact			
Bert Kretzschmar			
Office – 979 845-8900			
Mobile – 979 777-9033			
Home – 979 777-9033			
Incidents involving a Release (or Occupational Exposure) Environmental Health and Safety Office contact			
Between 8:00 a.m. and 5:00 p.m.			
Brent Mattox, Biosafety Officer (BSO) Alternate Responsible Official (ARO)			
Office – 979 865-2132			
Mobile – 979 450-0662			
After hours 5:00 pm			
Contact the University Police Department contact			
Lt. Bert Kretzschmar			
Office – 979 845-8900			
Mobile – 979 777-9033			
Home – 979 777-9033			
Other Contact information			
Vice President for Research/Responsible Official (RO)	Richard Ewing (RO)	979 845-8585 (Office) or 979 777-9033 (Mobile)	979 777-9033 (Mobile)
	Fuller Bazer (ARO)	979 693-2876 (Office) or 979 777-9033 (Mobile)	979 777-9033 (Mobile)
	Angelia Raines (ARO)	979 847-9362 (Office) or 979 777-9033 (Mobile)	979 777-9033 (Mobile)
Comparative Medicine Program	Melanie Ihrig	979 845-7433 (Office) or 979 777-9033 (Mobile)	979 777-9033 (Mobile)
	Elizabeth Browder	979 845-7433 (Office) or 979 777-9033 (Mobile)	979 777-9033 (Mobile)
	Frank Stein	979 845-6488 (Office) or 979 777-9033 (Mobile)	979 777-9033 (Mobile)
Institutional Biosafety Committee (IBC)	Thomas Ficht	979 845-4118 (Office) or 979 777-9033 (Mobile)	979 777-9033 (Mobile)
	Vernon Tesh	979 862-4113 (Office) or 979 777-9033 (Mobile)	979 777-9033 (Mobile)
	Tiffany Agnew	979 458-3624 (Office) or 979 777-9033 (Mobile)	979 777-9033 (Mobile)
Other Emergency Numbers	College Station Police	979 764-3600 or 9-111	
	Medical Emergency	9-911	
	College Station Fire	979 764-3700 or 9-911	
	Radiological Emergency	979 832-1111	
	University Maintenance	979 845-4311	

Emergency Telephone Numbers

Enter PI Name	Office: (979)845-4118 Home: Mobile: "
Emergency	9-911
University Police	(979) 845-2345
College Station Police	(979) 764-3600
College Station Fire	(979) 764-3700
Environmental Health & Safety	(979) 845-2132
TAMU Area Maintenance (HVAC failure, steam leak, gas leak)	(979) 845-5542
TAMU Maintenance (24 hours)	(979) 845-4311
Radiological Emergencies	(979) 862-1111
Responsible University Officials:	
RO-Richard Ewing	Work: (979) 845-8585 Mobile:
ARO-Angelia Raines	Work: (979) 847-9362 Mobile:
Biosafety Officer/ARO -Brent Mattox	Work: (979) 845-2132 Mobile:
Building Manager	Loren Skow 979-845-3194
Frank Stein	Work: (979) 845-6488 Mobile:
TAF Lab	5-4185
Neighboring labs to notify in case of simultaneous containment breach and spill outside BSC:	
Lab (enter additional locations)	enter additional laboratory phone number
Lab (enter additional locations)	enter additional laboratory phone number
Lab (enter additional locations)	enter additional laboratory phone number

Decontamination Procedures for Spills of Cultures
(Please customize for specific laboratories.)

1. Signal others in the BL3 labs of any spill outside the biological safety cabinet. All personnel should change out of contaminated clothing and wash any exposed skin with a disinfectant, such as Purell. Clothes must be removed within the BL3 area and will be autoclaved by those cleaning up.
2. Put on a clean scrub suit and go to the shower on the first floor animal facility. Shower thoroughly with soap.
3. Return to the lab for cleanup: Put on a PAPR and tyvek suit (contained in the SPILL KIT). Put on double gloves and shoe covers.
4. Use paper towels to cover the spill. Prevent creation of contaminated aerosols.
5. Saturate all materials with 10% bleach solution (see previous section for description).
6. Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in autoclave bags.
7. Disinfect all exposed surfaces using 1X Wexcide or 1% Virkon (surface disinfectant solution).
8. Wipe surface of full-face respirator with 1% Virkon or 1X Wexcide, being careful to avoid skin contact with Wexcide.
9. Remove all clothing and place in autoclave bag.
10. Remove full face respirator and spray off all surfaces in the lab with 1% Virkon or 1X Wexcide.
11. Make sure that all contaminated material is autoclaved, surface-disinfected or incinerated.
12. Inform others not to work in the lab until the air handling system is able to clear any residual organisms from the air (3h).
13. Return to the lab after 3 hours and perform another decontamination of all lab surfaces with 1% Virkon or 1X Wexcide.
14. Report accident to the Principal Investigator, who will report it to other officials.

Contents of spill kit located in BL-3 labs:

PAPR, Tyvek suit, clean scrub suit, absorbent material, Purell skin disinfectant, towel, copy of decontamination procedures for spills.

INCIDENT RESPONSE PLAN

PI – Ficht

PI - Adams

Texas A&M University, College Station, TX 77843
to ensure compliance with
42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

- 1.1 General. This is the incident response plan for the possession and use of *Brucella abortus*, *Brucella suis* and *Brucella melitensis* at Texas A&M University main campus (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121. This plan covers the use of these select agents when used in buildings
- 1.2 This plan describes the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

- 2.1 Principal Investigator (PI). The Principal Investigator, Dr. Thomas A. Ficht, has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to Dr. Ficht. The PI is responsible for ensuring all incidents regarding theft, loss or release are immediately reported to the proper institutional officials. This document outlines response actions concerning any theft, loss, or release from select biological agents and toxins (SBAT) facilities, including illness of personnel or visitors in SBAT facilities. Certain actions outlined below are performed in parallel rather than sequentially (see attached flowchart).
- 2.2 All lab personnel (including the PI) are responsible for immediately reporting an incident to the University Police Department (UPD) for theft or loss or to the Institutional Biosafety Officer (BSO) for release (including occupational exposure).
- 2.3 UPD – Responsible for immediately contacting the Alternate Responsible Official (ARO) and beginning an investigation of the incident. A written investigation report will be submitted to the Institutional Biosafety Committee (IBC), the PI and the ARO within 5 days of the incident. UPD will also work with the PI to conduct a security assessment following any incident involving loss or theft.
- 2.3 BSO - Responsible for immediately contacting the Alternate Responsible Official and beginning an investigation of the incident. A written investigation report will be submitted to the IBC, the PI and the ARO within 5 days of the incident. The BSO will also work with the PI to conduct a safety assessment following any incident involving a release (including occupational exposure).
- 2.4 ARO - Responsible for immediately contacting the Responsible Official, CDC, NIH (if rDNA) and other key institutional contacts regarding the incident. The ARO will work with the BSO, UPD and the PI to insure that the written report is correct and that the report will be submitted to CDC, NIH (if rDNA) and other key institutional contacts.

- 2.5 Responsible Official – Is responsible for compliance to the Select Agent regulations and insuring requirements (registration, investigations, etc) are properly carried out.
- 2.6 Contact information is found on the Emergency contact list. The list is attached to this document and is posted throughout the lab.
- 2.7 Annual Program Review. The Responsible Official or Alternate Responsible Official will audit the incident response program on an annual basis. This review will include drills and exercises to ensure the effectiveness of the incident response plan. Based on the outcome of drills, exercises or reported incidents, this incident response plan will be reviewed and updated as necessary.

3. Description of Work

This plan covers all work being performed at TAMU. Each lab will be responsible for providing information specific to the work being performed as follows:

La	Work description	Unique features of Agent	Biological Use Authorization	Biosafety Level
	Storage of <i>Brucella abortus</i> , <i>B. suis</i> , <i>B. melintensis</i>	Locked freezer	0741	3
	Work with <i>Brucella abortus</i> , <i>B. suis</i> , <i>B. melintensis</i>	BSC	0741	3
	Storage of <i>Brucella</i> -infected animal carcasses	Locked freezer	0741	3
	Inoculation of mice with <i>Brucella</i> spp. And necropsy of infected animals	BSC	0741	3

Additional information concerning the laboratories and the select agent use is contained in the facility’s CDC select agent application for registration on file at the CDC’s Select Agent Program office. A copy is also securely stored at the entity’s Office of Research Compliance or Environmental Health and Safety Office.

4. Response to theft:

- 4.1 Determination of Loss or Theft – The following are examples of events that may be considered a loss or theft. Possible loss or theft of the select agent will be reported initially to the Principal Investigator if any of the following have occurred:
 - 4.1.1 The lock on the Select Agent storage area has been found open or appears to have been tampered with;
 - 4.1.2 Evidence of forced entry into the laboratory or storage areas has been found;
 - 4.1.3 A discrepancy in the Select Agent inventory that can not be reconciled;
 - 4.1.4 An employee reports cultures or samples missing;
 - 4.1.5 A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2;
 - 4.1.6 An infected animal is missing from its microisolator cage.

4.2 Report/Investigation Process:

Theft (unauthorized removal) or **Loss** (failure to account for) a select agent or toxin

- 4.2.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected theft or loss of SBATS to

UPD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345). Based on circumstances, UPD will notify EHSD.

If the release is discovered and UPD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the person shall then notify the LD/PI.

After notification to UPD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact ORC.

- 4.2.1.1 Upon notification of discovery of a theft or loss, UPD will immediately notify ORC.
- 4.2.1.2 Upon notification from UPD, ORC will immediately notify the Responsible Official (RO) and Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, and UPD.
- 4.2.1.3 UPD (and ESHD, based on circumstances) will immediately investigate the incident. The investigation will include coordination with the LD/PI and others approved with access or visiting SBAT facilities. UPD will submit a written report to ORC within 5 days of being notified about the discovery of the theft or loss. If the investigation provides evidence that a theft or loss did not occur, circumstances will be documented in UPD's investigation report.
- 4.2.1.4 Based on the UPD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss or Release of Select Agents and Toxins) with CDC. ORC will maintain an official copy of information submitted to CDC and will provide a copy of the submission to the RO, UPD/EHSD, and LD/PI.
- 4.2.1.5 UPD will notify the appropriate Federal, State, or local law enforcement agencies.
- 4.2.1.6 The LD/PI will ensure notification to the funding agency
- 4.2.2 A risk assessment will be conducted immediately upon discovery of a loss or theft. The risk assessment will be a part of the investigation report.
 - 4.2.2.1 In addition to the investigation, upon notification of a theft or loss, UPD (with input from EHSD and the LD/PI) will conduct a risk assessment to determine if the laboratory is operating in a safe and secure manner and to attempt to determine the cause of the theft. This risk assessment shall include, but not be limited to a comprehensive laboratory survey, review of access logs, review of inventory records, and verification that all equipment is operating within normal parameters (e. g. biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of theft will also be reviewed and modified, as warranted. If deficiencies in safe and secure practices are discovered, all work in the laboratory will cease until corrective actions have been taken.

- 4.1.2.2 If deemed necessary, the EHSD/UPD will contact Biosafety Program Coordinator to convene a special meeting of the Institutional BioSafety Committee (IBC).
- 4.1.2.3 Documentation of the risk assessment will be maintained by UPD with a copy sent to the LD/PI, EHSD and ORC.
- 4.1.2.4 Security Risk Assessments will be completed by UPD, with input from the LD/PI (and EHSD, based on circumstances). The results of the risk assessment and findings, including any requirements for post theft procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI, EHSD, and ORC.
- 4.1.2.5 The ORC will contact CDC, and if needed, a copy of the assessment will be submitted. ORC will also update the RO.
- 4.2.3 UPD will establish and maintain a specific file for each theft or loss incident, with all pertinent information.
- 4.2.4 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected loss or theft to UPD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

5. Investigation

- 5.1 The Investigation Committee for all releases will be headed by the EHSD's Institutional Biosafety Officer (BSO) with input from UPD and the PI. UPD will lead investigations involving theft or loss, with input from the BSO and PI.
 - 5.1.1 The BSO/UPD will investigate the event as quickly as possible, but no later than 24 hours of the initial report or the incident.
 - 5.1.2 The investigation should include a review of all materials related to the research, including access logs, inventory logs, laboratory notes and laboratory plans (security, safety and incident response)
 - 5.1.3 Once the investigation is complete, the BSO or UPD will submit an investigation report to the IBB and RO.
 - 5.1.4 Once the Committee has determined the response and informed the RO and IBC (through the Office of Research Compliance), the IBC will review the report and make a recommendation to the RO of any additional actions that they believe are needed.
 - 5.1.5 After the RO has approved of the recommended actions, the PI will receive a written response from the IBC.

6. Reporting

- 6.1 All incident reports are included in the IBC agenda minutes for review by the full board at the next convened meeting. Serious events should be specifically presented to the IBC by the BSO/UPD or IBC Chair at the next convened meeting.
 - 6.1.1 The investigation report, at a minimum, shall include the following information:
 - 6.1.1.1 A detailed description of the incident.
 - 6.1.1.2 A list of all personnel involved in the incident.
 - 6.1.1.3 A description of what occurred and what has or needs to be done to prevent any future incident.
 - 6.1.1.4 An assessment of the safety or security risk of continuing the research.

- 6.1.1.5 A recommendation of any changes that need to be made to the plans (safety, security or incident response), medical surveillance or laboratory procedures to reduce the risk of a reoccurrence.
- 6.1.1.6 A recommendation for training, if needed.

6.1.2 Incidents involving SBAT will be immediately reported to the CDC with a written report (Form 3) submitted within seven (7) days.

6.1.3 Events involving rDNA must be reported to the NIH immediately in writing but no later than 30 days of the incident.

7. **Release of a Select Agent or Toxin.**

Examples of a possible release (including occupational exposures of the agent or toxin include but are not limited to the following:

7.1 A package containing the Select Agent or toxin that has been received, which has been damaged in transit, such that the primary containment vessel appears to have been compromised;

7.2 Simultaneous complete power failure of the Biosafety cabinet and loss of negative pressure in the BSL-3 suite during work in the Biosafety cabinet with open cultures;

7.3 Simultaneous spill of cultures outside the Biosafety cabinet and failure of negative pressure in the Biosafety Level 3 suite. In case of a spill, a spill kit containing absorbent material and disinfectant will be located in a designated lab for each Principal Investigator;

7.3.1 Personnel are advised to immediately leave the lab after removing any contaminated clothing and to return in Tyvek suits with Powered Air Purifying Respirator (PAPR) after the air has been scrubbed clean by air handlers (approx. one hour).

7.4 In case release of the Select Agent or toxin outside the BSL-3 laboratory is suspected, the Principal Investigator will notify the BSO and ARO as well as the Responsible Official, and the building manager.

7.5 Exposure of laboratory personnel to cultures. The following incidents may result in unintentional exposure to the Select Agent that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to BSO who will immediately contact the Scott & White Occupational Health office, where they will be evaluated for possible post-exposure prophylaxis. The exposure will be reported by the Principal Investigator to the BSO who reports immediately to the ARO, who will notify CDC of the exposure. The following are examples of unintentional exposure:

7.5.1 A spill of live culture outside the Biosafety cabinet;

7.5.2 Failure of the Biosafety cabinet during work with *Brucella*;

7.5.3 Needle stick or cut with sharps contaminated with *Brucella*;

7.5.4 If a bite from a *Brucella*-infected animal penetrates the double gloves and breaks the skin;

7.5.5 A centrifuge accident that results in aerosolization of *Brucella*.

8. **Process of reporting and investigating a Release:**

Release – Occupational exposure (clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been release outside of the primary bio-containment barrier), or release of an agent or toxin outside of the primary barriers of the biocontainment area.

- 8.1 All individuals approved for access or visiting SBAT facilities must upon discovery immediately report any actual or suspected release to the BSO of the Environment Health and Safety Department (EHSD). Based on circumstances, EHSD will notify the University Police Department (UPD). During normal business hours, call EHSD at 845-2132. If it is outside of normal business hours, call UPD who will notify EHSD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345).

If the release is discovered and the BSO is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the individual must then notify the LD/PI.

After notification to the BSO by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact the Office of Research Compliance (ORC).

- 8.1.1 Upon notification of discovery of a release, EHSD will immediately notify Scott & White Occupational Health office and ORC.
- 8.1.2 Upon notification from EHSD, ORC will immediately notify the ARO, the RO and the Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, EHSD, and UPD.
- 8.1.3 EHSD (and UPD, based on circumstances) will immediately investigate the incident. The investigation will include the coordination with the LD/PI and others approved with access or visiting SBAT facilities. EHSD will submit a written report to ORC within 5 days of being notified about discovery of the release. If the investigation provides evidence that a release did not occur, circumstances will be documented in EHSD's investigation report.
- 8.1.4 Based on the EHSD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss, or Release of Select Agents and Toxins) with the CDC within seven calendar days of the discovery of the release. ORC will maintain an official copy of information submitted to the CDC and will provide a copy of the submission to the RO, EHSD, and LD/PI.
- 8.1.5 EHSD will obtain confirmation from health care providers that reports to other state or federal health agencies have been submitted. The LD/PI will ensure notification to the funding agency.
- 8.2 A risk assessment will be conducted immediately upon discovery regarding any release.
- 8.2.1 In addition to the investigation, upon notification of a release, EHSD (under the direction of the Biological Safety Officer (BSO)) will conduct a risk assessment to determine if the laboratory is operating in a safe manner and attempt to determine the cause or most likely route of the release. This risk assessment shall include but not be limited to a comprehensive laboratory survey, review of access logs to determine potential occupational exposures, review of inventory records, and verification that all equipment is operating within normal parameters (e.g., biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of the release will also be reviewed by EHSD and modified, as warranted, in consultation with the LD/PI. If deficiencies in safe practices are discovered, all work in the laboratory will cease until corrective actions have been taken.

- 8.2.2 If deemed necessary based on the risk assessment, the BSO will contact ORC to convene a special meeting of the Institutional BioSafety Committee.
 - 8.2.3 Documentation of the risk assessment will be maintained by EHSD with a copy sent to the LD/PI and the ORC.
 - 8.2.4 Risk assessments will be completed with input from the LD/PI. The results of the risk assessment and findings, including any requirements for post decontamination procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI and ORC.
 - 8.2.5 ORC will contact CDC, and if needed, a copy of the risk assessment will be submitted. ORC will also update the RO.
- 8.3 The following additional steps will also be taken immediately upon discovery regarding an actual or suspected occupational exposure:
- 8.3.1 EHSD will direct the LD/PI to notify laboratory personnel and visitors that a potential exposure has occurred and refer them to Scott & White Occupational Health for consultation. EHSD will obtain access logs and other information to determine a complete list of potentially exposed personnel. EHSD will then follow-up with potentially exposed personnel to ensure notification.
 - 8.3.2 Individuals will be encouraged to contact Occupational Health at Scott & White Clinic, or to immediately identify to medical personnel, the agent they were potentially exposed to if treatment is sought. Scott & White Occupational Health Clinic or the attending physician will test for the organism (e. g. *Brucella* species), and begin prophylaxis as deemed appropriate by the attending physician.
 - 8.3.3 If an occupational exposure is confirmed through appropriate medical tests or as determined by a physician, all personnel and potentially exposed individuals will be immediately referred to Scott & White for screening, testing, or preventive prophylaxis as determined by the attending physician. If personnel or visitors are at remote locations (other university facilities, traveling), they should immediately report to a physician of choice and explain that a positive occupational exposure to a specific organism has occurred and specific treatment or screening is desired. Personal physicians should be encouraged to contact either EHSD or Scott and White Occupational Health if they have any questions.
 - 8.3.4 EHSD, in consultation with Scott & White, will perform periodic follow-up with the group of exposed or potentially exposed personnel for a period of time as appropriate for the organism.
- 8.4 EHSD will establish and maintain a specific file for each release incident, with all pertinent information.
- 8.5 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected release to EHSD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

9. Security Breach:

A security breach will be determined to have occurred if any of the following are observed:

- 9.1 The access control system has failed, leaving the BSL-3 suite accessible to unauthorized persons;
- 9.2 An unauthorized person is observed unaccompanied in the BSL-3 suite;
- 9.3 A lost or stolen card was used to access the BSL-3 suite;
- 9.4 An unauthorized person has accessed the computer used to control entry to the BSL-3 suite;
- 9.5 An unexpected or suspicious package arrives in the laboratory.

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the UPD and the ARO of the security breach and take steps to correct the problem. Corrective procedures will be secured immediately, but no later than 24 hours; an inventory will be performed of all samples and animals in the laboratory and in Select Agent storage. Any missing Select Agent samples or animals will be reported to ARO, RO and CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator, the ARO and the UPD will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

10. Severe weather or natural disasters.

The most likely occurrences in this area are severe thunderstorms, floods or tornadoes.

- 10.1 If severe weather (thunderstorms or flooding) is predicted, experiments with Select Agents should be suspended until the severe weather has passed to avoid power outages during the work. All samples should be secured inside the locked -80°C freezer or the locked +4°C storage.
- 10.2 If an earthquake is felt, workers should immediately leave the suite-if possible, shedding gloves and lab coat on the way out of the BSL-3 suite. Cleanup, if necessary, can be performed once it is safe to re-enter the building.
- 10.3 Power to the BSL-3 suite may be affected if the emergency generator is flooded. In this case, all samples should be secured inside the -80°C freezer. If the vivarium is threatened by flooding, animal cages should be fastened shut, put into secondary containers (biohazard bag or large Tupperware) and transported to secure holding until the threat of flooding has passed. If it becomes necessary to evacuate the College Station area, all animal experiments will be terminated before evacuation by euthanizing the animals and storing the carcasses in the secure select agent storage in room.
- 10.4 In case of a power outage, if there is no immediate danger to the building, secure all infectious samples inside a -80°C freezer, the +4°C refrigerator, or the incubators. The Biosafety cabinets and air handling system of the BSL-3 suite are on emergency backup power, which will prevent exposure to infectious samples in case of a power outage. Follow standard procedures for leaving the laboratory and return once the power has been restored to resume work.

11. Fire, Gas leak, Steam leak, Explosion, Bomb threat:

- 11.1 If work is being performed in the Biosafety cabinet, cap all samples, dispose of gloves and outer laboratory coat, and leave the laboratory immediately. If the fire is within the BSL 3 laboratory, and the worker feels (s)he can safely extinguish the fire, then the fire extinguisher located in the interior hall may be used. If a worker feels his or her safety threatened, (s)he should leave the laboratory immediately without stopping to decontaminate or secure any work, using the designated escape routes (through the locker rooms or the exterior "airlock" door on the west side of the building). Upon leaving the building, personnel should assemble outside the building at the assigned spot (southern corner of corner of Parking lot 13) and report to the Lab Safety Officer for attendance.

- 11.2 Notify the appropriate emergency responders: Fire 9-911 or 911 from mobile phones, the Principal Investigator and the Biosafety Officer. For steam and gas leaks, notify TAMU Operations and Maintenance.
- 11.3 In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police immediately by calling the emergency number, 9-911, 911, 845-8900, or 845-2345. Also inform the Principal Investigator and Responsible Official. Always be sure to give the number and location of the building and your name and telephone extension number.
 - 11.3.1 The University Police Department will assign personnel to investigate the call and take whatever police action they may deem necessary and reasonable for the safety of the campus community. The University Police will conduct a search of the building, or of specific locations in or around the building. When judged prudent and feasible to do so, the search will be conducted with the assistance and cooperation of the Principal Investigator and/or Responsible Official. After an evaluation/assessment of the content of the bomb threat, the decision to evacuate or close building shall be made jointly, whenever possible, by the Police and the Principal Investigator and/or Responsible Official.
 - 11.3.2 Any unusual or suspicious object should be reported immediately to the University Police or to any immediate supervisor or administrative officer. Suspected objects or materials should NOT be touched or disturbed. Every bomb threat or incident of a suspected explosive device should be considered valid until all reasonable precautions for public safety have been taken or until the danger to life and property is terminated.

12. **Failure of Select Agent Storage Freezer:**

- 12.2 If the -80°C freezer in [redacted] that is used to store *Brucella* strains fails, the strains will be moved to a temporary backup location, which is either the other -80°C Revco freezer located in room [redacted] in secure freezer in a locked BSL-2 laboratory. This freezer will be locked in order to limit access to personnel authorized to work with select agents.

13. **Workplace violence:**

- 13.1 Incidents of disruptive or threatening behavior on the part of an employee, student or visitor should be reported immediately to the Principal Investigator, who will report the incident to the Department Head, UPD, ARO and the Workplace Violence Response Team, as proscribed by the TAMU Personnel and Procedures manual section 290-09. If the individual accused of disruptive or threatening behavior is authorized for access to select agents, this person's access will be suspended pending the results of an investigation by the Workplace Violence Response Team. If an act of violence or a physical assault has occurred, or the threatening activity occurs within the BSL-3 laboratory, the person feeling threatened should call the police immediately to report the incident. If the person accused of violence has access to select agents, the person's access will be suspended pending the outcome of the investigation. Suspension of select agent access will be reported to the UPD, and ARO and a suspended individual's access will be inactivated within 24 hours.

14. **Entry of emergency responders into the BSL-3 laboratory.**

- 14.1 In a case in which a life-threatening injury or medical condition (i.e. heart attack) occurs inside the BSL-3 laboratory, emergency responders will be allowed to enter the laboratory. If possible, upon feeling ill the laboratory worker should immediately exit the suite to facilitate treatment by emergency responders. Personnel protective equipment, including Tyvek suits, PAPRs and gloves, are located inside the entries (locker rooms) to the BSL-3 suite. A spill kit containing absorbent materials and disinfectant is located under the bench in each of the labs. A First Aid kit is located inside the lab. If responders

are required to enter an area where a spill has occurred, they will be referred to Scott and White Clinic and offered post-exposure prophylaxis.

- 14.1.1 Entry procedure for the BSL-3 laboratory: Dress yourself in a Tyvek suit, gloves, shoe covers and PAPRs before entering the laboratories.
- 14.1.2 Providing first aid and emergency medical treatment in the BSL-3 laboratory: A person working inside the Biosafety hood is not considered to be contagious unless a spill has occurred. The person's gloves may be contaminated, and may be removed to facilitate treatment. If there is no space within the labs to put the person on the floor, move the person to the interior hallway to administer treatment.
- 14.1.3 Exit procedure from the BSL-3 laboratory: Emergency responders should remove Tyvek suit, PAPR, shoe covers and gloves before exiting and leave them behind in the BSL-3 laboratory. Hands should be washed immediately upon exit from the BSL-3 laboratory.
- 14.1.4 Decontamination procedures for medical equipment and clothing: Emergency responders should decontaminate equipment before leaving the laboratory by one of the following methods:
 - 14.1.4.1 Autoclaving. Autoclaves are located within the BSL3 suite or on the 2nd floor of the VRB.
 - 14.1.5 Wiping surfaces with 10% bleach followed by 1% Virkon-S.

15. Incident Response Plan Testing (Drills)

- 15.1 Drills or tabletop exercises will be conducted annually to test the effectiveness of the Biosafety plan. The drills or exercises will be coordinated with the TAMU Police Department and will include, but not be limited to, the Principal Investigator or designee, BSO, TAMU Fire Department representative and the Campus Emergency Planner.
- 15.2 The drill or exercise will include, but not be limited to, accessibility to restricted space, attempted or unauthorized entry into restricted spaces challenge, animal room security, staff knowledge of hazard/emergency protocols for their work location(s) and other situations that are deemed appropriate for each work location.
- 15.3 Following the drill or exercise, which will test the various components of the incident response plan for completeness, those involved will critique their findings for each drill/exercise location. The Principal Investigator working with the Responsible Official and Biosafety Officer will implement changes as necessary changes to the plan. Results of the drill or exercise will be reviewed by the Biological Safety Administrative Advisory Committee (Institutional Biosafety Committee).

16. Texas A&M University Crisis Management Plan

- 16.1 The entity crisis management plan is contained in a separate document and is referenced in the individual laboratory emergency response plan.
- 16.2 Additional information concerning the laboratory emergency response plan is contained in the laboratory's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or the Environmental Health & Safety Department.
- 16.3 The Alternate Responsible Official and Biosafety Officer should be contacted immediately in the case of any emergency in a select agent lab. The Alternate

Responsible Official will coordinate access and information issues with campus police, fire, and emergency responders.

16.4 If necessary, the Responsible Official will coordinate the emergency relocation of select agents to another secure location.

17. Site security and control are described in detail in the Select Agent Security Plan

17.1 The buildings are secured by a keyed lock. Sharing of keys with other personnel is not permitted.

17.2 Individuals not authorized for access to Select Agents must be accompanied by approved personnel at all times while in the buildings.

17.3 Data that could enable access to select agents by unauthorized personnel should be located on password-protected computers.

17.4 If approved personnel are observed violating security or Biosafety procedures, this observation should be reported immediately to the Principal Investigator. The Principal investigator will report the violation to the UPD who will investigate the allegation and determine whether the violator should have his/her Select Agent access suspended or revoked. Suspension of Select Agent access will be reported to the Alternate Responsible Official, the RO and the individual's key card access will be terminated within 24 hours.

18. Inventory Discrepancies:

18.1 Inventory discrepancies will be documented on the agent access form.

18.2 All discrepancies will be immediately reported to the Principal Investigator.

18.3 If the discrepancy is believed to be a result of loss or theft, the incident response procedures for loss or theft and release will be followed.

18.4 If the discrepancy is a result of a transfer, the transfer form will be documented.

19. References

19.1 42 CFR Part 73

19.2 7 CFR Part 331

19.3 9 CFR Part 121

19.4 Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention, National Institutes of Health, Fourth Edition, May 1999

19.5 Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents (Revised BMBL, Appendix F), published in Morbidity and Mortality Weekly Report, December 6, 2002.

SBAT Incident Response
Emergency Contact Numbers

PI Information			
PI Ficht			
Office – 979 845-4118			
Home -			
Building Manager Lorten Skow 979-845-3194			
Department Head Gerald Bratton 979-845-5941			
Incidents involving Theft or Loss University Police Department (UPD) contact			
Bert Kretzschmar Office – 979 845-8900			
Home -			
Incidents involving a Release (or Occupational Exposure) Environmental Health and Safety Office contact			
Between 8:00 a.m. and 5:00 p.m. Brent Mattox, Biosafety Officer (BSO) Alternate Responsible Official (ARO) Office – 979 865-2132			
After hours 5:00 pm Contact the University Police Department contact Lt. Bert Kretzschmar Office – 979 845-8900 Mobile – 979 845-8900 Hon			
Other Contact information			
Vice President for Research/Responsible Official (RO)	Richard Ewing (RO)	979 845-8585 (Office) o	(Mobile)
	Fuller Bazer (ARO)	979 693-2876 (Office) o	(Mobile)
	Angelia Raines (ARO)	979 847-9362 (Office) o	(Mobile)
Comparative Medicine Program	Melanie Ihrig	979 845-7433 (Office) o	(Mobile)
	Elizabeth Browder	979 845-7433 (Office) o	(Mobile)
	Frank Stein	979 845-6488 (Office) o	(Mobile)
Institutional Biosafety Committee (IBC)	Thomas Ficht	979 845-4118 (Office) o	(Mobile)
	Vernon Tesh	979 862-4113 (Office) o	(Mobile)
	Tiffany Agnew	979 458-3624 (Office) o	(Mobile)
Other Emergency Numbers	College Station Police	979 764-3600 or 9-911	
	Medical Emergency	9-911	
	College Station Fire	979 764-3700 or 9-911	
	Radiological Emergency	979 832-1111	
	University Maintenance	979 845-4311	

Decontamination Procedures for Spills of Cultures
(Please customize for specific laboratories.)

1. Signal others in the BL3 labs of any spill outside the biological safety cabinet. All personnel should change out of contaminated clothing and wash any exposed skin with a disinfectant, such as Purell. Clothes must be removed within the BL3 area and will be autoclaved by those cleaning up.
2. Put on a clean scrub suit and go to the shower on the first floor animal facility. Shower thoroughly with soap.
3. Return to the lab for cleanup: Put on a PAPR and tyvek suit (contained in the SPILL KIT). Put on double gloves and shoe covers.
4. Use paper towels to cover the spill. Prevent creation of contaminated aerosols.
5. Saturate all materials with 10% bleach solution (see previous section for description).
6. Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in autoclave bags.
7. Disinfect all exposed surfaces using 1X Wexcide or 1% Virkon (surface disinfectant solution).
8. Wipe surface of full-face respirator with 1% Virkon or 1X Wexcide, being careful to avoid skin contact with Wexcide.
9. Remove all clothing and place in autoclave bag.
10. Remove full face respirator and spray off all surfaces in the lab with 1% Virkon or 1X Wexcide.
11. Make sure that all contaminated material is autoclaved, surface-disinfected or incinerated.
12. Inform others not to work in the lab until the air handling system is able to clear any residual organisms from the air (3h).
13. Return to the lab after 3 hours and perform another decontamination of all lab surfaces with 1% Virkon or 1X Wexcide.
14. Report accident to the Principal Investigator, who will report it to other officials.

Contents of spill kit located in BL-3 labs:

PAPR, Tyvek suit, clean scrub suit, absorbent material, Purell skin disinfectant, towel, copy of decontamination procedures for spills.

INCIDENT RESPONSE PLAN

For BSL3 Buildings 1220-1228

PI – Ficht

PI Adams

Texas A&M University, College Station, TX 77843

to ensure compliance with

42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

- 1.1 General. This is the incident response plan for the possession and use of *Brucella abortus*, *Brucella suis* and *Brucella melitensis* at Texas A&M University main campus (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121. This plan covers the use of these select agents when used in buildings.
- 1.2 This plan describes the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

- 2.1 Principal Investigator (PI). The Principal Investigator, Dr. Thomas A. Ficht, has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to Dr. Ficht. The PI is responsible for ensuring all incidents regarding theft, loss or release are immediately reported to the proper institutional officials. This document outlines response actions concerning any theft, loss, or release from select biological agents and toxins (SBAT) facilities, including illness of personnel or visitors in SBAT facilities. Certain actions outlined below are performed in parallel rather than sequentially (see attached flowchart).
- 2.2 All lab personnel (including the PI) are responsible for immediately reporting an incident to the University Police Department (UPD) for theft or loss or to the Institutional Biosafety Officer (BSO) for release (including occupational exposure).
- 2.3 UPD – Responsible for immediately contacting the Alternate Responsible Official (ARO) and beginning an investigation of the incident. A written investigation report will be submitted to the Institutional Biosafety Committee (IBC), the PI and the ARO within 5 days of the incident. UPD will also work with the PI to conduct a security assessment following any incident involving loss or theft.
- 2.3 BSO - Responsible for immediately contacting the Alternate Responsible Official and beginning an investigation of the incident. A written investigation report will be submitted to the IBC, the PI and the ARO within 5 days of the incident. The BSO will also work with the PI to conduct a safety assessment following any incident involving a release (including occupational exposure).
- 2.4 ARO - Responsible for immediately contacting the Responsible Official, CDC, NIH (if rDNA) and other key institutional contacts regarding the incident. The ARO will work with the BSO, UPD and the PI to insure that the written report is correct and that the report will be submitted to CDC, NIH (if rDNA) and other key institutional contacts.

- 2.5 Responsible Official – Is responsible for compliance to the Select Agent regulations and insuring requirements (registration, investigations, etc) are properly carried out.
- 2.6 Contact information is found on the Emergency contact list. The list is attached to this document and is posted throughout the lab.
- 2.7 Annual Program Review. The Responsible Official or Alternate Responsible Official will audit the incident response program on an annual basis. This review will include drills and exercises to ensure the effectiveness of the incident response plan. Based on the outcome of drills, exercises or reported incidents, this incident response plan will be reviewed and updated as necessary.

3. Description of Work

This plan covers all work being performed at TAMU. Each lab will be responsible for providing information specific to the work being performed as follows:

Lab	Work description	Unique features of Agent	Biological Use Authorization	Biosafety Level
	Work with Brucella abortus, B. suis, B. melitensis	BSC	0741	3
	Inoculation of mice and ruminants with Brucella spp.	BSC	0741	3
	Storage of Brucella-infected animal carcasses	Locked freezer	0741	3

Additional information concerning the laboratories and the select agent use is contained in the facility's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or Environmental Health and Safety Office.

4. Response to theft:

- 4.1 Determination of Loss or Theft – The following are examples of events that may be considered a loss or theft. Possible loss or theft of the select agent will be reported initially to the Principal Investigator if any of the following have occurred:
- 4.1.1 The lock on the Select Agent storage area has been found open or appears to have been tampered with;
 - 4.1.2 Evidence of forced entry into the laboratory or storage areas has been found;
 - 4.1.3 A discrepancy in the Select Agent inventory that can not be reconciled;
 - 4.1.4 An employee reports cultures or samples missing;
 - 4.1.5 A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2;
 - 4.1.6 An infected animal is missing from its housing unit.

4.2 Report/Investigation Process:

Theft (unauthorized removal) or **Loss** (failure to account for) a select agent or toxin

- 4.2.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected theft or loss of SBATS to UPD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345). Based on circumstances, UPD will notify EHSD.

If the release is discovered and UPD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the person shall then notify the LD/PI.

After notification to UPD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact ORC.

- 4.2.1.1 Upon notification of discovery of a theft or loss, UPD will immediately notify ORC.
 - 4.2.1.2 Upon notification from UPD, ORC will immediately notify the Responsible Official (RO) and Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, and UPD.
 - 4.2.1.3 UPD (and ESHD, based on circumstances) will immediately investigate the incident. The investigation will include coordination with the LD/PI and others approved with access or visiting SBAT facilities. UPD will submit a written report to ORC within 5 days of being notified about the discovery of the theft or loss. If the investigation provides evidence that a theft or loss did not occur, circumstances will be documented in UPD's investigation report.
 - 4.2.1.4 Based on the UPD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss or Release of Select Agents and Toxins) with CDC. ORC will maintain an official copy of information submitted to CDC and will provide a copy of the submission to the RO, UPD/EHSD, and LD/PI.
 - 4.2.1.5 UPD will notify the appropriate Federal, State, or local law enforcement agencies.
 - 4.2.1.6 The LD/PI will ensure notification to the funding agency
- 4.2.2 A risk assessment will be conducted immediately upon discovery of a loss or theft. The risk assessment will be a part of the investigation report.
- 4.2.2.1 In addition to the investigation, upon notification of a theft or loss, UPD (with input from EHSD and the LD/PI) will conduct a risk assessment to determine if the laboratory is operating in a safe and secure manner and to attempt to determine the cause of the theft. This risk assessment shall include, but not be limited to a comprehensive laboratory survey, review of access logs, review of inventory records, and verification that all equipment is operating within normal parameters (e. g. biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of theft will also be reviewed and modified, as warranted. If deficiencies in safe and secure practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
 - 4.1.2.2 If deemed necessary, the EHSD/UPD will contact Biosafety Program Coordinator to convene a special meeting of the Institutional BioSafety Committee (IBC).

4.1.2.3 Documentation of the risk assessment will be maintained by UPD with a copy sent to the LD/PI, EHSD and ORC.

4.1.2.4 Security Risk Assessments will be completed by UPD, with input from the LD/PI (and EHSD, based on circumstances). The results of the risk assessment and findings, including any requirements for post theft procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI, EHSD, and ORC.

4.1.2.5 The ORC will contact CDC, and if needed, a copy of the assessment will be submitted. ORC will also update the RO.

4.2.3 UPD will establish and maintain a specific file for each theft or loss incident, with all pertinent information.

4.2.4 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected loss or theft to UPD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

5. Investigation

5.1 The Investigation Committee for all releases will be headed by the EHSD's Institutional Biosafety Officer (BSO) with input from UPD and the PI. UPD will lead investigations involving theft or loss, with input from the BSO and PI.

5.1.1 The BSO/UPD will investigate the event as quickly as possible, but no later than 24 hours of the initial report or the incident.

5.1.2 The investigation should include a review of all materials related to the research, including access logs, inventory logs, laboratory notes and laboratory plans (security, safety and incident response)

5.1.3 Once the investigation is complete, the BSO or UPD will submit an investigation report to the IBB and RO.

5.1.4 Once the Committee has determined the response and informed the RO and IBC (through the Office of Research Compliance), the IBC will review the report and make a recommendation to the RO of any additional actions that they believe are needed.

5.1.5 After the RO has approved of the recommended actions, the PI will receive a written response from the IBC.

6. Reporting

6.1 All incident reports are included in the IBC agenda minutes for review by the full board at the next convened meeting. Serious events should be specifically presented to the IBC by the BSO/UPD or IBC Chair at the next convened meeting.

6.1.1 The investigation report, at a minimum, shall include the following information:

6.1.1.1 A detailed description of the incident.

6.1.1.2 A list of all personnel involved in the incident.

6.1.1.3 A description of what occurred and what has or needs to be done to prevent any future incident.

6.1.1.4 An assessment of the safety or security risk of continuing the research.

6.1.1.5 A recommendation of any changes that need to be made to the plans (safety, security or incident response), medical surveillance or laboratory procedures to reduce the risk of a reoccurrence.

6.1.1.6 A recommendation for training, if needed.

6.1.2 Incidents involving SBAT will be immediately reported to the CDC with a written report (Form 3) submitted within seven (7) days.

6.1.3 Events involving rDNA must be reported to the NIH immediately in writing but no later than 30 days of the incident.

7. **Release of a Select Agent or Toxin.**

Examples of a possible release (including occupational exposures of the agent or toxin) include but are not limited to the following:

7.1 A package containing the Select Agent or toxin that has been received, which has been damaged in transit, such that the primary containment vessel appears to have been compromised;

7.2 Simultaneous complete power failure of the Biosafety cabinet and loss of negative pressure in the BSL-3 suite during work in the Biosafety cabinet with open cultures;

7.3 Simultaneous spill of cultures outside the Biosafety cabinet and failure of negative pressure in the Biosafety Level 3 area. In case of a spill, a spill kit containing absorbent material and disinfectant will be located in each building;

7.3.1 Personnel are advised to immediately leave the building after removing any contaminated clothing and to return in Tyvek suits with full face respirators (Powered Air Purifying Respirator (PAPR)) after the air has been scrubbed clean by air handlers (approx. one hour).

1.1.1. In case release of the Select Agent or toxin outside the BSL-3 laboratory is suspected, the Principal Investigator will notify the BSO, ORC as well as the RO, and the building manager.

7.5 Exposure of laboratory personnel to cultures. The following incidents may result in unintentional exposure to the Select Agent that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to the BSO, who will notify the Scott & White Occupational Health office to evaluate the need for post-exposure prophylaxis. The exposure will be reported by the Principal Investigator to the BSO who reports immediately to the Responsible Official, who will notify CDC of the exposure. The following are examples of unintentional exposure:

7.5.1 A spill of live culture outside the Biosafety cabinet;

7.5.2 Failure of the Biosafety cabinet during work with *Brucella*;

7.5.3 Needle stick or cut with sharps contaminated with *Brucella*;

7.5.4 If a bite from a *Brucella*-infected animal penetrates the double gloves and breaks the skin;

7.5.5 A centrifuge accident that results in aerosolization of *Brucella*.

8. **Process of reporting and investigating a Release:**

Release – Occupational exposure (clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been release outside of the primary bio-containment barrier.) or release of an agent or toxin outside of the primary barriers of the biocontainment area.

8.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected release to the BSO in the Environment Health and Safety Department (EHSD). Based on circumstances, the BSO will notify the

University Police Department (UPD). During normal business hours, call the BSO at the EHSD at 845-2132. If it is outside of normal business hours, call UPD who will notify EHSD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345).

If the release is discovered and the BSO is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the individual shall then notify the LD/PI.

After notification to the BSO by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact the Office of Research Compliance (ORC).

- 8.1.1 Upon notification of discovery of a release, the BSO will immediately notify Scott & White Occupational Health Clinic and ORC.
 - 8.1.2 Upon notification from the BSO, ORC will immediately notify the Responsible Official (RO) and the Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, EHSD, and UPD.
 - 8.1.3 The BSO (and UPD, based on circumstances) will immediately investigate the incident. The investigation will include the coordination with the LD/PI and others approved with access or visiting SBAT facilities. The BSO will submit a written report to ORC within 5 days of being notified about discovery of the release. If the investigation provides evidence that a release did not occur, circumstances will be documented in BSO's investigation report.
 - 8.1.4 Based on the BSO report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss, or Release of Select Agents and Toxins) with the CDC within seven calendar days of the discovery of the release. ORC will maintain an official copy of information submitted to the CDC and will provide a copy of the submission to the RO, BSO, and LD/PI.
 - 8.1.5 The BSO will obtain confirmation from health care providers that reports to other state or federal health agencies have been submitted. The LD/PI will ensure notification to the funding agency.
- 8.2 A risk assessment will be conducted immediately upon discovery regarding any release.
- 8.2.1 In addition to the investigation, upon notification of a release, EHSD (under the direction of the Biological Safety Officer (BSO)) will conduct a risk assessment to determine if the laboratory is operating in a safe manner and attempt to determine the cause or most likely route of the release. This risk assessment shall include but not be limited to a comprehensive laboratory survey, review of access logs to determine potential occupational exposures, review of inventory records, and verification that all equipment is operating within normal parameters (e.g., biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of the release will also be reviewed by the BSO and modified, as warranted, in consultation with the LD/PI. If deficiencies in safe practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
 - 8.2.2 If deemed necessary based on the risk assessment, the BSO will contact ORC to convene a special meeting of the Institutional BioSafety Committee.

- 8.2.3 Documentation of the risk assessment will be maintained by BSO with a copy sent to the LD/PI and the ORC.
- 8.2.4 Risk assessments will be completed with input from the LD/PI. The results of the risk assessment and findings, including any requirements for post decontamination procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI and ORC.
- 8.2.5 ORC will contact CDC, and if needed, a copy of the risk assessment will be submitted. ORC will also update the RO.
- 8.3 The following additional steps will also be taken immediately upon discovery regarding an actual or suspected occupational exposure:
 - 8.3.1 BSO will direct the LD/PI to notify laboratory personnel and visitors that a potential exposure has occurred and refer them to Scott & White Occupational Health for consultation. BSO will obtain access logs and other information to determine a complete list of potentially exposed personnel. BSO will then follow-up with potentially exposed personnel to ensure notification.
 - 8.3.2 Individuals will be encouraged to contact Occupational Health at Scott & White Clinic, or to immediately identify to medical personnel, the agent they were potentially exposed to if treatment is sought. Scott & White Occupational Health Clinic or the attending physician will screen for the organism (e. g. Brucella species), and begin prophylaxis as deemed appropriate by the attending physician.
 - 8.3.3 If an occupational exposure is confirmed through appropriate medical tests or as determined by a physician, all personnel and potentially exposed individuals will be immediately referred to Scott & White for screening, testing, or preventive prophylaxis as determined by the attending physician. If personnel or visitors are at remote locations (other university facilities, traveling), they should immediately report to a physician of choice and explain that a positive occupational exposure to a specific organism has occurred and specific treatment or screening is desired. Personal physicians should be encouraged to contact either the BSO or Scott and White Occupational Health if they have any questions.
 - 8.3.4 The BSO, in consultation with Scott & White, will perform periodic follow-up with the group of exposed or potentially exposed personnel for a period of time as appropriate for the organism.
- 8.4 EHSD will establish and maintain a specific file for each release incident, with all pertinent information.
- 8.5 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected release to the BSO and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

9. Security Breach:

A security breach will be determined to have occurred if any of the following are observed:

- 9.1 The access control system has failed, leaving the BSL-3 building accessible to unauthorized persons;
- 9.2 An unauthorized person is observed unaccompanied in the BSL-3 building;
- 9.3 A lost or stolen card was used to access the BSL-3 building;

- 9.4 An unauthorized person has accessed the computer used to control entry to the BSL-3 building;
- 9.5 An unexpected or suspicious package is found in or near a BSL-3 building.

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the UPD of the security breach and take steps to correct the problem. Corrective procedures will be secured immediately, but no later than 24 hours; an inventory will be performed of all samples and animals in the building. Any missing Select Agent samples or animals will be reported to CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator and the UPD and ORC will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

10. Severe weather or natural disasters.

The most likely occurrences in this area are severe thunderstorms, floods or tornadoes.

- 10.1 If severe weather (thunderstorms or flooding) is predicted, experiments with Select Agents should be suspended until the severe weather has passed to avoid power outages during the work.
- 10.2 If an earthquake is felt, workers should immediately leave the building--if possible, shedding gloves and lab coat on the way out of the BSL-3 building. Cleanup, if necessary, can be performed once it is safe to re-enter the building.

11. Fire, Gas leak, Steam leak, Explosion, Bomb threat:

- 11.1 If work is being performed in the Biosafety cabinet, cap all samples, dispose of gloves and outer laboratory coat, and leave the building immediately. If the worker feels (s)he can safely extinguish the fire, then the fire extinguisher located in the interior dressing area may be used. If a worker feels his or her safety threatened, (s)he should leave the building immediately without stopping to decontaminate or secure any work. Upon leaving the building, personnel should assemble outside the building one end of the compound at a safe distance from the building.
- 11.2 Notify the appropriate emergency responders: Fire 9-911 or 911 from mobile phones, the Principal Investigator, UPD and the BSO. For steam and gas leaks, notify TAMU Operations and Maintenance.
- 11.3 In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police immediately by calling the emergency number, 9-911 or 911 or 845-2345 or 845-8900. Also inform the Principal Investigator, BSO and ORC. Always be sure to give the number and location of the building and your name and telephone extension number.
 - 11.3.1 The University Police Department will assign personnel to investigate the call and take whatever police action they may deem necessary and reasonable for the safety of the campus community. The University Police will conduct a search of the building, or of specific locations in or around the building. When judged prudent and feasible to do so, the search will be conducted with the assistance and cooperation of the Principal Investigator and/or ORC. After an evaluation/assessment of the content of the bomb threat, the decision to evacuate or close building shall be made jointly, whenever possible, by the Police and the Principal Investigator and/or ORC.
 - 11.3.2 Any unusual or suspicious object should be reported immediately to the University Police or to any immediate supervisor or administrative officer. Suspected objects or materials should NOT be touched or disturbed. Every bomb threat or incident of a suspected explosive device should be considered valid until

all reasonable precautions for public safety have been taken or until the danger to life and property is terminated.

12. Failure of Select Agent Storage Freezer:

- 12.2 If a -80°C freezer in any building that is used to store Brucella strains fails, the strains will be moved in appropriate containment to a temporary backup location, which is in _____, or in secure freezer in a locked BSL-2 laboratory.

13. Workplace violence:

- 13.1 Incidents of disruptive or threatening behavior on the part of an employee, student or visitor should be reported immediately to the Principal Investigator, who will report the incident to the Department Head, UPD, ORC and the Workplace Violence Response Team, as proscribed by the TAMU Personnel and Procedures manual section 290-09. If the individual accused of disruptive or threatening behavior is authorized for access to select agents, this person's access will be suspended pending the results of an investigation by the Workplace Violence Response Team. If an act of violence or a physical assault has occurred, or the threatening activity occurs within the BSL-3 building, the person feeling threatened should call UPD immediately to report the incident. If the person accused of violence has access to select agents, the person's access will be suspended pending the outcome of the investigation. Suspension of select agent access will be reported to UPD and ORC and a suspended individual's access will be inactivated within 24 hours.

14. Entry of emergency responders into the BSL-3 laboratory.

- 14.1 In a case in which a life-threatening injury or medical condition (i.e. heart attack) occurs inside the BSL-3 building, emergency responders will be allowed to enter the laboratory. If possible, upon feeling ill the laboratory worker should immediately exit the building to facilitate treatment by emergency responders. Personnel protective equipment, including Tyvek suits, PAPRs and gloves, are located inside the entries (locker rooms) to the BSL-3 building. A spill kit containing absorbent materials and disinfectant is located in the interior dressing area. A First Aid kit is located in the interior dressing area. If responders are required to enter an area where a spill has occurred, they will be referred to the BSO and the Scott and White Occupational Health office and evaluated for possible post-exposure prophylaxis.
- 14.1.1 Entry procedure for the BSL-3 laboratory: Dress in a Tyvek suit, gloves, shoe covers and PAPRs before entering the building.
- 14.1.2 Providing first aid and emergency medical treatment in the BSL-3 laboratory: A person working inside the Biosafety hood is not considered to be contagious unless a spill has occurred. The person's gloves may be contaminated, and may be removed to facilitate treatment. If there is no space within the labs to put the person on the floor, move the person to the interior dressing area to administer treatment.
- 14.1.3 Exit procedure from the BSL-3 laboratory: Emergency responders must decontaminate with appropriate disinfectant, remove Tyvek suit, PAPRs, shoe covers and gloves in the inner dressing room before exiting. Hands should be washed immediately before and after exit from the BSL-3 laboratory.
- 14.1.4 Decontamination procedures for medical equipment and clothing: Emergency responders should decontaminate equipment before leaving the laboratory by one of the following methods:
- 14.1.4.1 Autoclaving. Autoclaves are located in Room _____
- 14.1.5 Decontaminate with 1% Virkon, 1X Wexcide or dilute sodium hypochlorite.

15. Incident Response Plan Testing (Drills)

- 15.1 Drills or tabletop exercises will be conducted annually to test the effectiveness of the Biosafety plan. The drills or exercises will be coordinated with the TAMU Police Department and will include, but not be limited to, the Principal Investigator or designee, BSO, TAMU Fire Department representative and the Campus Emergency Planner.
 - 15.2 The drill or exercise will include, but not be limited to, accessibility to restricted space, attempted or unauthorized entry into restricted spaces challenge, animal room security, staff knowledge of hazard/emergency protocols for their work location(s) and other situations that are deemed appropriate for each work location.
 - 15.3 Following the drill or exercise, which will test the various components of the incident response plan for completeness, those involved will critique their findings for each drill/exercise location. The Principal Investigator working with the ORC and BSO will implement changes as necessary changes to the plan. Results of the drill or exercise will be reviewed by the Biological Safety Administrative Advisory Committee (Institutional Biosafety Committee).
- 16. Texas A&M University Crisis Management Plan**
- 16.1 The entity crisis management plan is contained in a separate document and is referenced in the individual laboratory emergency response plan.
 - 16.2 Additional information concerning the laboratory emergency response plan is contained in the laboratory's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance and the Environmental Health & Safety Department.
 - 16.3 The ORC and BSO should be contacted immediately in the case of any emergency in a select agent lab. The ORC will coordinate access and information issues with campus police, fire, and emergency responders.
 - 16.4 If necessary, the ORC will coordinate the emergency relocation of select agents to another secure location.
- 17. Site security and control are described in detail in the Select Agent Security Plan**
- 17.1 The buildings are secured by a keyed lock. Sharing of keys with other personnel is not permitted.
 - 17.2 Individuals not authorized for access to Select Agents must be accompanied by approved personnel at all times while in the buildings.
 - 17.3 Data that could enable access to select agents by unauthorized personnel should be located on password-protected computers.
 - 17.4 If approved personnel are observed violating security or Biosafety procedures, this observation should be reported immediately to the Principal Investigator. The Principal investigator will investigate the allegation and determine whether the alleged violator should be reported to the ORC and/or the UPD to have their Select Agent access suspended or revoked. Suspension of Select Agent access will be reported to the ORC and the individual's key card access will be terminated within 24 hours.
- 18. Inventory Discrepancies:**
- 18.1 Inventory discrepancies will be documented on the agent access form.
 - 18.2 All discrepancies will be immediately reported to the Principal Investigator.
 - 18.3 If the discrepancy is believed to be a result of loss or theft, the incident response procedures for loss or theft and release will be followed.
 - 18.4 If the discrepancy is a result of a transfer, the transfer form will be documented.
- 19. References**
- 19.1 42 CFR Part 73
 - 19.2 7 CFR Part 331
 - 19.3 9 CFR Part 121
 - 19.4 Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention, National Institutes of Health, Fourth Edition, May 1999

- 19.5 Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents (Revised BMBL, Appendix F), published in Morbidity and Mortality Weekly Report, December 6, 2002.

SBAT Incident Response
Emergency Contact Numbers

PI Information			
PI Ficht Office – 979 845-4118 Mobile – 979 574-9466 Home -			
Building Manager Loren Skow Office – 979-845-3194			
Department Head Gerald Bratton Office – 979-845-5941			
Incidents involving Theft or Loss University Police Department (UPD) contact Bert Kretzschmar Office – 979 845-8900 Mobile - Home -			
Incidents involving a Release (or Occupational Exposure) Environmental Health and Safety Office contact Between 8:00 a.m. and 5:00 p.m. Brent Mattox, Biosafety Officer (BSO) Alternate Responsible Official (ARO) Office – 979 865-2132 Mobile – 979 450-0662 After hours 5:00 pm Contact the University Police Department contact Lt. Bert Kretzschmar Office – 979 845-8900 Mobile - 979 574-9466 Home -			
Other Contact information			
Vice President for Research/Responsible Official (RO)	Richard Ewing (RO)	979 845-8585 (Office) or	(Mobile)
	Fuller Bazer (ARO)	979 693-2876 (Office) or	(Mobile)
	Angelia Raines (ARO)	979 847-9362 (Office) or	(Mobile)
Comparative Medicine Program	Melanie Ihrig	979 845-7433 (Office) or	(Mobile)
	Elizabeth Browder	979 845-7433 (Office) or	(Mobile)
	Frank Stein	979 845-6488 (Office) or	(Mobile)
Institutional Biosafety Committee (IBC)	Thomas Ficht	979 845-4118 (Office) or	(Mobile)
	Vernon Tesh	979 862-4113 (Office) or	(Mobile)
	Tiffany Agnew	979 458-3624 (Office) or	(Mobile)
Other Emergency Numbers	College Station Police	979 764-3600 or 9-911	
	Medical Emergency	9-911	
	College Station Fire	979 764-3700 or 9-911	
	Radiological Emergency	979 832-1111	
	University Maintenance	979 845-4311	

Emergency Telephone Numbers

Thomas A. Ficht	Office: (979)845-4118 Home: (979) 845-4118 Mobile: (979) 845-4118
Emergency	9-911
University Police	(979) 845-2345
College Station Police	(979) 764-3600
College Station Fire	(979) 764-3700
Environmental Health & Safety	(979) 845-2132
TAMU Area Maintenance (HVAC failure, steam leak, gas leak)	(979) 845-5542
TAMU Maintenance (24 hours)	(979) 845-4311
Radiological Emergencies	(979) 862-1111
Responsible University Officials:	
RO-Richard Ewing	Work: (979) 845-8585 Mobile: (979) 845-8585
ARO-Angelia Raines	Work: (979) 847-9362 Mobile: (770) 789-3456
Biosafety Officer/ARO -Brent Mattox	Work: (979) 845-2132 Mobile: (979) 845-2132
Building Manager	Loren Skow 979-845-3194
Frank Stein	Work: (979) 845-6488 Mobile: (979) 845-6488
T. A. Ficht Lab	979-845-4185
Neighboring labs to notify in case of simultaneous containment breach and spill outside BSC:	
Lab (enter additional locations)	enter additional laboratory phone number
Lab (enter additional locations)	enter additional laboratory phone number
Lab (enter additional locations)	enter additional laboratory phone number

Decontamination Procedures for Spills of Cultures
(Please customize for specific laboratories.)

1. Signal others in the BL3 labs of any spill outside the biological safety cabinet. All personnel should change out of contaminated clothing and wash any exposed skin with a disinfectant, such as Purell. Clothes must be removed within the BL3 area and will be autoclaved by those cleaning up.
2. Put on a clean scrub suit and go to the shower on the first floor animal facility. Shower thoroughly with soap.
3. Return to the lab for cleanup: Put on a PAPR and tyvek suit (contained in the SPILL KIT). Put on double gloves and shoe covers.
4. Use paper towels to cover the spill. Prevent creation of contaminated aerosols.
5. Saturate all materials with 10% bleach solution (see previous section for description).
6. Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in autoclave bags.
7. Disinfect all exposed surfaces using 1X Wexcide or 1% Virkon (surface disinfectant solution).
8. Wipe surface of full-face respirator with 1% Virkon or 1X Wexcide, being careful to avoid skin contact with Wexcide.
9. Remove all clothing and place in autoclave bag.
10. Remove full face respirator and spray off all surfaces in the lab with 1% Virkon or 1X Wexcide.
11. Make sure that all contaminated material is autoclaved, surface-disinfected or incinerated.
12. Inform others not to work in the lab until the air handling system is able to clear any residual organisms from the air (3h).
13. Return to the lab after 3 hours and perform another decontamination of all lab surfaces with 1% Virkon or 1X Wexcide.
14. Report accident to the Principal Investigator, who will report it to other officials.

Contents of spill kit located in BL-3 labs:

Full-face respirator, Tyvek suit, clean scrub suit, absorbent material, Purell skin disinfectant, towel, copy of decontamination procedures for spills.

INCIDENT RESPONSE PLAN
For BSL3 Buildings
PI – Ficht
PI Adams
Texas A&M University, College Station, TX 77843
to ensure compliance with
42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

- 1.1 General. This is the incident response plan for the possession and use of *Brucella abortus*, *Brucella suis* and *Brucella melitensis* at Texas A&M University main campus (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121. This plan covers the use of these select agents when used in buildings . . .
- 1.2. This plan describes the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

- 2.1 Principal Investigator (PI). The Principal Investigator, Dr. Thomas A. Ficht, has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to Dr. Ficht. The PI is responsible for ensuring all incidents regarding theft, loss or release are immediately reported to the proper institutional officials. This document outlines response actions concerning any theft, loss, or release from select biological agents and toxins (SBAT) facilities, including illness of personnel or visitors in SBAT facilities. Certain actions outlined below are performed in parallel rather than sequentially (see attached flowchart).
- 2.2 All lab personnel (including the PI) are responsible for immediately reporting an incident to the University Police Department (UPD) for theft or loss or to the Institutional Biosafety Officer (BSO) for release (including occupational exposure).
- 2.3 UPD – Responsible for immediately contacting the Alternate Responsible Official (ARO) and beginning an investigation of the incident. A written investigation report will be submitted to the Institutional Biosafety Committee (IBC), the PI and the ARO within 5 days of the incident. UPD will also work with the PI to conduct a security assessment following any incident involving loss or theft.
- 2.3 BSO - Responsible for immediately contacting the Alternate Responsible Official and beginning an investigation of the incident. A written investigation report will be submitted to the IBC, the PI and the ARO within 5 days of the incident. The BSO will also work with the PI to conduct a safety assessment following any incident involving a release (including occupational exposure).
- 2.4 ARO - Responsible for immediately contacting the Responsible Official, CDC, NIH (if rDNA) and other key institutional contacts regarding the incident. The ARO will work with the BSO, UPD and the PI to insure that the written report is correct and that the report will be submitted to CDC, NIH (if rDNA) and other key institutional contacts.

2.5 Responsible Official – Is responsible for compliance to the Select Agent regulations and insuring requirements (registration, investigations, etc) are properly carried out.

2.6 Contact information is found on the Emergency contact list. The list is attached to this document and is posted throughout the lab.

2.7 Annual Program Review. The Responsible Official or Alternate Responsible Official will audit the incident response program on an annual basis. This review will include drills and exercises to ensure the effectiveness of the incident response plan. Based on the outcome of drills, exercises or reported incidents, this incident response plan will be reviewed and updated as necessary.

3. Description of Work

This plan covers all work being performed at TAMU. Each lab will be responsible for providing information specific to the work being performed as follows:

Lab	Work description	Unique features of Agent	Biological Use Authorization	Biosafety Level
	Work with Brucella abortus, B. suis, B. melitensis	BSC	0741	3
	Inoculation of mice and ruminants with Brucella spp.	BSC	0741	3
	Storage of Brucella-infected animal carcasses	Locked freezer	0741	3

Additional information concerning the laboratories and the select agent use is contained in the facility's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or Environmental Health and Safety Office.

4. Response to theft:

4.1 Determination of Loss or Theft – The following are examples of events that may be considered a loss or theft. Possible loss or theft of the select agent will be reported initially to the Principal Investigator if any of the following have occurred:

- 4.1.1 The lock on the Select Agent storage area has been found open or appears to have been tampered with;
- 4.1.2 Evidence of forced entry into the laboratory or storage areas has been found;
- 4.1.3 A discrepancy in the Select Agent inventory that can not be reconciled;
- 4.1.4 An employee reports cultures or samples missing;
- 4.1.5 A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2;
- 4.1.6 An infected animal is missing from its housing unit.

4.2 Report/Investigation Process:

Theft (unauthorized removal) or **Loss** (failure to account for) a select agent or toxin

4.2.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected theft or loss of SBATS to UPD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345). Based on circumstances, UPD will notify EHSD.

If the release is discovered and UPD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the person shall then notify the LD/PI.

After notification to UPD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact ORC.

- 4.2.1.1 Upon notification of discovery of a theft or loss, UPD will immediately notify ORC.
- 4.2.1.2 Upon notification from UPD, ORC will immediately notify the Responsible Official (RO) and Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, and UPD.
- 4.2.1.3 UPD (and ESHD, based on circumstances) will immediately investigate the incident. The investigation will include coordination with the LD/PI and others approved with access or visiting SBAT facilities. UPD will submit a written report to ORC within 5 days of being notified about the discovery of the theft or loss. If the investigation provides evidence that a theft or loss did not occur, circumstances will be documented in UPD's investigation report.
- 4.2.1.4 Based on the UPD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss or Release of Select Agents and Toxins) with CDC. ORC will maintain an official copy of information submitted to CDC and will provide a copy of the submission to the RO, UPD/EHSD, and LD/PI.
- 4.2.1.5 UPD will notify the appropriate Federal, State, or local law enforcement agencies.
- 4.2.1.6 The LD/PI will ensure notification to the funding agency
- 4.2.2 A risk assessment will be conducted immediately upon discovery of a loss or theft. The risk assessment will be a part of the investigation report.
 - 4.2.2.1 In addition to the investigation, upon notification of a theft or loss, UPD (with input from EHSD and the LD/PI) will conduct a risk assessment to determine if the laboratory is operating in a safe and secure manner and to attempt to determine the cause of the theft. This risk assessment shall include, but not be limited to a comprehensive laboratory survey, review of access logs, review of inventory records, and verification that all equipment is operating within normal parameters (e. g. biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of theft will also be reviewed and modified, as warranted. If deficiencies in safe and secure practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
 - 4.1.2.2 If deemed necessary, the EHSD/UPD will contact Biosafety Program Coordinator to convene a special meeting of the Institutional BioSafety Committee (IBC).

4.1.2.3 Documentation of the risk assessment will be maintained by UPD with a copy sent to the LD/PI, EHSD and ORC.

4.1.2.4 Security Risk Assessments will be completed by UPD, with input from the LD/PI (and EHSD, based on circumstances). The results of the risk assessment and findings, including any requirements for post theft procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI, EHSD, and ORC.

4.1.2.5 The ORC will contact CDC, and if needed, a copy of the assessment will be submitted. ORC will also update the RO.

4.2.3 UPD will establish and maintain a specific file for each theft or loss incident, with all pertinent information.

4.2.4 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected loss or theft to UPD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

5. Investigation

5.1 The Investigation Committee for all releases will be headed by the EHSD's Institutional Biosafety Officer (BSO) with input from UPD and the PI. UPD will lead investigations involving theft or loss, with input from the BSO and PI.

5.1.1 The BSO/UPD will investigate the event as quickly as possible, but no later than 24 hours of the initial report or the incident.

5.1.2 The investigation should include a review of all materials related to the research, including access logs, inventory logs, laboratory notes and laboratory plans (security, safety and incident response)

5.1.3 Once the investigation is complete, the BSO or UPD will submit an investigation report to the IBB and RO.

5.1.4 Once the Committee has determined the response and informed the RO and IBC (through the Office of Research Compliance), the IBC will review the report and make a recommendation to the RO of any additional actions that they believe are needed.

5.1.5 After the RO has approved of the recommended actions, the PI will receive a written response from the IBC.

6. Reporting

6.1 All incident reports are included in the IBC agenda minutes for review by the full board at the next convened meeting. Serious events should be specifically presented to the IBC by the BSO/UPD or IBC Chair at the next convened meeting.

6.1.1 The investigation report, at a minimum, shall include the following information:

6.1.1.1 A detailed description of the incident.

6.1.1.2 A list of all personnel involved in the incident.

6.1.1.3 A description of what occurred and what has or needs to be done to prevent any future incident.

6.1.1.4 An assessment of the safety or security risk of continuing the research.

6.1.1.5 A recommendation of any changes that need to be made to the plans (safety, security or incident response), medical surveillance or laboratory procedures to reduce the risk of a reoccurrence.

6.1.1.6 A recommendation for training, if needed.

6.1.2 Incidents involving SBAT will be immediately reported to the CDC with a written report (Form 3) submitted within seven (7) days.

6.1.3 Events involving rDNA must be reported to the NIH immediately in writing but no later than 30 days of the incident.

7. Release of a Select Agent or Toxin.

Examples of a possible release (including occupational exposures of the agent or toxin) include but are not limited to the following:

7.1 A package containing the Select Agent or toxin that has been received, which has been damaged in transit, such that the primary containment vessel appears to have been compromised;

7.2 Simultaneous complete power failure of the Biosafety cabinet and loss of negative pressure in the BSL-3 suite during work in the Biosafety cabinet with open cultures;

7.3 Simultaneous spill of cultures outside the Biosafety cabinet and failure of negative pressure in the Biosafety Level 3 area. In case of a spill, a spill kit containing absorbent material and disinfectant will be located in each building;

7.3.1 Personnel are advised to immediately leave the building after removing any contaminated clothing and to return in Tyvek suits with full face respirators (Powered Air Purifying Respirator (PAPR)) after the air has been scrubbed clean by air handlers (approx. one hour).

1.1.1. In case release of the Select Agent or toxin outside the BSL-3 laboratory is suspected, the Principal Investigator will notify the BSO, ORC as well as the RO, and the building manager.

7.5 Exposure of laboratory personnel to cultures. The following incidents may result in unintentional exposure to the Select Agent that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to the BSO, who will notify the Scott & White Occupational Health office to evaluate the need for post-exposure prophylaxis. The exposure will be reported by the Principal Investigator to the BSO who reports immediately to the Responsible Official, who will notify CDC of the exposure. The following are examples of unintentional exposure:

7.5.1 A spill of live culture outside the Biosafety cabinet;

7.5.2 Failure of the Biosafety cabinet during work with *Brucella*;

7.5.3 Needle stick or cut with sharps contaminated with *Brucella*;

7.5.4 If a bite from a *Brucella*-infected animal penetrates the double gloves and breaks the skin;

7.5.5 A centrifuge accident that results in aerosolization of *Brucella*.

8. Process of reporting and investigating a Release:

Release -- Occupational exposure (clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been release outside of the primary bio-containment barrier.) or release of an agent or toxin outside of the primary barriers of the biocontainment area.

8.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected release to the BSO in the Environment Health and Safety Department (EHSD). Based on circumstances, the BSO will notify the

University Police Department (UPD). During normal business hours, call the BSO at the EHSD at 845-2132. If it is outside of normal business hours, call UPD who will notify EHSD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345).

If the release is discovered and the BSO is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the individual shall then notify the LD/PI.

After notification to the BSO by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact the Office of Research Compliance (ORC).

- 8.1.1 Upon notification of discovery of a release, the BSO will immediately notify Scott & White Occupational Health Clinic and ORC.
 - 8.1.2 Upon notification from the BSO, ORC will immediately notify the Responsible Official (RO) and the Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, EHSD, and UPD.
 - 8.1.3 The BSO (and UPD, based on circumstances) will immediately investigate the incident. The investigation will include the coordination with the LD/PI and others approved with access or visiting SBAT facilities. The BSO will submit a written report to ORC within 5 days of being notified about discovery of the release. If the investigation provides evidence that a release did not occur, circumstances will be documented in BSO's investigation report.
 - 8.1.4 Based on the BSO report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss, or Release of Select Agents and Toxins) with the CDC within seven calendar days of the discovery of the release. ORC will maintain an official copy of information submitted to the CDC and will provide a copy of the submission to the RO, BSO, and LD/PI.
 - 8.1.5 The BSO will obtain confirmation from health care providers that reports to other state or federal health agencies have been submitted. The LD/PI will ensure notification to the funding agency.
- 8.2 A risk assessment will be conducted immediately upon discovery regarding any release.
- 8.2.1 In addition to the investigation, upon notification of a release, EHSD (under the direction of the Biological Safety Officer (BSO)) will conduct a risk assessment to determine if the laboratory is operating in a safe manner and attempt to determine the cause or most likely route of the release. This risk assessment shall include but not be limited to a comprehensive laboratory survey, review of access logs to determine potential occupational exposures, review of inventory records, and verification that all equipment is operating within normal parameters (e.g., biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of the release will also be reviewed by the BSO and modified, as warranted, in consultation with the LD/PI. If deficiencies in safe practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
 - 8.2.2 If deemed necessary based on the risk assessment, the BSO will contact ORC to convene a special meeting of the Institutional BioSafety Committee.

- 8.2.3 Documentation of the risk assessment will be maintained by BSO with a copy sent to the LD/PI and the ORC.
- 8.2.4 Risk assessments will be completed with input from the LD/PI. The results of the risk assessment and findings, including any requirements for post decontamination procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI and ORC.
- 8.2.5 ORC will contact CDC, and if needed, a copy of the risk assessment will be submitted. ORC will also update the RO.
- 8.3 The following additional steps will also be taken immediately upon discovery regarding an actual or suspected occupational exposure:
 - 8.3.1 BSO will direct the LD/PI to notify laboratory personnel and visitors that a potential exposure has occurred and refer them to Scott & White Occupational Health for consultation. BSO will obtain access logs and other information to determine a complete list of potentially exposed personnel. BSO will then follow-up with potentially exposed personnel to ensure notification.
 - 8.3.2 Individuals will be encouraged to contact Occupational Health at Scott & White Clinic, or to immediately identify to medical personnel, the agent they were potentially exposed to if treatment is sought. Scott & White Occupational Health Clinic or the attending physician will screen for the organism (e. g. Brucella species), and begin prophylaxis as deemed appropriate by the attending physician.
 - 8.3.3 If an occupational exposure is confirmed through appropriate medical tests or as determined by a physician, all personnel and potentially exposed individuals will be immediately referred to Scott & White for screening, testing, or preventive prophylaxis as determined by the attending physician. If personnel or visitors are at remote locations (other university facilities, traveling), they should immediately report to a physician of choice and explain that a positive occupational exposure to a specific organism has occurred and specific treatment or screening is desired. Personal physicians should be encouraged to contact either the BSO or Scott and White Occupational Health if they have any questions.
 - 8.3.4 The BSO, in consultation with Scott & White, will perform periodic follow-up with the group of exposed or potentially exposed personnel for a period of time as appropriate for the organism.
- 8.4 EHSD will establish and maintain a specific file for each release incident, with all pertinent information.
- 8.5 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected release to the BSO and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

9. Security Breach:

A security breach will be determined to have occurred if any of the following are observed:

- 9.1 The access control system has failed, leaving the BSL-3 building accessible to unauthorized persons;
- 9.2 An unauthorized person is observed unaccompanied in the BSL-3 building;
- 9.3 A lost or stolen card was used to access the BSL-3 building;

- 9.4 An unauthorized person has accessed the computer used to control entry to the BSL-3 building;
- 9.5 An unexpected or suspicious package is found in or near a BSL-3 building.

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the UPD of the security breach and take steps to correct the problem. Corrective procedures will be secured immediately, but no later than 24 hours; an inventory will be performed of all samples and animals in the building. Any missing Select Agent samples or animals will be reported to CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator and the UPD and ORC will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

10. Severe weather or natural disasters.

The most likely occurrences in this area are severe thunderstorms, floods or tornadoes.

- 10.1 If severe weather (thunderstorms or flooding) is predicted, experiments with Select Agents should be suspended until the severe weather has passed to avoid power outages during the work.
- 10.2 If an earthquake is felt, workers should immediately leave the building--if possible, shedding gloves and lab coat on the way out of the BSL-3 building. Cleanup, if necessary, can be performed once it is safe to re-enter the building.

11. Fire, Gas leak, Steam leak, Explosion, Bomb threat:

- 11.1 If work is being performed in the Biosafety cabinet, cap all samples, dispose of gloves and outer laboratory coat, and leave the building immediately. If the worker feels (s)he can safely extinguish the fire, then the fire extinguisher located in the interior dressing area may be used. If a worker feels his or her safety threatened, (s)he should leave the building immediately without stopping to decontaminate or secure any work. Upon leaving the building, personnel should assemble outside the building one end of the compound at a safe distance from the building.
- 11.2 Notify the appropriate emergency responders: Fire 9-911 or 911 from mobile phones, the Principal Investigator, UPD and the BSO. For steam and gas leaks, notify TAMU Operations and Maintenance.
- 11.3 In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police immediately by calling the emergency number, 9-911 or 911 or 845-2345 or 845-8900. Also inform the Principal Investigator, BSO and ORC. Always be sure to give the number and location of the building and your name and telephone extension number.
 - 11.3.1 The University Police Department will assign personnel to investigate the call and take whatever police action they may deem necessary and reasonable for the safety of the campus community. The University Police will conduct a search of the building, or of specific locations in or around the building. When judged prudent and feasible to do so, the search will be conducted with the assistance and cooperation of the Principal Investigator and/or ORC. After an evaluation/assessment of the content of the bomb threat, the decision to evacuate or close building shall be made jointly, whenever possible, by the Police and the Principal Investigator and/or ORC.
 - 11.3.2 Any unusual or suspicious object should be reported immediately to the University Police or to any immediate supervisor or administrative officer. Suspected objects or materials should NOT be touched or disturbed. Every bomb threat or incident of a suspected explosive device should be considered valid until

all reasonable precautions for public safety have been taken or until the danger to life and property is terminated.

12. Failure of Select Agent Storage Freezer:

- 12.2 If a -80°C freezer in any building that is used to store Brucella strains fails, the strains will be moved in appropriate containment to a temporary backup location, which is in room [Building] or in secure freezer in a locked BSL-2 laboratory.

13. Workplace violence:

- 13.1 Incidents of disruptive or threatening behavior on the part of an employee, student or visitor should be reported immediately to the Principal Investigator, who will report the incident to the Department Head, UPD, ORC and the Workplace Violence Response Team, as proscribed by the TAMU Personnel and Procedures manual section 290-09. If the individual accused of disruptive or threatening behavior is authorized for access to select agents, this person's access will be suspended pending the results of an investigation by the Workplace Violence Response Team. If an act of violence or a physical assault has occurred, or the threatening activity occurs within the BSL-3 building, the person feeling threatened should call UPD immediately to report the incident. If the person accused of violence has access to select agents, the person's access will be suspended pending the outcome of the investigation. Suspension of select agent access will be reported to UPD and ORC and a suspended individual's access will be inactivated within 24 hours.

14. Entry of emergency responders into the BSL-3 laboratory.

- 14.1 In a case in which a life-threatening injury or medical condition (i.e. heart attack) occurs inside the BSL-3 building, emergency responders will be allowed to enter the laboratory. If possible, upon feeling ill the laboratory worker should immediately exit the building to facilitate treatment by emergency responders. Personnel protective equipment, including Tyvek suits, PAPRs and gloves, are located inside the entries (locker rooms) to the BSL-3 building. A spill kit containing absorbent materials and disinfectant is located in the interior dressing area. A First Aid kit is located in the interior dressing area. If responders are required to enter an area where a spill has occurred, they will be referred to the BSO and the Scott and White Occupational Health office and evaluated for possible post-exposure prophylaxis.
- 14.1.1 Entry procedure for the BSL-3 laboratory: Dress in a Tyvek suit, gloves, shoe covers and PAPRs before entering the building.
- 14.1.2 Providing first aid and emergency medical treatment in the BSL-3 laboratory: A person working inside the Biosafety hood is not considered to be contagious unless a spill has occurred. The person's gloves may be contaminated, and may be removed to facilitate treatment. If there is no space within the labs to put the person on the floor, move the person to the interior dressing area to administer treatment.
- 14.1.3 Exit procedure from the BSL-3 laboratory: Emergency responders must decontaminate with appropriate disinfectant, remove Tyvek suit, PAPRs, shoe covers and gloves in the inner dressing room before exiting. Hands should be washed immediately before and after exit from the BSL-3 laboratory.
- 14.1.4 Decontamination procedures for medical equipment and clothing: Emergency responders should decontaminate equipment before leaving the laboratory by one of the following methods:
- 14.1.4.1 Autoclaving. Autoclaves are located in Room
- 14.1.5. Decontaminate with 1% Virkon, 1X Wexcide or dilute sodium hypochlorite.

15. Incident Response Plan Testing (Drills)

- 15.1 Drills or tabletop exercises will be conducted annually to test the effectiveness of the Biosafety plan. The drills or exercises will be coordinated with the TAMU Police Department and will include, but not be limited to, the Principal Investigator or designee, BSO, TAMU Fire Department representative and the Campus Emergency Planner.
 - 15.2 The drill or exercise will include, but not be limited to, accessibility to restricted space, attempted or unauthorized entry into restricted spaces challenge, animal room security, staff knowledge of hazard/emergency protocols for their work location(s) and other situations that are deemed appropriate for each work location.
 - 15.3 Following the drill or exercise, which will test the various components of the incident response plan for completeness, those involved will critique their findings for each drill/exercise location. The Principal Investigator working with the ORC and BSO will implement changes as necessary changes to the plan. Results of the drill or exercise will be reviewed by the Biological Safety Administrative Advisory Committee (Institutional Biosafety Committee).
- 16. Texas A&M University Crisis Management Plan**
- 16.1 The entity crisis management plan is contained in a separate document and is referenced in the individual laboratory emergency response plan.
 - 16.2 Additional information concerning the laboratory emergency response plan is contained in the laboratory's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance and the Environmental Health & Safety Department.
 - 16.3 The ORC and BSO should be contacted immediately in the case of any emergency in a select agent lab. The ORC will coordinate access and information issues with campus police, fire, and emergency responders.
 - 16.4 If necessary, the ORC will coordinate the emergency relocation of select agents to another secure location.
- 17. Site security and control are described in detail in the Select Agent Security Plan**
- 17.1 The buildings are secured by a keyed lock. Sharing of keys with other personnel is not permitted.
 - 17.2 Individuals not authorized for access to Select Agents must be accompanied by approved personnel at all times while in the buildings.
 - 17.3 Data that could enable access to select agents by unauthorized personnel should be located on password-protected computers.
 - 17.4 If approved personnel are observed violating security or Biosafety procedures, this observation should be reported immediately to the Principal Investigator. The Principal investigator will investigate the allegation and determine whether the alleged violator should be reported to the ORC and/or the UPD to have their Select Agent access suspended or revoked. Suspension of Select Agent access will be reported to the ORC and the individual's key card access will be terminated within 24 hours.
- 18. Inventory Discrepancies:**
- 18.1 Inventory discrepancies will be documented on the agent access form.
 - 18.2 All discrepancies will be immediately reported to the Principal Investigator.
 - 18.3 If the discrepancy is believed to be a result of loss or theft, the incident response procedures for loss or theft and release will be followed.
 - 18.4 If the discrepancy is a result of a transfer, the transfer form will be documented.
- 19. References**
- 19.1 42 CFR Part 73
 - 19.2 7 CFR Part 331
 - 19.3 9 CFR Part 121
 - 19.4 Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention, National Institutes of Health, Fourth Edition, May 1999

- 19.5 Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents (Revised BMBL, Appendix F), published in Morbidity and Mortality Weekly Report, December 6, 2002.

SBAT Incident Response
Emergency Contact Numbers

PI Information			
PI Ficht			
Office – 979 845-4118			
Mobile –			
Home –			
Building Manager			
Loren Skow			
Office – 979-845-3194			
Department Head			
Gerald Bratton			
Office – 979-845-5941			
Incidents involving Theft or Loss			
University Police Department (UPD) contact			
Bert Kretzschmar			
Office – 979 845-8900			
Mobile			
Home -			
Incidents involving a Release (or Occupational Exposure)			
Environmental Health and Safety Office contact			
Between 8:00 a.m. and 5:00 p.m.			
Brent Mattox, Biosafety Officer (BSO) Alternate Responsible Official (ARO)			
Office – 979 865-2132			
Mobile – 979 450-0662			
After hours 5:00 pm			
Contact the University Police Department contact			
Lt. Bert Kretzschmar			
Office – 979 845-8900			
Mobile –			
Home			
Other Contact information			
Vice President for Research/Responsible Official (RO)	Richard Ewing (RO)	979 845-8585 (Office) or	(Mobile)
	Fuller Bazer (ARO)	979 693-2876 (Office) or	(Mobile)
	Angelia Raines (ARO)	979 847-9362 (Office) or	(Mobile)
Comparative Medicine Program	Melanie Ihrig	979 845-7433 (Office) or	(Mobile)
	Elizabeth Browder	979 845-7433 (Office) or	(Mobile)
	Frank Stein	979 845-6488 (Office) or	(Mobile)
Institutional Biosafety Committee (IBC)	Thomas Ficht	979 845-4118 (Office) or	(Mobile)
	Vernon Tesh	979 862-4113 (Office) or	(Mobile)
	Tiffany Agnew	979 458-3624 (Office) or	(Mobile)
Other Emergency Numbers	College Station Police	979 764-3600 or 9-911	
	Medical Emergency	9-911	
	College Station Fire	979 764-3700 or 9-911	
	Radiological Emergency	979 832-1111	
	University Maintenance	979 845-4311	

Emergency Telephone Numbers

Thomas A. Ficht	Office: (979)845-4118 Home: (979) 845-4118 Mobile: (979) 845-4118
Emergency	9-911
University Police	(979) 845-2345
College Station Police	(979) 764-3600
College Station Fire	(979) 764-3700
Environmental Health & Safety	(979) 845-2132
TAMU Area Maintenance (HVAC failure, steam leak, gas leak)	(979) 845-5542
TAMU Maintenance (24 hours)	(979) 845-4311
Radiological Emergencies	(979) 862-1111
Responsible University Officials:	
RO-Richard Ewing	Work: (979) 845-8585 Mobile: (979) 845-8585
ARO-Angelia Raines	Work: (979) 847-9362 Mobile: (979) 847-9362
Biosafety Officer/ARO -Brent Mattox	Work: (979) 845-2132 Mobile: (979) 845-2132
Building Manager	Loren Skow 979-845-3194
Frank Stein	Work: (979) 845-6488 Mobile: (979) 845-6488
T. A. Ficht Lab	979-845-4185
Neighboring labs to notify in case of simultaneous containment breach and spill outside BSC:	
Lab (enter additional locations)	enter additional laboratory phone number
Lab (enter additional locations)	enter additional laboratory phone number
Lab (enter additional locations)	enter additional laboratory phone number

Decontamination Procedures for Spills of Cultures
(Please customize for specific laboratories.)

1. Signal others in the BL3 labs of any spill outside the biological safety cabinet. All personnel should change out of contaminated clothing and wash any exposed skin with a disinfectant, such as Purell. Clothes must be removed within the BL3 area and will be autoclaved by those cleaning up.
2. Put on a clean scrub suit and go to the shower on the first floor animal facility. Shower thoroughly with soap.
3. Return to the lab for cleanup: Put on a PAPR and tyvek suit (contained in the SPILL KIT). Put on double gloves and shoe covers.
4. Use paper towels to cover the spill. Prevent creation of contaminated aerosols.
5. Saturate all materials with 10% bleach solution (see previous section for description).
6. Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in autoclave bags.
7. Disinfect all exposed surfaces using 1X Wexcide or 1% Virkon (surface disinfectant solution).
8. Wipe surface of full-face respirator with 1% Virkon or 1X Wexcide, being careful to avoid skin contact with Wexcide.
9. Remove all clothing and place in autoclave bag.
10. Remove full face respirator and spray off all surfaces in the lab with 1% Virkon or 1X Wexcide.
11. Make sure that all contaminated material is autoclaved, surface-disinfected or incinerated.
12. Inform others not to work in the lab until the air handling system is able to clear any residual organisms from the air (3h).
13. Return to the lab after 3 hours and perform another decontamination of all lab surfaces with 1% Virkon or 1X Wexcide.
14. Report accident to the Principal Investigator, who will report it to other officials.

Contents of spill kit located in BL-3 labs:

Full-face respirator, Tyvek suit, clean scrub suit, absorbent material, Purell skin disinfectant, towel, copy of decontamination procedures for spills.

INCIDENT RESPONSE PLAN

and BSL2 Laboratories

PI – Vernon L. Tesh, Ph.D.

Texas A&M University Health Science Center, College Station, TX 77843-1114

to ensure compliance with

42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

- 1.1 General. This is the incident response plan for the possession and use of *Escherichia coli* DH5 α (pCKS112) at Texas A&M University Health Science Center (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121.
- 1.2 This plan describes the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

- 2.1 Principal Investigator (PI). The Principal Investigator, Dr. Vernon Tesh, has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to Dr. Tesh. The PI is responsible for ensuring all incidents regarding theft, loss or release are immediately reported to the proper institutional officials. This document outlines response actions concerning any theft, loss, or release from select biological agents and toxins (SBAT) facilities, including illness of personnel or visitors in SBAT facilities. Certain actions outlined below are performed in parallel rather than sequentially (see attached flowchart).
- 2.2 All lab personnel (including the PI) are responsible for immediately reporting an incident to the University Police Department (UPD) for theft or loss or to the Institutional Biosafety Officer (BSO) for release (including occupational exposure).
- 2.3 UPD – Responsible for immediately contacting the Alternate Responsible Official (ARO) and beginning an investigation of the incident. A written investigation report will be submitted to the Institutional Biosafety Committee (IBC), the PI and the ARO within 5 days of the incident. UPD will also work with the PI to conduct a security assessment following any incident involving loss or theft.
- 2.3 BSO - Responsible for immediately contacting the Alternate Responsible Official and beginning an investigation of the incident. A written investigation report will be submitted to the IBC, the PI and the ARO within 5 days of the incident. The BSO will also work with the PI to conduct a safety assessment following any incident involving a release (including occupational exposure).
- 2.4 ARO - Responsible for immediately contacting the Responsible Official, CDC, NIH (if rDNA) and other key institutional contacts regarding the incident. The ARO will work with the BSO, UPD and the PI to insure that the written report is correct and that the report will be submitted to CDC, NIH (if rDNA) and other key institutional contacts.
- 2.5 Responsible Official – Is responsible for compliance to the Select Agent regulations and insuring requirements (registration, investigations, etc) are properly carried out.

- 2.6 Contact information is found on the Emergency contact list. The list is attached to this document and is posted throughout the lab.
- 2.7 Annual Program Review. The Responsible Official or Alternate Responsible Official will audit the incident response program on an annual basis. This review will include drills and exercises to ensure the effectiveness of the incident response plan. Based on the outcome of drills, exercises or reported incidents, this incident response plan will be reviewed and updated as necessary.

3. Description of Work

This plan covers all work being performed at TAMU. Each lab will be responsible for providing information specific to the work being performed as follows:

Lab	Work description	Unique features of Agent	Biological Use Authorization	Biosafety Level
I 4	Storage of <i>Escherichia coli</i> DH5α(pCKS112)	Recombinant <i>E. coli</i> K12 strain expressing <i>stx1</i> operon under control of a thermoinducible promoter	Dr. Vernon Tesh and Dr. Rama Cherla are DOJ-approved to possess and use the agent	BL3
	Purification of Shiga toxin	Recombinant <i>E. coli</i> K12 strain expressing <i>stx1</i> operon under control of a thermoinducible promoter	Dr. Vernon Tesh and Dr. Rama Cherla are DOJ-approved to possess and use the agent	BL2

Additional information concerning the laboratories and the select agent use is contained in the facility's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or Environmental Health and Safety Office.

4. Response to theft:

- 4.1 Determination of Loss or Theft – The following are examples of events that may be considered a loss or theft. Possible loss or theft of the select agent will be reported initially to the Principal Investigator if any of the following have occurred:
- 4.1.1 The lock on the Select Agent storage area has been found open or appears to have been tampered with;
 - 4.1.2 Evidence of forced entry into the laboratory or storage areas has been found;
 - 4.1.3 A discrepancy in the Select Agent inventory that can not be reconciled;
 - 4.1.4 An employee reports cultures or samples missing;
 - 4.1.5 A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2;
 - 4.1.6 An infected animal is missing from its microisolator cage.

4.2 Report/Investigation Process:

Theft (unauthorized removal) or **Loss** (failure to account for) a select agent or toxin

- 4.2.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected theft or loss of SBATS to

UPD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345). Based on circumstances, UPD will notify EHSD.

If the release is discovered and UPD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the person shall then notify the LD/PI.

After notification to UPD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact ORC.

- 4.2.1.1 Upon notification of discovery of a theft or loss, UPD will immediately notify ORC.
- 4.2.1.2 Upon notification from UPD, ORC will immediately notify the Responsible Official (RO) and Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, and UPD.
- 4.2.1.3 UPD (and ESHD, based on circumstances) will immediately investigate the incident. The investigation will include coordination with the LD/PI and others approved with access or visiting SBAT facilities. UPD will submit a written report to ORC within 5 days of being notified about the discovery of the theft or loss. If the investigation provides evidence that a theft or loss did not occur, circumstances will be documented in UPD's investigation report.
- 4.2.1.4 Based on the UPD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss or Release of Select Agents and Toxins) with CDC. ORC will maintain an official copy of information submitted to CDC and will provide a copy of the submission to the RO, UPD/EHSD, and LD/PI.
- 4.2.1.5 UPD will notify the appropriate Federal, State, or local law enforcement agencies.
- 4.2.1.6 The LD/PI will ensure notification to the funding agency
- 4.2.2 A risk assessment will be conducted immediately upon discovery of a loss or theft. The risk assessment will be a part of the investigation report.
 - 4.2.2.1 In addition to the investigation, upon notification of a theft or loss, UPD (with input from EHSD and the LD/PI) will conduct a risk assessment to determine if the laboratory is operating in a safe and secure manner and to attempt to determine the cause of the theft. This risk assessment shall include, but not be limited to a comprehensive laboratory survey, review of access logs, review of inventory records, and verification that all equipment is operating within normal parameters (e. g. biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of theft will also be reviewed and modified, as warranted. If deficiencies in safe and secure practices are discovered, all work in the laboratory will cease until corrective actions have been taken.

- 4.1.2.2 If deemed necessary, the EHSD/UPD will contact Biosafety Program Coordinator to convene a special meeting of the Institutional BioSafety Committee (IBC).
- 4.1.2.3 Documentation of the risk assessment will be maintained by UPD with a copy sent to the LD/PI, EHSD and ORC.
- 4.1.2.4 Security Risk Assessments will be completed by UPD, with input from the LD/PI (and EHSD, based on circumstances). The results of the risk assessment and findings, including any requirements for post theft procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI, EHSD, and ORC.
- 4.1.2.5 The ORC will contact CDC, and if needed, a copy of the assessment will be submitted. ORC will also update the RO.
- 4.2.3 UPD will establish and maintain a specific file for each theft or loss incident, with all pertinent information.
- 4.2.4 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected loss or theft to UPD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

5. Investigation

- 5.1 The Investigation Committee for all releases will be headed by the EHSD's Institutional Biosafety Officer (BSO) with input from UPD and the PI. UPD will lead investigations involving theft or loss, with input from the BSO and PI.
 - 5.1.1 The BSO/UPD will investigate the event as quickly as possible, but no later than 24 hours of the initial report or the incident.
 - 5.1.2 The investigation should include a review of all materials related to the research, including access logs, inventory logs, laboratory notes and laboratory plans (security, safety and incident response)
 - 5.1.3 Once the investigation is complete, the BSO or UPD will submit an investigation report to the IBC and RO.
 - 5.1.4 Once the Committee has determined the response and informed the RO and IBC (through the Office of Research Compliance), the IBC will review the report and make a recommendation to the RO of any additional actions that they believe are needed.
 - 5.1.5 After the RO has approved of the recommended actions, the PI will receive a written response from the IBC.

6. Reporting

- 6.1 All incident reports are included in the IBC agenda minutes for review by the full board at the next convened meeting. Serious events should be specifically presented to the IBC by the BSO/UPD or IBC Chair at the next convened meeting.
 - 6.1.1 The investigation report, at a minimum, shall include the following information:
 - 6.1.1.1 A detailed description of the incident.
 - 6.1.1.2 A list of all personnel involved in the incident.
 - 6.1.1.3 A description of what occurred and what has or needs to be done to prevent any future incident.
 - 6.1.1.4 An assessment of the safety or security risk of continuing the research.

- 6.1.1.5 A recommendation of any changes that need to be made to the plans (safety, security or incident response), medical surveillance or laboratory procedures to reduce the risk of a reoccurrence.
- 6.1.1.6 A recommendation for training, if needed.

6.1.2 Incidents involving SBAT will be immediately reported to the CDC with a written report (Form 3) submitted within seven (7) days.

6.1.3 Events involving rDNA must be reported to the NIH immediately in writing but no later than 30 days of the incident.

7. **Release of a Select Agent or Toxin.**

Examples of a possible release (including occupational exposures of the agent or toxin) include but are not limited to the following:

- 7.1 A package containing the Select Agent or toxin that has been received, which has been damaged in transit, such that the primary containment vessel appears to have been compromised;
- 7.2 Simultaneous complete power failure of the Biosafety cabinet and negative pressure in the BSL-3 suite during work in the Biosafety cabinet with open cultures;
- 7.3 Simultaneous spill of cultures outside the Biosafety cabinet and failure of negative pressure in the Biosafety Level 3 suite. In case of a spill, a spill kit containing absorbent material and disinfectant will be located in a designated lab for each Principal Investigator;
 - 7.3.1 Personnel are advised to immediately leave the lab after removing any contaminated clothing and to return in Tyvek suits with full face respirators after the air has been scrubbed clean by air handlers (approx. one hour).
- 7.4 In case release of the Select Agent or toxin outside the BSL-3 laboratory is suspected, the Principal Investigator will notify the BSO, as well as the Responsible Official, and the building manager (Mr. George Martin, 845-7902).
- 7.5 Exposure of laboratory personnel to cultures. The following incidents may result in unintentional exposure to the Select Agent that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to TAMU Occupational Health, where they will be given the option to initiate post-exposure prophylaxis. The exposure will be reported by the Principal Investigator to the BSO who reports immediately to the Responsible Official, who will notify CDC of the exposure. The following are examples of unintentional exposure:
 - 7.5.1 A spill of live culture outside the Biosafety cabinet;
 - 7.5.2 Failure of the Biosafety cabinet during work with *E. coli* DH5 α (pCKS112);
 - 7.5.3 Needle stick or cut with sharps contaminated with *E. coli* DH5 α (pCKS112);
 - 7.5.4 A centrifuge accident that results in aerosolization of *E. coli* DH5 α (pCKS112).

8. **Process of reporting and investigating a Release:**

Release – Occupational exposure (clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been released outside of the primary bio-containment barrier) or release of an agent or toxin outside of the primary barriers of the biocontainment area.

- 8.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected release to the Environment Health and Safety Department (EHSD). Based on circumstances, EHSD will notify the University Police

Department (UPD). During normal business hours, call EHSD at 845-2132. If it is outside of normal business hours, call UPD who will notify EHSD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345).

If the release is discovered and EHSD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the individual shall then notify the LD/PI.

After notification to EHSD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact the Office of Research Compliance (ORC).

- 8.1.1 Upon notification of discovery of a release, EHSD will immediately notify Scott & White Occupational Health Clinic and ORC.
 - 8.1.2 Upon notification from EHSD, ORC will immediately notify the Responsible Official (RO) and the Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, EHSD, and UPD.
 - 8.1.3 EHSD (and UPD, based on circumstances) will immediately investigate the incident. The investigation will include the coordination with the LD/PI and others approved with access or visiting SBAT facilities. EHSD will submit a written report to ORC within 5 days of being notified about discovery of the release. If the investigation provides evidence that a release did not occur, circumstances will be documented in EHSD's investigation report.
 - 8.1.4 Based on the EHSD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss, or Release of Select Agents and Toxins) with the CDC within seven calendar days of the discovery of the release. ORC will maintain an official copy of information submitted to the CDC and will provide a copy of the submission to the RO, EHSD, and LD/PI.
 - 8.1.5 EHSD will obtain confirmation from health care providers that reports to other state or federal health agencies have been submitted. The LD/PI will ensure notification to the funding agency.
- 8.2 A risk assessment will be conducted immediately upon discovery regarding any release.
- 8.2.1 In addition to the investigation, upon notification of a release, EHSD (under the direction of the Biological Safety Officer (BSO)) will conduct a risk assessment to determine if the laboratory is operating in a safe manner and attempt to determine the cause or most likely route of the release. This risk assessment shall include but not be limited to a comprehensive laboratory survey, review of access logs to determine potential occupational exposures, review of inventory records, and verification that all equipment is operating within normal parameters (e.g., biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of the release will also be reviewed by EHSD and modified, as warranted, in consultation with the LD/PI. If deficiencies in safe practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
 - 8.2.2 If deemed necessary based on the risk assessment, the BSO will contact ORC to convene a special meeting of the Institutional BioSafety Committee.

- 8.2.3 Documentation of the risk assessment will be maintained by EHSD with a copy sent to the LD/PI and the ORC.
- 8.2.4 Risk assessments will be completed with input from the LD/PI. The results of the risk assessment and findings, including any requirements for post decontamination procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI and ORC.
- 8.2.5 ORC will contact CDC, and if needed, a copy of the risk assessment will be submitted. ORC will also update the RO.
- 8.3 The following additional steps will also be taken immediately upon discovery regarding an actual or suspected occupational exposure:
 - 8.3.1 EHSD will direct the LD/PI to notify laboratory personnel and visitors that a potential exposure has occurred and refer them to Scott & White Occupational Health for consultation. EHSD will obtain access logs and other information to determine a complete list of potentially exposed personnel. EHSD will then follow-up with potentially exposed personnel to ensure notification.
 - 8.3.2 Individuals will be encouraged to contact Occupational Health at Scott & White Clinic, or to immediately identify to medical personnel, the agent they were potentially exposed to if treatment is sought. Scott & White Occupational Health Clinic or the attending physician will screen for the organism (e. g. *Brucella* species), and begin prophylaxis as deemed appropriate by the attending physician.
 - 8.3.3 If an occupational exposure is confirmed through appropriate medical tests or as determined by a physician, all personnel and potentially exposed individuals will be immediately referred to Scott & White for screening, testing, or preventive prophylaxis as determined by the attending physician. If personnel or visitors are at remote locations (other university facilities, traveling), they should immediately report to a physician of choice and explain that a positive occupational exposure to a specific organism has occurred and specific treatment or screening is desired. Personal physicians should be encouraged to contact either EHSD or Scott and White Occupational Health if they have any questions.
 - 8.3.4 EHSD, in consultation with Scott & White, will perform periodic follow-up with the group of exposed or potentially exposed personnel for a period of time as appropriate for the organism.
- 8.4 EHSD will establish and maintain a specific file for each release incident, with all pertinent information.
- 8.5 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected release to EHSD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

9. Security Breach:

A security breach will be determined to have occurred if any of the following are observed:

- 9.1 The access control system has failed, leaving the BSL-3 suite accessible to unauthorized persons;
- 9.2 An unauthorized person is observed unaccompanied in the BSL-3 suite;
- 9.3 A lost or stolen card was used to access the BSL-3 suite;

- 9.4 An unauthorized person has accessed the computer used to control entry to the BSL-3 suite;
- 9.5 An unexpected or suspicious package arrives in the laboratory.

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the Responsible Official of the security breach and take steps to correct the problem. Corrective procedures will be secured immediately, but no later than 24 hours; an inventory will be performed of all samples and animals in the laboratory and in Select Agent storage. Any missing Select Agent samples or animals will be reported to CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator and the Responsible Official will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

10. Severe weather or natural disasters.

The most likely occurrences in this area are severe thunderstorms, floods or tornadoes.

If severe weather (thunderstorms or flooding) is predicted, experiments with Select Agents should be suspended until the severe weather has passed to avoid power outages during the work. All samples should be secured inside the locked -80°C freezer or the locked +4°C storage.

If an earthquake is felt, workers should immediately leave the suite-if possible, shedding gloves and lab coat on the way out of the BSL-3 suite. Cleanup, if necessary, can be performed once it is safe to re-enter the building.

- 10.3 Power to the BSL-3 suite may be affected if the emergency generator is flooded. In this case, all samples should be secured inside the -80°C freezer. If the vivarium is threatened by flooding, animal cages should be fastened shut, put into secondary containers (biohazard bag or large Tupperware) and transported to _____ or secure holding until the threat of flooding has passed. If it becomes necessary to evacuate the College Station area, all animal experiments will be terminated before evacuation by euthanizing the animals and storing the carcasses in the secure select agent storage in room.
- 10.4 In case of a power outage, if there is no immediate danger to the building, secure all infectious samples inside a -80°C freezer, the +4°C refrigerator, or the incubators. The Biosafety cabinets and air handling system of the BSL-3 suite are on emergency backup power, which will prevent exposure to infectious samples in case of a power outage. Follow standard procedures for leaving the laboratory and return once the power has been restored to resume work.

11. Fire, Gas leak, Steam leak, Explosion, Bomb threat:

- 11.1 If work is being performed in the Biosafety cabinet, cap all samples, dispose of gloves and outer laboratory coat, and leave the laboratory immediately. If the fire is within the BSL 3 laboratory, and the worker feels (s)he can safely extinguish the fire, then the fire extinguisher located in the interior hall may be used. If a worker feels his or her safety threatened, (s)he should leave the laboratory immediately without stopping to decontaminate or secure any work, using the designated escape routes (through the locker rooms or the exterior "airlock" door on the west side of the building). Upon leaving the building, personnel should assemble outside the _____ in the assigned spot (eastern corner of the passageway between the F _____ and t' _____) and report to the departmental Safety Officer for attendance.
- 11.2 Notify the appropriate emergency responders: Fire 9-911 or 911 from mobile phones, the Principal Investigator and the Biosafety Officer. For steam and gas leaks, notify TAMU Operations and Maintenance.

11.3 In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police immediately by calling the emergency number, 9-911 or 911. Also inform the Principal Investigator and Responsible Official. Always be sure to give the number and location of the building and your name and telephone extension number.

11.3.1 The University Police Department will assign personnel to investigate the call and take whatever police action they may deem necessary and reasonable for the safety of the campus community. The University Police will conduct a search of the building, or of specific locations in or around the building. When judged prudent and feasible to do so, the search will be conducted with the assistance and cooperation of the Principal Investigator and/or Responsible Official. After an evaluation/assessment of the content of the bomb threat, the decision to evacuate or close building shall be made jointly, whenever possible, by the Police and the Principal Investigator and/or Responsible Official.

11.3.2 Any unusual or suspicious object should be reported immediately to the University Police or to any immediate supervisor or administrative officer. Suspected objects or materials should NOT be touched or disturbed. Every bomb threat or incident of a suspected explosive device should be considered valid until all reasonable precautions for public safety have been taken or until the danger to life and property is terminated.

12. Failure of Select Agent Storage Freezer:

12.2 If the -80°C freezer in _____ is used to store *E. coli* DH5 α (pCK5112) fails, the strains will be moved to a temporary backup location, which is either the other -80°C Revco freezer located in the BSL-3 Suite or in a secure freezer in a locked BSL-2 laboratory. This freezer will be locked in order to limit access to personnel authorized to work with select agents.

13. Workplace violence:

13.1 Incidents of disruptive or threatening behavior on the part of an employee, student or visitor should be reported immediately to the Principal Investigator, who will report the incident to the Department Head, the Responsible Official and the Workplace Violence Response Team, as proscribed by the TAMU Personnel and Procedures manual section 290-09. If the individual accused of disruptive or threatening behavior is authorized for access to select agents, this person's access will be suspended pending the results of an investigation by the Workplace Violence Response Team. If an act of violence or a physical assault has occurred, or the threatening activity occurs within the BSL-3 laboratory, the person feeling threatened should call the police immediately to report the incident. If the person accused of violence has access to select agents, the person's access will be suspended pending the outcome of the investigation. Suspension of select agent access will be reported to the Responsible Official and a suspended individual's access will be inactivated within 24 hours.

14. Entry of emergency responders into the BSL-3 laboratory.

14.1 In a case in which a life-threatening injury or medical condition (i.e. heart attack) occurs inside the BSL-3 laboratory, emergency responders will be allowed to enter the laboratory. If possible, upon feeling ill the laboratory worker should immediately exit the suite to facilitate treatment by emergency responders. Personnel protective equipment, including Tyvek suits, N95 masks, HEPA-filtered respirators and gloves, are located inside the entries (locker rooms) to the BSL-3 suite. A spill kit containing absorbent materials and disinfectant is located under the bench in each of the labs. A First Aid kit is located inside the lab. If responders are required to enter an area where a spill has occurred, they will be referred to Scott and White Clinic and offered post-exposure prophylaxis.

- 14.1.1 Entry procedure for the BSL-3 laboratory: Dress yourself in a Tyvek suit, gloves, shoe covers and respiratory protection (N95 mask) before entering the laboratories.
- 14.1.2 Providing first aid and emergency medical treatment in the BSL-3 laboratory: A person working inside the Biosafety hood is not considered to be contagious unless a spill has occurred. The person's gloves may be contaminated, and may be removed to facilitate treatment. If there is no space within the labs to put the person on the floor, move the person to the interior hallway to administer treatment.
- 14.1.3 Exit procedure from the BSL-3 laboratory: Emergency responders should remove Tyvek suit, mask, shoe covers and gloves before exiting and leave them behind in the BSL-3 laboratory. Hands should be washed immediately upon exit from the BSL-3 laboratory.
- 14.1.4 Decontamination procedures for medical equipment and clothing: Emergency responders should decontaminate equipment before leaving the laboratory by one of the following methods:
 - 14.1.4.1 Autoclaving. Autoclaves are located within the BSL3 suite.
 - 14.1.4.2 Wiping surfaces with 10% bleach followed by 1% Virkon-S.

15. Incident Response Plan Testing (Drills)

- 15.1 Drills or tabletop exercises will be conducted annually to test the effectiveness of the Biosafety plan. The drills or exercises will be coordinated with the TAMU Police Department and will include, but not be limited to, the Principal Investigator or designee, BSO, TAMU Fire Department representative and the Campus Emergency Planner.
- 15.2 The drill or exercise will include, but not be limited to, accessibility to restricted space, attempted or unauthorized entry into restricted spaces challenge, animal room security, staff knowledge of hazard/emergency protocols for their work location(s) and other situations that are deemed appropriate for each work location.
- 15.3 Following the drill or exercise, which will test the various components of the incident response plan for completeness, those involved will critique their findings for each drill/exercise location. The Principal Investigator working with the Responsible Official and Biosafety Officer will implement changes as necessary changes to the plan. Results of the drill or exercise will be reviewed by the Biological Safety Administrative Advisory Committee (Institutional Biosafety Committee).

16. Texas A&M University Crisis Management Plan

- 16.1 The entity crisis management plan is contained in a separate document and is referenced in the individual laboratory emergency response plan.
- 16.2 Additional information concerning the laboratory emergency response plan is contained in the laboratory's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or the Environmental Health & Safety Department.
- 16.3 The Responsible Official and Biosafety Officer should be contacted immediately in the case of any emergency in a select agent lab. The Responsible Official will coordinate access and information issues with campus police, fire, and emergency responders.
- 16.4 If necessary, the Responsible Official will coordinate the emergency relocation of select agents to another secure location.

17. **Site security and control are described in detail in the Select Agent Security Plan**
 - 17.1 The buildings are secured by a keyed lock. Sharing of keys with other personnel is not permitted.
 - 17.2 Individuals not authorized for access to Select Agents must be accompanied by approved personnel at all times while in the buildings.
 - 17.3 Data that could enable access to select agents by unauthorized personnel should be located on password-protected computers.
 - 17.4 If approved personnel are observed violating security or Biosafety procedures, this observation should be reported immediately to the Principal Investigator. The Principal investigator will investigate the allegation and determine whether the violator should have his/her Select Agent access suspended or revoked. Suspension of Select Agent access will be reported to the Responsible Official and the individual's key card access will be terminated within 24 hours.

18. **Inventory Discrepancies:**
 - 18.1 Inventory discrepancies will be documented on the agent access form.
 - 18.2 All discrepancies will be immediately reported to the Principal Investigator.
 - 18.3 If the discrepancy is believed to be a result of loss or theft, the incident response procedures for loss or theft and release will be followed.
 - 18.4 If the discrepancy is a result of a transfer, the transfer form will be documented.

19. **References**
 - 19.1 42 CFR Part 73
 - 19.2 7 CFR Part 331
 - 19.3 9 CFR Part 121
 - 19.4 Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention, National Institutes of Health, Fourth Edition, May 1999
 - 19.5 Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents (Revised BMBL, Appendix F), published in Morbidity and Mortality Weekly Report, December 6, 2002.

SBAT Incident Response
Emergency Contact Numbers

PI Information			
<p align="center">PI Dr. Vernon L. Tesh Office – 862-4114 Mobile – Home –</p>			
<p align="center">Building Manager Mr. George Martin Office – 845-7907 Mobile – Home –</p>			
<p align="center">Department Head Dr. John M. Quarles Office – 845-1358 Home</p>			
<p align="center">Incidents involving Theft or Loss University Police Department (UPD) contact</p> <p align="center">Bert Kretzschmar Office – 979 845-8900 Mobile - Home –</p>			
<p align="center">Incidents involving a Release (or Occupational Exposure) Environmental Health and Safety Office contact</p> <p align="center">Between 8:00 a.m. and 5:00 p.m. Brent Mattox, Biosafety Officer (BSO) Alternate Responsible Official (ARO) Office – 979 865-2132 Mobile –</p> <p align="center">After hours 5:00 pm Contact the University Police Department contact Lt. Bert Kretzschmar Office – 979 845-8900 Mobile – Home -</p>			
Other Contact information			
Vice President for Research/Responsible Official (RO)	Richard Ewing (RO)	979 845-8585 (Office) or	(Mobile)
	Fuller Bazer (ARO)	979 693-2876 (Office) or	(Mobile)
	Angelia Raines (ARO)	979 847-9362 (Office) or	(Mobile)
Comparative Medicine Program	Melanie Ihrig	979 845-7433 (Office) or	(Mobile)
	Elizabeth Browder	979 845-7433 (Office) or	(Mobile)
	Frank Stein	979 845-6488 (Office) or	(Mobile)
Institutional Biosafety Committee (IBC)	Thomas Ficht	979 845-4118 (Office) or	(Mobile)
	Vernon Tesh	979 862-4113 (Office) or	(Mobile)
	Tiffany Agnew	979 458-3624 (Office) or	(Mobile)
Other Emergency Numbers	College Station Police	979 764-3600 or 9-911	
	Medical Emergency	9-911	

	College Station Fire	979 764-3700 or 9-911
	Radiological Emergency	979 832-1111
	University Maintenance	979 845-4311

Decontamination Procedures for Spills of Cultures
(Please customize for specific laboratories.)

1. Signal others in the BL3 labs of any spill outside the biological safety cabinet. All personnel should change out of contaminated clothing and wash any exposed skin with a disinfectant, such as Purell. Clothes must be removed within the BL3 area and will be autoclaved by those cleaning up.
2. Put on a clean scrub suit and go to the shower on the first floor animal facility. Shower thoroughly with soap.
3. Return to the lab for cleanup: Put on a full face respirator and tyvek suit (contained in the SPILL KIT). Put on double gloves and shoe covers.
4. Use paper towels to cover the spill. Prevent creation of contaminated aerosols.
5. Saturate all materials with 10% bleach solution (see previous section for description).
6. Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in autoclave bags.
7. Disinfect all exposed surfaces using 1X Wexcide or 1% Virkon (surface disinfectant solution).
8. Wipe surface of full-face respirator with 1% Virkon or 1X Wexcide, being careful to avoid skin contact with Wexcide.
9. Remove all clothing and place in autoclave bag.
10. Remove full face respirator and spray off all surfaces in the lab with 1% Virkon or 1X Wexcide.
11. Make sure that all contaminated material is autoclaved, surface-disinfected or incinerated.
12. Inform others not to work in the lab until the air handling system is able to clear any residual organisms from the air (3h).
13. Return to the lab after 3 hours and perform another decontamination of all lab surfaces with 1% Virkon or 1X Wexcide.
14. Report accident to the Principal Investigator, who will report it to other officials.

Contents of spill kit located in BL-3 labs:

Full-face respirator, Tyvek suit, clean scrub suit, absorbent material, Purell skin disinfectant, towel, copy of decontamination procedures for spills.

INCIDENT RESPONSE PLAN

PI – CMP Director, *Thomas Ficht, and James Samuel*

Texas A&M University, College Station, TX 77843
to ensure compliance with
42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

- 1.1 General. This is the incident response plan for the possession and use of *Coxiella burnetti* and *Brucella spp* at Texas A&M University main campus (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121. This plan covers the use of these select agents when used in
- 1.2 This plan describes the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

- 2.1 Principal Investigator (PI). The Principal Investigator, Thomas Ficht and James Samuel, has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to Thomas Ficht and James Samuel. The PI is responsible for ensuring all incidents regarding theft, loss or release are immediately reported to the proper institutional officials. This document outlines response actions concerning any theft, loss, or release from select biological agents and toxins (SBAT) facilities, including illness of personnel or visitors in SBAT facilities. Certain actions outlined below are performed in parallel rather than sequentially (see attached flowchart).
- 2.2 All lab personnel (including the PI) are responsible for immediately reporting an incident to the University Police Department (UPD) for theft or loss or to the Institutional Biosafety Officer (BSO) for release (including occupational exposure).
- 2.3 UPD – Responsible for immediately contacting the Alternate Responsible Official (ARO) and beginning an investigation of the incident. A written investigation report will be submitted to the Institutional Biosafety Committee (IBC), the PI and the ARO within 5 days of the incident. UPD will also work with the PI to conduct a security assessment following any incident involving loss or theft.
- 2.3 BSO - Responsible for immediately contacting the Alternate Responsible Official and beginning an investigation of the incident. A written investigation report will be submitted to the IBC, the PI and the ARO within 5 days of the incident. The BSO will also work with the PI to conduct a safety assessment following any incident involving a release (including occupational exposure).
- 2.4 ARO - Responsible for immediately contacting the Responsible Official, CDC, NIH (if rDNA) and other key institutional contacts regarding the incident. The ARO will work with the BSO, UPD and the PI to insure that the written report is correct and that the report will be submitted to CDC, NIH (if rDNA) and other key institutional contacts.

- 2.5 Responsible Official – Is responsible for compliance to the Select Agent regulations and insuring requirements (registration, investigations, etc) are properly carried out.
- 2.6 Contact information is found on the Emergency contact list. The list is attached to this document and is posted throughout the lab.
- 2.7 Annual Program Review. The Responsible Official or Alternate Responsible Official will audit the incident response program on an annual basis. This review will include drills and exercises to ensure the effectiveness of the incident response plan. Based on the outcome of drills, exercises or reported incidents, this incident response plan will be reviewed and updated as necessary.

3. **Description of Work**

This plan covers all work being performed at TAMU. Each lab will be responsible for providing information specific to the work being performed as follows:

Lab	Work description	Unique features of Agent	Biosafety Level	Biological Use Authorization
	Animal Housing	BSC	3	
	Animal Housing	BSC	3	
	Challenge, Lab work	BSC, Aerosol Chamber	3	

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Additional information concerning the laboratories and the select agent use is contained in the facility's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or Environmental Health and Safety Office.

4. **Response to theft:**

4.1 Determination of Loss or Theft – The following are examples of events that may be considered a loss or theft. Possible loss or theft of the select agent will be reported initially to the Principal Investigator if any of the following have occurred: **AGENTS ARE NOT STORED IN BUILDING**

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- 4.1.1 The lock on the Select Agent storage area has been found open or appears to have been tampered with;
- 4.1.2 Evidence of forced entry into the laboratory or storage areas has been found;
- 4.1.3 A discrepancy in the Select Agent inventory that can not be reconciled;
- 4.1.4 An employee reports cultures or samples missing;
- 4.1.5 A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2;
- 4.1.6 An infected animal is missing from its microisolator cage.

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4.2 Report/Investigation Process:

Theft (unauthorized removal) or **Loss** (failure to account for) a select agent or toxin
 4.2.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected theft or loss of SBATS to UPD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345). Based on circumstances, UPD will notify EHSD.

If the release is discovered and UPD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the person shall then notify the LD/PI.

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After notification to UPD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact ORC.

- 4.2.1.1 Upon notification of discovery of a theft or loss, UPD will immediately notify ORC.
- 4.2.1.2 Upon notification from UPD, ORC will immediately notify the Responsible Official (RO) and Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, and UPD.
- 4.2.1.3 UPD (and ESHD, based on circumstances) will immediately investigate the incident. The investigation will include coordination with the LD/PI and others approved with access or visiting SBAT facilities. UPD will submit a written report to ORC within 5 days of being notified about the discovery of the theft or loss. If the investigation provides evidence that a theft or loss did not occur, circumstances will be documented in UPD's investigation report.
- 4.2.1.4 Based on the UPD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss or Release of Select Agents and Toxins) with CDC. ORC will maintain an official copy of information submitted to CDC and will provide a copy of the submission to the RO, UPD/EHSD, and LD/PI.
- 4.2.1.5 UPD will notify the appropriate Federal, State, or local law enforcement agencies.
- 4.2.1.6 The LD/PI will ensure notification to the funding agency
- 4.2.2 A risk assessment will be conducted immediately upon discovery of a loss or theft. The risk assessment will be a part of the investigation report.
 - 4.2.2.1 In addition to the investigation, upon notification of a theft or loss, UPD (with input from EHSD and the LD/PI) will conduct a risk assessment to determine if the laboratory is operating in a safe and secure manner and to attempt to determine the cause of the theft. This risk assessment shall include, but not be limited to a comprehensive laboratory survey, review of access logs, review of inventory records, and verification that all equipment is operating within normal parameters (e. g. biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of theft will also be reviewed and modified, as warranted. If deficiencies in safe and secure practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
 - 4.1.2.2 If deemed necessary, the EHSD/UPD will contact Biosafety Program Coordinator to convene a special meeting of the Institutional BioSafety Committee (IBC).
 - 4.1.2.3 Documentation of the risk assessment will be maintained by UPD with a copy sent to the LD/PI, EHSD and ORC.

4.1.2.4 Security Risk Assessments will be completed by UPD, with input from the LD/PI (and EHSD, based on circumstances). The results of the risk assessment and findings, including any requirements for post theft procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI, EHSD, and ORC.

4.1.2.5 The ORC will contact CDC, and if needed, a copy of the assessment will be submitted. ORC will also update the RO.

4.2.3 UPD will establish and maintain a specific file for each theft or loss incident, with all pertinent information.

4.2.4 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected loss or theft to UPD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

5. Investigation

5.1 The Investigation Committee for all releases will be headed by the EHSD's Institutional Biosafety Officer (BSO) with input from UPD and the PI. UPD will lead investigations involving theft or loss, with input from the BSO and PI.

5.1.1 The BSO/UPD will investigate the event as quickly as possible, but no later than 24 hours of the initial report or the incident.

5.1.2 The investigation should include a review of all materials related to the research, including access logs, inventory logs, laboratory notes and laboratory plans (security, safety and incident response)

5.1.3 Once the investigation is complete, the BSO or UPD will submit an investigation report to the IBB and RO.

5.1.4 Once the Committee has determined the response and informed the RO and IBC (through the Office of Research Compliance), the IBC will review the report and make a recommendation to the RO of any additional actions that they believe are needed.

5.1.5 After the RO has approved of the recommended actions, the PI will receive a written response from the IBC.

6. Reporting

6.1 All incident reports are included in the IBC agenda minutes for review by the full board at the next convened meeting. Serious events should be specifically presented to the IBC by the BSO/UPD or IBC Chair at the next convened meeting.

6.1.1 The investigation report, at a minimum, shall include the following information:

6.1.1.1 A detailed description of the incident.

6.1.1.2 A list of all personnel involved in the incident.

6.1.1.3 A description of what occurred and what has or needs to be done to prevent any future incident.

6.1.1.4 An assessment of the safety or security risk of continuing the research.

6.1.1.5 A recommendation of any changes that need to be made to the plans (safety, security or incident response), medical surveillance or laboratory procedures to reduce the risk of a reoccurrence.

6.1.1.6 A recommendation for training, if needed.

6.1.2 Incidents involving SBAT will be immediately reported to the CDC with a written report (Form 3) submitted within seven (7) days.

- 6.1.3 Events involving rDNA must be reported to the NIH immediately in writing but no later than 30 days of the incident.

7. Release of a Select Agent or Toxin.

Examples of a possible release (including occupational exposures of the agent or toxin include but are not limited to the following:

- 7.1 A package containing the Select Agent or toxin that has been received which has been damaged in transit such that the primary containment vessel appears to have been compromised;
- 7.2 Simultaneous complete power failure of the Biosafety cabinet and negative pressure in the BSL-3 suite during work in the Biosafety cabinet with open cultures;
- 7.3 Simultaneous spill of cultures outside the Biosafety cabinet and failure of negative pressure in the Biosafety Level 3 suite. In case of a spill, a spill kit containing absorbent material and disinfectant will be located in a designated lab for each Principal Investigator;
- 7.3.1 Personnel are advised to immediately leave the lab after removing any contaminated clothing and to return in Tyvek suits with Powered Air Purifying Respirator (PAPR) after the air has been scrubbed clean by air handlers (approx. one hour).
- 7.4 In case release of the Select Agent or toxin outside the BSL-3 laboratory is suspected, the Principal Investigator will notify the BSO laboratories on the first floor of the VRB, as well as the Responsible Official, and the building manager.
- 7.5 Exposure of laboratory personnel to cultures. The following incidents may result in unintentional exposure to the Select Agent that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to TAMU Occupational Health, where they will be given the option to initiate post-exposure prophylaxis. The exposure will be reported by the Principal Investigator to the BSO who reports immediately to the Responsible Official, who will notify CDC of the exposure. The following are examples of unintentional exposure:
- 7.5.1 A spill of live culture outside the Biosafety cabinet;
- 7.5.2 Failure of the Biosafety cabinet during work with a select agent;
- 7.5.3 Needle stick or cut with sharps contaminated with a select agent;
- 7.5.4 If a bite from a select agent--infected animal penetrates the double gloves and breaks the skin;
- 7.5.5 A centrifuge accident that results in aerosolization of a select agent..

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8. Process of reporting and investigating a Release:

Release -- Occupational exposure (clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been release outside of the primary bio-containment barrier.) or release of an agent or toxin outside of the primary barriers of the biocontainment area.

- 8.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected release to the Environment Health and Safety Department (EHSD). Based on circumstances, EHSD will notify the University Police Department (UPD). During normal business hours, call EHSD at 845-2132. If it is

outside of normal business hours, call UPD who will notify EHSD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345).

If the release is discovered and EHSD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the individual shall then notify the LD/PI.

After notification to EHSD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact the Office of Research Compliance (ORC).

- 8.1.1 Upon notification of discovery of a release, EHSD will immediately notify Scott & White Occupational Health Clinic and ORC.
- 8.1.2 Upon notification from EHSD, ORC will immediately notify the Responsible Official (RO) and the Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, EHSD, and UPD.
- 8.1.3 EHSD (and UPD, based on circumstances) will immediately investigate the incident. The investigation will include the coordination with the LD/PI and others approved with access or visiting SBAT facilities. EHSD will submit a written report to ORC within 5 days of being notified about discovery of the release. If the investigation provides evidence that a release did not occur, circumstances will be documented in EHSD's investigation report.
- 8.1.4 Based on the EHSD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss, or Release of Select Agents and Toxins) with the CDC within seven calendar days of the discovery of the release. ORC will maintain an official copy of information submitted to the CDC and will provide a copy of the submission to the RO, EHSD, and LD/PI.
- 8.1.5 EHSD will obtain confirmation from health care providers that reports to other state or federal health agencies have been submitted. The LD/PI will ensure notification to the funding agency.
- 8.2 A risk assessment will be conducted immediately upon discovery regarding any release.
 - 8.2.1 In addition to the investigation, upon notification of a release, EHSD (under the direction of the Biological Safety Officer (BSO)) will conduct a risk assessment to determine if the laboratory is operating in a safe manner and attempt to determine the cause or most likely route of the release. This risk assessment shall include but not be limited to a comprehensive laboratory survey, review of access logs to determine potential occupational exposures, review of inventory records, and verification that all equipment is operating within normal parameters (e.g., biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of the release will also be reviewed by EHSD and modified, as warranted, in consultation with the LD/PI. If deficiencies in safe practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
 - 8.2.2 If deemed necessary based on the risk assessment, the BSO will contact ORC to convene a special meeting of the Institutional BioSafety Committee.
 - 8.2.3 Documentation of the risk assessment will be maintained by EHSD with a copy sent to the LD/PI and the ORC.

- 8.2.4 Risk assessments will be completed with input from the LD/PI. The results of the risk assessment and findings, including any requirements for post decontamination procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI and ORC.
- 8.2.5 ORC will contact CDC, and if needed, a copy of the risk assessment will be submitted. ORC will also update the RO.
- 8.3 The following additional steps will also be taken immediately upon discovery regarding an actual or suspected occupational exposure:
 - 8.3.1 EHSD will direct the LD/PI to notify laboratory personnel and visitors that a potential exposure has occurred and refer them to Scott & White Occupational Health for consultation. EHSD will obtain access logs and other information to determine a complete list of potentially exposed personnel. EHSD will then follow-up with potentially exposed personnel to ensure notification.
 - 8.3.2 Individuals will be encouraged to contact Occupational Health at Scott & White Clinic, or to immediately identify to medical personnel, the agent they were potentially exposed to if treatment is sought. Scott & White Occupational Health Clinic or the attending physician will screen for the organism (e. g. Brucella species), and begin prophylaxis as deemed appropriate by the attending physician.
 - 8.3.3 If an occupational exposure is confirmed through appropriate medical tests or as determined by a physician, all personnel and potentially exposed individuals will be immediately referred to Scott & White for screening, testing, or preventive prophylaxis as determined by the attending physician. If personnel or visitors are at remote locations (other university facilities, traveling), they should immediately report to a physician of choice and explain that a positive occupational exposure to a specific organism has occurred and specific treatment or screening is desired. Personal physicians should be encouraged to contact either EHSD or Scott and White Occupational Health if they have any questions.
 - 8.3.4 EHSD, in consultation with Scott & White, will perform periodic follow-up with the group of exposed or potentially exposed personnel for a period of time as appropriate for the organism.
- 8.4 EHSD will establish and maintain a specific file for each release incident, with all pertinent information.
- 8.5 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected release to EHSD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

9. Security Breach:

A security breach will be determined to have occurred if any of the following are observed:

- 9.1 The access control system has failed, leaving the BSL-3 suite accessible to unauthorized persons;
- 9.2 An unauthorized person is observed unaccompanied in the BSL-3 suite;
- 9.3 A lost or stolen card was used to access the BSL-3 suite;

- 9.4 An unauthorized person has accessed the computer used to control entry to the BSL-3 suite;
- 9.5 An unexpected or suspicious package arrives in the laboratory.

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the Responsible Official of the security breach and take steps to correct the problem. Corrective procedures will be secured immediately, but no later than 24 hours; an inventory will be performed of all samples and animals in the laboratory and in Select Agent storage. Any missing Select Agent samples or animals will be reported to CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator and the Responsible Official will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

10. Severe weather or natural disasters.

The most likely occurrences in this area are severe thunderstorms, floods or tornadoes.

- 10.1 If severe weather (thunderstorms or flooding) is predicted, experiments with Select Agents should be suspended until the severe weather has passed to avoid power outages during the work. All samples should be secured inside the locked -80°C freezer or the locked +4°C storage.
- 10.2 If an earthquake is felt, workers should immediately leave the suite-if possible, shedding gloves and lab coat on the way out of the BSL-3 suite. Cleanup, if necessary, can be performed once it is safe to re-enter the building.
- 10.3 Power to the BSL-3 suite may be affected if the emergency generator is flooded. In this case, all samples should be secured inside the -80°C freezer. If the vivarium is threatened by flooding, animal cages should be fastened shut, put into secondary containers (biohazard bag or large Tupperware) and transported to _____ for secure holding until the threat of flooding has passed. If it becomes necessary to evacuate the College Station area, all animal experiments will be terminated before evacuation by euthanizing the animals and storing the carcasses in the secure select agent storage in room.
- 10.4 In case of a power outage, if there is no immediate danger to the building, secure all infectious samples inside a -80°C freezer, the +4°C refrigerator, or the incubators. The Biosafety cabinets and air handling system of the BSL-3 suite are on emergency backup power, which will prevent exposure to infectious samples in case of a power outage. Follow standard procedures for leaving the laboratory and return once the power has been restored to resume work.

11. Fire, Gas leak, Steam leak, Explosion, Bomb threat:

- 11.1 If work is being performed in the Biosafety cabinet, cap all samples, dispose of gloves and outer laboratory coat, and leave the laboratory immediately. If the fire is within the BSL 3 laboratory, and the worker feels (s)he can safely extinguish the fire, then the fire extinguisher located in the interior hall may be used. If a worker feels his or her safety threatened, (s)he should leave the laboratory immediately without stopping to decontaminate or secure any work, using the designated escape routes (through the emergency exit located on the west side of the BSL-3 suite and immediately out of the back dock doors located on the north side of the facility). Upon leaving the building, personnel should assemble outside the _____ in the assigned spot _____ and report to the Area Coordinator for attendance.

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- 11.2 Notify the appropriate emergency responders: Fire 9-911 or 911 from mobile phones, the Principal Investigator and the Biosafety Officer. For steam and gas leaks, notify TAMU Operations and Maintenance.
- 11.3 In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police immediately by calling the emergency number, 9-911 or 911. Also inform the Principal Investigator and Responsible Official. Always be sure to give the number and location of the building and your name and telephone extension number.
- 11.3.1 The University Police Department will assign personnel to investigate the call and take whatever police action they may deem necessary and reasonable for the safety of the campus community. The University Police will conduct a search of the building, or of specific locations in or around the building. When judged prudent and feasible to do so, the search will be conducted with the assistance and cooperation of the Principal Investigator and/or Responsible Official. After an evaluation/assessment of the content of the bomb threat, the decision to evacuate or close building shall be made jointly, whenever possible, by the Police and the Principal Investigator and/or Responsible Official.
- 11.3.2 Any unusual or suspicious object should be reported immediately to the University Police or to any immediate supervisor or administrative officer. Suspected objects or materials should NOT be touched or disturbed. Every bomb threat or incident of a suspected explosive device should be considered valid until all reasonable precautions for public safety have been taken or until the danger to life and property is terminated.

12. Failure of Select Agent Storage Freezer:

- 12.1 Select agents are not stored at building

13. Workplace violence:

- 13.1 Incidents of disruptive or threatening behavior on the part of an employee, student or visitor should be reported immediately to the Principal Investigator, who will report the incident to the Department Head, the Responsible Official and the Workplace Violence Response Team, as proscribed by the TAMU Personnel and Procedures manual section 290-09. If the individual accused of disruptive or threatening behavior is authorized for access to select agents, this person's access will be suspended pending the results of an investigation by the Workplace Violence Response Team. If an act of violence or a physical assault has occurred, or the threatening activity occurs within the BSL-3 laboratory, the person feeling threatened should call the police immediately to report the incident. If the person accused of violence has access to select agents, the person's access will be suspended pending the outcome of the investigation. Suspension of select agent access will be reported to the Responsible Official and a suspended individual's access will be inactivated within 24 hours.

14. Entry of emergency responders into the BSL-3 laboratory.

- 14.1 In a case in which a life-threatening injury or medical condition (i.e. heart attack) occurs inside the BSL-3 laboratory, emergency responders will be allowed to enter the laboratory. If possible, upon feeling ill the laboratory worker should immediately exit the suite to facilitate treatment by emergency responders. Personnel protective equipment, including Tyvek suits, N95 masks, HEPA-filtered respirators and gloves, are located inside the entries (locker rooms) to the BSL-3 suite. A spill kit containing absorbent materials and disinfectant is located under the bench in each of the labs. A First Aid kit is located inside the lab. If responders are required to enter an area where a spill has

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occurred, they will be referred to Scott and White Clinic and offered post-exposure prophylaxis.

- 14.1.1 Entry procedure for the BSL-3 laboratory: Dress yourself in a Tyvek suit, gloves, shoe covers and respiratory protection (N95 mask) before entering the laboratories.
- 14.1.2 Providing first aid and emergency medical treatment in the BSL-3 laboratory: A person working inside the Biosafety hood is not considered to be contagious unless a spill has occurred. The person's gloves may be contaminated, and may be removed to facilitate treatment. If there is no space within the labs to put the person on the floor, move the person to the interior hallway to administer treatment.
- 14.1.3 Exit procedure from the BSL-3 laboratory: Emergency responders should remove Tyvek suit, mask, shoe covers and gloves before exiting and leave them behind in the BSL-3 laboratory. Hands should be washed immediately upon exit from the BSL-3 laboratory.
- 14.1.4 Decontamination procedures for medical equipment and clothing: Emergency responders should decontaminate equipment before leaving the laboratory by one of the following methods:
 - 14.1.4.1 Autoclaving. Autoclaves are located in the northwest corner of the facility in the wall between room _____ side the BSL-3 suite and the hallway outside the BSL-3 suite.
 - 14.1.4.2 Spraying surfaces with a Wexcide solution at 1 oz Wexcide to 1 gallon of water.

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15. Incident Response Plan Testing (Drills)

- 15.1 Drills or tabletop exercises will be conducted annually to test the effectiveness of the Biosafety plan. The drills or exercises will be coordinated with the TAMU Police Department and will include, but not be limited to, the Principal Investigator or designee, BSO, TAMU Fire Department representative and the Campus Emergency Planner.
- 15.2 The drill or exercise will include, but not be limited to, accessibility to restricted space, attempted or unauthorized entry into restricted spaces challenge, animal room security, staff knowledge of hazard/emergency protocols for their work location(s) and other situations that are deemed appropriate for each work location.
- 15.3 Following the drill or exercise, which will test the various components of the incident response plan for completeness, those involved will critique their findings for each drill/exercise location. The Principal Investigator working with the Responsible Official and Biosafety Officer will implement changes as necessary changes to the plan. Results of the drill or exercise will be reviewed by the Biological Safety Administrative Advisory Committee (Institutional Biosafety Committee).

16. Texas A&M University Crisis Management Plan

- 16.1 The entity crisis management plan is contained in a separate document and is referenced in the individual laboratory emergency response plan.
- 16.2 Additional information concerning the laboratory emergency response plan is contained in the laboratory's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or the Environmental Health & Safety Department.

- 16.3 The Responsible Official and Biosafety Officer should be contacted immediately in the case of any emergency in a select agent lab. The Responsible Official will coordinate access and information issues with campus police, fire, and emergency responders.
- 16.4 If necessary, the Responsible Official will coordinate the emergency relocation of select agents to another secure location.

17. Site security and control are described in detail in the Select Agent Security Plan

- 17.1 The buildings are secured by a keyed lock. Sharing of keys with other personnel is not permitted.
- 17.2 Individuals not authorized for access to Select Agents must be accompanied by approved personnel at all times while in the buildings.
- 17.3 Data that could enable access to select agents by unauthorized personnel should be located on password-protected computers.
- 17.4 If approved personnel are observed violating security or Biosafety procedures, this observation should be reported immediately to the Principal Investigator. The Principal investigator will investigate the allegation and determine whether the violator should have his/her Select Agent access suspended or revoked. Suspension of Select Agent access will be reported to the Responsible Official and the individual's key card access will be terminated within 24 hours.

18. Inventory Discrepancies:

- 18.1 Inventory discrepancies will be documented on the agent access form.
- 18.2 All discrepancies will be immediately reported to the Principal Investigator.
- 18.3 If the discrepancy is believed to be a result of loss or theft, the incident response procedures for loss or theft and release will be followed.
- 18.4 If the discrepancy is a result of a transfer, the transfer form will be documented.

19. References

- 19.1 42 CFR Part 73
- 19.2 7 CFR Part 331
- 19.3 9 CFR Part 121
- 19.4 Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention, National Institutes of Health, Fourth Edition, May 1999
- 19.5 Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents (Revised BMBL, Appendix F), published in Morbidity and Mortality Weekly Report, December 6, 2002.

SBAT Incident Response
Emergency Contact Numbers

PI Information			
PI Thomas Ficht Office – (979) 845-4118 Mobile – (979) 574-9466	PI James Samuel Office – (979) 862-1684 Mobile – (979) 220-8269		
Building Manager Dave Carlton Work: (979) 845-3091 Cell: (979) 777-0285			
Department Head CMP Director Office - (979) 845-7433			
Incidents involving Theft or Loss University Police Department (UPD) contact Bert Kretschmar Office – 979 845-8900			
Incidents involving a Release (or Occupational Exposure) Environmental Health and Safety Office contact Between 8:00 a.m. and 5:00 p.m. Brent Mattox, Biosafety Officer (BSO) Alternate Responsible Official (ARO) Office – 979 865-2132 Mobile – 979 450-0662 After hours 5:00 pm Contact the University Police Department contact Lt. Bert Kretschmar Office – 979 845-8900			
Other Contact information			
Vice President for Research/Responsible Official (RO)	Richard Ewing (RO)	979 845-8585 (Office)	Mobile)
	Fuller Bazer (ARO)	979 693-2876 (Office)	Mobile)
	Angelia Raines (ARO)	979 847-9362 (Office)	Mobile)
Comparative Medicine Program	Melanie Ihrig	979 845-7433 (Office)	Mobile)
	Elizabeth Browder	979 845-7433 (Office)	Mobile)
	Frank Stein	979 845-6488 (Office)	Mobile)
Institutional Biosafety Committee (IBC)	Thomas Ficht	979 845-4118 (Office)	Mobile)
	Vernon Tesh	979 862-4113 (Office)	Mobile)
	Tiffany Agnew	979 458-3624 (Office)	Mobile)
Other Emergency Numbers	College Station Police	979 764-3600 or 9-911	
	Medical Emergency	9-911	
	College Station Fire	979 764-3700 or 9-911	
	Radiological Emergency	979 832-1111	
	University Maintenance	979 845-4311	

Decontamination Procedures for Spills of Cultures
(Please customize for specific laboratories.)

1. Signal others in the BL3 labs of any spill outside the biological safety cabinet. All personnel should change out of contaminated clothing and wash any exposed skin with a disinfectant, such as Purell. Clothes must be removed within the BL3 area and will be autoclaved by those cleaning up.
2. Put on a clean scrub suit and go to the shower on the first floor animal facility. Shower thoroughly with soap.
3. Return to the lab for cleanup: Put on a full face respirator and tyvek suit (contained in the SPILL KIT). Put on double gloves and shoe covers.
4. Use paper towels to cover the spill. Prevent creation of contaminated aerosols.
5. Saturate all materials with 10% bleach solution (see previous section for description).
6. Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in autoclave bags.
7. Disinfect all exposed surfaces using 1X Wexcide or 1% Virkon (surface disinfectant solution).
8. Wipe surface of full-face respirator with 1% Virkon or 1X Wexcide, being careful to avoid skin contact with Wexcide.
9. Remove all clothing and place in autoclave bag.
10. Remove full face respirator and spray off all surfaces in the lab with 1% Virkon or 1X Wexcide.
11. Make sure that all contaminated material is autoclaved, surface-disinfected or incinerated.
12. Inform others not to work in the lab until the air handling system is able to clear any residual organisms from the air (3h).
13. Return to the lab after 3 hours and perform another decontamination of all lab surfaces with 1% Virkon or 1X Wexcide.
14. Report accident to the Principal Investigator, who will report it to other officials.

Contents of spill kit located in BL-3 labs:

Full-face respirator, Tyvek suit, clean scrub suit, absorbent material, Purell skin disinfectant, towel, copy of decontamination procedures for spills.

INCIDENT RESPONSE PLAN

PI – CMP Director, *Thomas Ficht, and James Samuel*

Texas A&M University, College Station, TX 77843
to ensure compliance with
42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

- 1.1 General. This is the incident response plan for the possession and use of *Coxiella burnetii* and *Brucella spp* at Texas A&M University main campus (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121. This plan covers the use of these select agents when used in
- 1.2. This plan describes the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

- 2.1 Principal Investigator (PI). The Principal Investigator, Thomas Ficht and James Samuel, has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to Thomas Ficht and James Samuel. The PI is responsible for ensuring all incidents regarding theft, loss or release are immediately reported to the proper institutional officials. This document outlines response actions concerning any theft, loss, or release from select biological agents and toxins (SBAT) facilities, including illness of personnel or visitors in SBAT facilities. Certain actions outlined below are performed in parallel rather than sequentially (see attached flowchart).
- 2.2 All lab personnel (including the PI) are responsible for immediately reporting an incident to the University Police Department (UPD) for theft or loss or to the Institutional Biosafety Officer (BSO) for release (including occupational exposure).
- 2.3 UPD – Responsible for immediately contacting the Alternate Responsible Official (ARO) and beginning an investigation of the incident. A written investigation report will be submitted to the Institutional Biosafety Committee (IBC), the PI and the ARO within 5 days of the incident. UPD will also work with the PI to conduct a security assessment following any incident involving loss or theft.
- 2.3 BSO - Responsible for immediately contacting the Alternate Responsible Official and beginning an investigation of the incident. A written investigation report will be submitted to the IBC, the PI and the ARO within 5 days of the incident. The BSO will also work with the PI to conduct a safety assessment following any incident involving a release (including occupational exposure).
- 2.4 ARO - Responsible for immediately contacting the Responsible Official, CDC, NIH (if rDNA) and other key institutional contacts regarding the incident. The ARO will work with the BSO, UPD and the PI to insure that the written report is correct and that the report will be submitted to CDC, NIH (if rDNA) and other key institutional contacts.

- 2.5 Responsible Official – Is responsible for compliance to the Select Agent regulations and insuring requirements (registration, investigations, etc) are properly carried out.
- 2.6 Contact information is found on the Emergency contact list. The list is attached to this document and is posted throughout the lab.
- 2.7 Annual Program Review. The Responsible Official or Alternate Responsible Official will audit the incident response program on an annual basis. This review will include drills and exercises to ensure the effectiveness of the incident response plan. Based on the outcome of drills, exercises or reported incidents, this incident response plan will be reviewed and updated as necessary.

3. Description of Work

This plan covers all work being performed at TAMU. Each lab will be responsible for providing information specific to the work being performed as follows:

Lab	Work description	Unique features of Agent	Biosafety Level	Biological Use Authorization
	Animal Housing	BSC	3	
	Animal Housing	BSC	3	
	Challenge, Lab work	BSC, Aerosol Chamber	3	

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Additional information concerning the laboratories and the select agent use is contained in the facility's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or Environmental Health and Safety Office.

4. Response to theft:

4.1 Determination of Loss or Theft – The following are examples of events that may be considered a loss or theft. Possible loss or theft of the select agent will be reported initially to the Principal Investigator if any of the following have occurred: **AGENTS ARE NOT STORED IN BUILDING**

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- 4.1.1 The lock on the Select Agent storage area has been found open or appears to have been tampered with;
- 4.1.2 Evidence of forced entry into the laboratory or storage areas has been found;
- 4.1.3 A discrepancy in the Select Agent inventory that can not be reconciled;
- 4.1.4 An employee reports cultures or samples missing;
- 4.1.5 A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2;
- 4.1.6 An infected animal is missing from its microisolator cage.

4.2 Report/Investigation Process:

Theft (unauthorized removal) or **Loss** (failure to account for) a select agent or toxin
 4.2.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected theft or loss of SBATS to UPD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345). Based on circumstances, UPD will notify EHSD.

If the release is discovered and UPD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the person shall then notify the LD/PI.

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After notification to UPD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact ORC.

- 4.2.1.1 Upon notification of discovery of a theft or loss, UPD will immediately notify ORC.
- 4.2.1.2 Upon notification from UPD, ORC will immediately notify the Responsible Official (RO) and Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, and UPD.
- 4.2.1.3 UPD (and ESHD, based on circumstances) will immediately investigate the incident. The investigation will include coordination with the LD/PI and others approved with access or visiting SBAT facilities. UPD will submit a written report to ORC within 5 days of being notified about the discovery of the theft or loss. If the investigation provides evidence that a theft or loss did not occur, circumstances will be documented in UPD's investigation report.
- 4.2.1.4 Based on the UPD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss or Release of Select Agents and Toxins) with CDC. ORC will maintain an official copy of information submitted to CDC and will provide a copy of the submission to the RO, UPD/EHSD, and LD/PI.
- 4.2.1.5 UPD will notify the appropriate Federal, State, or local law enforcement agencies.
- 4.2.1.6 The LD/PI will ensure notification to the funding agency
- 4.2.2 A risk assessment will be conducted immediately upon discovery of a loss or theft. The risk assessment will be a part of the investigation report.
 - 4.2.2.1 In addition to the investigation, upon notification of a theft or loss, UPD (with input from EHSD and the LD/PI) will conduct a risk assessment to determine if the laboratory is operating in a safe and secure manner and to attempt to determine the cause of the theft. This risk assessment shall include, but not be limited to a comprehensive laboratory survey, review of access logs, review of inventory records, and verification that all equipment is operating within normal parameters (e. g. biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of theft will also be reviewed and modified, as warranted. If deficiencies in safe and secure practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
- 4.1.2.2 If deemed necessary, the EHSD/UPD will contact Biosafety Program Coordinator to convene a special meeting of the Institutional BioSafety Committee (IBC).
- 4.1.2.3 Documentation of the risk assessment will be maintained by UPD with a copy sent to the LD/PI, EHSD and ORC.

- 4.1.2.4 Security Risk Assessments will be completed by UPD, with input from the LD/PI (and EHSD, based on circumstances). The results of the risk assessment and findings, including any requirements for post theft procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI, EHSD, and ORC.
- 4.1.2.5 The ORC will contact CDC, and if needed, a copy of the assessment will be submitted. ORC will also update the RO.
- 4.2.3 UPD will establish and maintain a specific file for each theft or loss incident, with all pertinent information.
- 4.2.4 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected loss or theft to UPD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

5. Investigation

- 5.1 The Investigation Committee for all releases will be headed by the EHSD's Institutional Biosafety Officer (BSO) with input from UPD and the PI. UPD will lead investigations involving theft or loss, with input from the BSO and PI.
 - 5.1.1 The BSO/UPD will investigate the event as quickly as possible, but no later than 24 hours of the initial report or the incident.
 - 5.1.2 The investigation should include a review of all materials related to the research, including access logs, inventory logs, laboratory notes and laboratory plans (security, safety and incident response)
 - 5.1.3 Once the investigation is complete, the BSO or UPD will submit an investigation report to the IBB and RO.
 - 5.1.4 Once the Committee has determined the response and informed the RO and IBC (through the Office of Research Compliance), the IBC will review the report and make a recommendation to the RO of any additional actions that they believe are needed.
 - 5.1.5 After the RO has approved of the recommended actions, the PI will receive a written response from the IBC.

6. Reporting

- 6.1 All incident reports are included in the IBC agenda minutes for review by the full board at the next convened meeting. Serious events should be specifically presented to the IBC by the BSO/UPD or IBC Chair at the next convened meeting.
 - 6.1.1 The investigation report, at a minimum, shall include the following information:
 - 6.1.1.1 A detailed description of the incident.
 - 6.1.1.2 A list of all personnel involved in the incident.
 - 6.1.1.3 A description of what occurred and what has or needs to be done to prevent any future incident.
 - 6.1.1.4 An assessment of the safety or security risk of continuing the research.
 - 6.1.1.5 A recommendation of any changes that need to be made to the plans (safety, security or incident response), medical surveillance or laboratory procedures to reduce the risk of a reoccurrence.
 - 6.1.1.6 A recommendation for training, if needed.
 - 6.1.2 Incidents involving SBAT will be immediately reported to the CDC with a written report (Form 3) submitted within seven (7) days.

- 6.1.3 Events involving rDNA must be reported to the NIH immediately in writing but no later than 30 days of the incident.

7. Release of a Select Agent or Toxin.

Examples of a possible release (including occupational exposures of the agent or toxin include but are not limited to the following:

- 7.1 A package containing the Select Agent or toxin that has been received which has been damaged in transit such that the primary containment vessel appears to have been compromised;
- 7.2 Simultaneous complete power failure of the Biosafety cabinet and negative pressure in the BSL-3 suite during work in the Biosafety cabinet with open cultures;
- 7.3 Simultaneous spill of cultures outside the Biosafety cabinet and failure of negative pressure in the Biosafety Level 3 suite. In case of a spill, a spill kit containing absorbent material and disinfectant will be located in a designated lab for each Principal Investigator;
- 7.3.1 Personnel are advised to immediately leave the lab after removing any contaminated clothing and to return in Tyvek suits with Powered Air Purifying Respirator (PAPR) after the air has been scrubbed clean by air handlers (approx. one hour).
- 7.4 In case release of the Select Agent or toxin outside the BSL-3 laboratory is suspected, the Principal Investigator will notify the BSO laboratories on well as the Responsible Official, and the building manager.
- 7.5 Exposure of laboratory personnel to cultures. The following incidents may result in unintentional exposure to the Select Agent that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to TAMU Occupational Health, where they will be given the option to initiate post-exposure prophylaxis. The exposure will be reported by the Principal Investigator to the BSO who reports immediately to the Responsible Official, who will notify CDC of the exposure. The following are examples of unintentional exposure:
- 7.5.1 A spill of live culture outside the Biosafety cabinet;
- 7.5.2 Failure of the Biosafety cabinet during work with a select agent;
- 7.5.3 Needle stick or cut with sharps contaminated with a select agent;
- 7.5.4 If a bite from a select agent--infected animal penetrates the double gloves and breaks the skin;
- 7.5.5 A centrifuge accident that results in aerosolization of a select agent..

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8. Process of reporting and investigating a Release:

Release – Occupational exposure (clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been release outside of the primary bio-containment barrier.) or release of an agent or toxin outside of the primary barriers of the biocontainment area.

- 8.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected release to the Environment Health and Safety Department (EHSD). Based on circumstances, EHSD will notify the University Police Department (UPD). During normal business hours, call EHSD at 845-2132. If it is

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outside of normal business hours, call UPD who will notify EHSD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345).

If the release is discovered and EHSD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the individual shall then notify the LD/PI.

After notification to EHSD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact the Office of Research Compliance (ORC).

- 8.1.1 Upon notification of discovery of a release, EHSD will immediately notify Scott & White Occupational Health Clinic and ORC.
- 8.1.2 Upon notification from EHSD, ORC will immediately notify the Responsible Official (RO) and the Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, EHSD, and UPD.
- 8.1.3 EHSD (and UPD, based on circumstances) will immediately investigate the incident. The investigation will include the coordination with the LD/PI and others approved with access or visiting SBAT facilities. EHSD will submit a written report to ORC within 5 days of being notified about discovery of the release. If the investigation provides evidence that a release did not occur, circumstances will be documented in EHSD's investigation report.
- 8.1.4 Based on the EHSD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss, or Release of Select Agents and Toxins) with the CDC within seven calendar days of the discovery of the release. ORC will maintain an official copy of information submitted to the CDC and will provide a copy of the submission to the RO, EHSD, and LD/PI.
- 8.1.5 EHSD will obtain confirmation from health care providers that reports to other state or federal health agencies have been submitted. The LD/PI will ensure notification to the funding agency.
- 8.2 A risk assessment will be conducted immediately upon discovery regarding any release.
 - 8.2.1 In addition to the investigation, upon notification of a release, EHSD (under the direction of the Biological Safety Officer (BSO)) will conduct a risk assessment to determine if the laboratory is operating in a safe manner and attempt to determine the cause or most likely route of the release. This risk assessment shall include but not be limited to a comprehensive laboratory survey, review of access logs to determine potential occupational exposures, review of inventory records, and verification that all equipment is operating within normal parameters (e.g., biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of the release will also be reviewed by EHSD and modified, as warranted, in consultation with the LD/PI. If deficiencies in safe practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
 - 8.2.2 If deemed necessary based on the risk assessment, the BSO will contact ORC to convene a special meeting of the Institutional BioSafety Committee.
 - 8.2.3 Documentation of the risk assessment will be maintained by EHSD with a copy sent to the LD/PI and the ORC.

- 8.2.4 Risk assessments will be completed with input from the LD/PI. The results of the risk assessment and findings, including any requirements for post decontamination procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI and ORC.
- 8.2.5 ORC will contact CDC, and if needed, a copy of the risk assessment will be submitted. ORC will also update the RO.
- 8.3 The following additional steps will also be taken immediately upon discovery regarding an actual or suspected occupational exposure:
 - 8.3.1 EHSD will direct the LD/PI to notify laboratory personnel and visitors that a potential exposure has occurred and refer them to Scott & White Occupational Health for consultation. EHSD will obtain access logs and other information to determine a complete list of potentially exposed personnel. EHSD will then follow-up with potentially exposed personnel to ensure notification.
 - 8.3.2 Individuals will be encouraged to contact Occupational Health at Scott & White Clinic, or to immediately identify to medical personnel, the agent they were potentially exposed to if treatment is sought. Scott & White Occupational Health Clinic or the attending physician will screen for the organism (e. g. Brucella species), and begin prophylaxis as deemed appropriate by the attending physician.
 - 8.3.3 If an occupational exposure is confirmed through appropriate medical tests or as determined by a physician, all personnel and potentially exposed individuals will be immediately referred to Scott & White for screening, testing, or preventive prophylaxis as determined by the attending physician. If personnel or visitors are at remote locations (other university facilities, traveling), they should immediately report to a physician of choice and explain that a positive occupational exposure to a specific organism has occurred and specific treatment or screening is desired. Personal physicians should be encouraged to contact either EHSD or Scott and White Occupational Health if they have any questions.
 - 8.3.4 EHSD, in consultation with Scott & White, will perform periodic follow-up with the group of exposed or potentially exposed personnel for a period of time as appropriate for the organism.
- 8.4 EHSD will establish and maintain a specific file for each release incident, with all pertinent information.
- 8.5 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected release to EHSD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

9. Security Breach:

A security breach will be determined to have occurred if any of the following are observed:

- 9.1 The access control system has failed, leaving the BSL-3 suite accessible to unauthorized persons;
- 9.2 An unauthorized person is observed unaccompanied in the BSL-3 suite;
- 9.3 A lost or stolen card was used to access the BSL-3 suite;

- 9.4 An unauthorized person has accessed the computer used to control entry to the BSL-3 suite;
- 9.5 An unexpected or suspicious package arrives in the laboratory.

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the Responsible Official of the security breach and take steps to correct the problem. Corrective procedures will be secured immediately, but no later than 24 hours; an inventory will be performed of all samples and animals in the laboratory and in Select Agent storage. Any missing Select Agent samples or animals will be reported to CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator and the Responsible Official will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

10. Severe weather or natural disasters.

The most likely occurrences in this area are severe thunderstorms, floods or tornadoes.

- 10.1 If severe weather (thunderstorms or flooding) is predicted, experiments with Select Agents should be suspended until the severe weather has passed to avoid power outages during the work. All samples should be secured inside the locked -80°C freezer or the locked +4°C storage.
- 10.2 If an earthquake is felt, workers should immediately leave the suite-if possible, shedding gloves and lab coat on the way out of the BSL-3 suite. Cleanup, if necessary, can be performed once it is safe to re-enter the building.
- 10.3 Power to the BSL-3 suite may be affected if the emergency generator is flooded. In this case, all samples should be secured inside the -80°C freezer. If the vivarium is threatened by flooding, animal cages should be fastened shut, put into secondary containers (biohazard bag or large Tupperware) and transported _____ for secure holding until the threat of flooding has passed. If it becomes necessary to evacuate the College Station area, all animal experiments will be terminated before evacuation by euthanizing the animals and storing the carcasses in the secure select agent storage in room.
- 10.4 In case of a power outage, if there is no immediate danger to the building, secure all infectious samples inside a -80°C freezer, the +4°C refrigerator, or the incubators. The Biosafety cabinets and air handling system of the BSL-3 suite are on emergency backup power, which will prevent exposure to infectious samples in case of a power outage. Follow standard procedures for leaving the laboratory and return once the power has been restored to resume work.

11. Fire, Gas leak, Steam leak, Explosion, Bomb threat:

- 11.1 If work is being performed in the Biosafety cabinet, cap all samples, dispose of gloves and outer laboratory coat, and leave the laboratory immediately. If the fire is within the BSL 3 laboratory, and the worker feels (s)he can safely extinguish the fire, then the fire extinguisher located in the interior hall may be used. If a worker feels his or her safety threatened, (s)he should leave the laboratory immediately without stopping to decontaminate or secure any work, using the designated escape routes (through the emergency exit located on the west side of the BSL-3 suite and immediately out of the back dock doors located on the north side of the facility). Upon leaving the building, personnel should assemble outside the _____ in the assigned spot (_____ and _____) and report to the Area Coordinator for attendance.

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- 11.2 Notify the appropriate emergency responders: Fire 9-911 or 911 from mobile phones, the Principal Investigator and the Biosafety Officer. For steam and gas leaks, notify TAMU Operations and Maintenance.
- 11.3 In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police immediately by calling the emergency number, 9-911 or 911. Also inform the Principal Investigator and Responsible Official. Always be sure to give the number and location of the building and your name and telephone extension number.
 - 11.3.1 The University Police Department will assign personnel to investigate the call and take whatever police action they may deem necessary and reasonable for the safety of the campus community. The University Police will conduct a search of the building, or of specific locations in or around the building. When judged prudent and feasible to do so, the search will be conducted with the assistance and cooperation of the Principal Investigator and/or Responsible Official. After an evaluation/assessment of the content of the bomb threat, the decision to evacuate or close building shall be made jointly, whenever possible, by the Police and the Principal Investigator and/or Responsible Official.
 - 11.3.2 Any unusual or suspicious object should be reported immediately to the University Police or to any immediate supervisor or administrative officer. Suspected objects or materials should NOT be touched or disturbed. Every bomb threat or incident of a suspected explosive device should be considered valid until all reasonable precautions for public safety have been taken or until the danger to life and property is terminated.

12. Failure of Select Agent Storage Freezer:

- 12.1 Select agents are not stored at building

13. Workplace violence:

- 13.1 Incidents of disruptive or threatening behavior on the part of an employee, student or visitor should be reported immediately to the Principal Investigator, who will report the incident to the Department Head, the Responsible Official and the Workplace Violence Response Team, as proscribed by the TAMU Personnel and Procedures manual section 290-09. If the individual accused of disruptive or threatening behavior is authorized for access to select agents, this person's access will be suspended pending the results of an investigation by the Workplace Violence Response Team. If an act of violence or a physical assault has occurred, or the threatening activity occurs within the BSL-3 laboratory, the person feeling threatened should call the police immediately to report the incident. If the person accused of violence has access to select agents, the person's access will be suspended pending the outcome of the investigation. Suspension of select agent access will be reported to the Responsible Official and a suspended individual's access will be inactivated within 24 hours.

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14. Entry of emergency responders into the BSL-3 laboratory.

- 14.1 In a case in which a life-threatening injury or medical condition (i.e. heart attack) occurs inside the BSL-3 laboratory, emergency responders will be allowed to enter the laboratory. If possible, upon feeling ill the laboratory worker should immediately exit the suite to facilitate treatment by emergency responders. Personnel protective equipment, including Tyvek suits, N95 masks, HEPA-filtered respirators and gloves, are located inside the entries (locker rooms) to the BSL-3 suite. A spill kit containing absorbent materials and disinfectant is located under the bench in each of the labs. A First Aid kit is located inside the lab. If responders are required to enter an area where a spill has

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occurred, they will be referred to Scott and White Clinic and offered post-exposure prophylaxis.

- 14.1.1 Entry procedure for the BSL-3 laboratory: Dress yourself in a Tyvek suit, gloves, shoe covers and respiratory protection (N95 mask) before entering the laboratories.
- 14.1.2 Providing first aid and emergency medical treatment in the BSL-3 laboratory: A person working inside the Biosafety hood is not considered to be contagious unless a spill has occurred. The person's gloves may be contaminated, and may be removed to facilitate treatment. If there is no space within the labs to put the person on the floor, move the person to the interior hallway to administer treatment.
- 14.1.3 Exit procedure from the BSL-3 laboratory: Emergency responders should remove Tyvek suit, mask, shoe covers and gloves before exiting and leave them behind in the BSL-3 laboratory. Hands should be washed immediately upon exit from the BSL-3 laboratory.
- 14.1.4 Decontamination procedures for medical equipment and clothing: Emergency responders should decontaminate equipment before leaving the laboratory by one of the following methods:
 - 14.1.4.1 ~~Autoclaving~~ Autoclaves are located in the northwest corner of the ~~in the wall between room~~ inside the BSL-3 suite ~~and the hallway outside the BSL-3 suite.~~
 - 14.1.4.2 Spraying surfaces with a Wexcide solution at 1 oz Wexcide to 1 gallon of water.

Deleted: within the BSL3 suite or on the 2nd floor of the VRB

Deleted: Wiping surfaces with 10% bleach followed by 1% Virkon-S

15. Incident Response Plan Testing (Drills)

- 15.1 Drills or tabletop exercises will be conducted annually to test the effectiveness of the Biosafety plan. The drills or exercises will be coordinated with the TAMU Police Department and will include, but not be limited to, the Principal Investigator or designee, BSO, TAMU Fire Department representative and the Campus Emergency Planner.
- 15.2 The drill or exercise will include, but not be limited to, accessibility to restricted space, attempted or unauthorized entry into restricted spaces challenge, animal room security, staff knowledge of hazard/emergency protocols for their work location(s) and other situations that are deemed appropriate for each work location.
- 15.3 Following the drill or exercise, which will test the various components of the incident response plan for completeness, those involved will critique their findings for each drill/exercise location. The Principal Investigator working with the Responsible Official and Biosafety Officer will implement changes as necessary changes to the plan. Results of the drill or exercise will be reviewed by the Biological Safety Administrative Advisory Committee (Institutional Biosafety Committee).

16. Texas A&M University Crisis Management Plan

- 16.1 The entity crisis management plan is contained in a separate document and is referenced in the individual laboratory emergency response plan.
- 16.2 Additional information concerning the laboratory emergency response plan is contained in the laboratory's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or the Environmental Health & Safety Department.

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- 16.3 The Responsible Official and Biosafety Officer should be contacted immediately in the case of any emergency in a select agent lab. The Responsible Official will coordinate access and information issues with campus police, fire, and emergency responders.
- 16.4 If necessary, the Responsible Official will coordinate the emergency relocation of select agents to another secure location.

17. Site security and control are described in detail in the Select Agent Security Plan

- 17.1 The buildings are secured by a keyed lock. Sharing of keys with other personnel is not permitted.
- 17.2 Individuals not authorized for access to Select Agents must be accompanied by approved personnel at all times while in the buildings.
- 17.3 Data that could enable access to select agents by unauthorized personnel should be located on password-protected computers.
- 17.4 If approved personnel are observed violating security or Biosafety procedures, this observation should be reported immediately to the Principal Investigator. The Principal investigator will investigate the allegation and determine whether the violator should have his/her Select Agent access suspended or revoked. Suspension of Select Agent access will be reported to the Responsible Official and the individual's key card access will be terminated within 24 hours.

18. Inventory Discrepancies:

- 18.1 Inventory discrepancies will be documented on the agent access form.
- 18.2 All discrepancies will be immediately reported to the Principal Investigator.
- 18.3 If the discrepancy is believed to be a result of loss or theft, the incident response procedures for loss or theft and release will be followed.
- 18.4 If the discrepancy is a result of a transfer, the transfer form will be documented.

19. References

- 19.1 42 CFR Part 73
- 19.2 7 CFR Part 331
- 19.3 9 CFR Part 121
- 19.4 Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention, National Institutes of Health, Fourth Edition, May 1999
- 19.5 Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents (Revised BMBL, Appendix F), published in Morbidity and Mortality Weekly Report, December 6, 2002.

SBAT Incident Response
Emergency Contact Numbers

PI Information	
PI Thomas Ficht Office – (979) 845-4118 Mobile – (979) 574-9466	PI James Samuel Office – (979) 862-1684 Mobile – (979) 220-8269
Building Manager Dave Carlton Work: (979) 845-3091	
Department Head CMP Director Office - (979) 845-7433	
Incidents involving Theft or Loss University Police Department (UPD) contact Bert Kretzschmar Office – 979 845-8900	
Incidents involving a Release (or Occupational Exposure) Environmental Health and Safety Office contact Between 8:00 a.m. and 5:00 p.m. Brent Mattox, Biosafety Officer (BSO) Alternate Responsible Official (ARO) Office – 979 865-2132 After hours 5:00 pm Contact the University Police Department contact Lt. Bert Kretzschmar Office – 979 845-8900	
Other Contact information	
Vice President for Research/Responsible Official (RO)	Richard Ewing (RO) 979 845-8585 (Office) (Mobile)
	Fuller Bazer (ARO) 979 693-2876 (Office) (Mobile)
	Angelia Raines (ARO) 979 847-9362 (Office) (Mobile)
Comparative Medicine Program	Melanie Ihrig 979 845-7433 (Office) (Mobile)
	Elizabeth Browder 979 845-7433 (Office) (Mobile)
	Frank Stein 979 845-6488 (Office) (Mobile)
Institutional Biosafety Committee (IBC)	Thomas Ficht 979 845-4118 (Office) (Mobile)
	Vernon Tesh 979 862-4113 (Office) (Mobile)
	Tiffany Agnew 979 458-3624 (Office) (Mobile)
Other Emergency Numbers	College Station Police 979 764-3600 or 9-911
	Medical Emergency 9-911
	College Station Fire 979 764-3700 or 9-911
	Radiological Emergency 979 832-1111
	University Maintenance 979 845-4311

Decontamination Procedures for Spills of Cultures
(Please customize for specific laboratories.)

1. Signal others in the BL3 labs of any spill outside the biological safety cabinet. All personnel should change out of contaminated clothing and wash any exposed skin with a disinfectant, such as Purell. Clothes must be removed within the BL3 area and will be autoclaved by those cleaning up.
2. Put on a clean scrub suit and go to the shower on the first floor animal facility. Shower thoroughly with soap.
3. Return to the lab for cleanup: Put on a full face respirator and tyvek suit (contained in the SPILL KIT). Put on double gloves and shoe covers.
4. Use paper towels to cover the spill. Prevent creation of contaminated aerosols.
5. Saturate all materials with 10% bleach solution (see previous section for description).
6. Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in autoclave bags.
7. Disinfect all exposed surfaces using 1X Wexcide or 1% Virkon (surface disinfectant solution).
8. Wipe surface of full-face respirator with 1% Virkon or 1X Wexcide, being careful to avoid skin contact with Wexcide.
9. Remove all clothing and place in autoclave bag.
10. Remove full face respirator and spray off all surfaces in the lab with 1% Virkon or 1X Wexcide.
11. Make sure that all contaminated material is autoclaved, surface-disinfected or incinerated.
12. Inform others not to work in the lab until the air handling system is able to clear any residual organisms from the air (3h).
13. Return to the lab after 3 hours and perform another decontamination of all lab surfaces with 1% Virkon or 1X Wexcide.
14. Report accident to the Principal Investigator, who will report it to other officials.

Contents of spill kit located in BL-3 labs:

Full-face respirator, Tyvek suit, clean scrub suit, absorbent material, Purell skin disinfectant, towel, copy of decontamination procedures for spills.

INCIDENT RESPONSE PLAN

For

PI – Ficht

PI - Adams

Texas A&M University, College Station, TX 77843

to ensure compliance with

42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

- 1.1 General. This is the incident response plan for the possession and use of *Brucella abortus*, *Brucella suis* and *Brucella melitensis* at Texas A&M University main campus (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121. This plan covers the use of these select agents when used in buildings
- 1.2 This plan describes the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

- 2.1 Principal Investigator (PI). The Principal Investigator, Dr. Thomas A. Ficht, has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to Dr. Ficht. The PI is responsible for ensuring all incidents regarding theft, loss or release are immediately reported to the proper institutional officials. This document outlines response actions concerning any theft, loss, or release from select biological agents and toxins (SBAT) facilities, including illness of personnel or visitors in SBAT facilities. Certain actions outlined below are performed in parallel rather than sequentially (see attached flowchart).
- 2.2 All lab personnel (including the PI) are responsible for immediately reporting an incident to the University Police Department (UPD) for theft or loss or to the Institutional Biosafety Officer (BSO) for release (including occupational exposure).
- 2.3 UPD – Responsible for immediately contacting the Alternate Responsible Official (ARO) and beginning an investigation of the incident. A written investigation report will be submitted to the Institutional Biosafety Committee (IBC), the PI and the ARO within 5 days of the incident. UPD will also work with the PI to conduct a security assessment following any incident involving loss or theft.
- 2.3 BSO - Responsible for immediately contacting the Alternate Responsible Official and beginning an investigation of the incident. A written investigation report will be submitted to the IBC, the PI and the ARO within 5 days of the incident. The BSO will also work with the PI to conduct a safety assessment following any incident involving a release (including occupational exposure).
- 2.4 ARO - Responsible for immediately contacting the Responsible Official, CDC, NIH (if rDNA) and other key institutional contacts regarding the incident. The ARO will work with the BSO, UPD and the PI to insure that the written report is correct and that the report will be submitted to CDC, NIH (if rDNA) and other key institutional contacts.

- 2.5 Responsible Official – Is responsible for compliance to the Select Agent regulations and insuring requirements (registration, investigations, etc) are properly carried out.
- 2.6 Contact information is found on the Emergency contact list. The list is attached to this document and is posted throughout the lab.
- 2.7 Annual Program Review. The Responsible Official or Alternate Responsible Official will audit the incident response program on an annual basis. This review will include drills and exercises to ensure the effectiveness of the incident response plan. Based on the outcome of drills, exercises or reported incidents, this incident response plan will be reviewed and updated as necessary.

3. Description of Work

This plan covers all work being performed at TAMU. Each lab will be responsible for providing information specific to the work being performed as follows:

Lab	Work description	Unique features of Agent	Biological Use Authorization	Biosafety Level
	Storage of <i>Brucella abortus</i> , <i>B. suis</i> , <i>B. melintensis</i>	Locked freezer	0741	3
	Work with <i>Brucella abortus</i> , <i>B. suis</i> , <i>B. melintensis</i>	BSC	0741	3
	Storage of <i>Brucella</i> -infected animal carcasses	Locked freezer	0741	3
	Inoculation of mice with <i>Brucella</i> spp. And necropsy of infected animals	BSC	0741	3

Additional information concerning the laboratories and the select agent use is contained in the facility's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or Environmental Health and Safety Office.

4. Response to theft:

4.1 Determination of Loss or Theft – The following are examples of events that may be considered a loss or theft. Possible loss or theft of the select agent will be reported initially to the Principal Investigator if any of the following have occurred:

- 4.1.1 The lock on the Select Agent storage area has been found open or appears to have been tampered with;
- 4.1.2 Evidence of forced entry into the laboratory or storage areas has been found;
- 4.1.3 A discrepancy in the Select Agent inventory that can not be reconciled;
- 4.1.4 An employee reports cultures or samples missing;
- 4.1.5 A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2;
- 4.1.6 An infected animal is missing from its microisolator cage.

4.2 Report/Investigation Process:

Theft (unauthorized removal) or **Loss** (failure to account for) a select agent or toxin

- 4.2.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected theft or loss of SBATS to

UPD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345). Based on circumstances, UPD will notify EHSD.

If the release is discovered and UPD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the person shall then notify the LD/PI.

After notification to UPD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact ORC.

- 4.2.1.1 Upon notification of discovery of a theft or loss, UPD will immediately notify ORC.
- 4.2.1.2 Upon notification from UPD, ORC will immediately notify the Responsible Official (RO) and Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, and UPD.
- 4.2.1.3 UPD (and ESHD, based on circumstances) will immediately investigate the incident. The investigation will include coordination with the LD/PI and others approved with access or visiting SBAT facilities. UPD will submit a written report to ORC within 5 days of being notified about the discovery of the theft or loss. If the investigation provides evidence that a theft or loss did not occur, circumstances will be documented in UPD's investigation report.
- 4.2.1.4 Based on the UPD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss or Release of Select Agents and Toxins) with CDC. ORC will maintain an official copy of information submitted to CDC and will provide a copy of the submission to the RO, UPD/EHSD, and LD/PI.
- 4.2.1.5 UPD will notify the appropriate Federal, State, or local law enforcement agencies.
- 4.2.1.6 The LD/PI will ensure notification to the funding agency
- 4.2.2 A risk assessment will be conducted immediately upon discovery of a loss or theft. The risk assessment will be a part of the investigation report.
 - 4.2.2.1 In addition to the investigation, upon notification of a theft or loss, UPD (with input from EHSD and the LD/PI) will conduct a risk assessment to determine if the laboratory is operating in a safe and secure manner and to attempt to determine the cause of the theft. This risk assessment shall include, but not be limited to a comprehensive laboratory survey, review of access logs, review of inventory records, and verification that all equipment is operating within normal parameters (e. g. biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of theft will also be reviewed and modified, as warranted. If deficiencies in safe and secure practices are discovered, all work in the laboratory will cease until corrective actions have been taken.

- 4.1.2.2 If deemed necessary, the EHSD/UPD will contact Biosafety Program Coordinator to convene a special meeting of the Institutional BioSafety Committee (IBC).
- 4.1.2.3 Documentation of the risk assessment will be maintained by UPD with a copy sent to the LD/PI, EHSD and ORC.
- 4.1.2.4 Security Risk Assessments will be completed by UPD, with input from the LD/PI (and EHSD, based on circumstances). The results of the risk assessment and findings, including any requirements for post theft procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI, EHSD, and ORC.
- 4.1.2.5 The ORC will contact CDC, and if needed, a copy of the assessment will be submitted. ORC will also update the RO.

- 4.2.3 UPD will establish and maintain a specific file for each theft or loss incident, with all pertinent information.
- 4.2.4 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected loss or theft to UPD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

5. Investigation

- 5.1 The Investigation Committee for all releases will be headed by the EHSD's Institutional Biosafety Officer (BSO) with input from UPD and the PI. UPD will lead investigations involving theft or loss, with input from the BSO and PI.
 - 5.1.1 The BSO/UPD will investigate the event as quickly as possible, but no later than 24 hours of the initial report or the incident.
 - 5.1.2 The investigation should include a review of all materials related to the research, including access logs, inventory logs, laboratory notes and laboratory plans (security, safety and incident response)
 - 5.1.3 Once the investigation is complete, the BSO or UPD will submit an investigation report to the IBB and RO.
 - 5.1.4 Once the Committee has determined the response and informed the RO and IBC (through the Office of Research Compliance), the IBC will review the report and make a recommendation to the RO of any additional actions that they believe are needed.
 - 5.1.5 After the RO has approved of the recommended actions, the PI will receive a written response from the IBC.

6. Reporting

- 6.1 All incident reports are included in the IBC agenda minutes for review by the full board at the next convened meeting. Serious events should be specifically presented to the IBC by the BSO/UPD or IBC Chair at the next convened meeting.
 - 6.1.1 The investigation report, at a minimum, shall include the following information:
 - 6.1.1.1 A detailed description of the incident.
 - 6.1.1.2 A list of all personnel involved in the incident.
 - 6.1.1.3 A description of what occurred and what has or needs to be done to prevent any future incident.
 - 6.1.1.4 An assessment of the safety or security risk of continuing the research.

- 6.1.1.5 A recommendation of any changes that need to be made to the plans (safety, security or incident response), medical surveillance or laboratory procedures to reduce the risk of a reoccurrence.
- 6.1.1.6 A recommendation for training, if needed.

6.1.2 Incidents involving SBAT will be immediately reported to the CDC with a written report (Form 3) submitted within seven (7) days.

6.1.3 Events involving rDNA must be reported to the NIH immediately in writing but no later than 30 days of the incident.

7. **Release of a Select Agent or Toxin.**

Examples of a possible release (including occupational exposures of the agent or toxin include but are not limited to the following:

7.1 A package containing the Select Agent or toxin that has been received, which has been damaged in transit, such that the primary containment vessel appears to have been compromised;

7.2 Simultaneous complete power failure of the Biosafety cabinet and loss of negative pressure in the BSL-3 suite during work in the Biosafety cabinet with open cultures;

7.3 Simultaneous spill of cultures outside the Biosafety cabinet and failure of negative pressure in the Biosafety Level 3 suite. In case of a spill, a spill kit containing absorbent material and disinfectant will be located in a designated lab for each Principal Investigator;

7.3.1 Personnel are advised to immediately leave the lab after removing any contaminated clothing and to return in Tyvek suits with Powered Air Purifying Respirator (PAPR) after the air has been scrubbed clean by air handlers (approx. one hour).

7.4 In case release of the Select Agent or toxin outside the BSL-3 laboratory is suspected, the Principal Investigator will notify the BSO and ARO as well as the Responsible Official, and the building manager.

7.5 Exposure of laboratory personnel to cultures. The following incidents may result in unintentional exposure to the Select Agent that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to BSO who will immediately contact the Scott & White Occupational Health office, where they will be evaluated for possible post-exposure prophylaxis. The exposure will be reported by the Principal Investigator to the BSO who reports immediately to the ARO, who will notify CDC of the exposure. The following are examples of unintentional exposure:

7.5.1 A spill of live culture outside the Biosafety cabinet;

7.5.2 Failure of the Biosafety cabinet during work with *Brucella*;

7.5.3 Needle stick or cut with sharps contaminated with *Brucella*;

7.5.4 If a bite from a *Brucella*-infected animal penetrates the double gloves and breaks the skin;

7.5.5 A centrifuge accident that results in aerosolization of *Brucella*.

8. **Process of reporting and investigating a Release:**

Release – Occupational exposure (clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been release outside of the primary bio-containment barrier), or release of an agent or toxin outside of the primary barriers of the biocontainment area.

- 8.1 All individuals approved for access or visiting SBAT facilities must upon discovery immediately report any actual or suspected release to the BSO of the Environment Health and Safety Department (EHSD). Based on circumstances, EHSD will notify the University Police Department (UPD). During normal business hours, call EHSD at 845-2132. If it is outside of normal business hours, call UPD who will notify EHSD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345).

If the release is discovered and the BSO is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the individual must then notify the LD/PI.

After notification to the BSO by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact the Office of Research Compliance (ORC).

- 8.1.1 Upon notification of discovery of a release, EHSD will immediately notify Scott & White Occupational Health office and ORC.
- 8.1.2 Upon notification from EHSD, ORC will immediately notify the ARO, the RO and the Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, EHSD, and UPD.
- 8.1.3 EHSD (and UPD, based on circumstances) will immediately investigate the incident. The investigation will include the coordination with the LD/PI and others approved with access or visiting SBAT facilities. EHSD will submit a written report to ORC within 5 days of being notified about discovery of the release. If the investigation provides evidence that a release did not occur, circumstances will be documented in EHSD's investigation report.
- 8.1.4 Based on the EHSD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss, or Release of Select Agents and Toxins) with the CDC within seven calendar days of the discovery of the release. ORC will maintain an official copy of information submitted to the CDC and will provide a copy of the submission to the RO, EHSD, and LD/PI.
- 8.1.5 EHSD will obtain confirmation from health care providers that reports to other state or federal health agencies have been submitted. The LD/PI will ensure notification to the funding agency.
- 8.2 A risk assessment will be conducted immediately upon discovery regarding any release.
- 8.2.1 In addition to the investigation, upon notification of a release, EHSD (under the direction of the Biological Safety Officer (BSO)) will conduct a risk assessment to determine if the laboratory is operating in a safe manner and attempt to determine the cause or most likely route of the release. This risk assessment shall include but not be limited to a comprehensive laboratory survey, review of access logs to determine potential occupational exposures, review of inventory records, and verification that all equipment is operating within normal parameters (e.g., biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of the release will also be reviewed by EHSD and modified, as warranted, in consultation with the LD/PI. If deficiencies in safe practices are discovered, all work in the laboratory will cease until corrective actions have been taken.

- 8.2.2 If deemed necessary based on the risk assessment, the BSO will contact ORC to convene a special meeting of the Institutional BioSafety Committee.
- 8.2.3 Documentation of the risk assessment will be maintained by EHSD with a copy sent to the LD/PI and the ORC.
- 8.2.4 Risk assessments will be completed with input from the LD/PI. The results of the risk assessment and findings, including any requirements for post decontamination procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI and ORC.
- 8.2.5 ORC will contact CDC, and if needed, a copy of the risk assessment will be submitted. ORC will also update the RO.
- 8.3 The following additional steps will also be taken immediately upon discovery regarding an actual or suspected occupational exposure:
 - 8.3.1 EHSD will direct the LD/PI to notify laboratory personnel and visitors that a potential exposure has occurred and refer them to Scott & White Occupational Health for consultation. EHSD will obtain access logs and other information to determine a complete list of potentially exposed personnel. EHSD will then follow-up with potentially exposed personnel to ensure notification.
 - 8.3.2 Individuals will be encouraged to contact Occupational Health at Scott & White Clinic, or to immediately identify to medical personnel, the agent they were potentially exposed to if treatment is sought. Scott & White Occupational Health Clinic or the attending physician will test for the organism (e. g. *Brucella* species), and begin prophylaxis as deemed appropriate by the attending physician.
 - 8.3.3 If an occupational exposure is confirmed through appropriate medical tests or as determined by a physician, all personnel and potentially exposed individuals will be immediately referred to Scott & White for screening, testing, or preventive prophylaxis as determined by the attending physician. If personnel or visitors are at remote locations (other university facilities, traveling), they should immediately report to a physician of choice and explain that a positive occupational exposure to a specific organism has occurred and specific treatment or screening is desired. Personal physicians should be encouraged to contact either EHSD or Scott and White Occupational Health if they have any questions.
 - 8.3.4 EHSD, in consultation with Scott & White, will perform periodic follow-up with the group of exposed or potentially exposed personnel for a period of time as appropriate for the organism.
- 8.4 EHSD will establish and maintain a specific file for each release incident, with all pertinent information.
- 8.5 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected release to EHSD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

9. Security Breach:

A security breach will be determined to have occurred if any of the following are observed:

- 9.1 The access control system has failed, leaving the BSL-3 suite accessible to unauthorized persons;
- 9.2 An unauthorized person is observed unaccompanied in the BSL-3 suite;
- 9.3 A lost or stolen card was used to access the BSL-3 suite;
- 9.4 An unauthorized person has accessed the computer used to control entry to the BSL-3 suite;
- 9.5 An unexpected or suspicious package arrives in the laboratory.

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the UPD and the ARO of the security breach and take steps to correct the problem. Corrective procedures will be secured immediately, but no later than 24 hours; an inventory will be performed of all samples and animals in the laboratory and in Select Agent storage. Any missing Select Agent samples or animals will be reported to ARO, RO and CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator, the ARO and the UPD will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

10. Severe weather or natural disasters.

The most likely occurrences in this area are severe thunderstorms, floods or tornadoes.

- 10.1 If severe weather (thunderstorms or flooding) is predicted, experiments with Select Agents should be suspended until the severe weather has passed to avoid power outages during the work. All samples should be secured inside the locked -80°C freezer or the locked +4°C storage.
- 10.2 If an earthquake is felt, workers should immediately leave the suite-if possible, shedding gloves and lab coat on the way out of the BSL-3 suite. Cleanup, if necessary, can be performed once it is safe to re-enter the building.
- 10.3 Power to the BSL-3 suite may be affected if the emergency generator is flooded. In this case, all samples should be secured inside the -80°C freezer. If the vivarium is threatened by flooding, animal cages should be fastened shut, put into secondary containers (biohazard bag or large Tupperware) and transported to _____ or secure holding until the threat of flooding has passed. If it becomes necessary to evacuate the College Station area, all animal experiments will be terminated before evacuation by euthanizing the animals and storing the carcasses in the secure select agent storage in room.
- 10.4 In case of a power outage, if there is no immediate danger to the building, secure all infectious samples inside a -80°C freezer, the +4°C refrigerator, or the incubators. The Biosafety cabinets and air handling system of the BSL-3 suite are on emergency backup power, which will prevent exposure to infectious samples in case of a power outage. Follow standard procedures for leaving the laboratory and return once the power has been restored to resume work.

11. Fire, Gas leak, Steam leak, Explosion, Bomb threat:

- 11.1 If work is being performed in the Biosafety cabinet, cap all samples, dispose of gloves and outer laboratory coat, and leave the laboratory immediately. If the fire is within the BSL 3 laboratory, and the worker feels (s)he can safely extinguish the fire, then the fire extinguisher located in the interior hall may be used. If a worker feels his or her safety threatened, (s)he should leave the laboratory immediately without stopping to decontaminate or secure any work, using the designated escape routes (through the locker rooms or the exterior "airlock" door on the west side of the building). Upon leaving the building, personnel should assemble outside the _____ at the assigned spot (southern _____) and report to the Lab Safety Officer for attendance.

- 11.2 Notify the appropriate emergency responders: Fire 9-911 or 911 from mobile phones, the Principal Investigator and the Biosafety Officer. For steam and gas leaks, notify TAMU Operations and Maintenance.
- 11.3 In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police immediately by calling the emergency number, 9-911, 911, 845-8900, or 845-2345. Also inform the Principal Investigator and Responsible Official. Always be sure to give the number and location of the building and your name and telephone extension number.
 - 11.3.1 The University Police Department will assign personnel to investigate the call and take whatever police action they may deem necessary and reasonable for the safety of the campus community. The University Police will conduct a search of the building, or of specific locations in or around the building. When judged prudent and feasible to do so, the search will be conducted with the assistance and cooperation of the Principal Investigator and/or Responsible Official. After an evaluation/assessment of the content of the bomb threat, the decision to evacuate or close building shall be made jointly, whenever possible, by the Police and the Principal Investigator and/or Responsible Official.
 - 11.3.2 Any unusual or suspicious object should be reported immediately to the University Police or to any immediate supervisor or administrative officer. Suspected objects or materials should NOT be touched or disturbed. Every bomb threat or incident of a suspected explosive device should be considered valid until all reasonable precautions for public safety have been taken or until the danger to life and property is terminated.

12. Failure of Select Agent Storage Freezer:

- 12.2 If the -80°C freezer in _____ that is used to store *Brucella* strains fails, the strains will be moved to a temporary backup location, which is either the other -80°C Revco freezer located in room _____ r in secure freezer in a locked BSL-2 laboratory. This freezer will be locked in order to limit access to personnel authorized to work with select agents.

13. Workplace violence:

- 13.1 Incidents of disruptive or threatening behavior on the part of an employee, student or visitor should be reported immediately to the Principal Investigator, who will report the incident to the Department Head, UPD, ARO and the Workplace Violence Response Team, as proscribed by the TAMU Personnel and Procedures manual section 290-09. If the individual accused of disruptive or threatening behavior is authorized for access to select agents, this person's access will be suspended pending the results of an investigation by the Workplace Violence Response Team. If an act of violence or a physical assault has occurred, or the threatening activity occurs within the BSL-3 laboratory, the person feeling threatened should call the police immediately to report the incident. If the person accused of violence has access to select agents, the person's access will be suspended pending the outcome of the investigation. Suspension of select agent access will be reported to the UPD, and ARO and a suspended individual's access will be inactivated within 24 hours.

14. Entry of emergency responders into the BSL-3 laboratory.

- 14.1 In a case in which a life-threatening injury or medical condition (i.e. heart attack) occurs inside the BSL-3 laboratory, emergency responders will be allowed to enter the laboratory. If possible, upon feeling ill the laboratory worker should immediately exit the suite to facilitate treatment by emergency responders. Personnel protective equipment, including Tyvek suits, PAPRs and gloves, are located inside the entries (locker rooms) to the BSL-3 suite. A spill kit containing absorbent materials and disinfectant is located under the bench in each of the labs. A First Aid kit is located inside the lab. If responders

are required to enter an area where a spill has occurred, they will be referred to Scott and White Clinic and offered post-exposure prophylaxis.

14.1.1 Entry procedure for the BSL-3 laboratory: Dress yourself in a Tyvek suit, gloves, shoe covers and PAPRs before entering the laboratories.

14.1.2 Providing first aid and emergency medical treatment in the BSL-3 laboratory: A person working inside the Biosafety hood is not considered to be contagious unless a spill has occurred. The person's gloves may be contaminated, and may be removed to facilitate treatment. If there is no space within the labs to put the person on the floor, move the person to the interior hallway to administer treatment.

14.1.3 Exit procedure from the BSL-3 laboratory: Emergency responders should remove Tyvek suit, PAPR, shoe covers and gloves before exiting and leave them behind in the BSL-3 laboratory. Hands should be washed immediately upon exit from the BSL-3 laboratory.

14.1.4 Decontamination procedures for medical equipment and clothing: Emergency responders should decontaminate equipment before leaving the laboratory by one of the following methods:

14.1.4.1 Autoclaving. Autoclaves are located within the BSL3 suite or on the

14.1.5 Wiping surfaces with 10% bleach followed by 1% Virkon-S.

15. Incident Response Plan Testing (Drills)

15.1 Drills or tabletop exercises will be conducted annually to test the effectiveness of the Biosafety plan. The drills or exercises will be coordinated with the TAMU Police Department and will include, but not be limited to, the Principal Investigator or designee, BSO, TAMU Fire Department representative and the Campus Emergency Planner.

15.2 The drill or exercise will include, but not be limited to, accessibility to restricted space, attempted or unauthorized entry into restricted spaces challenge, animal room security, staff knowledge of hazard/emergency protocols for their work location(s) and other situations that are deemed appropriate for each work location.

15.3 Following the drill or exercise, which will test the various components of the incident response plan for completeness, those involved will critique their findings for each drill/exercise location. The Principal Investigator working with the Responsible Official and Biosafety Officer will implement changes as necessary changes to the plan. Results of the drill or exercise will be reviewed by the Biological Safety Administrative Advisory Committee (Institutional Biosafety Committee).

16. Texas A&M University Crisis Management Plan

16.1 The entity crisis management plan is contained in a separate document and is referenced in the individual laboratory emergency response plan.

16.2 Additional information concerning the laboratory emergency response plan is contained in the laboratory's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or the Environmental Health & Safety Department.

16.3 The Alternate Responsible Official and Biosafety Officer should be contacted immediately in the case of any emergency in a select agent lab. The Alternate

Responsible Official will coordinate access and information issues with campus police, fire, and emergency responders.

- 16.4 If necessary, the Responsible Official will coordinate the emergency relocation of select agents to another secure location.

17. Site security and control are described in detail in the Select Agent Security Plan

- 17.1 The buildings are secured by a keyed lock. Sharing of keys with other personnel is not permitted.
- 17.2 Individuals not authorized for access to Select Agents must be accompanied by approved personnel at all times while in the buildings.
- 17.3 Data that could enable access to select agents by unauthorized personnel should be located on password-protected computers.
- 17.4 If approved personnel are observed violating security or Biosafety procedures, this observation should be reported immediately to the Principal Investigator. The Principal investigator will report the violation to the UPD who will investigate the allegation and determine whether the violator should have his/her Select Agent access suspended or revoked. Suspension of Select Agent access will be reported to the Alternate Responsible Official, the RO and the individual's key card access will be terminated within 24 hours.

18. Inventory Discrepancies:

- 18.1 Inventory discrepancies will be documented on the agent access form.
- 18.2 All discrepancies will be immediately reported to the Principal Investigator.
- 18.3 If the discrepancy is believed to be a result of loss or theft, the incident response procedures for loss or theft and release will be followed.
- 18.4 If the discrepancy is a result of a transfer, the transfer form will be documented.

19. References

- 19.1 42 CFR Part 73
- 19.2 7 CFR Part 331
- 19.3 9 CFR Part 121
- 19.4 Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention, National Institutes of Health, Fourth Edition, May 1999
- 19.5 Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents (Revised BMBL, Appendix F), published in Morbidity and Mortality Weekly Report, December 6, 2002.

SBAT Incident Response
Emergency Contact Numbers

PI Information			
PI Ficht Office – 979 845-4118			
Building Manager Lorten Skow 979-845-3194			
Department Head Gerald Bratton 979-845-5941			
Incidents involving Theft or Loss University Police Department (UPD) contact Bert Kretzschmar Office – 979 845-8900 H			
Incidents involving a Release (or Occupational Exposure) Environmental Health and Safety Office contact Between 8:00 a.m. and 5:00 p.m. Brent Mattox, Biosafety Officer (BSO) Alternate Responsible Official (ARO) After hours 5:00 pm Contact the University Police Department contact Lt. Bert Kretzschmar Office – 979 845-8900			
Other Contact information			
Vice President for Research/Responsible Official (RO)	Richard Ewing (RO)	979 845-8585 (Office) c	(Mobile)
	Fuller Bazer (ARO)	979 693-2876 (Office) c	(Mobile)
	Angelia Raines (ARO)	979 847-9362 (Office) c	(Mobile)
Comparative Medicine Program	Melanie Ihrig	979 845-7433 (Office) c	(Mobile)
	Elizabeth Browder	979 845-7433 (Office) c	(Mobile)
	Frank Stein	979 845-6488 (Office) c	(Mobile)
Institutional Biosafety Committee (IBC)	Thomas Ficht	979 845-4118 (Office) c	(Mobile)
	Vernon Tesh	979 862-4113 (Office) c	(Mobile)
	Tiffany Agnew	979 458-3624 (Office) c	(Mobile)
Other Emergency Numbers	College Station Police	979 764-3600 or 9-911	
	Medical Emergency	9-911	
	College Station Fire	979 764-3700 or 9-911	
	Radiological Emergency	979 832-1111	
	University Maintenance	979 845-4311	

Emergency Telephone Numbers

Enter PI Name	Office: (979)845-4118
Emergency	9-911
University Police	(979) 845-2345
College Station Police	(979) 764-3600
College Station Fire	(979) 764-3700
Environmental Health & Safety	(979) 845-2132
TAMU Area Maintenance (HVAC failure, steam leak, gas leak)	(979) 845-5542
TAMU Maintenance (24 hours)	(979) 845-4311
Radiological Emergencies	(979) 862-1111
Responsible University Officials:	
RO-Richard Ewing	Work: (979) 845-8585
ARO-Angelia Raines	Work: (979) 847-9362
Biosafety Officer/ARO -Brent Mattox	Work: (979) 845-2132
Building Manager	Loren Skow 979-845-3194
Frank Stein	Work: (979) 845-6488
TAF Lab	5-4185
Neighboring labs to notify in case of simultaneous containment breach and spill outside BSC:	
Lab (enter additional locations)	enter additional laboratory phone number
Lab (enter additional locations)	enter additional laboratory phone number
Lab (enter additional locations)	enter additional laboratory phone number

Decontamination Procedures for Spills of Cultures
(Please customize for specific laboratories.)

1. Signal others in the BL3 labs of any spill outside the biological safety cabinet. All personnel should change out of contaminated clothing and wash any exposed skin with a disinfectant, such as Purell. Clothes must be removed within the BL3 area and will be autoclaved by those cleaning up.
2. Put on a clean scrub suit and go to the shower on the first floor animal facility. Shower thoroughly with soap.
3. Return to the lab for cleanup: Put on a PAPR and tyvek suit (contained in the SPILL KIT). Put on double gloves and shoe covers.
4. Use paper towels to cover the spill. Prevent creation of contaminated aerosols.
5. Saturate all materials with 10% bleach solution (see previous section for description).
6. Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in autoclave bags.
7. Disinfect all exposed surfaces using 1X Wexcide or 1% Virkon (surface disinfectant solution).
8. Wipe surface of full-face respirator with 1% Virkon or 1X Wexcide, being careful to avoid skin contact with Wexcide.
9. Remove all clothing and place in autoclave bag.
10. Remove full face respirator and spray off all surfaces in the lab with 1% Virkon or 1X Wexcide.
11. Make sure that all contaminated material is autoclaved, surface-disinfected or incinerated.
12. Inform others not to work in the lab until the air handling system is able to clear any residual organisms from the air (3h).
13. Return to the lab after 3 hours and perform another decontamination of all lab surfaces with 1% Virkon or 1X Wexcide.
14. Report accident to the Principal Investigator, who will report it to other officials.

Contents of spill kit located in BL-3 labs:

PAPR, Tyvek suit, clean scrub suit, absorbent material, Purell skin disinfectant, towel, copy of decontamination procedures for spills.

INCIDENT RESPONSE PLAN

PI – Ficht

PI - Adams

Texas A&M University, College Station, TX 77843

to ensure compliance with

42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

- 1.1 General. This is the incident response plan for the possession and use of *Brucella abortus*, *Brucella suis* and *Brucella melitensis* at Texas A&M University main campus (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121. This plan covers the use of these select agents when used in buildings
- 1.2. This plan describes the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

- 2.1 Principal Investigator (PI). The Principal Investigator, Dr. Thomas A. Ficht, has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to Dr. Ficht. The PI is responsible for ensuring all incidents regarding theft, loss or release are immediately reported to the proper institutional officials. This document outlines response actions concerning any theft, loss, or release from select biological agents and toxins (SBAT) facilities, including illness of personnel or visitors in SBAT facilities. Certain actions outlined below are performed in parallel rather than sequentially (see attached flowchart).
- 2.2 All lab personnel (including the PI) are responsible for immediately reporting an incident to the University Police Department (UPD) for theft or loss or to the Institutional Biosafety Officer (BSO) for release (including occupational exposure).
- 2.3 UPD – Responsible for immediately contacting the Alternate Responsible Official (ARO) and beginning an investigation of the incident. A written investigation report will be submitted to the Institutional Biosafety Committee (IBC), the PI and the ARO within 5 days of the incident. UPD will also work with the PI to conduct a security assessment following any incident involving loss or theft.
- 2.3 BSO - Responsible for immediately contacting the Alternate Responsible Official and beginning an investigation of the incident. A written investigation report will be submitted to the IBC, the PI and the ARO within 5 days of the incident. The BSO will also work with the PI to conduct a safety assessment following any incident involving a release (including occupational exposure).
- 2.4 ARO - Responsible for immediately contacting the Responsible Official, CDC, NIH (if rDNA) and other key institutional contacts regarding the incident. The ARO will work with the BSO, UPD and the PI to insure that the written report is correct and that the report will be submitted to CDC, NIH (if rDNA) and other key institutional contacts.

- 2.5 Responsible Official – Is responsible for compliance to the Select Agent regulations and insuring requirements (registration, investigations, etc) are properly carried out.
- 2.6 Contact information is found on the Emergency contact list. The list is attached to this document and is posted throughout the lab.
- 2.7 Annual Program Review. The Responsible Official or Alternate Responsible Official will audit the incident response program on an annual basis. This review will include drills and exercises to ensure the effectiveness of the incident response plan. Based on the outcome of drills, exercises or reported incidents, this incident response plan will be reviewed and updated as necessary.

3. Description of Work

This plan covers all work being performed at TAMU. Each lab will be responsible for providing information specific to the work being performed as follows:

Lab	Work description	Unique features of Agent	Biological Use Authorization	Biosafety Level
	Storage of <i>Brucella abortus</i> , <i>B. suis</i> , <i>B. melintensis</i>	Locked freezer	0741	3
	Work with <i>Brucella abortus</i> , <i>B. suis</i> , <i>B. melintensis</i>	BSC	0741	3
	Storage of <i>Brucella</i> -infected animal carcasses	Locked freezer	0741	3
	Inoculation of mice with <i>Brucella</i> spp. And necropsy of infected animals	BSC	0741	3

Additional information concerning the laboratories and the select agent use is contained in the facility's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or Environmental Health and Safety Office.

4. Response to theft:

- 4.1 Determination of Loss or Theft – The following are examples of events that may be considered a loss or theft. Possible loss or theft of the select agent will be reported initially to the Principal Investigator if any of the following have occurred:
- 4.1.1 The lock on the Select Agent storage area has been found open or appears to have been tampered with;
 - 4.1.2 Evidence of forced entry into the laboratory or storage areas has been found;
 - 4.1.3 A discrepancy in the Select Agent inventory that can not be reconciled;
 - 4.1.4 An employee reports cultures or samples missing;
 - 4.1.5 A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2;
 - 4.1.6 An infected animal is missing from its microisolator cage.

4.2 Report/Investigation Process:

Theft (unauthorized removal) or **Loss** (failure to account for) a select agent or toxin

- 4.2.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected theft or loss of SBATS to

UPD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345). Based on circumstances, UPD will notify EHSD.

If the release is discovered and UPD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the person shall then notify the LD/PI.

After notification to UPD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact ORC.

- 4.2.1.1 Upon notification of discovery of a theft or loss, UPD will immediately notify ORC.
- 4.2.1.2 Upon notification from UPD, ORC will immediately notify the Responsible Official (RO) and Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, and UPD.
- 4.2.1.3 UPD (and ESHD, based on circumstances) will immediately investigate the incident. The investigation will include coordination with the LD/PI and others approved with access or visiting SBAT facilities. UPD will submit a written report to ORC within 5 days of being notified about the discovery of the theft or loss. If the investigation provides evidence that a theft or loss did not occur, circumstances will be documented in UPD's investigation report.
- 4.2.1.4 Based on the UPD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss or Release of Select Agents and Toxins) with CDC. ORC will maintain an official copy of information submitted to CDC and will provide a copy of the submission to the RO, UPD/EHSD, and LD/PI.
- 4.2.1.5 UPD will notify the appropriate Federal, State, or local law enforcement agencies.
- 4.2.1.6 The LD/PI will ensure notification to the funding agency
- 4.2.2 A risk assessment will be conducted immediately upon discovery of a loss or theft. The risk assessment will be a part of the investigation report.
 - 4.2.2.1 In addition to the investigation, upon notification of a theft or loss, UPD (with input from EHSD and the LD/PI) will conduct a risk assessment to determine if the laboratory is operating in a safe and secure manner and to attempt to determine the cause of the theft. This risk assessment shall include, but not be limited to a comprehensive laboratory survey, review of access logs, review of inventory records, and verification that all equipment is operating within normal parameters (e. g. biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of theft will also be reviewed and modified, as warranted. If deficiencies in safe and secure practices are discovered, all work in the laboratory will cease until corrective actions have been taken.

- 4.1.2.2 If deemed necessary, the EHSD/UPD will contact Biosafety Program Coordinator to convene a special meeting of the Institutional BioSafety Committee (IBC).
- 4.1.2.3 Documentation of the risk assessment will be maintained by UPD with a copy sent to the LD/PI, EHSD and ORC.
- 4.1.2.4 Security Risk Assessments will be completed by UPD, with input from the LD/PI (and EHSD, based on circumstances). The results of the risk assessment and findings, including any requirements for post theft procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI, EHSD, and ORC.
- 4.1.2.5 The ORC will contact CDC, and if needed, a copy of the assessment will be submitted. ORC will also update the RO.

- 4.2.3 UPD will establish and maintain a specific file for each theft or loss incident, with all pertinent information.
- 4.2.4 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected loss or theft to UPD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

5. Investigation

- 5.1 The Investigation Committee for all releases will be headed by the EHSD's Institutional Biosafety Officer (BSO) with input from UPD and the PI. UPD will lead investigations involving theft or loss, with input from the BSO and PI.
 - 5.1.1 The BSO/UPD will investigate the event as quickly as possible, but no later than 24 hours of the initial report or the incident.
 - 5.1.2 The investigation should include a review of all materials related to the research, including access logs, inventory logs, laboratory notes and laboratory plans (security, safety and incident response)
 - 5.1.3 Once the investigation is complete, the BSO or UPD will submit an investigation report to the IBB and RO.
 - 5.1.4 Once the Committee has determined the response and informed the RO and IBC (through the Office of Research Compliance), the IBC will review the report and make a recommendation to the RO of any additional actions that they believe are needed.
 - 5.1.5 After the RO has approved of the recommended actions, the PI will receive a written response from the IBC.

6. Reporting

- 6.1 All incident reports are included in the IBC agenda minutes for review by the full board at the next convened meeting. Serious events should be specifically presented to the IBC by the BSO/UPD or IBC Chair at the next convened meeting.
 - 6.1.1 The investigation report, at a minimum, shall include the following information:
 - 6.1.1.1 A detailed description of the incident.
 - 6.1.1.2 A list of all personnel involved in the incident.
 - 6.1.1.3 A description of what occurred and what has or needs to be done to prevent any future incident.
 - 6.1.1.4 An assessment of the safety or security risk of continuing the research.

6.1.1.5 A recommendation of any changes that need to be made to the plans (safety, security or incident response), medical surveillance or laboratory procedures to reduce the risk of a reoccurrence.

6.1.1.6 A recommendation for training, if needed.

6.1.2 Incidents involving SBAT will be immediately reported to the CDC with a written report (Form 3) submitted within seven (7) days.

6.1.3 Events involving rDNA must be reported to the NIH immediately in writing but no later than 30 days of the incident.

7. **Release of a Select Agent or Toxin.**

Examples of a possible release (including occupational exposures of the agent or toxin include but are not limited to the following:

7.1 A package containing the Select Agent or toxin that has been received, which has been damaged in transit, such that the primary containment vessel appears to have been compromised;

7.2 Simultaneous complete power failure of the Biosafety cabinet and loss of negative pressure in the BSL-3 suite during work in the Biosafety cabinet with open cultures;

7.3 Simultaneous spill of cultures outside the Biosafety cabinet and failure of negative pressure in the Biosafety Level 3 suite. In case of a spill, a spill kit containing absorbent material and disinfectant will be located in a designated lab for each Principal Investigator;

7.3.1 Personnel are advised to immediately leave the lab after removing any contaminated clothing and to return in Tyvek suits with Powered Air Purifying Respirator (PAPR) after the air has been scrubbed clean by air handlers (approx. one hour).

7.4 In case release of the Select Agent or toxin outside the BSL-3 laboratory is suspected, the Principal Investigator will notify the BSO and ARO as well as the Responsible Official, and the building manager.

7.5 Exposure of laboratory personnel to cultures. The following incidents may result in unintentional exposure to the Select Agent that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to BSO who will immediately contact the Scott & White Occupational Health office, where they will be evaluated for possible post-exposure prophylaxis. The exposure will be reported by the Principal Investigator to the BSO who reports immediately to the ARO, who will notify CDC of the exposure. The following are examples of unintentional exposure:

7.5.1 A spill of live culture outside the Biosafety cabinet;

7.5.2 Failure of the Biosafety cabinet during work with *Brucella*;

7.5.3 Needle stick or cut with sharps contaminated with *Brucella*;

7.5.4 If a bite from a *Brucella*-infected animal penetrates the double gloves and breaks the skin;

7.5.5 A centrifuge accident that results in aerosolization of *Brucella*.

8. **Process of reporting and investigating a Release:**

Release – Occupational exposure (clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been release outside of the primary bio-containment barrier), or release of an agent or toxin outside of the primary barriers of the biocontainment area.

- 8.1 All individuals approved for access or visiting SBAT facilities must upon discovery immediately report any actual or suspected release to the BSO of the Environment Health and Safety Department (EHSD). Based on circumstances, EHSD will notify the University Police Department (UPD). During normal business hours, call EHSD at 845-2132. If it is outside of normal business hours, call UPD who will notify EHSD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345).

If the release is discovered and the BSO is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the individual must then notify the LD/PI.

After notification to the BSO by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact the Office of Research Compliance (ORC).

- 8.1.1 Upon notification of discovery of a release, EHSD will immediately notify Scott & White Occupational Health office and ORC.
- 8.1.2 Upon notification from EHSD, ORC will immediately notify the ARO, the RO and the Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, EHSD, and UPD.
- 8.1.3 EHSD (and UPD, based on circumstances) will immediately investigate the incident. The investigation will include the coordination with the LD/PI and others approved with access or visiting SBAT facilities. EHSD will submit a written report to ORC within 5 days of being notified about discovery of the release. If the investigation provides evidence that a release did not occur, circumstances will be documented in EHSD's investigation report.
- 8.1.4 Based on the EHSD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss, or Release of Select Agents and Toxins) with the CDC within seven calendar days of the discovery of the release. ORC will maintain an official copy of information submitted to the CDC and will provide a copy of the submission to the RO, EHSD, and LD/PI.
- 8.1.5 EHSD will obtain confirmation from health care providers that reports to other state or federal health agencies have been submitted. The LD/PI will ensure notification to the funding agency.
- 8.2 A risk assessment will be conducted immediately upon discovery regarding any release.
- 8.2.1 In addition to the investigation, upon notification of a release, EHSD (under the direction of the Biological Safety Officer (BSO)) will conduct a risk assessment to determine if the laboratory is operating in a safe manner and attempt to determine the cause or most likely route of the release. This risk assessment shall include but not be limited to a comprehensive laboratory survey, review of access logs to determine potential occupational exposures, review of inventory records, and verification that all equipment is operating within normal parameters (e.g., biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of the release will also be reviewed by EHSD and modified, as warranted, in consultation with the LD/PI. If deficiencies in safe practices are discovered, all work in the laboratory will cease until corrective actions have been taken.

- 8.2.2 If deemed necessary based on the risk assessment, the BSO will contact ORC to convene a special meeting of the Institutional BioSafety Committee.
 - 8.2.3 Documentation of the risk assessment will be maintained by EHSD with a copy sent to the LD/PI and the ORC.
 - 8.2.4 Risk assessments will be completed with input from the LD/PI. The results of the risk assessment and findings, including any requirements for post decontamination procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI and ORC.
 - 8.2.5 ORC will contact CDC, and if needed, a copy of the risk assessment will be submitted. ORC will also update the RO.
- 8.3 The following additional steps will also be taken immediately upon discovery regarding an actual or suspected occupational exposure:
- 8.3.1 EHSD will direct the LD/PI to notify laboratory personnel and visitors that a potential exposure has occurred and refer them to Scott & White Occupational Health for consultation. EHSD will obtain access logs and other information to determine a complete list of potentially exposed personnel. EHSD will then follow-up with potentially exposed personnel to ensure notification.
 - 8.3.2 Individuals will be encouraged to contact Occupational Health at Scott & White Clinic, or to immediately identify to medical personnel, the agent they were potentially exposed to if treatment is sought. Scott & White Occupational Health Clinic or the attending physician will test for the organism (e. g. *Brucella* species), and begin prophylaxis as deemed appropriate by the attending physician.
 - 8.3.3 If an occupational exposure is confirmed through appropriate medical tests or as determined by a physician, all personnel and potentially exposed individuals will be immediately referred to Scott & White for screening, testing, or preventive prophylaxis as determined by the attending physician. If personnel or visitors are at remote locations (other university facilities, traveling), they should immediately report to a physician of choice and explain that a positive occupational exposure to a specific organism has occurred and specific treatment or screening is desired. Personal physicians should be encouraged to contact either EHSD or Scott and White Occupational Health if they have any questions.
 - 8.3.4 EHSD, in consultation with Scott & White, will perform periodic follow-up with the group of exposed or potentially exposed personnel for a period of time as appropriate for the organism.
- 8.4 EHSD will establish and maintain a specific file for each release incident, with all pertinent information.
- 8.5 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected release to EHSD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

9. Security Breach:

A security breach will be determined to have occurred if any of the following are observed:

- 9.1 The access control system has failed, leaving the BSL-3 suite accessible to unauthorized persons;
- 9.2 An unauthorized person is observed unaccompanied in the BSL-3 suite;
- 9.3 A lost or stolen card was used to access the BSL-3 suite;
- 9.4 An unauthorized person has accessed the computer used to control entry to the BSL-3 suite;
- 9.5 An unexpected or suspicious package arrives in the laboratory.

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the UPD and the ARO of the security breach and take steps to correct the problem. Corrective procedures will be secured immediately, but no later than 24 hours; an inventory will be performed of all samples and animals in the laboratory and in Select Agent storage. Any missing Select Agent samples or animals will be reported to ARO, RO and CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator, the ARO and the UPD will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

10. Severe weather or natural disasters.

The most likely occurrences in this area are severe thunderstorms, floods or tornadoes.

- 10.1 If severe weather (thunderstorms or flooding) is predicted, experiments with Select Agents should be suspended until the severe weather has passed to avoid power outages during the work. All samples should be secured inside the locked -80°C freezer or the locked +4°C storage.
- 10.2 If an earthquake is felt, workers should immediately leave the suite-if possible, shedding gloves and lab coat on the way out of the BSL-3 suite. Cleanup, if necessary, can be performed once it is safe to re-enter the building.
- 10.3 Power to the BSL-3 suite may be affected if the emergency generator is flooded. In this case, all samples should be secured inside the -80°C freezer. If the vivarium is threatened by flooding, animal cages should be fastened shut, put into secondary containers (biohazard bag or large Tupperware) and transported to LARR (CMP) for secure holding until the threat of flooding has passed. If it becomes necessary to evacuate the College Station area, all animal experiments will be terminated before evacuation by euthanizing the animals and storing the carcasses in the secure select agent storage in room.
- 10.4 In case of a power outage, if there is no immediate danger to the building, secure all infectious samples inside a -80°C freezer, the +4°C refrigerator, or the incubators. The Biosafety cabinets and air handling system of the BSL-3 suite are on emergency backup power, which will prevent exposure to infectious samples in case of a power outage. Follow standard procedures for leaving the laboratory and return once the power has been restored to resume work.

11. Fire, Gas leak, Steam leak, Explosion, Bomb threat:

- 11.1 If work is being performed in the Biosafety cabinet, cap all samples, dispose of gloves and outer laboratory coat, and leave the laboratory immediately. If the fire is within the BSL 3 laboratory, and the worker feels (s)he can safely extinguish the fire, then the fire extinguisher located in the interior hall may be used. If a worker feels his or her safety threatened, (s)he should leave the laboratory immediately without stopping to decontaminate or secure any work, using the designated escape routes (through the locker rooms or the exterior "airlock" door on the west side of the building). Upon leaving the building, personnel should assemble outside the assigned spot and report to the Lab Safety Officer for attendance.

- 11.2 Notify the appropriate emergency responders: Fire 9-911 or 911 from mobile phones, the Principal Investigator and the Biosafety Officer. For steam and gas leaks, notify TAMU Operations and Maintenance.
- 11.3 In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police immediately by calling the emergency number, 9-911, 911, 845-8900, or 845-2345. Also inform the Principal Investigator and Responsible Official. Always be sure to give the number and location of the building and your name and telephone extension number.
 - 11.3.1 The University Police Department will assign personnel to investigate the call and take whatever police action they may deem necessary and reasonable for the safety of the campus community. The University Police will conduct a search of the building, or of specific locations in or around the building. When judged prudent and feasible to do so, the search will be conducted with the assistance and cooperation of the Principal Investigator and/or Responsible Official. After an evaluation/assessment of the content of the bomb threat, the decision to evacuate or close building shall be made jointly, whenever possible, by the Police and the Principal Investigator and/or Responsible Official.
 - 11.3.2 Any unusual or suspicious object should be reported immediately to the University Police or to any immediate supervisor or administrative officer. Suspected objects or materials should NOT be touched or disturbed. Every bomb threat or incident of a suspected explosive device should be considered valid until all reasonable precautions for public safety have been taken or until the danger to life and property is terminated.

12. Failure of Select Agent Storage Freezer:

- 12.2 If the -80°C freezer in [redacted] (that is used to store *Brucella* strains) fails, the strains will be moved to a temporary backup location, which is either the other -80°C Revco freezer located in [redacted] or in secure freezer in a locked BSL-2 laboratory. This freezer will be locked in order to limit access to personnel authorized to work with select agents.

13. Workplace violence:

- 13.1 Incidents of disruptive or threatening behavior on the part of an employee, student or visitor should be reported immediately to the Principal Investigator, who will report the incident to the Department Head, UPD, ARO and the Workplace Violence Response Team, as proscribed by the TAMU Personnel and Procedures manual section 290-09. If the individual accused of disruptive or threatening behavior is authorized for access to select agents, this person's access will be suspended pending the results of an investigation by the Workplace Violence Response Team. If an act of violence or a physical assault has occurred, or the threatening activity occurs within the BSL-3 laboratory, the person feeling threatened should call the police immediately to report the incident. If the person accused of violence has access to select agents, the person's access will be suspended pending the outcome of the investigation. Suspension of select agent access will be reported to the UPD, and ARO and a suspended individual's access will be inactivated within 24 hours.

14. Entry of emergency responders into the BSL-3 laboratory.

- 14.1 In a case in which a life-threatening injury or medical condition (i.e. heart attack) occurs inside the BSL-3 laboratory, emergency responders will be allowed to enter the laboratory. If possible, upon feeling ill the laboratory worker should immediately exit the suite to facilitate treatment by emergency responders. Personnel protective equipment, including Tyvek suits, PAPRs and gloves, are located inside the entries (locker rooms) to the BSL-3 suite. A spill kit containing absorbent materials and disinfectant is located under the bench in each of the labs. A First Aid kit is located inside the lab. If responders

are required to enter an area where a spill has occurred, they will be referred to Scott and White Clinic and offered post-exposure prophylaxis.

- 14.1.1 Entry procedure for the BSL-3 laboratory: Dress yourself in a Tyvek suit, gloves, shoe covers and PAPRs before entering the laboratories.
- 14.1.2 Providing first aid and emergency medical treatment in the BSL-3 laboratory: A person working inside the Biosafety hood is not considered to be contagious unless a spill has occurred. The person's gloves may be contaminated, and may be removed to facilitate treatment. If there is no space within the labs to put the person on the floor, move the person to the interior hallway to administer treatment.
- 14.1.3 Exit procedure from the BSL-3 laboratory: Emergency responders should remove Tyvek suit, PAPR, shoe covers and gloves before exiting and leave them behind in the BSL-3 laboratory. Hands should be washed immediately upon exit from the BSL-3 laboratory.
- 14.1.4 Decontamination procedures for medical equipment and clothing: Emergency responders should decontaminate equipment before leaving the laboratory by one of the following methods:
 - 14.1.4.1 Autoclaving. Autoclaves are located within the BSL3 suite or on the
 - 14.1.5 Wiping surfaces with 10% bleach followed by 1% Virkon-S.

15. Incident Response Plan Testing (Drills)

- 15.1 Drills or tabletop exercises will be conducted annually to test the effectiveness of the Biosafety plan. The drills or exercises will be coordinated with the TAMU Police Department and will include, but not be limited to, the Principal Investigator or designee, BSO, TAMU Fire Department representative and the Campus Emergency Planner.
- 15.2 The drill or exercise will include, but not be limited to, accessibility to restricted space, attempted or unauthorized entry into restricted spaces challenge, animal room security, staff knowledge of hazard/emergency protocols for their work location(s) and other situations that are deemed appropriate for each work location.
- 15.3 Following the drill or exercise, which will test the various components of the incident response plan for completeness, those involved will critique their findings for each drill/exercise location. The Principal Investigator working with the Responsible Official and Biosafety Officer will implement changes as necessary changes to the plan. Results of the drill or exercise will be reviewed by the Biological Safety Administrative Advisory Committee (Institutional Biosafety Committee).

16. Texas A&M University Crisis Management Plan

- 16.1 The entity crisis management plan is contained in a separate document and is referenced in the individual laboratory emergency response plan.
- 16.2 Additional information concerning the laboratory emergency response plan is contained in the laboratory's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or the Environmental Health & Safety Department.
- 16.3 The Alternate Responsible Official and Biosafety Officer should be contacted immediately in the case of any emergency in a select agent lab. The Alternate

Responsible Official will coordinate access and information issues with campus police, fire, and emergency responders.

16.4 If necessary, the Responsible Official will coordinate the emergency relocation of select agents to another secure location.

17. Site security and control are described in detail in the Select Agent Security Plan

17.1 The buildings are secured by a keyed lock. Sharing of keys with other personnel is not permitted.

17.2 Individuals not authorized for access to Select Agents must be accompanied by approved personnel at all times while in the buildings.

17.3 Data that could enable access to select agents by unauthorized personnel should be located on password-protected computers.

17.4 If approved personnel are observed violating security or Biosafety procedures, this observation should be reported immediately to the Principal Investigator. The Principal investigator will report the violation to the UPD who will investigate the allegation and determine whether the violator should have his/her Select Agent access suspended or revoked. Suspension of Select Agent access will be reported to the Alternate Responsible Official, the RO and the individual's key card access will be terminated within 24 hours.

18. Inventory Discrepancies:

18.1 Inventory discrepancies will be documented on the agent access form.

18.2 All discrepancies will be immediately reported to the Principal Investigator.

18.3 If the discrepancy is believed to be a result of loss or theft, the incident response procedures for loss or theft and release will be followed.

18.4 If the discrepancy is a result of a transfer, the transfer form will be documented.

19. References

19.1 42 CFR Part 73

19.2 7 CFR Part 331

19.3 9 CFR Part 121

19.4 Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention, National Institutes of Health, Fourth Edition, May 1999

19.5 Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents (Revised BMBL, Appendix F), published in Morbidity and Mortality Weekly Report, December 6, 2002.

SBAT Incident Response
Emergency Contact Numbers

PI Information			
PI Ficht Office – 979 845-4118			
Building Manager Lorten Skow 979-845-3194			
Department Head Gerald Bratton 979-845-5941			
Incidents involving Theft or Loss University Police Department (UPD) contact Bert Kretzschmar Office – 979 845-8900			
Incidents involving a Release (or Occupational Exposure) Environmental Health and Safety Office contact Between 8:00 a.m. and 5:00 p.m. Brent Mattox, Biosafety Officer (BSO) Alternate Responsible Official (ARO) Office – 979 865-2132 Mobile – 979 450-0662 After hours 5:00 pm Contact the University Police Department contact Lt. Bert Kretzschmar Office – 979 845-8900			
Other Contact information			
Vice President for Research/Responsible Official (RO)	Richard Ewing (RO)	979 845-8585 (Office) or	(Mobile)
	Fuller Bazer (ARO)	979 693-2876 (Office) or	(Mobile)
	Angelia Raines (ARO)	979 847-9362 (Office) or	(Mobile)
Comparative Medicine Program	Melanie Ihrig	979 845-7433 (Office) or	(Mobile)
	Elizabeth Browder	979 845-7433 (Office) or	(Mobile)
	Frank Stein	979 845-6488 (Office) or	(Mobile)
Institutional Biosafety Committee (IBC)	Thomas Ficht	979 845-4118 (Office) or	(Mobile)
	Vernon Tesh	979 862-4113 (Office) or	(Mobile)
	Tiffany Agnew	979 458-3624 (Office) or	(Mobile)
Other Emergency Numbers	College Station Police	979 764-3600 or 9-911	
	Medical Emergency	9-911	
	College Station Fire	979 764-3700 or 9-911	
	Radiological Emergency	979 832-1111	
	University Maintenance	979 845-4311	

Emergency Telephone Numbers

Enter PI Name	Office: (979)845-4118 Home: Mobile:
Emergency	9-911
University Police	(979) 845-2345
College Station Police	(979) 764-3600
College Station Fire	(979) 764-3700
Environmental Health & Safety	(979) 845-2132
TAMU Area Maintenance (HVAC failure, steam leak, gas leak)	(979) 845-5542
TAMU Maintenance (24 hours)	(979) 845-4311
Radiological Emergencies	(979) 862-1111
Responsible University Officials: RO-Richard Ewing	Work: (979) 845-8585
ARO-Angelia Raines	Work: (979) 847-9362 Mobile: (979) 555-5555
Biosafety Officer/ARO -Brent Mattox	Work: (979) 845-2132
Building Manager	Loren Skow 979-845-3194
Frank Stein	Work: (979) 845-6488
TAF Lab	5-4185
Neighboring labs to notify in case of simultaneous containment breach and spill outside BSC:	
Lab (enter additional locations)	enter additional laboratory phone number
Lab (enter additional locations)	enter additional laboratory phone number
Lab (enter additional locations)	enter additional laboratory phone number

Decontamination Procedures for Spills of Cultures
(Please customize for specific laboratories.)

1. Signal others in the BL3 labs of any spill outside the biological safety cabinet. All personnel should change out of contaminated clothing and wash any exposed skin with a disinfectant, such as Purell. Clothes must be removed within the BL3 area and will be autoclaved by those cleaning up.
2. Put on a clean scrub suit and go to the shower on the first floor animal facility. Shower thoroughly with soap.
3. Return to the lab for cleanup: Put on a PAPR and tyvek suit (contained in the SPILL KIT). Put on double gloves and shoe covers.
4. Use paper towels to cover the spill. Prevent creation of contaminated aerosols.
5. Saturate all materials with 10% bleach solution (see previous section for description).
6. Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in autoclave bags.
7. Disinfect all exposed surfaces using 1X Wexcide or 1% Virkon (surface disinfectant solution).
8. Wipe surface of full-face respirator with 1% Virkon or 1X Wexcide, being careful to avoid skin contact with Wexcide.
9. Remove all clothing and place in autoclave bag.
10. Remove full face respirator and spray off all surfaces in the lab with 1% Virkon or 1X Wexcide.
11. Make sure that all contaminated material is autoclaved, surface-disinfected or incinerated.
12. Inform others not to work in the lab until the air handling system is able to clear any residual organisms from the air (3h).
13. Return to the lab after 3 hours and perform another decontamination of all lab surfaces with 1% Virkon or 1X Wexcide.
14. Report accident to the Principal Investigator, who will report it to other officials.

Contents of spill kit located in BL-3 labs:

PAPR, Tyvek suit, clean scrub suit, absorbent material, Purell skin disinfectant, towel, copy of decontamination procedures for spills.

INCIDENT RESPONSE PLAN
For BSL3 Building:
PI – Ficht
PI Adams
Texas A&M University, College Station, TX 77843
to ensure compliance with
42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

- 1.1 General. This is the incident response plan for the possession and use of *Brucella abortus*, *Brucella suis* and *Brucella melitensis* at Texas A&M University main campus (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121. This plan covers the use of these select agents when used in
- 1.2. This plan describes the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

- 2.1 Principal Investigator (PI). The Principal Investigator, Dr. Thomas A. Ficht, has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to Dr. Ficht. The PI is responsible for ensuring all incidents regarding theft, loss or release are immediately reported to the proper institutional officials. This document outlines response actions concerning any theft, loss, or release from select biological agents and toxins (SBAT) facilities, including illness of personnel or visitors in SBAT facilities. Certain actions outlined below are performed in parallel rather than sequentially (see attached flowchart).
- 2.2 All lab personnel (including the PI) are responsible for immediately reporting an incident to the University Police Department (UPD) for theft or loss or to the Institutional Biosafety Officer (BSO) for release (including occupational exposure).
- 2.3 UPD – Responsible for immediately contacting the Alternate Responsible Official (ARO) and beginning an investigation of the incident. A written investigation report will be submitted to the Institutional Biosafety Committee (IBC), the PI and the ARO within 5 days of the incident. UPD will also work with the PI to conduct a security assessment following any incident involving loss or theft.
- 2.3 BSO - Responsible for immediately contacting the Alternate Responsible Official and beginning an investigation of the incident. A written investigation report will be submitted to the IBC, the PI and the ARO within 5 days of the incident. The BSO will also work with the PI to conduct a safety assessment following any incident involving a release (including occupational exposure).
- 2.4 ARO - Responsible for immediately contacting the Responsible Official, CDC, NIH (if rDNA) and other key institutional contacts regarding the incident. The ARO will work with the BSO, UPD and the PI to insure that the written report is correct and that the report will be submitted to CDC, NIH (if rDNA) and other key institutional contacts.

- 2.5 Responsible Official -- Is responsible for compliance to the Select Agent regulations and insuring requirements (registration, investigations, etc) are properly carried out.
- 2.6 Contact information is found on the Emergency contact list. The list is attached to this document and is posted throughout the lab.
- 2.7 Annual Program Review. The Responsible Official or Alternate Responsible Official will audit the incident response program on an annual basis. This review will include drills and exercises to ensure the effectiveness of the incident response plan. Based on the outcome of drills, exercises or reported incidents, this incident response plan will be reviewed and updated as necessary.

3. Description of Work

This plan covers all work being performed at TAMU. Each lab will be responsible for providing information specific to the work being performed as follows:

Lab	Work description	Unique features of Agent	Biological Use Authorization	Biosafety Level
	Work with Brucella abortus, B. suis, B. melitensis	BSC	0741	3
	Inoculation of mice and ruminants with Brucella spp.	BSC	0741	3
	Storage of Brucella-infected animal carcasses	Locked freezer	0741	3

Additional information concerning the laboratories and the select agent use is contained in the facility's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or Environmental Health and Safety Office.

4. Response to theft:

- 4.1 Determination of Loss or Theft – The following are examples of events that may be considered a loss or theft. Possible loss or theft of the select agent will be reported initially to the Principal Investigator if any of the following have occurred:
- 4.1.1 The lock on the Select Agent storage area has been found open or appears to have been tampered with;
 - 4.1.2 Evidence of forced entry into the laboratory or storage areas has been found;
 - 4.1.3 A discrepancy in the Select Agent inventory that can not be reconciled;
 - 4.1.4 An employee reports cultures or samples missing;
 - 4.1.5 A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2;
 - 4.1.6 An infected animal is missing from its housing unit.
- 4.2 Report/Investigation Process:
- Theft** (unauthorized removal) or **Loss** (failure to account for) a select agent or toxin
- 4.2.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected theft or loss of SBATS to UPD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345). Based on circumstances, UPD will notify EHSD.

If the release is discovered and UPD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the person shall then notify the LD/PI.

After notification to UPD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact ORC.

- 4.2.1.1 Upon notification of discovery of a theft or loss, UPD will immediately notify ORC.
- 4.2.1.2 Upon notification from UPD, ORC will immediately notify the Responsible Official (RO) and Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, and UPD.
- 4.2.1.3 UPD (and ESHD, based on circumstances) will immediately investigate the incident. The investigation will include coordination with the LD/PI and others approved with access or visiting SBAT facilities. UPD will submit a written report to ORC within 5 days of being notified about the discovery of the theft or loss. If the investigation provides evidence that a theft or loss did not occur, circumstances will be documented in UPD's investigation report.
- 4.2.1.4 Based on the UPD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss or Release of Select Agents and Toxins) with CDC. ORC will maintain an official copy of information submitted to CDC and will provide a copy of the submission to the RO, UPD/EHSD, and LD/PI.
- 4.2.1.5 UPD will notify the appropriate Federal, State, or local law enforcement agencies.
- 4.2.1.6 The LD/PI will ensure notification to the funding agency
- 4.2.2 A risk assessment will be conducted immediately upon discovery of a loss or theft. The risk assessment will be a part of the investigation report.
 - 4.2.2.1 In addition to the investigation, upon notification of a theft or loss, UPD (with input from EHSD and the LD/PI) will conduct a risk assessment to determine if the laboratory is operating in a safe and secure manner and to attempt to determine the cause of the theft. This risk assessment shall include, but not be limited to a comprehensive laboratory survey, review of access logs, review of inventory records, and verification that all equipment is operating within normal parameters (e. g. biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of theft will also be reviewed and modified, as warranted. If deficiencies in safe and secure practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
 - 4.1.2.2 If deemed necessary, the EHSD/UPD will contact Biosafety Program Coordinator to convene a special meeting of the Institutional BioSafety Committee (IBC).

4.1.2.3 Documentation of the risk assessment will be maintained by UPD with a copy sent to the LD/PI, EHSD and ORC.

4.1.2.4 Security Risk Assessments will be completed by UPD, with input from the LD/PI (and EHSD, based on circumstances). The results of the risk assessment and findings, including any requirements for post theft procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI, EHSD, and ORC.

4.1.2.5 The ORC will contact CDC, and if needed, a copy of the assessment will be submitted. ORC will also update the RO.

4.2.3 UPD will establish and maintain a specific file for each theft or loss incident, with all pertinent information.

4.2.4 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected loss or theft to UPD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

5. Investigation

5.1 The Investigation Committee for all releases will be headed by the EHSD's Institutional Biosafety Officer (BSO) with input from UPD and the PI. UPD will lead investigations involving theft or loss, with input from the BSO and PI.

5.1.1 The BSO/UPD will investigate the event as quickly as possible, but no later than 24 hours of the initial report or the incident.

5.1.2 The investigation should include a review of all materials related to the research, including access logs, inventory logs, laboratory notes and laboratory plans (security, safety and incident response)

5.1.3 Once the investigation is complete, the BSO or UPD will submit an investigation report to the IBB and RO.

5.1.4 Once the Committee has determined the response and informed the RO and IBC (through the Office of Research Compliance), the IBC will review the report and make a recommendation to the RO of any additional actions that they believe are needed.

5.1.5 After the RO has approved of the recommended actions, the PI will receive a written response from the IBC.

6. Reporting

6.1 All incident reports are included in the IBC agenda minutes for review by the full board at the next convened meeting. Serious events should be specifically presented to the IBC by the BSO/UPD or IBC Chair at the next convened meeting.

6.1.1 The investigation report, at a minimum, shall include the following information:

6.1.1.1 A detailed description of the incident.

6.1.1.2 A list of all personnel involved in the incident.

6.1.1.3 A description of what occurred and what has or needs to be done to prevent any future incident.

6.1.1.4 An assessment of the safety or security risk of continuing the research.

6.1.1.5 A recommendation of any changes that need to be made to the plans (safety, security or incident response), medical surveillance or laboratory procedures to reduce the risk of a reoccurrence.

6.1.1.6 A recommendation for training, if needed.

6.1.2 Incidents involving SBAT will be immediately reported to the CDC with a written report (Form 3) submitted within seven (7) days.

6.1.3 Events involving rDNA must be reported to the NIH immediately in writing but no later than 30 days of the incident.

7. **Release of a Select Agent or Toxin.**

Examples of a possible release (including occupational exposures of the agent or toxin) include but are not limited to the following:

7.1 A package containing the Select Agent or toxin that has been received, which has been damaged in transit, such that the primary containment vessel appears to have been compromised;

7.2 Simultaneous complete power failure of the Biosafety cabinet and loss of negative pressure in the BSL-3 suite during work in the Biosafety cabinet with open cultures;

7.3 Simultaneous spill of cultures outside the Biosafety cabinet and failure of negative pressure in the Biosafety Level 3 area. In case of a spill, a spill kit containing absorbent material and disinfectant will be located in each building;

7.3.1 Personnel are advised to immediately leave the building after removing any contaminated clothing and to return in Tyvek suits with full face respirators (Powered Air Purifying Respirator (PAPR)) after the air has been scrubbed clean by air handlers (approx. one hour).

1.1.1. In case release of the Select Agent or toxin outside the BSL-3 laboratory is suspected, the Principal Investigator will notify the BSO, ORC as well as the RO, and the building manager.

7.5 Exposure of laboratory personnel to cultures. The following incidents may result in unintentional exposure to the Select Agent that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to the BSO, who will notify the Scott & White Occupational Health office to evaluate the need for post-exposure prophylaxis. The exposure will be reported by the Principal Investigator to the BSO who reports immediately to the Responsible Official, who will notify CDC of the exposure. The following are examples of unintentional exposure:

7.5.1 A spill of live culture outside the Biosafety cabinet;

7.5.2 Failure of the Biosafety cabinet during work with *Brucella*;

7.5.3 Needle stick or cut with sharps contaminated with *Brucella*;

7.5.4 If a bite from a *Brucella*-infected animal penetrates the double gloves and breaks the skin;

7.5.5 A centrifuge accident that results in aerosolization of *Brucella*.

8. **Process of reporting and investigating a Release:**

Release – Occupational exposure (clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been release outside of the primary bio-containment barrier.) or release of an agent or toxin outside of the primary barriers of the biocontainment area.

8.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected release to the BSO in the Environment Health and Safety Department (EHSD). Based on circumstances, the BSO will notify the

University Police Department (UPD). During normal business hours, call the BSO at the EHSD at 845-2132. If it is outside of normal business hours, call UPD who will notify EHSD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345).

If the release is discovered and the BSO is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the individual shall then notify the LD/PI.

After notification to the BSO by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact the Office of Research Compliance (ORC).

- 8.1.1 Upon notification of discovery of a release, the BSO will immediately notify Scott & White Occupational Health Clinic and ORC.
 - 8.1.2 Upon notification from the BSO, ORC will immediately notify the Responsible Official (RO) and the Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, EHSD, and UPD.
 - 8.1.3 The BSO (and UPD, based on circumstances) will immediately investigate the incident. The investigation will include the coordination with the LD/PI and others approved with access or visiting SBAT facilities. The BSO will submit a written report to ORC within 5 days of being notified about discovery of the release. If the investigation provides evidence that a release did not occur, circumstances will be documented in BSO's investigation report.
 - 8.1.4 Based on the BSO report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss, or Release of Select Agents and Toxins) with the CDC within seven calendar days of the discovery of the release. ORC will maintain an official copy of information submitted to the CDC and will provide a copy of the submission to the RO, BSO, and LD/PI.
 - 8.1.5 The BSO will obtain confirmation from health care providers that reports to other state or federal health agencies have been submitted. The LD/PI will ensure notification to the funding agency.
- 8.2 A risk assessment will be conducted immediately upon discovery regarding any release.
- 8.2.1 In addition to the investigation, upon notification of a release, EHSD (under the direction of the Biological Safety Officer (BSO)) will conduct a risk assessment to determine if the laboratory is operating in a safe manner and attempt to determine the cause or most likely route of the release. This risk assessment shall include but not be limited to a comprehensive laboratory survey, review of access logs to determine potential occupational exposures, review of inventory records, and verification that all equipment is operating within normal parameters (e.g., biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of the release will also be reviewed by the BSO and modified, as warranted, in consultation with the LD/PI. If deficiencies in safe practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
 - 8.2.2 If deemed necessary based on the risk assessment, the BSO will contact ORC to convene a special meeting of the Institutional BioSafety Committee.

- 8.2.3 Documentation of the risk assessment will be maintained by BSO with a copy sent to the LD/PI and the ORC.
- 8.2.4 Risk assessments will be completed with input from the LD/PI. The results of the risk assessment and findings, including any requirements for post decontamination procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI and ORC.
- 8.2.5 ORC will contact CDC, and if needed, a copy of the risk assessment will be submitted. ORC will also update the RO.
- 8.3 The following additional steps will also be taken immediately upon discovery regarding an actual or suspected occupational exposure:
 - 8.3.1 BSO will direct the LD/PI to notify laboratory personnel and visitors that a potential exposure has occurred and refer them to Scott & White Occupational Health for consultation. BSO will obtain access logs and other information to determine a complete list of potentially exposed personnel. BSO will then follow-up with potentially exposed personnel to ensure notification.
 - 8.3.2 Individuals will be encouraged to contact Occupational Health at Scott & White Clinic, or to immediately identify to medical personnel, the agent they were potentially exposed to if treatment is sought. Scott & White Occupational Health Clinic or the attending physician will screen for the organism (e. g. Brucella species), and begin prophylaxis as deemed appropriate by the attending physician.
 - 8.3.3 If an occupational exposure is confirmed through appropriate medical tests or as determined by a physician, all personnel and potentially exposed individuals will be immediately referred to Scott & White for screening, testing, or preventive prophylaxis as determined by the attending physician. If personnel or visitors are at remote locations (other university facilities, traveling), they should immediately report to a physician of choice and explain that a positive occupational exposure to a specific organism has occurred and specific treatment or screening is desired. Personal physicians should be encouraged to contact either the BSO or Scott and White Occupational Health if they have any questions.
 - 8.3.4 The BSO, in consultation with Scott & White, will perform periodic follow-up with the group of exposed or potentially exposed personnel for a period of time as appropriate for the organism.
- 8.4 EHSD will establish and maintain a specific file for each release incident, with all pertinent information.
- 8.5 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected release to the BSO and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

9. Security Breach:

A security breach will be determined to have occurred if any of the following are observed:

- 9.1 The access control system has failed, leaving the BSL-3 building accessible to unauthorized persons;
- 9.2 An unauthorized person is observed unaccompanied in the BSL-3 building;
- 9.3 A lost or stolen card was used to access the BSL-3 building;

- 9.4 An unauthorized person has accessed the computer used to control entry to the BSL-3 building;
- 9.5 An unexpected or suspicious package is found in or near a BSL-3 building.

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the UPD of the security breach and take steps to correct the problem. Corrective procedures will be secured immediately, but no later than 24 hours; an inventory will be performed of all samples and animals in the building. Any missing Select Agent samples or animals will be reported to CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator and the UPD and ORC will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

10. Severe weather or natural disasters.

The most likely occurrences in this area are severe thunderstorms, floods or tornadoes.

- 10.1 If severe weather (thunderstorms or flooding) is predicted, experiments with Select Agents should be suspended until the severe weather has passed to avoid power outages during the work.
- 10.2 If an earthquake is felt, workers should immediately leave the building--if possible, shedding gloves and lab coat on the way out of the BSL-3 building. Cleanup, if necessary, can be performed once it is safe to re-enter the building.

11. Fire, Gas leak, Steam leak, Explosion, Bomb threat:

- 11.1 If work is being performed in the Biosafety cabinet, cap all samples, dispose of gloves and outer laboratory coat, and leave the building immediately. If the worker feels (s)he can safely extinguish the fire, then the fire extinguisher located in the interior dressing area may be used. If a worker feels his or her safety threatened, (s)he should leave the building immediately without stopping to decontaminate or secure any work. Upon leaving the building, personnel should assemble outside the building one end of the compound at a safe distance from the building.
- 11.2 Notify the appropriate emergency responders: Fire 9-911 or 911 from mobile phones, the Principal Investigator, UPD and the BSO. For steam and gas leaks, notify TAMU Operations and Maintenance.
- 11.3 In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police immediately by calling the emergency number, 9-911 or 911 or 845-2345 or 845-8900. Also inform the Principal Investigator, BSO and ORC. Always be sure to give the number and location of the building and your name and telephone extension number.
 - 11.3.1 The University Police Department will assign personnel to investigate the call and take whatever police action they may deem necessary and reasonable for the safety of the campus community. The University Police will conduct a search of the building, or of specific locations in or around the building. When judged prudent and feasible to do so, the search will be conducted with the assistance and cooperation of the Principal Investigator and/or ORC. After an evaluation/assessment of the content of the bomb threat, the decision to evacuate or close building shall be made jointly, whenever possible, by the Police and the Principal Investigator and/or ORC.
 - 11.3.2 Any unusual or suspicious object should be reported immediately to the University Police or to any immediate supervisor or administrative officer. Suspected objects or materials should NOT be touched or disturbed. Every bomb threat or incident of a suspected explosive device should be considered valid until

all reasonable precautions for public safety have been taken or until the danger to life and property is terminated.

12. Failure of Select Agent Storage Freezer:

- 12.2 If a -80°C freezer in any building that is used to store Brucella strains fails, the strains will be moved in appropriate containment to a temporary backup location, which is in room _____, or in secure freezer in a locked BSL-2 laboratory.

13. Workplace violence:

- 13.1 Incidents of disruptive or threatening behavior on the part of an employee, student or visitor should be reported immediately to the Principal Investigator, who will report the incident to the Department Head, UPD, ORC and the Workplace Violence Response Team, as proscribed by the TAMU Personnel and Procedures manual section 290-09. If the individual accused of disruptive or threatening behavior is authorized for access to select agents, this person's access will be suspended pending the results of an investigation by the Workplace Violence Response Team. If an act of violence or a physical assault has occurred, or the threatening activity occurs within the BSL-3 building, the person feeling threatened should call UPD immediately to report the incident. If the person accused of violence has access to select agents, the person's access will be suspended pending the outcome of the investigation. Suspension of select agent access will be reported to UPD and ORC and a suspended individual's access will be inactivated within 24 hours.

14. Entry of emergency responders into the BSL-3 laboratory.

- 14.1 In a case in which a life-threatening injury or medical condition (i.e. heart attack) occurs inside the BSL-3 building, emergency responders will be allowed to enter the laboratory. If possible, upon feeling ill the laboratory worker should immediately exit the building to facilitate treatment by emergency responders. Personnel protective equipment, including Tyvek suits, PAPRs and gloves, are located inside the entries (locker rooms) to the BSL-3 building. A spill kit containing absorbent materials and disinfectant is located in the interior dressing area. A First Aid kit is located in the interior dressing area. If responders are required to enter an area where a spill has occurred, they will be referred to the BSO and the Scott and White Occupational Health office and evaluated for possible post-exposure prophylaxis.
- 14.1.1 Entry procedure for the BSL-3 laboratory: Dress in a Tyvek suit, gloves, shoe covers and PAPRs before entering the building.
- 14.1.2 Providing first aid and emergency medical treatment in the BSL-3 laboratory: A person working inside the Biosafety hood is not considered to be contagious unless a spill has occurred. The person's gloves may be contaminated, and may be removed to facilitate treatment. If there is no space within the labs to put the person on the floor, move the person to the interior dressing area to administer treatment.
- 14.1.3 Exit procedure from the BSL-3 laboratory: Emergency responders must decontaminate with appropriate disinfectant, remove Tyvek suit, PAPRs, shoe covers and gloves in the inner dressing room before exiting. Hands should be washed immediately before and after exit from the BSL-3 laboratory.
- 14.1.4 Decontamination procedures for medical equipment and clothing: Emergency responders should decontaminate equipment before leaving the laboratory by one of the following methods:
- 14.1.4.1 Autoclaving. Autoclaves are located in Room _____
- 14.1.5. Decontaminate with 1% Virkon, 1X Wexcide or dilute sodium hypochlorite.

15. Incident Response Plan Testing (Drills)

- 15.1 Drills or tabletop exercises will be conducted annually to test the effectiveness of the Biosafety plan. The drills or exercises will be coordinated with the TAMU Police Department and will include, but not be limited to, the Principal Investigator or designee, BSO, TAMU Fire Department representative and the Campus Emergency Planner.
 - 15.2 The drill or exercise will include, but not be limited to, accessibility to restricted space, attempted or unauthorized entry into restricted spaces challenge, animal room security, staff knowledge of hazard/emergency protocols for their work location(s) and other situations that are deemed appropriate for each work location.
 - 15.3 Following the drill or exercise, which will test the various components of the incident response plan for completeness, those involved will critique their findings for each drill/exercise location. The Principal Investigator working with the ORC and BSO will implement changes as necessary changes to the plan. Results of the drill or exercise will be reviewed by the Biological Safety Administrative Advisory Committee (Institutional Biosafety Committee).
- 16. Texas A&M University Crisis Management Plan**
- 16.1 The entity crisis management plan is contained in a separate document and is referenced in the individual laboratory emergency response plan.
 - 16.2 Additional information concerning the laboratory emergency response plan is contained in the laboratory's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance and the Environmental Health & Safety Department.
 - 16.3 The ORC and BSO should be contacted immediately in the case of any emergency in a select agent lab. The ORC will coordinate access and information issues with campus police, fire, and emergency responders.
 - 16.4 If necessary, the ORC will coordinate the emergency relocation of select agents to another secure location.
- 17. Site security and control are described in detail in the Select Agent Security Plan**
- 17.1 The buildings are secured by a keyed lock. Sharing of keys with other personnel is not permitted.
 - 17.2 Individuals not authorized for access to Select Agents must be accompanied by approved personnel at all times while in the buildings.
 - 17.3 Data that could enable access to select agents by unauthorized personnel should be located on password-protected computers.
 - 17.4 If approved personnel are observed violating security or Biosafety procedures, this observation should be reported immediately to the Principal Investigator. The Principal investigator will investigate the allegation and determine whether the alleged violator should be reported to the ORC and/or the UPD to have their Select Agent access suspended or revoked. Suspension of Select Agent access will be reported to the ORC and the individual's key card access will be terminated within 24 hours.
- 18. Inventory Discrepancies:**
- 18.1 Inventory discrepancies will be documented on the agent access form.
 - 18.2 All discrepancies will be immediately reported to the Principal Investigator.
 - 18.3 If the discrepancy is believed to be a result of loss or theft, the incident response procedures for loss or theft and release will be followed.
 - 18.4 If the discrepancy is a result of a transfer, the transfer form will be documented.
- 19. References**
- 19.1 42 CFR Part 73
 - 19.2 7 CFR Part 331
 - 19.3 9 CFR Part 121
 - 19.4 Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention, National Institutes of Health, Fourth Edition, May 1999

- 19.5 Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents (Revised BMBL, Appendix F), published in Morbidity and Mortality Weekly Report, December 6, 2002.

SBAT Incident Response
Emergency Contact Numbers

PI Information			
PI Ficht Office – 979 845-4118			
Building Manager Loren Skow Office – 979-845-3194			
Department Head Gerald Bratton Office – 979-845-5941			
Incidents involving Theft or Loss University Police Department (UPD) contact Bert Kretzschmar Office – 979 845-8900			
Incidents involving a Release (or Occupational Exposure) Environmental Health and Safety Office contact Between 8:00 a.m. and 5:00 p.m. Brent Mattox, Biosafety Officer (BSO) Alternate Responsible Official (ARO) Office – 979 865-2132 After hours 5:00 pm Contact the University Police Department contact Lt. Bert Kretzschmar Office – 979 845-8900			
Other Contact information			
Vice President for Research/Responsible Official (RO)	Richard Ewing (RO)	979 845-8585 (Office) o	(Mobile)
	Fuller Bazer (ARO)	979 693-2876 (Office) o	(Mobile)
	Angelia Raines (ARO)	979 847-9362 (Office) o	(Mobile)
Comparative Medicine Program	Melanie Ihrig	979 845-7433 (Office) o	(Mobile)
	Elizabeth Browder	979 845-7433 (Office) o	(Mobile)
	Frank Stein	979 845-6488 (Office) o	(Mobile)
Institutional Biosafety Committee (IBC)	Thomas Ficht	979 845-4118 (Office) o	(Mobile)
	Vernon Tesh	979 862-4113 (Office) o	(Mobile)
	Tiffany Agnew	979 458-3624 (Office) o	(Mobile)
Other Emergency Numbers	College Station Police	979 764-3600 or 9-911	
	Medical Emergency	9-911	
	College Station Fire	979 764-3700 or 9-911	
	Radiological Emergency	979 832-1111	
	University Maintenance	979 845-4311	

Emergency Telephone Numbers

Thomas A. Ficht	Office: (979)845-4118 Home:
Emergency	9-911
University Police	(979) 845-2345
College Station Police	(979) 764-3600
College Station Fire	(979) 764-3700
Environmental Health & Safety	(979) 845-2132
TAMU Area Maintenance (HVAC failure, steam leak, gas leak)	(979) 845-5542
TAMU Maintenance (24 hours)	(979) 845-4311
Radiological Emergencies	(979) 862-1111
Responsible University Officials:	
RO-Richard Ewing	Work: (979) 845-8585
ARO-Angelia Raines	Work: (979) 847-9362
Biosafety Officer/ARO -Brent Mattox	Work: (979) 845-2132
Building Manager	Loren Skow 979-845-3194
Frank Stein	Work: (979) 845-6488 M:
T. A. Ficht Lab	979-845-4185
Neighboring labs to notify in case of simultaneous containment breach and spill outside BSC:	
Lab (enter additional locations)	enter additional laboratory phone number
Lab (enter additional locations)	enter additional laboratory phone number
Lab (enter additional locations)	enter additional laboratory phone number

Decontamination Procedures for Spills of Cultures
(Please customize for specific laboratories.)

1. Signal others in the BL3 labs of any spill outside the biological safety cabinet. All personnel should change out of contaminated clothing and wash any exposed skin with a disinfectant, such as Purell. Clothes must be removed within the BL3 area and will be autoclaved by those cleaning up.
2. Put on a clean scrub suit and go to the shower on the first floor animal facility. Shower thoroughly with soap.
3. Return to the lab for cleanup: Put on a PAPR and tyvek suit (contained in the SPILL KIT). Put on double gloves and shoe covers.
4. Use paper towels to cover the spill. Prevent creation of contaminated aerosols.
5. Saturate all materials with 10% bleach solution (see previous section for description).
6. Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in autoclave bags.
7. Disinfect all exposed surfaces using 1X Wexcide or 1% Virkon (surface disinfectant solution).
8. Wipe surface of full-face respirator with 1% Virkon or 1X Wexcide, being careful to avoid skin contact with Wexcide.
9. Remove all clothing and place in autoclave bag.
10. Remove full face respirator and spray off all surfaces in the lab with 1% Virkon or 1X Wexcide.
11. Make sure that all contaminated material is autoclaved, surface-disinfected or incinerated.
12. Inform others not to work in the lab until the air handling system is able to clear any residual organisms from the air (3h).
13. Return to the lab after 3 hours and perform another decontamination of all lab surfaces with 1% Virkon or 1X Wexcide.
14. Report accident to the Principal Investigator, who will report it to other officials.

Contents of spill kit located in BL-3 labs:

Full-face respirator, Tyvek suit, clean scrub suit, absorbent material, Purell skin disinfectant, towel, copy of decontamination procedures for spills.

INCIDENT RESPONSE PLAN

For BSL3 Buildings

PI – Ficht

PI Adams

Texas A&M University, College Station, TX 77843

to ensure compliance with

42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

- 1.1 General. This is the incident response plan for the possession and use of *Brucella abortus*, *Brucella suis* and *Brucella melitensis* at Texas A&M University main campus (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121. This plan covers the use of these select agents when used in buildings.
- 1.2 This plan describes the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

- 2.1 Principal Investigator (PI). The Principal Investigator, Dr. Thomas A. Ficht, has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to Dr. Ficht. The PI is responsible for ensuring all incidents regarding theft, loss or release are immediately reported to the proper institutional officials. This document outlines response actions concerning any theft, loss, or release from select biological agents and toxins (SBAT) facilities, including illness of personnel or visitors in SBAT facilities. Certain actions outlined below are performed in parallel rather than sequentially (see attached flowchart).
- 2.2 All lab personnel (including the PI) are responsible for immediately reporting an incident to the University Police Department (UPD) for theft or loss or to the Institutional Biosafety Officer (BSO) for release (including occupational exposure).
- 2.3 UPD – Responsible for immediately contacting the Alternate Responsible Official (ARO) and beginning an investigation of the incident. A written investigation report will be submitted to the Institutional Biosafety Committee (IBC), the PI and the ARO within 5 days of the incident. UPD will also work with the PI to conduct a security assessment following any incident involving loss or theft.
- 2.3 BSO - Responsible for immediately contacting the Alternate Responsible Official and beginning an investigation of the incident. A written investigation report will be submitted to the IBC, the PI and the ARO within 5 days of the incident. The BSO will also work with the PI to conduct a safety assessment following any incident involving a release (including occupational exposure).
- 2.4 ARO - Responsible for immediately contacting the Responsible Official, CDC, NIH (if rDNA) and other key institutional contacts regarding the incident. The ARO will work with the BSO, UPD and the PI to insure that the written report is correct and that the report will be submitted to CDC, NIH (if rDNA) and other key institutional contacts.

- 2.5 Responsible Official – Is responsible for compliance to the Select Agent regulations and insuring requirements (registration, investigations, etc) are properly carried out.
- 2.6 Contact information is found on the Emergency contact list. The list is attached to this document and is posted throughout the lab.
- 2.7 Annual Program Review. The Responsible Official or Alternate Responsible Official will audit the incident response program on an annual basis. This review will include drills and exercises to ensure the effectiveness of the incident response plan. Based on the outcome of drills, exercises or reported incidents, this incident response plan will be reviewed and updated as necessary.

3. Description of Work

This plan covers all work being performed at TAMU. Each lab will be responsible for providing information specific to the work being performed as follows:

Lab	Work description	Unique features of Agent	Biological Use Authorization	Biosafety Level
	Work with Brucella abortus, B. suis, B. melitensis	BSC	0741	3
	Inoculation of mice and ruminants with Brucella spp.	BSC	0741	3
	Storage of Brucella-infected animal carcasses	Locked freezer	0741	3

Additional information concerning the laboratories and the select agent use is contained in the facility's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or Environmental Health and Safety Office.

4. Response to theft:

- 4.1 Determination of Loss or Theft – The following are examples of events that may be considered a loss or theft. Possible loss or theft of the select agent will be reported initially to the Principal Investigator if any of the following have occurred:
- 4.1.1 The lock on the Select Agent storage area has been found open or appears to have been tampered with;
 - 4.1.2 Evidence of forced entry into the laboratory or storage areas has been found;
 - 4.1.3 A discrepancy in the Select Agent inventory that can not be reconciled;
 - 4.1.4 An employee reports cultures or samples missing;
 - 4.1.5 A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2;
 - 4.1.6 An infected animal is missing from its housing unit.
- 4.2 Report/Investigation Process:
- Theft** (unauthorized removal) or **Loss** (failure to account for) a select agent or toxin
- 4.2.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected theft or loss of SBATS to UPD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345). Based on circumstances, UPD will notify EHSD.

If the release is discovered and UPD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the person shall then notify the LD/PI.

After notification to UPD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact ORC.

- 4.2.1.1 Upon notification of discovery of a theft or loss, UPD will immediately notify ORC.
- 4.2.1.2 Upon notification from UPD, ORC will immediately notify the Responsible Official (RO) and Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, and UPD.
- 4.2.1.3 UPD (and ESHD, based on circumstances) will immediately investigate the incident. The investigation will include coordination with the LD/PI and others approved with access or visiting SBAT facilities. UPD will submit a written report to ORC within 5 days of being notified about the discovery of the theft or loss. If the investigation provides evidence that a theft or loss did not occur, circumstances will be documented in UPD's investigation report.
- 4.2.1.4 Based on the UPD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss or Release of Select Agents and Toxins) with CDC. ORC will maintain an official copy of information submitted to CDC and will provide a copy of the submission to the RO, UPD/EHSD, and LD/PI.
- 4.2.1.5 UPD will notify the appropriate Federal, State, or local law enforcement agencies.
- 4.2.1.6 The LD/PI will ensure notification to the funding agency
- 4.2.2 A risk assessment will be conducted immediately upon discovery of a loss or theft. The risk assessment will be a part of the investigation report.
 - 4.2.2.1 In addition to the investigation, upon notification of a theft or loss, UPD (with input from EHSD and the LD/PI) will conduct a risk assessment to determine if the laboratory is operating in a safe and secure manner and to attempt to determine the cause of the theft. This risk assessment shall include, but not be limited to a comprehensive laboratory survey, review of access logs, review of inventory records, and verification that all equipment is operating within normal parameters (e. g. biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of theft will also be reviewed and modified, as warranted. If deficiencies in safe and secure practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
 - 4.1.2.2 If deemed necessary, the EHSD/UPD will contact Biosafety Program Coordinator to convene a special meeting of the Institutional BioSafety Committee (IBC).

4.1.2.3 Documentation of the risk assessment will be maintained by UPD with a copy sent to the LD/PI, EHSD and ORC.

4.1.2.4 Security Risk Assessments will be completed by UPD, with input from the LD/PI (and EHSD, based on circumstances). The results of the risk assessment and findings, including any requirements for post theft procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI, EHSD, and ORC.

4.1.2.5 The ORC will contact CDC, and if needed, a copy of the assessment will be submitted. ORC will also update the RO.

4.2.3 UPD will establish and maintain a specific file for each theft or loss incident, with all pertinent information.

4.2.4 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected loss or theft to UPD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

5. Investigation

5.1 The Investigation Committee for all releases will be headed by the EHSD's Institutional Biosafety Officer (BSO) with input from UPD and the PI. UPD will lead investigations involving theft or loss, with input from the BSO and PI.

5.1.1 The BSO/UPD will investigate the event as quickly as possible, but no later than 24 hours of the initial report or the incident.

5.1.2 The investigation should include a review of all materials related to the research, including access logs, inventory logs, laboratory notes and laboratory plans (security, safety and incident response)

5.1.3 Once the investigation is complete, the BSO or UPD will submit an investigation report to the IBB and RO.

5.1.4 Once the Committee has determined the response and informed the RO and IBC (through the Office of Research Compliance), the IBC will review the report and make a recommendation to the RO of any additional actions that they believe are needed.

5.1.5 After the RO has approved of the recommended actions, the PI will receive a written response from the IBC.

6. Reporting

6.1 All incident reports are included in the IBC agenda minutes for review by the full board at the next convened meeting. Serious events should be specifically presented to the IBC by the BSO/UPD or IBC Chair at the next convened meeting.

6.1.1 The investigation report, at a minimum, shall include the following information:

6.1.1.1 A detailed description of the incident.

6.1.1.2 A list of all personnel involved in the incident.

6.1.1.3 A description of what occurred and what has or needs to be done to prevent any future incident.

6.1.1.4 An assessment of the safety or security risk of continuing the research.

6.1.1.5 A recommendation of any changes that need to be made to the plans (safety, security or incident response), medical surveillance or laboratory procedures to reduce the risk of a reoccurrence.

6.1.1.6 A recommendation for training, if needed.

6.1.2 Incidents involving SBAT will be immediately reported to the CDC with a written report (Form 3) submitted within seven (7) days.

6.1.3 Events involving rDNA must be reported to the NIH immediately in writing but no later than 30 days of the incident.

7. **Release of a Select Agent or Toxin.**

Examples of a possible release (including occupational exposures of the agent or toxin) include but are not limited to the following:

7.1 A package containing the Select Agent or toxin that has been received, which has been damaged in transit, such that the primary containment vessel appears to have been compromised;

7.2 Simultaneous complete power failure of the Biosafety cabinet and loss of negative pressure in the BSL-3 suite during work in the Biosafety cabinet with open cultures;

7.3 Simultaneous spill of cultures outside the Biosafety cabinet and failure of negative pressure in the Biosafety Level 3 area. In case of a spill, a spill kit containing absorbent material and disinfectant will be located in each building;

7.3.1 Personnel are advised to immediately leave the building after removing any contaminated clothing and to return in Tyvek suits with full face respirators (Powered Air Purifying Respirator (PAPR)) after the air has been scrubbed clean by air handlers (approx. one hour).

1.1.1. In case release of the Select Agent or toxin outside the BSL-3 laboratory is suspected, the Principal Investigator will notify the BSO, ORC as well as the RO, and the building manager.

7.5 Exposure of laboratory personnel to cultures. The following incidents may result in unintentional exposure to the Select Agent that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to the BSO, who will notify the Scott & White Occupational Health office to evaluate the need for post-exposure prophylaxis. The exposure will be reported by the Principal Investigator to the BSO who reports immediately to the Responsible Official, who will notify CDC of the exposure. The following are examples of unintentional exposure:

7.5.1 A spill of live culture outside the Biosafety cabinet;

7.5.2 Failure of the Biosafety cabinet during work with *Brucella*;

7.5.3 Needle stick or cut with sharps contaminated with *Brucella*;

7.5.4 If a bite from a *Brucella*-infected animal penetrates the double gloves and breaks the skin;

7.5.5 A centrifuge accident that results in aerosolization of *Brucella*.

8. **Process of reporting and investigating a Release:**

Release – Occupational exposure (clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been release outside of the primary bio-containment barrier.) or release of an agent or toxin outside of the primary barriers of the biocontainment area.

8.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected release to the BSO in the Environment Health and Safety Department (EHSD). Based on circumstances, the BSO will notify the

University Police Department (UPD). During normal business hours, call the BSO at the EHSD at 845-2132. If it is outside of normal business hours, call UPD who will notify EHSD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345).

If the release is discovered and the BSO is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the individual shall then notify the LD/PI.

After notification to the BSO by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact the Office of Research Compliance (ORC).

- 8.1.1 Upon notification of discovery of a release, the BSO will immediately notify Scott & White Occupational Health Clinic and ORC.
- 8.1.2 Upon notification from the BSO, ORC will immediately notify the Responsible Official (RO) and the Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, EHSD, and UPD.
- 8.1.3 The BSO (and UPD, based on circumstances) will immediately investigate the incident. The investigation will include the coordination with the LD/PI and others approved with access or visiting SBAT facilities. The BSO will submit a written report to ORC within 5 days of being notified about discovery of the release. If the investigation provides evidence that a release did not occur, circumstances will be documented in BSO's investigation report.
- 8.1.4 Based on the BSO report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss, or Release of Select Agents and Toxins) with the CDC within seven calendar days of the discovery of the release. ORC will maintain an official copy of information submitted to the CDC and will provide a copy of the submission to the RO, BSO, and LD/PI.
- 8.1.5 The BSO will obtain confirmation from health care providers that reports to other state or federal health agencies have been submitted. The LD/PI will ensure notification to the funding agency.
- 8.2 A risk assessment will be conducted immediately upon discovery regarding any release.
 - 8.2.1 In addition to the investigation, upon notification of a release, EHSD (under the direction of the Biological Safety Officer (BSO)) will conduct a risk assessment to determine if the laboratory is operating in a safe manner and attempt to determine the cause or most likely route of the release. This risk assessment shall include but not be limited to a comprehensive laboratory survey, review of access logs to determine potential occupational exposures, review of inventory records, and verification that all equipment is operating within normal parameters (e.g., biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of the release will also be reviewed by the BSO and modified, as warranted, in consultation with the LD/PI. If deficiencies in safe practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
 - 8.2.2 If deemed necessary based on the risk assessment, the BSO will contact ORC to convene a special meeting of the Institutional BioSafety Committee.

- 8.2.3 Documentation of the risk assessment will be maintained by BSO with a copy sent to the LD/PI and the ORC.
- 8.2.4 Risk assessments will be completed with input from the LD/PI. The results of the risk assessment and findings, including any requirements for post decontamination procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI and ORC.
- 8.2.5 ORC will contact CDC, and if needed, a copy of the risk assessment will be submitted. ORC will also update the RO.
- 8.3 The following additional steps will also be taken immediately upon discovery regarding an actual or suspected occupational exposure:
 - 8.3.1 BSO will direct the LD/PI to notify laboratory personnel and visitors that a potential exposure has occurred and refer them to Scott & White Occupational Health for consultation. BSO will obtain access logs and other information to determine a complete list of potentially exposed personnel. BSO will then follow-up with potentially exposed personnel to ensure notification.
 - 8.3.2 Individuals will be encouraged to contact Occupational Health at Scott & White Clinic, or to immediately identify to medical personnel, the agent they were potentially exposed to if treatment is sought. Scott & White Occupational Health Clinic or the attending physician will screen for the organism (e. g. Brucella species), and begin prophylaxis as deemed appropriate by the attending physician.
 - 8.3.3 If an occupational exposure is confirmed through appropriate medical tests or as determined by a physician, all personnel and potentially exposed individuals will be immediately referred to Scott & White for screening, testing, or preventive prophylaxis as determined by the attending physician. If personnel or visitors are at remote locations (other university facilities, traveling), they should immediately report to a physician of choice and explain that a positive occupational exposure to a specific organism has occurred and specific treatment or screening is desired. Personal physicians should be encouraged to contact either the BSO or Scott and White Occupational Health if they have any questions.
 - 8.3.4 The BSO, in consultation with Scott & White, will perform periodic follow-up with the group of exposed or potentially exposed personnel for a period of time as appropriate for the organism.
- 8.4 EHSD will establish and maintain a specific file for each release incident, with all pertinent information.
- 8.5 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected release to the BSO and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

9. Security Breach:

A security breach will be determined to have occurred if any of the following are observed:

- 9.1 The access control system has failed, leaving the BSL-3 building accessible to unauthorized persons;
- 9.2 An unauthorized person is observed unaccompanied in the BSL-3 building;
- 9.3 A lost or stolen card was used to access the BSL-3 building;

- 9.4 An unauthorized person has accessed the computer used to control entry to the BSL-3 building;
- 9.5 An unexpected or suspicious package is found in or near a BSL-3 building.

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the UPD of the security breach and take steps to correct the problem. Corrective procedures will be secured immediately, but no later than 24 hours; an inventory will be performed of all samples and animals in the building. Any missing Select Agent samples or animals will be reported to CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator and the UPD and ORC will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

10. Severe weather or natural disasters.

The most likely occurrences in this area are severe thunderstorms, floods or tornadoes.

- 10.1 If severe weather (thunderstorms or flooding) is predicted, experiments with Select Agents should be suspended until the severe weather has passed to avoid power outages during the work.
- 10.2 If an earthquake is felt, workers should immediately leave the building--if possible, shedding gloves and lab coat on the way out of the BSL-3 building. Cleanup, if necessary, can be performed once it is safe to re-enter the building.

11. Fire, Gas leak, Steam leak, Explosion, Bomb threat:

- 11.1 If work is being performed in the Biosafety cabinet, cap all samples, dispose of gloves and outer laboratory coat, and leave the building immediately. If the worker feels (s)he can safely extinguish the fire, then the fire extinguisher located in the interior dressing area may be used. If a worker feels his or her safety threatened, (s)he should leave the building immediately without stopping to decontaminate or secure any work. Upon leaving the building, personnel should assemble outside the building one end of the compound at a safe distance from the building.
- 11.2 Notify the appropriate emergency responders: Fire 9-911 or 911 from mobile phones, the Principal Investigator, UPD and the BSO. For steam and gas leaks, notify TAMU Operations and Maintenance.
- 11.3 In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police immediately by calling the emergency number, 9-911 or 911 or 845-2345 or 845-8900. Also inform the Principal Investigator, BSO and ORC. Always be sure to give the number and location of the building and your name and telephone extension number.
 - 11.3.1 The University Police Department will assign personnel to investigate the call and take whatever police action they may deem necessary and reasonable for the safety of the campus community. The University Police will conduct a search of the building, or of specific locations in or around the building. When judged prudent and feasible to do so, the search will be conducted with the assistance and cooperation of the Principal Investigator and/or ORC. After an evaluation/assessment of the content of the bomb threat, the decision to evacuate or close building shall be made jointly, whenever possible, by the Police and the Principal Investigator and/or ORC.
 - 11.3.2 Any unusual or suspicious object should be reported immediately to the University Police or to any immediate supervisor or administrative officer. Suspected objects or materials should NOT be touched or disturbed. Every bomb threat or incident of a suspected explosive device should be considered valid until

all reasonable precautions for public safety have been taken or until the danger to life and property is terminated.

12. Failure of Select Agent Storage Freezer:

- 12.2 If a -80°C freezer in any building that is used to store Brucella strains fails, the strains will be moved in appropriate containment to a temporary backup location, which is in or in secure freezer in a locked BSL-2 laboratory.

13. Workplace violence:

- 13.1 Incidents of disruptive or threatening behavior on the part of an employee, student or visitor should be reported immediately to the Principal Investigator, who will report the incident to the Department Head, UPD, ORC and the Workplace Violence Response Team, as proscribed by the TAMU Personnel and Procedures manual section 290-09. If the individual accused of disruptive or threatening behavior is authorized for access to select agents, this person's access will be suspended pending the results of an investigation by the Workplace Violence Response Team. If an act of violence or a physical assault has occurred, or the threatening activity occurs within the BSL-3 building, the person feeling threatened should call UPD immediately to report the incident. If the person accused of violence has access to select agents, the person's access will be suspended pending the outcome of the investigation. Suspension of select agent access will be reported to UPD and ORC and a suspended individual's access will be inactivated within 24 hours.

14. Entry of emergency responders into the BSL-3 laboratory.

- 14.1 In a case in which a life-threatening injury or medical condition (i.e. heart attack) occurs inside the BSL-3 building, emergency responders will be allowed to enter the laboratory. If possible, upon feeling ill the laboratory worker should immediately exit the building to facilitate treatment by emergency responders. Personnel protective equipment, including Tyvek suits, PAPRs and gloves, are located inside the entries (locker rooms) to the BSL-3 building. A spill kit containing absorbent materials and disinfectant is located in the interior dressing area. A First Aid kit is located in the interior dressing area. If responders are required to enter an area where a spill has occurred, they will be referred to the BSO and the Scott and White Occupational Health office and evaluated for possible post-exposure prophylaxis.
- 14.1.1 Entry procedure for the BSL-3 laboratory: Dress in a Tyvek suit, gloves, shoe covers and PAPRs before entering the building.
- 14.1.2 Providing first aid and emergency medical treatment in the BSL-3 laboratory: A person working inside the Biosafety hood is not considered to be contagious unless a spill has occurred. The person's gloves may be contaminated, and may be removed to facilitate treatment. If there is no space within the labs to put the person on the floor, move the person to the interior dressing area to administer treatment.
- 14.1.3 Exit procedure from the BSL-3 laboratory: Emergency responders must decontaminate with appropriate disinfectant, remove Tyvek suit, PAPRs, shoe covers and gloves in the inner dressing room before exiting. Hands should be washed immediately before and after exit from the BSL-3 laboratory.
- 14.1.4 Decontamination procedures for medical equipment and clothing: Emergency responders should decontaminate equipment before leaving the laboratory by one of the following methods:
- 14.1.4.1 Autoclaving. Autoclaves are located in _____
- 14.1.5 Decontaminate with 1% Virkon, 1X Wexcide or dilute sodium hypochlorite.

15. Incident Response Plan Testing (Drills)

- 15.1 Drills or tabletop exercises will be conducted annually to test the effectiveness of the Biosafety plan. The drills or exercises will be coordinated with the TAMU Police Department and will include, but not be limited to, the Principal Investigator or designee, BSO, TAMU Fire Department representative and the Campus Emergency Planner.
 - 15.2 The drill or exercise will include, but not be limited to, accessibility to restricted space, attempted or unauthorized entry into restricted spaces challenge, animal room security, staff knowledge of hazard/emergency protocols for their work location(s) and other situations that are deemed appropriate for each work location.
 - 15.3 Following the drill or exercise, which will test the various components of the incident response plan for completeness, those involved will critique their findings for each drill/exercise location. The Principal Investigator working with the ORC and BSO will implement changes as necessary changes to the plan. Results of the drill or exercise will be reviewed by the Biological Safety Administrative Advisory Committee (Institutional Biosafety Committee).
- 16. Texas A&M University Crisis Management Plan**
- 16.1 The entity crisis management plan is contained in a separate document and is referenced in the individual laboratory emergency response plan.
 - 16.2 Additional information concerning the laboratory emergency response plan is contained in the laboratory's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance and the Environmental Health & Safety Department.
 - 16.3 The ORC and BSO should be contacted immediately in the case of any emergency in a select agent lab. The ORC will coordinate access and information issues with campus police, fire, and emergency responders.
 - 16.4 If necessary, the ORC will coordinate the emergency relocation of select agents to another secure location.
- 17. Site security and control are described in detail in the Select Agent Security Plan**
- 17.1 The buildings are secured by a keyed lock. Sharing of keys with other personnel is not permitted.
 - 17.2 Individuals not authorized for access to Select Agents must be accompanied by approved personnel at all times while in the buildings.
 - 17.3 Data that could enable access to select agents by unauthorized personnel should be located on password-protected computers.
 - 17.4 If approved personnel are observed violating security or Biosafety procedures, this observation should be reported immediately to the Principal Investigator. The Principal investigator will investigate the allegation and determine whether the alleged violator should be reported to the ORC and/or the UPD to have their Select Agent access suspended or revoked. Suspension of Select Agent access will be reported to the ORC and the individual's key card access will be terminated within 24 hours.
- 18. Inventory Discrepancies:**
- 18.1 Inventory discrepancies will be documented on the agent access form.
 - 18.2 All discrepancies will be immediately reported to the Principal Investigator.
 - 18.3 If the discrepancy is believed to be a result of loss or theft, the incident response procedures for loss or theft and release will be followed.
 - 18.4 If the discrepancy is a result of a transfer, the transfer form will be documented.
- 19. References**
- 19.1 42 CFR Part 73
 - 19.2 7 CFR Part 331
 - 19.3 9 CFR Part 121
 - 19.4 Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention, National Institutes of Health, Fourth Edition, May 1999

- 19.5 Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents (Revised BMBL, Appendix F), published in Morbidity and Mortality Weekly Report, December 6, 2002.

SBAT Incident Response
Emergency Contact Numbers

PI Information			
PI Ficht Office – 979 845-4118			
Building Manager Loren Skow Office – 979-845-3194			
Department Head Gerald Bratton Office – 979-845-5941			
Incidents involving Theft or Loss University Police Department (UPD) contact Bert Kretzschmar Office – 979 845-8900			
Incidents involving a Release (or Occupational Exposure) Environmental Health and Safety Office contact Between 8:00 a.m. and 5:00 p.m. Brent Mattox, Biosafety Officer (BSO) Alternate Responsible Official (ARO) Office – 979 865-2132 After hours 5:00 pm Contact the University Police Department contact Lt. Bert Kretzschmar Office – 979 845-8900			
Other Contact information			
Vice President for Research/Responsible Official (RO)	Richard Ewing (RO)	979 845-8585 (Office) o	(Mobile)
	Fuller Bazer (ARO)	979 693-2876 (Office) o	(Mobile)
	Angelia Raines (ARO)	979 847-9362 (Office) o	(Mobile)
Comparative Medicine Program	Melanie Ihrig	979 845-7433 (Office) o	(Mobile)
	Elizabeth Browder	979 845-7433 (Office) o	(Mobile)
	Frank Stein	979 845-6488 (Office) o	(Mobile)
Institutional Biosafety Committee (IBC)	Thomas Ficht	979 845-4118 (Office) o	(Mobile)
	Vernon Tesh	979 862-4113 (Office) o	(Mobile)
	Tiffany Agnew	979 458-3624 (Office) o	(Mobile)
Other Emergency Numbers	College Station Police	979 764-3600 or 9-911	
	Medical Emergency	9-911	
	College Station Fire	979 764-3700 or 9-911	
	Radiological Emergency	979 832-1111	
	University Maintenance	979 845-4311	

Emergency Telephone Numbers

Thomas A. Ficht	Office: (979)845-4118
Emergency	9-911
University Police	(979) 845-2345
College Station Police	(979) 764-3600
College Station Fire	(979) 764-3700
Environmental Health & Safety	(979) 845-2132
TAMU Area Maintenance (HVAC failure, steam leak, gas leak)	(979) 845-5542
TAMU Maintenance (24 hours)	(979) 845-4311
Radiological Emergencies	(979) 862-1111
Responsible University Officials:	
RO-Richard Ewing	Work: (979) 845-8585
ARO-Angelia Raines	Work: (979) 847-9362
Biosafety Officer/ARO -Brent Mattox	Work: (979) 845-2132
Building Manager	Loren Skow 979-845-3194
Frank Stein	Work: (979) 845-6488
T. A. Ficht Lab	979-845-4185
Neighboring labs to notify in case of simultaneous containment breach and spill outside BSC:	
Lab (enter additional locations)	enter additional laboratory phone number
Lab (enter additional locations)	enter additional laboratory phone number
Lab (enter additional locations)	enter additional laboratory phone number

Decontamination Procedures for Spills of Cultures
(Please customize for specific laboratories.)

1. Signal others in the BL3 labs of any spill outside the biological safety cabinet. All personnel should change out of contaminated clothing and wash any exposed skin with a disinfectant, such as Purell. Clothes must be removed within the BL3 area and will be autoclaved by those cleaning up.
2. Put on a clean scrub suit and go to the shower on the first floor animal facility. Shower thoroughly with soap.
3. Return to the lab for cleanup: Put on a PAPR and tyvek suit (contained in the SPILL KIT). Put on double gloves and shoe covers.
4. Use paper towels to cover the spill. Prevent creation of contaminated aerosols.
5. Saturate all materials with 10% bleach solution (see previous section for description).
6. Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in autoclave bags.
7. Disinfect all exposed surfaces using 1X Wexcide or 1% Virkon (surface disinfectant solution).
8. Wipe surface of full-face respirator with 1% Virkon or 1X Wexcide, being careful to avoid skin contact with Wexcide.
9. Remove all clothing and place in autoclave bag.
10. Remove full face respirator and spray off all surfaces in the lab with 1% Virkon or 1X Wexcide.
11. Make sure that all contaminated material is autoclaved, surface-disinfected or incinerated.
12. Inform others not to work in the lab until the air handling system is able to clear any residual organisms from the air (3h).
13. Return to the lab after 3 hours and perform another decontamination of all lab surfaces with 1% Virkon or 1X Wexcide.
14. Report accident to the Principal Investigator, who will report it to other officials.

Contents of spill kit located in BL-3 labs:

Full-face respirator, Tyvek suit, clean scrub suit, absorbent material, Purell skin disinfectant, towel, copy of decontamination procedures for spills.

INCIDENT RESPONSE PLAN

PI – CMP Director, *Thomas Ficht, and James Samuel*

Texas A&M University, College Station, TX 77843
to ensure compliance with
42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

- 1.1 General. This is the incident response plan for the possession and use of *Coxiella burnetti* and *Brucella spp* at Texas A&M University main campus (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121. This plan covers the use of these select agents when used
- 1.2 This plan describes the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

- 2.1 Principal Investigator (PI). The Principal Investigator, Thomas Ficht and James Samuel, has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to Thomas Ficht and James Samuel. The PI is responsible for ensuring all incidents regarding theft, loss or release are immediately reported to the proper institutional officials. This document outlines response actions concerning any theft, loss, or release from select biological agents and toxins (SBAT) facilities, including illness of personnel or visitors in SBAT facilities. Certain actions outlined below are performed in parallel rather than sequentially (see attached flowchart).
- 2.2 All lab personnel (including the PI) are responsible for immediately reporting an incident to the University Police Department (UPD) for theft or loss or to the Institutional Biosafety Officer (BSO) for release (including occupational exposure).
- 2.3 UPD – Responsible for immediately contacting the Alternate Responsible Official (ARO) and beginning an investigation of the incident. A written investigation report will be submitted to the Institutional Biosafety Committee (IBC), the PI and the ARO within 5 days of the incident. UPD will also work with the PI to conduct a security assessment following any incident involving loss or theft.
- 2.3 BSO - Responsible for immediately contacting the Alternate Responsible Official and beginning an investigation of the incident. A written investigation report will be submitted to the IBC, the PI and the ARO within 5 days of the incident. The BSO will also work with the PI to conduct a safety assessment following any incident involving a release (including occupational exposure).
- 2.4 ARO - Responsible for immediately contacting the Responsible Official, CDC, NIH (if rDNA) and other key institutional contacts regarding the incident. The ARO will work with the BSO, UPD and the PI to insure that the written report is correct and that the report will be submitted to CDC, NIH (if rDNA) and other key institutional contacts.

- 2.5 Responsible Official – Is responsible for compliance to the Select Agent regulations and insuring requirements (registration, investigations, etc) are properly carried out.
- 2.6 Contact information is found on the Emergency contact list. The list is attached to this document and is posted throughout the lab.
- 2.7 Annual Program Review. The Responsible Official or Alternate Responsible Official will audit the incident response program on an annual basis. This review will include drills and exercises to ensure the effectiveness of the incident response plan. Based on the outcome of drills, exercises or reported incidents, this incident response plan will be reviewed and updated as necessary.

3. Description of Work

This plan covers all work being performed at TAMU. Each lab will be responsible for providing information specific to the work being performed as follows:

Lab	Work description	Unique features of Agent	Biosafety Level	Biological Use Authorization
	Animal Housing	BSC	3	
	Animal Housing	BSC	3	
	Challenge, Lab work	BSC, Aerosol Chamber	3	

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Additional information concerning the laboratories and the select agent use is contained in the facility's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or Environmental Health and Safety Office.

4. Response to theft:

4.1 Determination of Loss or Theft – The following are examples of events that may be considered a loss or theft. Possible loss or theft of the select agent will be reported initially to the Principal Investigator if any of the following have occurred: **AGENTS ARE NOT STORED IN BUILDING**

- 4.1.1 The lock on the Select Agent storage area has been found open or appears to have been tampered with;
- 4.1.2 Evidence of forced entry into the laboratory or storage areas has been found;
- 4.1.3 A discrepancy in the Select Agent inventory that can not be reconciled;
- 4.1.4 An employee reports cultures or samples missing;
- 4.1.5 A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2;
- 4.1.6 An infected animal is missing from its microisolator cage.

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4.2 Report/Investigation Process:

Theft (unauthorized removal) or **Loss** (failure to account for) a select agent or toxin
4.2.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected theft or loss of SBATS to UPD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345). Based on circumstances, UPD will notify EHSD.

If the release is discovered and UPD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the person shall then notify the LD/PI.

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After notification to UPD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact ORC.

- 4.2.1.1 Upon notification of discovery of a theft or loss, UPD will immediately notify ORC.
- 4.2.1.2 Upon notification from UPD, ORC will immediately notify the Responsible Official (RO) and Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, and UPD.
- 4.2.1.3 UPD (and ESHD, based on circumstances) will immediately investigate the incident. The investigation will include coordination with the LD/PI and others approved with access or visiting SBAT facilities. UPD will submit a written report to ORC within 5 days of being notified about the discovery of the theft or loss. If the investigation provides evidence that a theft or loss did not occur, circumstances will be documented in UPD's investigation report.
- 4.2.1.4 Based on the UPD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss or Release of Select Agents and Toxins) with CDC. ORC will maintain an official copy of information submitted to CDC and will provide a copy of the submission to the RO, UPD/EHSD, and LD/PI.
- 4.2.1.5 UPD will notify the appropriate Federal, State, or local law enforcement agencies.
- 4.2.1.6 The LD/PI will ensure notification to the funding agency
- 4.2.2 A risk assessment will be conducted immediately upon discovery of a loss or theft. The risk assessment will be a part of the investigation report.
 - 4.2.2.1 In addition to the investigation, upon notification of a theft or loss, UPD (with input from EHSD and the LD/PI) will conduct a risk assessment to determine if the laboratory is operating in a safe and secure manner and to attempt to determine the cause of the theft. This risk assessment shall include, but not be limited to a comprehensive laboratory survey, review of access logs, review of inventory records, and verification that all equipment is operating within normal parameters (e. g. biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of theft will also be reviewed and modified, as warranted. If deficiencies in safe and secure practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
 - 4.1.2.2 If deemed necessary, the EHSD/UPD will contact Biosafety Program Coordinator to convene a special meeting of the Institutional BioSafety Committee (IBC).
 - 4.1.2.3 Documentation of the risk assessment will be maintained by UPD with a copy sent to the LD/PI, EHSD and ORC.

4.1.2.4 Security Risk Assessments will be completed by UPD, with input from the LD/PI (and EHSD, based on circumstances). The results of the risk assessment and findings, including any requirements for post theft procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI, EHSD, and ORC.

4.1.2.5 The ORC will contact CDC, and if needed, a copy of the assessment will be submitted. ORC will also update the RO.

4.2.3 UPD will establish and maintain a specific file for each theft or loss incident, with all pertinent information.

4.2.4 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected loss or theft to UPD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

5. Investigation

5.1 The Investigation Committee for all releases will be headed by the EHSD's Institutional Biosafety Officer (BSO) with input from UPD and the PI. UPD will lead investigations involving theft or loss, with input from the BSO and PI.

5.1.1 The BSO/UPD will investigate the event as quickly as possible, but no later than 24 hours of the initial report or the incident.

5.1.2 The investigation should include a review of all materials related to the research, including access logs, inventory logs, laboratory notes and laboratory plans (security, safety and incident response)

5.1.3 Once the investigation is complete, the BSO or UPD will submit an investigation report to the IBB and RO.

5.1.4 Once the Committee has determined the response and informed the RO and IBC (through the Office of Research Compliance), the IBC will review the report and make a recommendation to the RO of any additional actions that they believe are needed.

5.1.5 After the RO has approved of the recommended actions, the PI will receive a written response from the IBC.

6. Reporting

6.1 All incident reports are included in the IBC agenda minutes for review by the full board at the next convened meeting. Serious events should be specifically presented to the IBC by the BSO/UPD or IBC Chair at the next convened meeting.

6.1.1 The investigation report, at a minimum, shall include the following information:

6.1.1.1 A detailed description of the incident.

6.1.1.2 A list of all personnel involved in the incident.

6.1.1.3 A description of what occurred and what has or needs to be done to prevent any future incident.

6.1.1.4 An assessment of the safety or security risk of continuing the research.

6.1.1.5 A recommendation of any changes that need to be made to the plans (safety, security or incident response), medical surveillance or laboratory procedures to reduce the risk of a reoccurrence.

6.1.1.6 A recommendation for training, if needed.

6.1.2 Incidents involving SBAT will be immediately reported to the CDC with a written report (Form 3) submitted within seven (7) days.

- 6.1.3 Events involving rDNA must be reported to the NIH immediately in writing but no later than 30 days of the incident.

7. Release of a Select Agent or Toxin.

Examples of a possible release (including occupational exposures of the agent or toxin include but are not limited to the following:

- 7.1 A package containing the Select Agent or toxin that has been received which has been damaged in transit such that the primary containment vessel appears to have been compromised;
- 7.2 Simultaneous complete power failure of the Biosafety cabinet and negative pressure in the BSL-3 suite during work in the Biosafety cabinet with open cultures;
- 7.3 Simultaneous spill of cultures outside the Biosafety cabinet and failure of negative pressure in the Biosafety Level 3 suite. In case of a spill, a spill kit containing absorbent material and disinfectant will be located in a designated lab for each Principal Investigator;
 - 7.3.1 Personnel are advised to immediately leave the lab after removing any contaminated clothing and to return in Tyvek suits with Powered Air Purifying Respirator (PAPR) after the air has been scrubbed clean by air handlers (approx. one hour).
- 7.4 In case release of the Select Agent or toxin outside the BSL-3 laboratory is suspected, the Principal Investigator will notify the BSO laboratories on the first floor of the VRB, as well as the Responsible Official, and the building manager.
- 7.5 Exposure of laboratory personnel to cultures. The following incidents may result in unintentional exposure to the Select Agent that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to TAMU Occupational Health, where they will be given the option to initiate post-exposure prophylaxis. The exposure will be reported by the Principal Investigator to the BSO who reports immediately to the Responsible Official, who will notify CDC of the exposure. The following are examples of unintentional exposure:
 - 7.5.1 A spill of live culture outside the Biosafety cabinet;
 - 7.5.2 Failure of the Biosafety cabinet during work with a select agent;
 - 7.5.3 Needle stick or cut with sharps contaminated with a select agent;
 - 7.5.4 If a bite from a select agent--infected animal penetrates the double gloves and breaks the skin;
 - 7.5.5 A centrifuge accident that results in aerosolization of a select agent..

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8. Process of reporting and investigating a Release:

Release – Occupational exposure (clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been release outside of the primary bio-containment barrier.) or release of an agent or toxin outside of the primary barriers of the biocontainment area.

- 8.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected release to the Environment Health and Safety Department (EHSD). Based on circumstances, EHSD will notify the University Police Department (UPD). During normal business hours, call EHSD at 845-2132. If it is

outside of normal business hours, call UPD who will notify EHSD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345).

If the release is discovered and EHSD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the individual shall then notify the LD/PI.

After notification to EHSD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact the Office of Research Compliance (ORC).

- 8.1.1 Upon notification of discovery of a release, EHSD will immediately notify Scott & White Occupational Health Clinic and ORC.
- 8.1.2 Upon notification from EHSD, ORC will immediately notify the Responsible Official (RO) and the Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, EHSD, and UPD.
- 8.1.3 EHSD (and UPD, based on circumstances) will immediately investigate the incident. The investigation will include the coordination with the LD/PI and others approved with access or visiting SBAT facilities. EHSD will submit a written report to ORC within 5 days of being notified about discovery of the release. If the investigation provides evidence that a release did not occur, circumstances will be documented in EHSD's investigation report.
- 8.1.4 Based on the EHSD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss, or Release of Select Agents and Toxins) with the CDC within seven calendar days of the discovery of the release. ORC will maintain an official copy of information submitted to the CDC and will provide a copy of the submission to the RO, EHSD, and LD/PI.
- 8.1.5 EHSD will obtain confirmation from health care providers that reports to other state or federal health agencies have been submitted. The LD/PI will ensure notification to the funding agency.
- 8.2 A risk assessment will be conducted immediately upon discovery regarding any release.
 - 8.2.1 In addition to the investigation, upon notification of a release, EHSD (under the direction of the Biological Safety Officer (BSO)) will conduct a risk assessment to determine if the laboratory is operating in a safe manner and attempt to determine the cause or most likely route of the release. This risk assessment shall include but not be limited to a comprehensive laboratory survey, review of access logs to determine potential occupational exposures, review of inventory records, and verification that all equipment is operating within normal parameters (e.g., biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of the release will also be reviewed by EHSD and modified, as warranted, in consultation with the LD/PI. If deficiencies in safe practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
 - 8.2.2 If deemed necessary based on the risk assessment, the BSO will contact ORC to convene a special meeting of the Institutional BioSafety Committee.
 - 8.2.3 Documentation of the risk assessment will be maintained by EHSD with a copy sent to the LD/PI and the ORC.

- 8.2.4 Risk assessments will be completed with input from the LD/PI. The results of the risk assessment and findings, including any requirements for post decontamination procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI and ORC.
- 8.2.5 ORC will contact CDC, and if needed, a copy of the risk assessment will be submitted. ORC will also update the RO.
- 8.3 The following additional steps will also be taken immediately upon discovery regarding an actual or suspected occupational exposure:
 - 8.3.1 EHSD will direct the LD/PI to notify laboratory personnel and visitors that a potential exposure has occurred and refer them to Scott & White Occupational Health for consultation. EHSD will obtain access logs and other information to determine a complete list of potentially exposed personnel. EHSD will then follow-up with potentially exposed personnel to ensure notification.
 - 8.3.2 Individuals will be encouraged to contact Occupational Health at Scott & White Clinic, or to immediately identify to medical personnel, the agent they were potentially exposed to if treatment is sought. Scott & White Occupational Health Clinic or the attending physician will screen for the organism (e. g. Brucella species), and begin prophylaxis as deemed appropriate by the attending physician.
 - 8.3.3 If an occupational exposure is confirmed through appropriate medical tests or as determined by a physician, all personnel and potentially exposed individuals will be immediately referred to Scott & White for screening, testing, or preventive prophylaxis as determined by the attending physician. If personnel or visitors are at remote locations (other university facilities, traveling), they should immediately report to a physician of choice and explain that a positive occupational exposure to a specific organism has occurred and specific treatment or screening is desired. Personal physicians should be encouraged to contact either EHSD or Scott and White Occupational Health if they have any questions.
 - 8.3.4 EHSD, in consultation with Scott & White, will perform periodic follow-up with the group of exposed or potentially exposed personnel for a period of time as appropriate for the organism.
- 8.4 EHSD will establish and maintain a specific file for each release incident, with all pertinent information.
- 8.5 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected release to EHSD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

9. Security Breach:

A security breach will be determined to have occurred if any of the following are observed:

- 9.1 The access control system has failed, leaving the BSL-3 suite accessible to unauthorized persons;
- 9.2 An unauthorized person is observed unaccompanied in the BSL-3 suite;
- 9.3 A lost or stolen card was used to access the BSL-3 suite;

- 9.4 An unauthorized person has accessed the computer used to control entry to the BSL-3 suite;
- 9.5 An unexpected or suspicious package arrives in the laboratory.

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the Responsible Official of the security breach and take steps to correct the problem. Corrective procedures will be secured immediately, but no later than 24 hours; an inventory will be performed of all samples and animals in the laboratory and in Select Agent storage. Any missing Select Agent samples or animals will be reported to CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator and the Responsible Official will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

10. Severe weather or natural disasters.

The most likely occurrences in this area are severe thunderstorms, floods or tornadoes.

- 10.1 If severe weather (thunderstorms or flooding) is predicted, experiments with Select Agents should be suspended until the severe weather has passed to avoid power outages during the work. All samples should be secured inside the locked -80°C freezer or the locked +4°C storage.
- 10.2 If an earthquake is felt, workers should immediately leave the suite-if possible, shedding gloves and lab coat on the way out of the BSL-3 suite. Cleanup, if necessary, can be performed once it is safe to re-enter the building.
- 10.3 Power to the BSL-3 suite may be affected if the emergency generator is flooded. In this case, all samples should be secured inside the -80°C freezer. If the vivarium is threatened by flooding, animal cages should be fastened shut, put into secondary containers (biohazard bag or large Tupperware) and transported to _____, for secure holding until the threat of flooding has passed. If it becomes necessary to evacuate the College Station area, all animal experiments will be terminated before evacuation by euthanizing the animals and storing the carcasses in the secure select agent storage in room.
- 10.4 In case of a power outage, if there is no immediate danger to the building, secure all infectious samples inside a -80°C freezer, the +4°C refrigerator, or the incubators. The Biosafety cabinets and air handling system of the BSL-3 suite are on emergency backup power, which will prevent exposure to infectious samples in case of a power outage. Follow standard procedures for leaving the laboratory and return once the power has been restored to resume work.

11. Fire, Gas leak, Steam leak, Explosion, Bomb threat:

- 11.1 If work is being performed in the Biosafety cabinet, cap all samples, dispose of gloves and outer laboratory coat, and leave the laboratory immediately. If the fire is within the BSL 3 laboratory, and the worker feels (s)he can safely extinguish the fire, then the fire extinguisher located in the interior hall may be used. If a worker feels his or her safety threatened, (s)he should leave the laboratory immediately without stopping to decontaminate or secure any work, using the designated escape routes (through the emergency exit located on the west side of the BSL-3 suite and immediately out of the back dock doors located on the north side of the facility). Upon leaving the building, personnel should assemble outside the _____ in the assigned spot _____ and report to the Area Coordinator for attendance.

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- 11.2 Notify the appropriate emergency responders: Fire 9-911 or 911 from mobile phones, the Principal Investigator and the Biosafety Officer. For steam and gas leaks, notify TAMU Operations and Maintenance.
- 11.3 In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police immediately by calling the emergency number, 9-911 or 911. Also inform the Principal Investigator and Responsible Official. Always be sure to give the number and location of the building and your name and telephone extension number.
 - 11.3.1 The University Police Department will assign personnel to investigate the call and take whatever police action they may deem necessary and reasonable for the safety of the campus community. The University Police will conduct a search of the building, or of specific locations in or around the building. When judged prudent and feasible to do so, the search will be conducted with the assistance and cooperation of the Principal Investigator and/or Responsible Official. After an evaluation/assessment of the content of the bomb threat, the decision to evacuate or close building shall be made jointly, whenever possible, by the Police and the Principal Investigator and/or Responsible Official.
 - 11.3.2 Any unusual or suspicious object should be reported immediately to the University Police or to any immediate supervisor or administrative officer. Suspected objects or materials should NOT be touched or disturbed. Every bomb threat or incident of a suspected explosive device should be considered valid until all reasonable precautions for public safety have been taken or until the danger to life and property is terminated.

12. Failure of Select Agent Storage Freezer:

- 12.1 Select agents are not stored at building

13. Workplace violence:

- 13.1 Incidents of disruptive or threatening behavior on the part of an employee, student or visitor should be reported immediately to the Principal Investigator, who will report the incident to the Department Head, the Responsible Official and the Workplace Violence Response Team, as proscribed by the TAMU Personnel and Procedures manual section 290-09. If the individual accused of disruptive or threatening behavior is authorized for access to select agents, this person's access will be suspended pending the results of an investigation by the Workplace Violence Response Team. If an act of violence or a physical assault has occurred, or the threatening activity occurs within the BSL-3 laboratory, the person feeling threatened should call the police immediately to report the incident. If the person accused of violence has access to select agents, the person's access will be suspended pending the outcome of the investigation. Suspension of select agent access will be reported to the Responsible Official and a suspended individual's access will be inactivated within 24 hours.

14. Entry of emergency responders into the BSL-3 laboratory.

- 14.1 In a case in which a life-threatening injury or medical condition (i.e. heart attack) occurs inside the BSL-3 laboratory, emergency responders will be allowed to enter the laboratory. If possible, upon feeling ill the laboratory worker should immediately exit the suite to facilitate treatment by emergency responders. Personnel protective equipment, including Tyvek suits, N95 masks, HEPA-filtered respirators and gloves, are located inside the entries (locker rooms) to the BSL-3 suite. A spill kit containing absorbent materials and disinfectant is located under the bench in each of the labs. A First Aid kit is located inside the lab. If responders are required to enter an area where a spill has

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occurred, they will be referred to Scott and White Clinic and offered post-exposure prophylaxis.

- 14.1.1 Entry procedure for the BSL-3 laboratory: Dress yourself in a Tyvek suit, gloves, shoe covers and respiratory protection (N95 mask) before entering the laboratories.
- 14.1.2 Providing first aid and emergency medical treatment in the BSL-3 laboratory: A person working inside the Biosafety hood is not considered to be contagious unless a spill has occurred. The person's gloves may be contaminated, and may be removed to facilitate treatment. If there is no space within the labs to put the person on the floor, move the person to the interior hallway to administer treatment.
- 14.1.3 Exit procedure from the BSL-3 laboratory: Emergency responders should remove Tyvek suit, mask, shoe covers and gloves before exiting and leave them behind in the BSL-3 laboratory. Hands should be washed immediately upon exit from the BSL-3 laboratory.
- 14.1.4 Decontamination procedures for medical equipment and clothing: Emergency responders should decontaminate equipment before leaving the laboratory by one of the following methods:
 - 14.1.4.1 Autoclaving. Autoclaves are located in the northwest corner of the facility in the wall between room _____ and the hallway outside the BSL-3 suite.
 - 14.1.4.2 Spraying surfaces with a Wexicide solution at 1 oz Wexicide to 1 gallon of water.

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15. Incident Response Plan Testing (Drills)

- 15.1 Drills or tabletop exercises will be conducted annually to test the effectiveness of the Biosafety plan. The drills or exercises will be coordinated with the TAMU Police Department and will include, but not be limited to, the Principal Investigator or designee, BSO, TAMU Fire Department representative and the Campus Emergency Planner.
- 15.2 The drill or exercise will include, but not be limited to, accessibility to restricted space, attempted or unauthorized entry into restricted spaces challenge, animal room security, staff knowledge of hazard/emergency protocols for their work location(s) and other situations that are deemed appropriate for each work location.
- 15.3 Following the drill or exercise, which will test the various components of the incident response plan for completeness, those involved will critique their findings for each drill/exercise location. The Principal Investigator working with the Responsible Official and Biosafety Officer will implement changes as necessary changes to the plan. Results of the drill or exercise will be reviewed by the Biological Safety Administrative Advisory Committee (Institutional Biosafety Committee).

16. Texas A&M University Crisis Management Plan

- 16.1 The entity crisis management plan is contained in a separate document and is referenced in the individual laboratory emergency response plan.
- 16.2 Additional information concerning the laboratory emergency response plan is contained in the laboratory's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or the Environmental Health & Safety Department.

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- 16.3 The Responsible Official and Biosafety Officer should be contacted immediately in the case of any emergency in a select agent lab. The Responsible Official will coordinate access and information issues with campus police, fire, and emergency responders.
- 16.4 If necessary, the Responsible Official will coordinate the emergency relocation of select agents to another secure location.
- 17. Site security and control are described in detail in the Select Agent Security Plan**
- 17.1 The buildings are secured by a keyed lock. Sharing of keys with other personnel is not permitted.
- 17.2 Individuals not authorized for access to Select Agents must be accompanied by approved personnel at all times while in the buildings.
- 17.3 Data that could enable access to select agents by unauthorized personnel should be located on password-protected computers.
- 17.4 If approved personnel are observed violating security or Biosafety procedures, this observation should be reported immediately to the Principal Investigator. The Principal investigator will investigate the allegation and determine whether the violator should have his/her Select Agent access suspended or revoked. Suspension of Select Agent access will be reported to the Responsible Official and the individual's key card access will be terminated within 24 hours.
- 18. Inventory Discrepancies:**
- 18.1 Inventory discrepancies will be documented on the agent access form.
- 18.2 All discrepancies will be immediately reported to the Principal Investigator.
- 18.3 If the discrepancy is believed to be a result of loss or theft, the incident response procedures for loss or theft and release will be followed.
- 18.4 If the discrepancy is a result of a transfer, the transfer form will be documented.
- 19. References**
- 19.1 42 CFR Part 73
- 19.2 7 CFR Part 331
- 19.3 9 CFR Part 121
- 19.4 Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention, National Institutes of Health, Fourth Edition, May 1999
- 19.5 Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents (Revised BMBL, Appendix F), published in Morbidity and Mortality Weekly Report, December 6, 2002.

SBAT Incident Response
Emergency Contact Numbers

PI Information			
PI Thomas Ficht Office – (979) 845-4118		PI James Samuel Office – (979) 862-1684	
Building Manager Dave Carlton Work: (979) 845-3091			
Department Head CMP Director Office - (979) 845-7433			
Incidents involving Theft or Loss University Police Department (UPD) contact Bert Kretschmar Office – 979 845-8900			
Incidents involving a Release (or Occupational Exposure) Environmental Health and Safety Office contact Between 8:00 a.m. and 5:00 p.m. Brent Mattox, Biosafety Officer (BSO) Alternate Responsible Official (ARO) Office – 979 865-2132 After hours 5:00 pm Contact the University Police Department contact Lt. Bert Kretschmar Office – 979 845-8900			
Other Contact information			
Vice President for Research/Responsible Official (RO)	Richard Ewing (RO)	979 845-8585 (Office)	(Mobile)
	Fuller Bazer (ARO)	979 693-2876 (Office)	(Mobile)
	Angelia Raines (ARO)	979 847-9362 (Office)	(Mobile)
Comparative Medicine Program	Melanie Ihrig	979 845-7433 (Office)	(Mobile)
	Elizabeth Browder	979 845-7433 (Office)	(Mobile)
	Frank Stein	979 845-6488 (Office)	(Mobile)
Institutional Biosafety Committee (IBC)	Thomas Ficht	979 845-4118 (Office)	(Mobile)
	Vernon Tesh	979 862-4113 (Office)	(Mobile)
	Tiffany Agnew	979 458-3624 (Office)	(Mobile)
Other Emergency Numbers	College Station Police	979 764-3600 or 9-911	
	Medical Emergency	9-911	
	College Station Fire	979 764-3700 or 9-911	
	Radiological Emergency	979 832-1111	
	University Maintenance	979 845-4311	

Decontamination Procedures for Spills of Cultures
(Please customize for specific laboratories.)

1. Signal others in the BL3 labs of any spill outside the biological safety cabinet. All personnel should change out of contaminated clothing and wash any exposed skin with a disinfectant, such as Purell. Clothes must be removed within the BL3 area and will be autoclaved by those cleaning up.
2. Put on a clean scrub suit and go to the shower on the first floor animal facility. Shower thoroughly with soap.
3. Return to the lab for cleanup: Put on a full face respirator and tyvek suit (contained in the SPILL KIT). Put on double gloves and shoe covers.
4. Use paper towels to cover the spill. Prevent creation of contaminated aerosols.
5. Saturate all materials with 10% bleach solution (see previous section for description).
6. Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in autoclave bags.
7. Disinfect all exposed surfaces using 1X Wexcide or 1% Virkon (surface disinfectant solution).
8. Wipe surface of full-face respirator with 1% Virkon or 1X Wexcide, being careful to avoid skin contact with Wexcide.
9. Remove all clothing and place in autoclave bag.
10. Remove full face respirator and spray off all surfaces in the lab with 1% Virkon or 1X Wexcide.
11. Make sure that all contaminated material is autoclaved, surface-disinfected or incinerated.
12. Inform others not to work in the lab until the air handling system is able to clear any residual organisms from the air (3h).
13. Return to the lab after 3 hours and perform another decontamination of all lab surfaces with 1% Virkon or 1X Wexcide.
14. Report accident to the Principal Investigator, who will report it to other officials.

Contents of spill kit located in BL-3 labs:

Full-face respirator, Tyvek suit, clean scrub suit, absorbent material, Purell skin disinfectant, towel, copy of decontamination procedures for spills.

INCIDENT RESPONSE PLAN

PI – CMP Director, *Thomas Ficht, and James Samuel*

Texas A&M University, College Station, TX 77843
to ensure compliance with
42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

- 1.1 General. This is the incident response plan for the possession and use of *Coxiella burnetti* and *Brucella spp* at Texas A&M University main campus (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121. This plan covers the use of these select agents when used in
- 1.2. This plan describes the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

- 2.1 Principal Investigator (PI). The Principal Investigator, Thomas Ficht and James Samuel, has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to Thomas Ficht and James Samuel. The PI is responsible for ensuring all incidents regarding theft, loss or release are immediately reported to the proper institutional officials. This document outlines response actions concerning any theft, loss, or release from select biological agents and toxins (SBAT) facilities, including illness of personnel or visitors in SBAT facilities. Certain actions outlined below are performed in parallel rather than sequentially (see attached flowchart).
- 2.2 All lab personnel (including the PI) are responsible for immediately reporting an incident to the University Police Department (UPD) for theft or loss or to the Institutional Biosafety Officer (BSO) for release (including occupational exposure).
- 2.3 UPD – Responsible for immediately contacting the Alternate Responsible Official (ARO) and beginning an investigation of the incident. A written investigation report will be submitted to the Institutional Biosafety Committee (IBC), the PI and the ARO within 5 days of the incident. UPD will also work with the PI to conduct a security assessment following any incident involving loss or theft.
- 2.3 BSO - Responsible for immediately contacting the Alternate Responsible Official and beginning an investigation of the incident. A written investigation report will be submitted to the IBC, the PI and the ARO within 5 days of the incident. The BSO will also work with the PI to conduct a safety assessment following any incident involving a release (including occupational exposure).
- 2.4 ARO - Responsible for immediately contacting the Responsible Official, CDC, NIH (if rDNA) and other key institutional contacts regarding the incident. The ARO will work with the BSO, UPD and the PI to insure that the written report is correct and that the report will be submitted to CDC, NIH (if rDNA) and other key institutional contacts.

- 2.5 Responsible Official – Is responsible for compliance to the Select Agent regulations and insuring requirements (registration, investigations, etc) are properly carried out.
- 2.6 Contact information is found on the Emergency contact list. The list is attached to this document and is posted throughout the lab.
- 2.7 Annual Program Review. The Responsible Official or Alternate Responsible Official will audit the incident response program on an annual basis. This review will include drills and exercises to ensure the effectiveness of the incident response plan. Based on the outcome of drills, exercises or reported incidents, this incident response plan will be reviewed and updated as necessary.

3. Description of Work

This plan covers all work being performed at TAMU. Each lab will be responsible for providing information specific to the work being performed as follows:

Lab	Work description	Unique features of Agent	Biosafety Level	Biological Use Authorization
	Animal Housing	BSC	3	
	Animal Housing	BSC	3	
	Challenge, Lab work	BSC, Aerosol Chamber	3	

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Additional information concerning the laboratories and the select agent use is contained in the facility's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or Environmental Health and Safety Office.

4. Response to theft:

- 4.1 Determination of Loss or Theft – The following are examples of events that may be considered a loss or theft. Possible loss or theft of the select agent will be reported initially to the Principal Investigator if any of the following have occurred: **AGENTS ARE NOT STORED IN BUILDING**
 - 4.1.1 The lock on the Select Agent storage area has been found open or appears to have been tampered with;
 - 4.1.2 Evidence of forced entry into the laboratory or storage areas has been found;
 - 4.1.3 A discrepancy in the Select Agent inventory that can not be reconciled;
 - 4.1.4 An employee reports cultures or samples missing;
 - 4.1.5 A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2;
 - 4.1.6 An infected animal is missing from its microisolator cage.

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4.2 Report/Investigation Process:

- Theft** (unauthorized removal) or **Loss** (failure to account for) a select agent or toxin
- 4.2.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected theft or loss of SBATS to UPD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345). Based on circumstances, UPD will notify EHSD.

If the release is discovered and UPD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the person shall then notify the LD/PI.

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After notification to UPD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact ORC.

- 4.2.1.1 Upon notification of discovery of a theft or loss, UPD will immediately notify ORC.
- 4.2.1.2 Upon notification from UPD, ORC will immediately notify the Responsible Official (RO) and Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, and UPD.
- 4.2.1.3 UPD (and ESHD, based on circumstances) will immediately investigate the incident. The investigation will include coordination with the LD/PI and others approved with access or visiting SBAT facilities. UPD will submit a written report to ORC within 5 days of being notified about the discovery of the theft or loss. If the investigation provides evidence that a theft or loss did not occur, circumstances will be documented in UPD's investigation report.
- 4.2.1.4 Based on the UPD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss or Release of Select Agents and Toxins) with CDC. ORC will maintain an official copy of information submitted to CDC and will provide a copy of the submission to the RO, UPD/EHSD, and LD/PI.
- 4.2.1.5 UPD will notify the appropriate Federal, State, or local law enforcement agencies.
- 4.2.1.6 The LD/PI will ensure notification to the funding agency
- 4.2.2 A risk assessment will be conducted immediately upon discovery of a loss or theft. The risk assessment will be a part of the investigation report.
 - 4.2.2.1 In addition to the investigation, upon notification of a theft or loss, UPD (with input from EHSD and the LD/PI) will conduct a risk assessment to determine if the laboratory is operating in a safe and secure manner and to attempt to determine the cause of the theft. This risk assessment shall include, but not be limited to a comprehensive laboratory survey, review of access logs, review of inventory records, and verification that all equipment is operating within normal parameters (e. g. biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of theft will also be reviewed and modified, as warranted. If deficiencies in safe and secure practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
- 4.1.2.2 If deemed necessary, the EHSD/UPD will contact Biosafety Program Coordinator to convene a special meeting of the Institutional BioSafety Committee (IBC).
- 4.1.2.3 Documentation of the risk assessment will be maintained by UPD with a copy sent to the LD/PI, EHSD and ORC.

- 4.1.2.4 Security Risk Assessments will be completed by UPD, with input from the LD/PI (and EHSD, based on circumstances). The results of the risk assessment and findings, including any requirements for post theft procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI, EHSD, and ORC.
- 4.1.2.5 The ORC will contact CDC, and if needed, a copy of the assessment will be submitted. ORC will also update the RO.
- 4.2.3 UPD will establish and maintain a specific file for each theft or loss incident, with all pertinent information.
- 4.2.4 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected loss or theft to UPD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

5. Investigation

- 5.1 The Investigation Committee for all releases will be headed by the EHSD's Institutional Biosafety Officer (BSO) with input from UPD and the PI. UPD will lead investigations involving theft or loss, with input from the BSO and PI.
 - 5.1.1 The BSO/UPD will investigate the event as quickly as possible, but no later than 24 hours of the initial report or the incident.
 - 5.1.2 The investigation should include a review of all materials related to the research, including access logs, inventory logs, laboratory notes and laboratory plans (security, safety and incident response)
 - 5.1.3 Once the investigation is complete, the BSO or UPD will submit an investigation report to the IBB and RO.
 - 5.1.4 Once the Committee has determined the response and informed the RO and IBC (through the Office of Research Compliance), the IBC will review the report and make a recommendation to the RO of any additional actions that they believe are needed.
 - 5.1.5 After the RO has approved of the recommended actions, the PI will receive a written response from the IBC.

6. Reporting

- 6.1 All incident reports are included in the IBC agenda minutes for review by the full board at the next convened meeting. Serious events should be specifically presented to the IBC by the BSO/UPD or IBC Chair at the next convened meeting.
 - 6.1.1 The investigation report, at a minimum, shall include the following information:
 - 6.1.1.1 A detailed description of the incident.
 - 6.1.1.2 A list of all personnel involved in the incident.
 - 6.1.1.3 A description of what occurred and what has or needs to be done to prevent any future incident.
 - 6.1.1.4 An assessment of the safety or security risk of continuing the research.
 - 6.1.1.5 A recommendation of any changes that need to be made to the plans (safety, security or incident response), medical surveillance or laboratory procedures to reduce the risk of a reoccurrence.
 - 6.1.1.6 A recommendation for training, if needed.
 - 6.1.2 Incidents involving SBAT will be immediately reported to the CDC with a written report (Form 3) submitted within seven (7) days.

6.1.3 Events involving rDNA must be reported to the NIH immediately in writing but no later than 30 days of the incident.

7. Release of a Select Agent or Toxin.

Examples of a possible release (including occupational exposures of the agent or toxin include but are not limited to the following:

- 7.1 A package containing the Select Agent or toxin that has been received which has been damaged in transit such that the primary containment vessel appears to have been compromised;
- 7.2 Simultaneous complete power failure of the Biosafety cabinet and negative pressure in the BSL-3 suite during work in the Biosafety cabinet with open cultures;
- 7.3 Simultaneous spill of cultures outside the Biosafety cabinet and failure of negative pressure in the Biosafety Level 3 suite. In case of a spill, a spill kit containing absorbent material and disinfectant will be located in a designated lab for each Principal Investigator;
 - 7.3.1 Personnel are advised to immediately leave the lab after removing any contaminated clothing and to return in Tyvek suits with Powered Air Purifying Respirator (PAPR) after the air has been scrubbed clean by air handlers (approx. one hour).
- 7.4 In case release of the Select Agent or toxin outside the BSL-3 laboratory is suspected, the Principal Investigator will notify the BSO laboratories on the first floor of the VRB, as well as the Responsible Official, and the building manager.
- 7.5 Exposure of laboratory personnel to cultures. The following incidents may result in unintentional exposure to the Select Agent that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to TAMU Occupational Health, where they will be given the option to initiate post-exposure prophylaxis. The exposure will be reported by the Principal Investigator to the BSO who reports immediately to the Responsible Official, who will notify CDC of the exposure. The following are examples of unintentional exposure:
 - 7.5.1 A spill of live culture outside the Biosafety cabinet;
 - 7.5.2 Failure of the Biosafety cabinet during work with a select agent;
 - 7.5.3 Needle stick or cut with sharps contaminated with a select agent;
 - 7.5.4 If a bite from a select agent--infected animal penetrates the double gloves and breaks the skin;
 - 7.5.5 A centrifuge accident that results in aerosolization of a select agent..

Deleted: full face respirators

Deleted: This doesn't pertain to CMP area

8. Process of reporting and investigating a Release:

Release – Occupational exposure (clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been release outside of the primary bio-containment barrier.) or release of an agent or toxin outside of the primary barriers of the biocontainment area.

- 8.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected release to the Environment Health and Safety Department (EHSD). Based on circumstances, EHSD will notify the University Police Department (UPD). During normal business hours, call EHSD at 845-2132. If it is

outside of normal business hours, call UPD who will notify EHSD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345).

If the release is discovered and EHSD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the individual shall then notify the LD/PI.

After notification to EHSD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact the Office of Research Compliance (ORC).

- 8.1.1 Upon notification of discovery of a release, EHSD will immediately notify Scott & White Occupational Health Clinic and ORC.
 - 8.1.2 Upon notification from EHSD, ORC will immediately notify the Responsible Official (RO) and the Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, EHSD, and UPD.
 - 8.1.3 EHSD (and UPD, based on circumstances) will immediately investigate the incident. The investigation will include the coordination with the LD/PI and others approved with access or visiting SBAT facilities. EHSD will submit a written report to ORC within 5 days of being notified about discovery of the release. If the investigation provides evidence that a release did not occur, circumstances will be documented in EHSD's investigation report.
 - 8.1.4 Based on the EHSD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss, or Release of Select Agents and Toxins) with the CDC within seven calendar days of the discovery of the release. ORC will maintain an official copy of information submitted to the CDC and will provide a copy of the submission to the RO, EHSD, and LD/PI.
 - 8.1.5 EHSD will obtain confirmation from health care providers that reports to other state or federal health agencies have been submitted. The LD/PI will ensure notification to the funding agency.
- 8.2 A risk assessment will be conducted immediately upon discovery regarding any release.
- 8.2.1 In addition to the investigation, upon notification of a release, EHSD (under the direction of the Biological Safety Officer (BSO)) will conduct a risk assessment to determine if the laboratory is operating in a safe manner and attempt to determine the cause or most likely route of the release. This risk assessment shall include but not be limited to a comprehensive laboratory survey, review of access logs to determine potential occupational exposures, review of inventory records, and verification that all equipment is operating within normal parameters (e.g., biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of the release will also be reviewed by EHSD and modified, as warranted, in consultation with the LD/PI. If deficiencies in safe practices are discovered, all work in the laboratory will cease until corrective actions have been taken.
 - 8.2.2 If deemed necessary based on the risk assessment, the BSO will contact ORC to convene a special meeting of the Institutional BioSafety Committee.
 - 8.2.3 Documentation of the risk assessment will be maintained by EHSD with a copy sent to the LD/PI and the ORC.

- 8.2.4 Risk assessments will be completed with input from the LD/PI. The results of the risk assessment and findings, including any requirements for post decontamination procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI and ORC.
- 8.2.5 ORC will contact CDC, and if needed, a copy of the risk assessment will be submitted. ORC will also update the RO.
- 8.3 The following additional steps will also be taken immediately upon discovery regarding an actual or suspected occupational exposure:
- 8.3.1 EHSD will direct the LD/PI to notify laboratory personnel and visitors that a potential exposure has occurred and refer them to Scott & White Occupational Health for consultation. EHSD will obtain access logs and other information to determine a complete list of potentially exposed personnel. EHSD will then follow-up with potentially exposed personnel to ensure notification.
- 8.3.2 Individuals will be encouraged to contact Occupational Health at Scott & White Clinic, or to immediately identify to medical personnel, the agent they were potentially exposed to if treatment is sought. Scott & White Occupational Health Clinic or the attending physician will screen for the organism (e. g. Brucella species), and begin prophylaxis as deemed appropriate by the attending physician.
- 8.3.3 If an occupational exposure is confirmed through appropriate medical tests or as determined by a physician, all personnel and potentially exposed individuals will be immediately referred to Scott & White for screening, testing, or preventive prophylaxis as determined by the attending physician. If personnel or visitors are at remote locations (other university facilities, traveling), they should immediately report to a physician of choice and explain that a positive occupational exposure to a specific organism has occurred and specific treatment or screening is desired. Personal physicians should be encouraged to contact either EHSD or Scott and White Occupational Health if they have any questions.
- 8.3.4 EHSD, in consultation with Scott & White, will perform periodic follow-up with the group of exposed or potentially exposed personnel for a period of time as appropriate for the organism.
- 8.4 EHSD will establish and maintain a specific file for each release incident, with all pertinent information.
- 8.5 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected release to EHSD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

9. Security Breach:

A security breach will be determined to have occurred if any of the following are observed:

- 9.1 The access control system has failed, leaving the BSL-3 suite accessible to unauthorized persons;
- 9.2 An unauthorized person is observed unaccompanied in the BSL-3 suite;
- 9.3 A lost or stolen card was used to access the BSL-3 suite;

- 9.4 An unauthorized person has accessed the computer used to control entry to the BSL-3 suite;
- 9.5 An unexpected or suspicious package arrives in the laboratory.

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the Responsible Official of the security breach and take steps to correct the problem. Corrective procedures will be secured immediately, but no later than 24 hours; an inventory will be performed of all samples and animals in the laboratory and in Select Agent storage. Any missing Select Agent samples or animals will be reported to CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator and the Responsible Official will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

10. Severe weather or natural disasters.

The most likely occurrences in this area are severe thunderstorms, floods or tornadoes.

- 10.1 If severe weather (thunderstorms or flooding) is predicted, experiments with Select Agents should be suspended until the severe weather has passed to avoid power outages during the work. All samples should be secured inside the locked -80°C freezer or the locked +4°C storage.
- 10.2 If an earthquake is felt, workers should immediately leave the suite-if possible, shedding gloves and lab coat on the way out of the BSL-3 suite. Cleanup, if necessary, can be performed once it is safe to re-enter the building.
- 10.3 Power to the BSL-3 suite may be affected if the emergency generator is flooded. In this case, all samples should be secured inside the -80°C freezer. If the vivarium is threatened by flooding, animal cages should be fastened shut, put into secondary containers (biohazard bag or large Tupperware) and transported to LARR (CMP) for secure holding until the threat of flooding has passed. If it becomes necessary to evacuate the College Station area, all animal experiments will be terminated before evacuation by euthanizing the animals and storing the carcasses in the secure select agent storage in room.
- 10.4 In case of a power outage, if there is no immediate danger to the building, secure all infectious samples inside a -80°C freezer, the +4°C refrigerator, or the incubators. The Biosafety cabinets and air handling system of the BSL-3 suite are on emergency backup power, which will prevent exposure to infectious samples in case of a power outage. Follow standard procedures for leaving the laboratory and return once the power has been restored to resume work.

11. Fire, Gas leak, Steam leak, Explosion, Bomb threat:

- 11.1 If work is being performed in the Biosafety cabinet, cap all samples, dispose of gloves and outer laboratory coat, and leave the laboratory immediately. If the fire is within the BSL 3 laboratory, and the worker feels (s)he can safely extinguish the fire, then the fire extinguisher located in the interior hall may be used. If a worker feels his or her safety threatened, (s)he should leave the laboratory immediately without stopping to decontaminate or secure any work, using the designated escape routes (through the emergency exit located on the west side of the BSL-3 suite and immediately out of the back dock doors located on the north side of the facility). Upon leaving the building, personnel should assemble outside the building in the assigned spot _____ and report to the Area Coordinator for attendance.

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Deleted: VRB

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Deleted: Lab Safety Officer

Deleted: July 20, 2007

- 11.2 Notify the appropriate emergency responders: Fire 9-911 or 911 from mobile phones, the Principal Investigator and the Biosafety Officer. For steam and gas leaks, notify TAMU Operations and Maintenance.
- 11.3 In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police immediately by calling the emergency number, 9-911 or 911. Also inform the Principal Investigator and Responsible Official. Always be sure to give the number and location of the building and your name and telephone extension number.
 - 11.3.1 The University Police Department will assign personnel to investigate the call and take whatever police action they may deem necessary and reasonable for the safety of the campus community. The University Police will conduct a search of the building, or of specific locations in or around the building. When judged prudent and feasible to do so, the search will be conducted with the assistance and cooperation of the Principal Investigator and/or Responsible Official. After an evaluation/assessment of the content of the bomb threat, the decision to evacuate or close building shall be made jointly, whenever possible, by the Police and the Principal Investigator and/or Responsible Official.
 - 11.3.2 Any unusual or suspicious object should be reported immediately to the University Police or to any immediate supervisor or administrative officer. Suspected objects or materials should NOT be touched or disturbed. Every bomb threat or incident of a suspected explosive device should be considered valid until all reasonable precautions for public safety have been taken or until the danger to life and property is terminated.

12. Failure of Select Agent Storage Freezer:

- 12.1 Select agents are not stored at building.

13. Workplace violence:

- 13.1 Incidents of disruptive or threatening behavior on the part of an employee, student or visitor should be reported immediately to the Principal Investigator, who will report the incident to the Department Head, the Responsible Official and the Workplace Violence Response Team, as proscribed by the TAMU Personnel and Procedures manual section 290-09. If the individual accused of disruptive or threatening behavior is authorized for access to select agents, this person's access will be suspended pending the results of an investigation by the Workplace Violence Response Team. If an act of violence or a physical assault has occurred, or the threatening activity occurs within the BSL-3 laboratory, the person feeling threatened should call the police immediately to report the incident. If the person accused of violence has access to select agents, the person's access will be suspended pending the outcome of the investigation. Suspension of select agent access will be reported to the Responsible Official and a suspended individual's access will be inactivated within 24 hours.

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14. Entry of emergency responders into the BSL-3 laboratory.

- 14.1 In a case in which a life-threatening injury or medical condition (i.e. heart attack) occurs inside the BSL-3 laboratory, emergency responders will be allowed to enter the laboratory. If possible, upon feeling ill the laboratory worker should immediately exit the suite to facilitate treatment by emergency responders. Personnel protective equipment, including Tyvek suits, N95 masks, HEPA-filtered respirators and gloves, are located inside the entries (locker rooms) to the BSL-3 suite. A spill kit containing absorbent materials and disinfectant is located under the bench in each of the labs. A First Aid kit is located inside the lab. If responders are required to enter an area where a spill has

occurred, they will be referred to Scott and White Clinic and offered post-exposure prophylaxis.

- 14.1.1 Entry procedure for the BSL-3 laboratory: Dress yourself in a Tyvek suit, gloves, shoe covers and respiratory protection (N95 mask) before entering the laboratories.
- 14.1.2 Providing first aid and emergency medical treatment in the BSL-3 laboratory: A person working inside the Biosafety hood is not considered to be contagious unless a spill has occurred. The person's gloves may be contaminated, and may be removed to facilitate treatment. If there is no space within the labs to put the person on the floor, move the person to the interior hallway to administer treatment.
- 14.1.3 Exit procedure from the BSL-3 laboratory: Emergency responders should remove Tyvek suit, mask, shoe covers and gloves before exiting and leave them behind in the BSL-3 laboratory. Hands should be washed immediately upon exit from the BSL-3 laboratory.
- 14.1.4 Decontamination procedures for medical equipment and clothing: Emergency responders should decontaminate equipment before leaving the laboratory by one of the following methods:
 - 14.1.4.1 Autoclaving. Autoclaves are located in the northwest corner of the VR facility in the wall between room 138 (inside the BSL-3 suite and the hallway outside the BSL-3 suite.
 - 14.1.4.2 Spraying surfaces with a Wexcide solution at 1 oz Wexcide to 1 gallon of water.

Deleted: within the BSL3 suite or on the 2nd floor of the VRB

Deleted: Wiping surfaces with 10% bleach followed by 1% Virkon-S

15. Incident Response Plan Testing (Drills)

- 15.1 Drills or tabletop exercises will be conducted annually to test the effectiveness of the Biosafety plan. The drills or exercises will be coordinated with the TAMU Police Department and will include, but not be limited to, the Principal Investigator or designee, BSO, TAMU Fire Department representative and the Campus Emergency Planner.
- 15.2 The drill or exercise will include, but not be limited to, accessibility to restricted space, attempted or unauthorized entry into restricted spaces challenge, animal room security, staff knowledge of hazard/emergency protocols for their work location(s) and other situations that are deemed appropriate for each work location.
- 15.3 Following the drill or exercise, which will test the various components of the incident response plan for completeness, those involved will critique their findings for each drill/exercise location. The Principal Investigator working with the Responsible Official and Biosafety Officer will implement changes as necessary changes to the plan. Results of the drill or exercise will be reviewed by the Biological Safety Administrative Advisory Committee (Institutional Biosafety Committee).

16. Texas A&M University Crisis Management Plan

- 16.1 The entity crisis management plan is contained in a separate document and is referenced in the individual laboratory emergency response plan.
- 16.2 Additional information concerning the laboratory emergency response plan is contained in the laboratory's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or the Environmental Health & Safety Department.

- 16.3 The Responsible Official and Biosafety Officer should be contacted immediately in the case of any emergency in a select agent lab. The Responsible Official will coordinate access and information issues with campus police, fire, and emergency responders.
- 16.4 If necessary, the Responsible Official will coordinate the emergency relocation of select agents to another secure location.

17. Site security and control are described in detail in the Select Agent Security Plan

- 17.1 The buildings are secured by a keyed lock. Sharing of keys with other personnel is not permitted.
- 17.2 Individuals not authorized for access to Select Agents must be accompanied by approved personnel at all times while in the buildings.
- 17.3 Data that could enable access to select agents by unauthorized personnel should be located on password-protected computers.
- 17.4 If approved personnel are observed violating security or Biosafety procedures, this observation should be reported immediately to the Principal Investigator. The Principal investigator will investigate the allegation and determine whether the violator should have his/her Select Agent access suspended or revoked. Suspension of Select Agent access will be reported to the Responsible Official and the individual's key card access will be terminated within 24 hours.

18. Inventory Discrepancies:

- 18.1 Inventory discrepancies will be documented on the agent access form.
- 18.2 All discrepancies will be immediately reported to the Principal Investigator.
- 18.3 If the discrepancy is believed to be a result of loss or theft, the incident response procedures for loss or theft and release will be followed.
- 18.4 If the discrepancy is a result of a transfer, the transfer form will be documented.

19. References

- 19.1 42 CFR Part 73
- 19.2 7 CFR Part 331
- 19.3 9 CFR Part 121
- 19.4 Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention, National Institutes of Health, Fourth Edition, May 1999
- 19.5 Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents (Revised BMBL, Appendix F), published in Morbidity and Mortality Weekly Report, December 6, 2002.

SBAT Incident Response
Emergency Contact Numbers

PI Information			
PI Thomas Ficht Office – (979) 845-4118		PI James Samuel Office – (979) 862-1684	
<p align="center">Building Manager Dave Carlton Work: (979) 845-3091 Cell: (979) 777-0285</p>			
<p align="center">Department Head CMP Director Office - (979) 845-7433</p>			
<p align="center">Incidents involving Theft or Loss University Police Department (UPD) contact</p> <p align="center">Bert Kretzschmar Office – 979 845-8900</p>			
<p align="center">Incidents involving a Release (or Occupational Exposure) Environmental Health and Safety Office contact</p> <p align="center">Between 8:00 a.m. and 5:00 p.m. Brent Mattox, Biosafety Officer (BSO) Alternate Responsible Official (ARO)</p> <p align="center">After hours 5:00 pm Contact the University Police Department contact Lt. Bert Kretzschmar Office – 979 845-8900</p>			
Other Contact information			
Vice President for Research/Responsible Official (RO)	Richard Ewing (RO)	979 845-8585 (Office)	(Mobile)
	Fuller Bazer (ARO)	979 693-2876 (Office)	(Mobile)
	Angelia Raines (ARO)	979 847-9362 (Office)	(Mobile)
Comparative Medicine Program	Melanie Ihrig	979 845-7433 (Office)	(Mobile)
	Elizabeth Browder	979 845-7433 (Office)	(Mobile)
	Frank Stein	979 845-6488 (Office)	(Mobile)
Institutional Biosafety Committee (IBC)	Thomas Ficht	979 845-4118 (Office)	(Mobile)
	Vernon Tesh	979 862-4113 (Office)	(Mobile)
	Tiffany Agnew	979 458-3624 (Office)	(Mobile)
Other Emergency Numbers	College Station Police	979 764-3600 or 9-911	
	Medical Emergency	9-911	
	College Station Fire	979 764-3700 or 9-911	
	Radiological Emergency	979 832-1111	
	University Maintenance	979 845-4311	

Decontamination Procedures for Spills of Cultures
(Please customize for specific laboratories.)

1. Signal others in the BL3 labs of any spill outside the biological safety cabinet. All personnel should change out of contaminated clothing and wash any exposed skin with a disinfectant, such as Purell. Clothes must be removed within the BL3 area and will be autoclaved by those cleaning up.
2. Put on a clean scrub suit and go to the shower on the first floor animal facility. Shower thoroughly with soap.
3. Return to the lab for cleanup: Put on a full face respirator and tyvek suit (contained in the SPILL KIT). Put on double gloves and shoe covers.
4. Use paper towels to cover the spill. Prevent creation of contaminated aerosols.
5. Saturate all materials with 10% bleach solution (see previous section for description).
6. Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in autoclave bags.
7. Disinfect all exposed surfaces using 1X Wexcide or 1% Virkon (surface disinfectant solution).
8. Wipe surface of full-face respirator with 1% Virkon or 1X Wexcide, being careful to avoid skin contact with Wexcide.
9. Remove all clothing and place in autoclave bag.
10. Remove full face respirator and spray off all surfaces in the lab with 1% Virkon or 1X Wexcide.
11. Make sure that all contaminated material is autoclaved, surface-disinfected or incinerated.
12. Inform others not to work in the lab until the air handling system is able to clear any residual organisms from the air (3h).
13. Return to the lab after 3 hours and perform another decontamination of all lab surfaces with 1% Virkon or 1X Wexcide.
14. Report accident to the Principal Investigator, who will report it to other officials.

Contents of spill kit located in BL-3 labs:

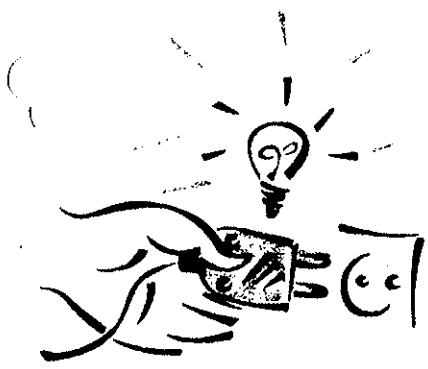
Full-face respirator, Tyvek suit, clean scrub suit, absorbent material, Purell skin disinfectant, towel, copy of decontamination procedures for spills.

Regulations:		- CMP		- Ficht		- Ficht		- Samuel	
General: Describe response procedures for: theft, loss, or release of SBAT; inventory discrepancies, security breaches (including cis); natural disasters, workplace violence, bomb threat, sus. Packages, physical plant emergencies.	Comments: Plan covers all buildings CMP personnel go to - uses "type of incident" format and then covers each bldg. Does not address some items on checklist.				These buildings should have a separate incident response plan due to the unique nature and location				
R.O. Alt. R.O, BSO, etc contact info	Not identified	OK (pg 1)					OK (pg 1)		
Bldg owner/mgr contact info									
tenant offices info	Not identified	Not identified							not identified
Physical Security official contact info	needs improvement	OK (pg 1)							
Personnel Roles, lines of auth and communication	Good	weak							weak
Coor. With local emerg. Responders	not addressed	OK (pg 5,6)							OK (pg 6)
Procedures for employees performing rescue or medical duties	needs improvement	no mention of first aid kit inside (pg 5,6)							OK (pg 6)
Emerg. Med. Tmt & 1st aid	not identified	OK							OK (pg 6)
List PPE & emer equip & locations	includes statements regarding reentry - good	Mentions general security - what about incident-specific security							Mentions general security - what about incident-specific security
Site security and Control	Identifies evacuation gathering points	Where do personnel go, how to exit?							Where do personnel go, how to exit?
Emerg. Evac. Procedures - routes, distances, place of refuge	Identifies evacuation gathering points	Where do personnel go, how to exit?							
Decontamination Proc	none found	OK							OK

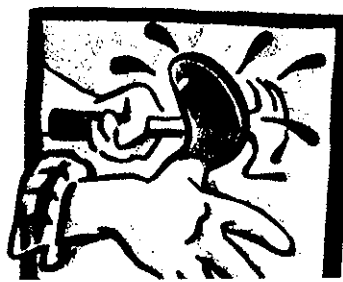
Review and Revision - annually and after drills and incidents	none mentioned	Annual mentioned, clarify that also occurs post-drills and incidents		Annual mentioned, clarify that also occurs post-drills and incidents

CMP

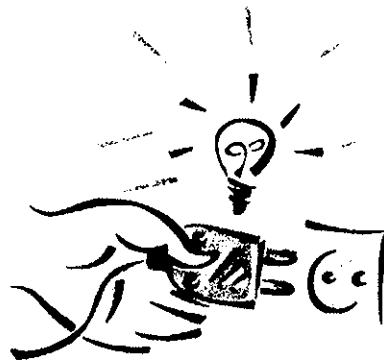
EMERGENCY RESPONSE PLAN



CMP Emergency Response Plan



POWER OUTAGES



Contact Numbers:

Dave Carlton, Facilities Coordinator
Cell 777-0258 Home

John Park, Program Manager
Cell 777-7013 Home

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

1. In the event of a power outage, the Physical Plant Radio Room is notified through the Hawkeye system and has been instructed to notify CMP personnel. If you are called, you must respond to the radio room call & remain at the facility until the problem has been resolved.

The duty supervisor should keep a written log of all events: recording times communications, contacts, time of resolution and determined problem.

2. The emergency power generator will engage within seconds after the power outage and will sustain:
 - lights
 - security system
 - air handlers
 - select power plugs in the Biohazard & Surgery area.

Fuel & function of the generator is the responsibility of Physical Plant.

3. Communication with the Radio Room during the outage is essential (845-4311). They should be able to find out how serious the problem is and give an approximate time that the power will be off.

For all outages, contact the CMP Facilities Coordinator (777-0258) or their representative (218- 8598) to inform him/her of the problem.

5. CMP personnel should check:
 - All ventilated housing racks/blowers. In the event of an extended power outage, emergency power outlets are located in the O.R. Training Room.
 - All animal rooms to make sure the emergency backup lights and air handlers have engaged.
 - Room temperatures to insure a temperature problem does not develop.

 6. Once power is restored:
 - CMP personnel should check the alarm panels and reset if necessary.
 - Physical plant personnel and/or CMP building maintenance personnel should check the building ventilation/air conditioning systems (including chilled & hot water pumps) and animal room light timers to ensure proper operation.
 - Employee time clocks must be reset.
- NOTE: If you do not know how to reset the time clock and cannot reach someone that does, employees should be instructed to sign in and sign out until a reset can be performed.**
7. Check all other animal care facilities to determine if power problems are widespread or limited to Main.

SUPPORT

Contact Numbers:

Dave Carlton, Facilities Coordinator
Cell 777-0258 Home

John Park, Program Manager
Cell 777-7013 Home

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

1. Power outages at the support facility are not monitored. If the power goes out at MAIN, you must also check Support.
 2. For all outages, contact David Carlton or his designate to inform him/her of the problem.
 3. Contact the Radio Room and inform them of the problem (845-4311). Follow procedures described under LARR MAIN.
- Flash lights are located on the grey metal bookshelf in the Support supervisor's office (Bldg. 1198). A florescent lantern is located in the LARR-Support clinic room.
5. The primary concern with power outages is temperature regulation:

SUMMER - Primary concern is Bldgs 6, B, and clinic where animals are housed in enclosed HVAC equipped facilities.

WINTER - concerns should be with the building heaters. There is no alternative light or heat source for any buildings at LARR Support. Each bldg's temperature should be monitored to make sure temperatures do not get too cold. If the power is out for an extended period of time, and the temperature is falling to 50 degrees or below, fleece pads and towels will need to be provided for all animals that lie directly on the cold concrete (i.e. any dog that is too small to jump up in the resting board).

C

Contact Numbers:

George Martin, Facilities Coordinator
Cell 228-3380 Home

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

In the event of a power outage the Radio Room should contact George Martin and CMP personnel. COM personnel are responsible for responding and following up with Physical Plant personnel, if needed. CMP is notified as an FYI. COM personnel may contact CMP personnel if assistance is needed. If the Radio room is unable to contact George Martin or his designate, CMP personnel must respond.

2. The lights and the air handlers will all run off the emergency generators (fuel & function of these generators are the responsibility of the Physical Plant).
3. Each room must be checked to make sure that the lights and air are working appropriately.
4. Contact the Radio Room and make sure they are aware of the problem (845-4311).
5. Remain in close contact with Physical Plant and the repair personnel until the situation is resolved.
6. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty veterinarian.
7. Check all other animal care facilities to determine if power problems are widespread.

Contact Numbers:

Dr. Steve Rholes, Dept Head

Home ----- 5 Office 845-2500

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

1. In the event of a power outage, the Radio room should notify Dr. Rholes and CMP personnel.
2. CMP personnel should contact Dr. Rholes to ensure he is aware of the problem and that notification to the PI has taken place, if needed.
3. If they cannot be reached, there is a list of names for each investigator by the phone in the Psychology facility. Proceed to call the investigator or a technician from each lab to notify them of the situation. In the event that you are not able to reach someone with any of the labs, proceed on to the next lab personnel.
4. The lights and some of the plugs are the only things hooked up to the emergency generators.
NOTE: The air handlers are NOT functional during power outages.
5. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty veterinarian.
6. Check all other animal care facilities to determine if power problems are widespread.

Contact Numbers:

Noberto Espitia, Building Proctor
Cell 255-7746 Home

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

1. In the event of a power outage the Radio Room should contact Noberto Espitia and CMP personnel. CVM personnel are responsible for responding and following up with Physical Plant personnel, if needed. CMP is notified as an FYI. CVM personnel may contact CMP personnel if assistance is needed. If the Radio room is unable to contact Noberto Espitia or his designate, CMP personnel must respond.

2. The lights & air handlers are all run off the emergency generators (fuel and function of these generators are the responsibility of the Physical Plant).
3. Each room must be checked to make sure that the lights and air are working appropriately.
4. Contact the Radio Room and make sure they are aware of the problem (845-4311).
5. Remain in close contact with Physical plant and the repair personnel until situation is resolved.
6. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty veterinarian.
7. Check all other animal care facilities to determine if power problems are widespread.

VTPP VIV III BLDG #1020

Contact Numbers:

Judy Walters, Building Proctor
Home Office 845-5997

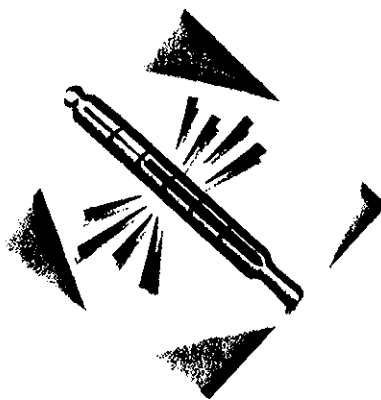
CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

1. In the event of a power outage the Radio Room should contact Judy Walters and CMP personnel. VTPP personnel are responsible for responding and following up with Physical Plant personnel, if needed. CMP is notified as an FYI. CVM personnel may contact CMP personnel if assistance is needed. If the Radio room is unable to contact Judy Walters or her designate, CMP personnel must respond.
2. This building does not have emergency power. During a power outage, each room must be monitored to assure temperatures remain within the appropriate range for each species.
3. Contact the Radio Room and make sure they are aware of the problem (845-4311).
4. Remain in close contact with Physical plant and the repair personnel until situation is resolved.
5. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty veterinarian.
6. Check all other animal care facilities to determine if power problems are widespread.

TEMPERATURE PROBLEMS



Contact Numbers:

Dave Carlton, Facilities Coordinator
Cell 777-0258 Home

John Park, Program Manager
Cell 777-7013 Home

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

This facility has both high-low temp alarms (ABSL3 and 200 area) and high temp alarms only (100 area).

1. If an alarm is activated, the temperature alarm panel will beep and the room(s) involved will light up on the panel. The panel is located on the back wall of the AIN supervisor office.
PLEASE NOTE: The panel will not function again until it has been reset. Therefore when the alarm has signaled, you must respond, resolve the problem & reset the temperature alarm panel.
2. The Radio room is automatically notified (Hawkeye) after hours and on weekends /holidays. The Radio room will then contact CMP personnel.
3. Check the thermometer readings in all room(s) that have been identified by the control panel. Ensure the thermostat is working properly.
4. If the temperature is too high (>85) in the room, the animal room doors may be propped open until the problem is corrected (even cubicles). If the temperature is too low, space heaters (located in the tool room) should be put in the critical rooms until the problem is corrected.
5. Contact Dave Carlton or his designate and inform him/her of the problem.

6. Contact the Radio Room and request a repair technician, if needed (845-4311).

The on-call supervisor or other responsible CMP personnel must remain at the facility until each room(s) has reached normal temperatures. Once normal temps have been achieved:

- Push the Reset button on the panel.
- Close any animal room doors that had been opened due to high temps.
- Turn off any supplemental heat sources.

Contact Numbers:

Dave Carlton, Facilities Coordinator
Cell 777-0258 Home

John Park, Program Manager
Cell 777-7013 Home

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

Bldgs 6, B, and Clinic are the ONLY facilities with temperature alarms at Support.

1. If a temperature alarm occurs, CMP personnel will be notified by the Radio Room. The alarm notification sent to the Radio Room should indicate which building is in alarm.
2. Respond to the building in alarm to assess the temperature conditions.
3. If a temperature problem is identified, contact Dave Carlton or his designate and inform him/her of the problem.
4. Contact the Radio Room and request a repair technician, if needed (845-4311).
5. The on-call supervisor or other responsible CMP personnel must remain at the facility until each room(s) has reached normal temperatures.
6. The ambient temperature must not fall below 45°F or rise above 85°F for more than four consecutive hours when dogs or cats are present.
7. With temperature extremes, additional heating or cooling sources may be needed to maintain temps in a building. The duty supervisor can place a space heater or box fan in the building(s). Heaters, fans, & extension cords are located in the south toolshed. Fans/heaters should be placed in an area where they will not get wet (on a cart) and the cords positioned so the animals can not reach them.

8. When building temps drop below 50°F fleece pads & towels (support laundry) must be placed with animals that lie directly on the concrete (i.e. any dog that is too small to jump up in the resting board, or animals that do not have resting boards).
9. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty vet.

COLLEGE OF MEDICINE REYNOLD'S BLDG #1504

Contact Numbers:

George Martin, Facilities Coordinator
Cell 228-3380 Home ...

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

This facility is equipped with high-low temp alarms.

1. In the event of a temp alarm, an automatic phone dialing system will attempt to contact George Martin or his designate. If the event that COM personnel fail to respond, the dialing system will attempt to contact the CMP On-Call Supervisor.
 2. Once an alarm notification has been received, you can remotely identify the room/area in alarm and determine what the current temperature is by calling 862-7399. Once the system answers:
 - Press "0" when the system answers your call.
 - Once prompted, enter "10" (pass-number) followed by the "#" key.
 - Listen to the entire message and then press "1" followed by the "#" key.
 - To check room temps, enter each room's probe no. (list below) followed by the # key.
- NOTE: You can only check one probe at a time. To check additional probes, repeat instruction above.

- 49
- 50
- 51
- 52
- 53
54
55
56
57
58
59
- 60

- 61
- 62
- 63

NOTE: *Be patient and listen to each entire message. Enter all numbers firmly.*

3. Once the room in alarm has been identified:
 - Call the Radio Room and request a technician to respond (845-4311).
 - Give the Radio Room operator the building name/number, room number(s) involved.
4. You will need to stay in close contact with the repair technician until the situation has been resolved and the temperature(s) has been stabilized.
5. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty vet.

Contact Numbers:

Dr. Steve Rholes, Dept Head
Home ; Office 845-2500

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

This facility is equipped with high-low temp alarms.

1. If a temperature alarm occurs, CMP personnel will be notified by the Radio Room.
 2. Each room must be checked to find the problem (there is not a alarm panel that shows which room is in alarm). *More than one room may be involved.*
 3. Once the room in alarm has been identified:
 - Call the Radio Room and request a technician to respond (845-4311).
 - Give the Radio Room operator the building name/number, room number(s) involved.
 4. You will need to stay in close contact with the repair technician until the situation has been resolved and the temperature(s) has been stabilized.
 5. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty vet.
-

Contact Numbers:

Noberto Espitia, Building Proctor
Cell 255-7746 Home

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

There are no temperature alarms at this facility.

1. Once a temperature problem has been identified:
 - Call the Radio Room and request a technician to respond (845-4311).
 - Give the Radio Room operator the building name/number, room number(s) involved.
2. You will need to stay in close contact with the repair technician until the situation has been resolved and the temperature(s) has been stabilized.
3. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty vet.

Contact Numbers:

Judy Walters, Building Proctor
Home 693-3680 Office 845-5997

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

This facility is equipped with high-low temp alarms.

If a temperature alarm occurs, the Radio Room should contact Judy Walters or her designate. In the event that VTPP personnel fail to respond, the Radio Room should contact the CMP On-Call Supervisor.

2. Each room must be checked to find the problem (there is not a alarm panel that shows which room is in alarm). *More than one room may be involved.*

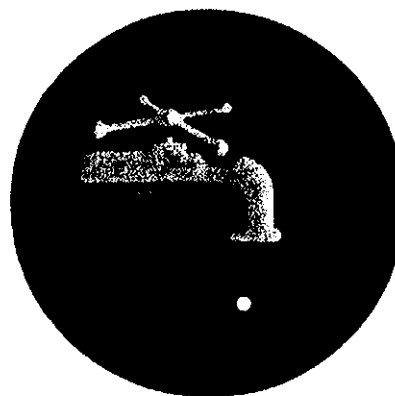
Once the room in alarm has been identified:

- Call the Radio Room and request a technician to respond (845-4311).
- Give the Radio Room operator the building name/number, room number(s) involved.

4. You will need to stay in close contact with the repair technician until the situation has been resolved and the temperature(s) has been stabilized.

5. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty vet.

WATER PROBLEMS



Contact Numbers:

Dave Carlton, Facilities Coordinator
Cell 777-0258 Home

John Park, Program Manager
Cell 777-7013 Home

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

1. Contact David Carlton or his designate.
2. A CMP employee should be designated to oversee the problem. This person must remain at the facility and in close contact with the repair personnel until the water problem is resolved.
3. The CMP On-Call Supervisor is responsible for ensuring all animals have access to water.
4. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty vet.
NOTE: There are no automated watering systems in use.

----- SUPPORT

Contact Numbers:

Dave Carlton, Facilities Coordinator

John Park, Program Manager

On-Call Supervisor

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

1. Contact David Carlton or his designate.
2. A CMP employee should be designated to oversee the problem. This person must remain at the facility and in close contact with the repair personnel until the water problem is resolved.
3. The CMP On-Call Supervisor is responsible for ensuring all animals have access to water. If water is off for longer than 4 hours you must provide all animals with water and make sure each animal receives a water bowl/bottle filled with fresh, clean water. For dogs on automated watering, provide water in bowls. All rabbits should be placed on water bottles.
4. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty vet.

NOTE: If the water has still not come on 12 hours after animals have been watered you must give fresh water to all animals that need it. After that you must continue to monitor the situation until the water has been turned back on.

Contact Numbers:

George Martin, Facilities Coordinator
Cell 228-3380 Home

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

1. Contact George Martin or his designate.
2. The CMP On-Call Supervisor is responsible for ensuring all animals have access to water.
3. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty vet.
NOTE: There are no automated watering systems in use.

Contact Numbers:

Dr. Steve Rholes, Dept Head
Home Office 845-2500

CMP On-Call Supervisor
Cell

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

1. Contact Dr. Rholes or his designate.
2. A CMP employee should be designated to oversee the problem. This person must remain at the facility and in close contact with the repair personnel until the water problem is resolved.
3. The CMP On-Call Supervisor is responsible for ensuring all animals have access to water.

If the problem presents an animal health related issue, (or you need assistance) contact the on-duty vet.
NOTE: There are no automated watering systems in use.

C

Contact Numbers:

Noberto Espitia, Building Proctor
Cell 255-7746 Home

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

1. Contact Noberto Espitia or his designate.
2. The CMP On-Call Supervisor is responsible for ensuring all animals have access to water.
3. If the problem presents an animal health related issue, (or you need assistance) contact the on-duty vet.
NOTE: There are no automated watering systems in use.

Contact Numbers:

Judy Walters, Building Proctor
Home Office 845-5997

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

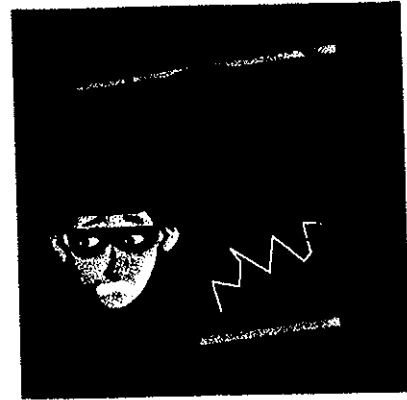
Physical Plant Radio Room
24hr 845-4311

1. Contact Judy Walters or her designate.
2. The CMP On-Call Supervisor is responsible for ensuring all animals have access to water. If water is off for longer than 4 hours you must provide all animals with water and make sure each animal receives a water bowl/bottle filled with fresh, clean water. For dogs on automated watering, provide water in bowls. All rabbits should be placed on water bottles.

If the problem presents an animal health related issue, (or you need assistance) contact the on-duty vet.

NOTE: If the water has still not come on 12 hours after animals have been watered you must give fresh water to all animals that need it. After that you must continue to monitor the situation until the water has been turned back on.

INTRUDER/SECURITY ALARM



Contact Numbers:

**University Police Department (UPD)
Emergency 9-911 Non-Emergency 845-2345**

**Dave Carlton, Facilities Coordinator
Cell 777-0258 Home**

**John Park, Program Manager
Cell 777-7013 Home**

**On-Call Supervisor
Cell 777-7014**

**On-Call Veterinarian
24hr 845-7433**

**Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home**

**Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home**

INTRUDER ALARM

1. The security system is controlled through a computer that locks & unlocks doors automatically. When doors are locked, the security alarm is engaged.
2. Locked doors that are forced opened will trigger the alarm immediately, unless they are equipped with a card scanner. These doors will trigger the alarm if held open for more than >15 seconds.
3. A door can be unlocked and the alarm disengaged by double scanning (swiping) with an authorized ID card.
4. The alarm is NOT audible and will automatically notify the Radio Room and UPD when it is activated.

5. The Facility Coordinator (On-Call Supervisor on weekends and holidays) will be contacted by UPD if the intruder alarm has been triggered.

The Facility Coordinator or On-Call Supervisor must respond to the call and meet the UPD officer at LARR MAIN to complete a security check of the facility.

FACILITY BREAK-INS

1. **DO NOT** enter the building any further than you already have. **DO NOT** touch anything located inside or outside of the building.
2. Use a cellular phone or go to another facility to use a telephone.
3. Call UPD (9-911 from campus; 911 from off-campus).
4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.

(C)

Contact Numbers:

University Police Department (UPD)
Emergency 9-911 Non-Emergency 845-2345

Dave Carlton, Facilities Coordinator
Cell 777-0258 Home

John Park, Program Manager
Cell 777-7013 Home

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home 777-0074

Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home 777-0000

INTRUDER ALARMS

There are no intruder alarms located in any building at the Support facility.

FACILITY BREAK-INS

1. If you have concerns that someone may still be in the area, leave the Support area immediately.

DO NOT enter any Support building further than you already have. DO NOT touch anything located inside or outside of the buildings.

3. Use your cellular phone or go to another facility to use a telephone.
4. Call UPD (9-911 from campus; 911 from off-campus)
5. Have UPD meet you at LARR Main and then follow them back to Support to complete a security check of the area (they will need your keys to access the buildings).
6. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.

Contact Numbers:

University Police Department (UPD)
Emergency 9-911 Non-Emergency 845-2345

George Martin, Facilities Coordinator
Cell 228-3380 Home

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home

Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home

INTRUDER ALARMS

The intruder alarm at the College of Medicine is not an audible alarm and CMP will **NOT** be notified.

FACILITY BREAK-INS

1. DO NOT enter the building any further than you already have. DO NOT touch anything located inside or outside of the building.
2. Use a cellular phone or go to another facility to use a telephone.

3. Call UPD (9-911 from campus; 911 from off-campus).
4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.
5. Call George Martin.

Contact Numbers:

University Police Department (UPD)
Emergency 9-911 Non-Emergency 845-2345

Dr. Steve Rholes, Dept Head
Home Office 845-2500

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home

Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home

INTRUDER ALARMS

There are no intruder alarms at the Psychology building.

FACILITY BREAK-INS

1. DO NOT enter the building any further than you already have. DO NOT touch anything located inside or outside of the building.
2. Use a cellular phone or go to another facility to use a telephone.
3. Call UPD (9-911 from campus; 911 from off-campus).
4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.

5. Call Dr. Rholes.

Contact Numbers:

University Police Department (UPD)
Emergency 9-911 Non-Emergency 845-2345

Noberto Espitia, Building Proctor
Cell 255-7746 Home :

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home

Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home

INTRUDER ALARM

The intruder alarm at the Vet Research Tower is an audible alarm. CMP will **NOT** be notified. In the event you discover an intruder alarm, notify Noberto Espitia. All follow up information will be obtained through Noberto.

FACILITY BREAK-INS

1. **DO NOT** enter the building any further than you already have. **DO NOT** touch anything located inside or outside of the building.
2. Use a cellular phone or go to another facility to use a telephone.
3. Call UPD (9-911 from campus; 911 from off-campus).
4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.
5. Call Noberto Espitia.

Contact Numbers:

University Police Department (UPD)
Emergency 9-911 Non-Emergency 845-2345

Judy Walters, Building Proctor
Home 693-3680 Office 845-5997

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Physical Plant Radio Room
24hr 845-4311

Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home

Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home

INTRUDER ALARMS

There are no intruder alarms at Viv III.

FACILITY BREAK-INS

1. **DO NOT** enter the building any further than you already have. **DO NOT** touch anything located inside or outside of the building.
2. Use a cellular phone or go to another facility to use a telephone.
3. Call UPD (9-911 from campus; 911 from off-campus).
4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.
5. Call Judy Walters.

FIRE ALARMS/FIRES



Contact Numbers:

College Station Fire Department
Emergency 9-911 Non-Emergency 764-3700

Physical Plant Radio Room (Non-Emergency)
24hr 845-4311

Dave Carlton, Facilities Coordinator
Cell 777-0258 Home 764-3700

John Park, Program Manager
Cell 777-7013 Home 764-3700

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home 764-3700

Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home 764-3700

1. The fire alarm panel is located in the men's ABSL3 entryway. There are six zones labeled on the panel and a schematic of the building labeled with corresponding zones highlighted. All Supervisors are to meet in Main Supervisor's office or front desk if a fire exists in the area of the supervisor's office. All other personnel must EXIT the building immediately and congregate in the vet school parking lot. Weekend/Holiday crews will meet at the supervisor's office and consult the supervisor in charge for instructions.
2. The first supervisor to the office will silence (push silence button) the audible alarm at the fire panel. Allow the alarm to sound for at least 30 seconds before silencing.

3. Use the intercom (overhead page code 89) to announce the fire alarm and request evacuation of the building.

Retrieve the "____ FIRE ALARM SOP" binder located on the shelf of the supervisor's office or on the receptionist desk. One supervisor or designated person should remain at the office to coordinate assignments.

5. If a fire exists:

Small fires: Working in pairs, attempt to contain with an extinguisher. If fire cannot be contained, exit area immediately. Close all doors while exiting the facility.

Large fires: Close all doors in immediate area of building and exit building immediately.

4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.
5. If the fire presents an animal health related issue, (or you need assistance) contact the on-duty veterinarian.
4. Re-entry to the building is at the discretion of the Fire Dept and/or the Director of CMP.

Contact Numbers:

College Station Fire Department
Emergency 9-911 Non-Emergency 764-3700

Physical Plant Radio Room (Non-Emergency)
24hr 845-4311

Dave Carlton, Facilities Coordinator
Cell 777-0258 Home 777-5000

John Park, Program Manager
Cell 777-7013 Home 777-5000

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home 777-5000

Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home 777-5000

There are no fire alarms located in any of the buildings at Support

If a fire occurs while you are in the area:

- Evacuate personnel
- CALL 9-911

2. There are three extinguishers in the Support area:
 - In the hallway of the office building
 - In the hallway of the clinic building.
 - In the South Toolshed
3. Small fires: Working in pairs, attempt to contain with an extinguisher.
If fire cannot be contained, exit area immediately. Close all doors while exiting the facility.
Large fires: Close all doors in immediate area of building and exit building immediately.
4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.
5. If the fire presents an animal health related issue, (or you need assistance) contact the on-duty veterinarian.
4. Re-entry to the building is at the discretion of the Fire Dept and/or the Director of CMP.

Contact Numbers:

**College Station Fire Department
Emergency 9-911 Non-Emergency 764-3700**

**Physical Plant Radio Room (Non-Emergency)
24hr 845-4311**

**George Martin, Facilities Coordinator
Cell 228-3380 Home**

**CMP On-Call Supervisor
Cell 777-7014**

**On-Call Veterinarian
24hr 845-7433**

**Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home**

**Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home**

1. If a fire alarm occurs exit the building by the closest exit. Upper floors use stairwells ONLY.

CMP personnel should meet at the end bldg entrance to the Wehner Bldg (end adjacent to the COM dock) until all are accounted for.

3. If a fire exists:

Small fires: If a small fire occurs, use the fire extinguishers and hoses found at various locations throughout the hallways to extinguish the fire. If fire cannot be contained, exit area immediately. Close all doors while exiting the facility.

Large fires: Pull any fire alarm located in the hallways (usually near the service elevator stairwell). Close all doors in immediate area of building and exit building immediately. Upper floors use stairwells ONLY.

4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.

5. If the fire presents an animal health related issue, (or you need assistance) contact the on-duty veterinarian.

6. Re-entry to the building is at the discretion of the Fire Dept. and/or the COM Building Proctor.

Contact Numbers:

**College Station Fire Department
Emergency 9-911 Non-Emergency 764-3700**

**Physical Plant Radio Room (Non-Emergency)
24hr 845-4311**

**Dr. Steve Rholes, Dept Head
Home 775-3215 Office 845-2500**

**CMP On-Call Supervisor
Cell 777-7014**

**On-Call Veterinarian
24hr 845-7433**

**Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home**

**Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home**

1. If a fire alarm occurs exit the building by the closest exit.

2. CMP personnel should meet at across the street from the loading area at the entrance to the Military Sciences Bldg. until all are accounted for.

If a fire exists:

Small fires: If a small fire occurs, use the fire extinguishers and hoses found at various locations throughout the hallways to extinguish the fire. If fire cannot be contained, exit area immediately. Close all doors while exiting the facility.

Large fires: Pull any fire alarm located in the hallways. Close all doors in immediate area of building and exit building immediately.

4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.
5. If the fire presents an animal health related issue, (or you need assistance) contact the on-duty veterinarian.
6. Re-entry to the building is at the discretion of the Fire Dept. and/or the Psych Building Proctor.

Contact Numbers:

College Station Fire Department
Emergency 9-911 Non-Emergency 764-3700

Physical Plant Radio Room (Non-Emergency)
24hr 845-4311

Noberto Espitia, Building Proctor
Cell 255-7746 Home

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home

Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home

1. If a fire alarm occurs exit the building by the closest exit. Upper floors use stairwells ONLY.
2. CMP personnel should meet at the parking area located directly across from the service vehicle parking area until all are accounted for.
3. If a fire exists:

Small fires: If a small fire occurs, use the fire extinguishers and hoses found at various locations throughout the hallways to extinguish the fire. If fire cannot be contained, exit area immediately. Close all doors while exiting the facility.

Large fires: Pull any fire alarm located in the hallways. Close all doors in immediate area of building and exit building immediately. Upper floors use stairwells ONLY.

4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.
5. If the fire presents an animal health related issue, (or you need assistance) contact the on-duty veterinarian.
6. Re-entry to the building is at the discretion of the Fire Dept. and/or the CVM Building Proctor.

Contact Numbers:

College Station Fire Department
Emergency 9-911 Non-Emergency 764-3700

Physical Plant Radio Room (Non-Emergency)
24hr 845-4311

Judy Walters, Building Proctor
Home Office 845-5997

CMP On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Dr. Elizabeth Browder, Attending Veterinarian
Cell 777-0132 Home

Dr. Melanie Ihrig, CMP Director
Cell 229-2696 Home

1. If a fire alarm occurs exit the building by the closest exit.
2. CMP personnel should meet at the parking lot across from the Viv III loading dock until all are accounted for.
3. If a fire exists:

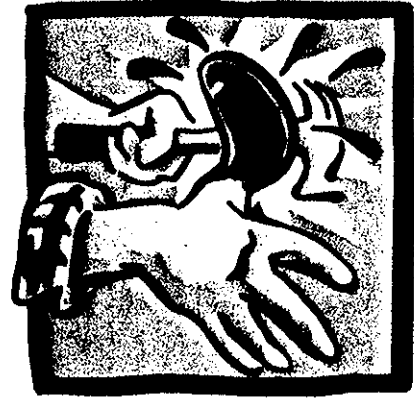
Small fires: If a small fire occurs, use the fire extinguishers and hoses found at various locations throughout the hallways to extinguish the fire. If fire cannot be contained, exit area immediately. Close all doors while exiting the facility.

Large fires: Pull any fire alarm located in the hallways. Close all doors in immediate area of building and exit building immediately.

4. Call Dr. Browder. If you cannot reach Dr. Browder, call Dr. Ihrig.
5. If the fire presents an animal health related issue, (or you need assistance) contact the on-duty veterinarian.
6. Re-entry to the building is at the discretion of the Fire Dept. and/or the COM Building Proctor.

****It is University Policy that the primary concern during fires is human life and health. Therefore, rescuing animals will only be attempted following the arrival and under the direction of the fire dept.**

PERSONNEL INJURIES/ EMERGENCY SERVICES



Contact Numbers:

TAMU EMS/Ambulance
Emergency 9-911 Non-Emergency 845-1525

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

Scott & White Occupational Medicine
691-3458

St. Joseph Hospital
776-3777

College Station Medical Center
764-5100

ALL FACILITIES

1. When employees are injured on the job or have an illness that requires medical assistance, it is imperative that proper treatment be obtained. It is also important that the employee's supervisor is notified. If the injury/emergency presents an animal health related issue, (or you need veterinary assistance) contact the on-duty veterinarian.
2. For on the job injuries, it is important to complete the procedures described below to ensure documentation is available to provide medical benefits for the injured employee and to comply with applicable reporting requirements of the state and TAMU.
 - The employee sustains an on-the-job injury and informs the supervisor of the incident.
 - The employee's supervisor or designee completes a **First Report of Injury (TWCC-1)** form immediately or as soon as possible.
 - The employee's supervisor or the departmental representative responsible for overseeing Workers' Compensation Insurance (WCI) documentation faxes the completed **First Report of Injury (TWCC-1)** form to the WCO at 847-8546.
 - The employee's department retains a copy of the First Report of Injury.

3. All correspondence regarding the injury or illness should be maintained in a confidential medical file in the employee's department and retained in accordance to the Retention Schedule for Texas A&M University System.
4. For more information regarding the TAMU WCI Program, please visit their website <http://hr.tamu.edu/relations/wrkscomp.html>

ANIMAL EMERGENCIES & EUTHANASIA



Contact Numbers:

On-Call Supervisor
Cell 777-7014

On-Call Veterinarian
24hr 845-7433

ALL FACILITIES

1. Remember for all animal emergencies:
 - Keep yourself and the animal SAFE from harm.
 - SECURE the animal (isolate if it is housed with other animals).
 - SEEK assistance.
2. Observe the animal personally so you can:
 - Render the animal safe and secure
 - Render immediate first aid if needed (short of giving an animal medications or drugs)
 - Answer questions on a first hand basis.
3. Contact the investigator & inform them of the animal health problem (follow procedures outlined in *SOP: A-I. G.4.: Investigator Contact Log Documentation*).
4. Investigator phone numbers can be found on the weekend/holiday notes in the folder on the LARR Main Supervisor's desk.
5. Call the vet and inform them of all animal health problems and how they are being resolved.
NOTE: Be sure you have observed the animal yourself before contacting the duty veterinarian.
6. If a health problem cannot be resolved to your satisfaction with an investigator, contact the duty veterinarian again.
7. Keep the duty Veterinarian informed of all animal health problems and their resolutions

NOTE:

Animals are to be euthanized by CMP animal care staff only following written approval or request of the principal investigator, his/her designated representative, or a CMP veterinarian.

In emergency situations permission from the investigator (document all pertinent information in the Investigator Contact Log as described in SOP A-I.G.4.) or a CMP veterinarian may be given over the phone, but should be followed up in writing in a timely manner.

BLDG

&

FICHT/ADAMS

INCIDENT RESPONSE PLAN

INCIDENT RESPONSE PLAN

And BSL3 buildings

Texas A&M University, College Station, TX 77843

to ensure compliance with

42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

- 1.1. **General.** This is the incident response plan for the possession and use of *Brucella abortus*, *Brucella suis* and *Brucella melitensis* at Texas A&M University main campus (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121. This plan covers the use of *Brucella* strains in the _____ at Texas A&M University, BSL-3 laboratory _____ and in buildings _____.
- 1.2. This plan describe the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

- 2.1. **Principal Investigator.** The principal investigator, Dr. Thomas A. Ficht has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to Dr. Ficht.
- 2.2. **Oversight by Responsible Official and Alternate Responsible Official.** Oversight of the select agent program is performed by the Responsible Official, the Alternate Responsible Official and the Biosafety Officer. Richard Ewing, Vice President for Research, is the Responsible Official at TAMU. The Alternate Responsible Officials is Angelia Raines. The Biosafety Officer is Brent Mattox. Dr. Ficht will report incidents, as required, to the Biosafety Officer and the Responsible Official or Alternate Responsible Official. Where required, the Responsible Official will report incidents to CDC.
- 2.3. **Annual Program Review.** The Responsible Official or Alternate Responsible Official will audit the incident response program on an annual basis. This review will include drills and exercises to ensure the effectiveness of the incident response plan. Based on the outcome of drills, exercises or reported incidents, this incident response plan may be updated.
- 2.4. **Contact Information.** The **Principal Investigator**, Thomas A. Ficht, may be contacted during business hours at (979) 845-4118, at home _____, and on his mobile phone at (979) 574-9466. His email address is tficht@cvm.tamu.edu. The **Responsible Official**, Richard Ewing, may be contacted during normal business hours at (979) 845-8585 and at all other times at _____. His email address is rewing@vprmail.tamu.edu. If the Responsible Official is unavailable, the **Alternate Responsible Official** Angelia Raines may be contacted

during normal business hours at (979) 847-9362 and at all other times at (979) 789-3456. Her email address is araines@vprmail.tamu.edu. The **Biosafety Officer**, Brent Mattox can be reached at (979) 845-2132 during business hours, and after hours at (979) 450-0662. The mailing address for the Responsible Official, Alternate Responsible Official and Biosafety Officer is Environmental Health & Safety, xxxx TAMUs, College Station, TX, 77843. His email address is bsmattox@neo.tamu.edu.

3. Description of Work

This plan covers the following work.

Lab	Work description	Unique features	Biological Use Authorization	Biosafety Level
	Storage of <i>Brucella abortus</i> , <i>B. suis</i> , <i>B. melitensis</i>	Locked freezer	0741	3
	Work with <i>Brucella abortus</i> , <i>B. suis</i> , <i>B. melitensis</i>	BSC	0741	3
	Storage of <i>Brucella</i> -infected animal carcasses	Locked freezer	0741	3
	Inoculation of mice with <i>Brucella</i> spp. and necropsy of infected animals	BSC	0741	3

Additional information concerning the laboratories and the select agent use is contained in the facility's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Environmental Health and Safety.

4. Response to theft, loss or release of *Brucella abortus*, *Brucella suis*, or *Brucella melitensis*

4.1. Determination of Loss or Theft. Possible loss or theft of the select agent will be reported to the Principal Investigator if any of the following have occurred:

- 4.1.1. The lock on the Select Agent storage area has been found open or appears to have been tampered with.
- 4.1.2. Evidence of forced entry into the laboratory or storage areas has been found.
- 4.1.3. A discrepancy in the Select Agent inventory has been identified.
- 4.1.4. An employee reports cultures or samples missing.
- 4.1.5. A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2.
- 4.1.6. A *Brucella*-infected mouse is missing from its microisolator cage.

4.2. Investigation of Loss or Theft by the Principal Investigator. Upon receiving a report of possible loss or theft of select agents, the Principal Investigator will immediately contact all personnel authorized for select agent access and call a meeting to determine whether the report of possible loss or theft can be explained by other means. For example, if an employee reports a malfunctioning lock, failure to note destruction of a strain in the inventory, or locates missing samples, the incident will be considered resolved, and no further report will be made.

4.2.1. Loss or Theft has not occurred: If the incident can be explained by means other than loss or theft (i.e. an employee reports having broken a lock or forgetting to record destruction of a culture, or has replaced the culture in the wrong

location), the incident will be considered resolved and internal laboratory report will be filed. Procedures will be reviewed with laboratory personnel to prevent re-occurrence of the incident.

- 4.2.2. **Loss or Theft has occurred:** If no alternative explanation for the possible loss or theft of select agent can be found, the Principal Investigator will notify the Responsible Official for assistance in filing CDC Form 3, Report of Loss or Theft of select agent.
 - 4.3. **Release of a Select Agent or Toxin.** Possible release of *Brucella* will be reported if any of the following has occurred:
 - 4.3.1. A package containing *Brucella* has been received, which has been damaged in transit, such that the primary containment vessel appears to have been compromised.
 - 4.3.2. Simultaneous failure of the biosafety cabinet and negative pressure in the BSL-3 suite during work in the biosafety cabinet with open *Brucella* cultures.
 - 4.3.3. Simultaneous spill of *Brucella* cultures outside the Biosafety cabinet and failure of negative pressure in the Biosafety Level 3 suite. In case of a spill, a spill kit containing absorbent material and disinfectant is located in a sealed container under the sink in room 129, 130 and 135.
 - 4.3.3.1. Personnel are advised to immediately leave the lab after removing any contaminated clothing and to return in tyvek suits with full face respirators after the air has been scrubbed clean by air handlers (approx one hour).
 - 4.3.4. In case release of *Brucella* outside the BSL-3 laboratory is suspected, the Principal Investigator will notify laboratories on the on the first floor of the VRB, as well as the Responsible Official.
 - 4.4. Exposure of laboratory personnel to *Brucella* cultures. The following incidents may result in unintentional exposure to *Brucella* that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to TAMU Occupational Health, where they will be given the option to initiate post-exposure prophylaxis. The exposure will be reported by the Principal Investigator to the Responsible Official, who will notify CDC of the exposure. A spill kit containing absorbent material and disinfectant is located in rooms
 - 4.4.1. A spill of live *Brucella* culture outside the biosafety cabinet
 - 4.4.2. Failure of the Biosafety Cabinet during work with *Brucella*
 - 4.4.3. Needle stick or cut with sharps contaminated with *Brucella*
 - 4.4.4. A bite from a *Brucella* infected animal, if the bite penetrates the double gloves and breaks the skin
 - 4.4.5. A centrifuge accident that results in aerosolization of *Brucella*.
5. **Security Breaches** A security breach will be determined to have occurred if any of the following are observed:
- 5.1. The access control system has failed, leaving the BSL-3 suite accessible to unauthorized persons.
 - 5.2. An unauthorized person is observed unaccompanied in the BSL-3 suite
A lost or stolen card was used to access the BSL-3 laboratory
 - 5.3. An unauthorized person has accessed the computer used to control entry to the BSL-3 suite.
 - 5.4. An unexpected or suspicious package arrives in the laboratory

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the Responsible Official of the security

breach and take steps to correct the problem. Within 24 hours, an inventory will be performed of all samples in the laboratory and in select agent storage. Any missing select agent samples will be reported to CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator and the Responsible Official will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

6. Severe weather or natural disasters. The most likely occurrences in this area are severe thunderstorms, floods or earthquakes.

- 6.1. If severe weather (thunderstorms or flooding) is predicted, experiments with select agents should be suspended until the severe weather has passed to avoid power outages during the work. All samples should be secured inside the locked -80°C freezer or the locked $+4^{\circ}\text{C}$ storage.
- 6.2. If an earthquake is felt, workers should immediately leave the building—if possible, shedding gloves and lab coat on the way out of the BSL-3 suite. Cleanup, if necessary, can be performed once it is safe to re-enter the building.
- 6.3. Power to the BSL-3 suite may be affected if the emergency generator is flooded. In this case, all samples should be secured inside the -80°C freezer. If the vivarium is threatened by flooding, animal cages should be fastened shut, put into secondary containers (biohazard bag or large Tupperware) and transported to LARR (CMP) for secure holding until the threat of flooding has passed. If it becomes necessary to evacuate the College Station area, all animal experiments will be terminated before evacuation by euthanizing the animals and storing the carcasses in the secure select agent storage in room _____.
- 6.4. In case of a power outage, if there is no immediate danger to the building, secure all infectious samples inside the -80°C freezer, the $+4^{\circ}\text{C}$ refrigerator, or the incubators. The Biosafety cabinets and air handling system of the BSL-3 suite are on emergency backup power, which will prevent exposure to infectious samples in case of a power outage. Follow standard procedures for leaving the laboratory and return once the power has been restored to resume work.

7. Fire, Gas leak, Steam leak, Explosion, Bomb threat:

- 7.1. If work is being performed in the Biosafety cabinet, cap all samples, dispose of gloves and outer laboratory coat, and leave the laboratory immediately. If the fire is within the BSL-3 laboratory, and the worker feels (s)he can safely extinguish the fire, then the fire extinguisher located in the interior hall may be used. If a worker feels his or her safety threatened, (s)he should leave the laboratory immediately without stopping to decontaminate or secure any work, using the designated escape routes (through the locker rooms or the exterior "airlock" door on the west side of the building). Upon leaving the building, personnel should assemble outside the assigned spot / _____ report to the Lab Safety Officer for attendance.
- 7.2. Notify the appropriate emergency responders: Fire 4-911 or 911 from mobile phones, the Principal Investigator and the Biosafety Officer. For steam and gas leaks, notify TAMU Operations and Maintenance at xxx-xxxx.
- 7.3. In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police should be notified immediately by calling the emergency number, 9-1-1. Also inform the Principal Investigator and Responsible Official. Always be sure to give the name of the building, room number, your name and telephone extension number.
 - 7.3.1. The University Police will assign personnel to investigate the call and take whatever police action may deemed necessary and reasonable for the safety of the campus community. The Police will conduct a search of the building, or of specific locations in or around the building. When judged prudent and feasible

to do so, the search will be conducted with the assistance and cooperation of the Principal Investigator and/or Responsible Official. After an evaluation/assessment of the content of the bomb threat, the decision to evacuate or close building shall be made jointly, whenever possible, by the Police and the Principal Investigator and/or Responsible Official.

- 7.3.2. Any unusual or suspicious object should be reported immediately to the University Police or to any immediate supervisor or administrative officer. Suspected objects or materials should **NOT** be touched or disturbed. Every bomb threat or incident of a suspected explosive device should be considered valid until all reasonable precautions for public safety have been taken or until the danger to life and property is terminated.

8. Failure of Select Agent Storage Freezer:

- 8.1. If the -80°C freezer in _____ that is used to store *Brucella* strains fails, the strains will be moved to a temporary backup location, which is either the other -80°C Revco freezer located in room _____ or in secure freezer in a locked BSL-2 laboratory. This freezer will be padlocked in order to limit access to personnel authorized to work with select agents.

9. Workplace violence:

- 9.1. Incidents of disruptive or threatening behavior on the part of an employee, student or visitor should be reported immediately to the Principal Investigator, who will report the incident to the Department Head, the Responsible Official and the Workplace Violence Response Team, as proscribed by the TAMU Personnel and Procedures manual section 290-09. If the individual accused of disruptive or threatening behavior is authorized for access to select agents, this person's access will be suspended pending the results of an investigation by the Workplace Violence Response Team. If an act of violence or a physical assault has occurred, or the threatening activity occurs within the BSL-3 laboratory, the person feeling threatened should call the police immediately to report the incident. If the person accused of violence has access to select agents, the person's access will be suspended pending the outcome of the investigation. Suspension of select agent access will be reported to the Responsible Official and a suspended individual's keycard access will be inactivated within 24 hours.

10. Entry of emergency responders into the BSL-3 laboratory.

- 10.1. In a case in which a life-threatening injury or medical condition (i.e. heart attack) occurs inside the BSL-3 laboratory, emergency responders will be allowed to enter the laboratory. If possible, upon feeling ill the laboratory worker should immediately exit the suite to facilitate treatment by emergency responders. An off-master key for emergency responders is located in the building's "Knox box" for Fire response. Personnel protective equipment, including Tyvek suits, N95 masks, HEPA-filtered respirators and gloves, are located inside the entries (locker rooms) to the BSL-3 suite. A spill kit containing absorbent materials and disinfectant is located under the bench in each of the labs _____. A First Aid kit is located inside the locker rooms of the BSL-3 suite. If responders are required to enter an area where a spill has occurred, they will be referred to Scoot and White Clinic and offered post-exposure prophylaxis consisting of oral doxycycline.

10.1.1. Entry procedure for the BSL-3 laboratory: Don a Tyvek suit, gloves, shoe covers and respiratory protection (N95 mask) before entering laboratories

10.1.2. Providing first aid and emergency medical treatment in the BSL-3 laboratory: A person working inside the biosafety hood is not considered to be contagious unless a spill has occurred. The person's gloves may be contaminated, and

may be removed to facilitate treatment. If there is no space within the labs to put the person on the floor, move the person to the interior hallway to administer treatment.

- 10.1.3. Exit procedure from the BSL-3 laboratory: Emergency responders should remove Tyvek suit, mask, shoe covers and gloves before exiting and leave them behind in the BSL-3 laboratory. Hands should be washed immediately upon exit from the BSL-3 laboratory.
- 10.1.4. Decontamination procedures for medical equipment and clothing: Emergency responders should decontaminate equipment before leaving the laboratory by one of the following methods:
 - 10.1.4.1. Autoclaving. Autoclaves are located within the BSL3 suite or on the 2nd floor of the VRB.
 - 10.1.4.2. Wiping surfaces with 10% bleach, followed by 1% Virkon-S.

11. Incident Response Plan Testing

- 11.1. Drills or tabletop exercises will be conducted annually to test the effectiveness of the biosafety plan. The drills or exercises will be coordinated with the TAMU Police Department and will include, but not be limited to, the Principal Investigator or designee, EH&S Biosafety Officer, TAMU Fire Department representative and the Campus Emergency Planner.
- 11.2. The drill or exercise will include, but not be limited to, accessibility to restricted space, attempted or unauthorized entry into restricted spaces challenge, animal room security, staff knowledge of hazard/emergency protocols for their work location(s) and other situations that are deemed appropriate for each work location.
- 11.3. Following the drill or exercise, which will test the various components of the incident response plan for completeness, those involved will critique their findings for each drill/exercise location. The Principal Investigator working with the Responsible Official and Biosafety Officer will implement changes as necessary changes to the plan. Results of the drill or exercise will be reviewed by the Biological Safety Administrative Advisory Committee (Biosafety Committee).

12. Emergency Response Plans

- 12.1. The entity emergency response plan is contained in a separate document and is referenced in the individual laboratory emergency response plan.
- 12.2. Additional information concerning the laboratory emergency response plan is contained in the laboratory's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Environmental Health & Safety.
- 12.3. The Responsible Official and Biosafety Officer should be contacted immediately in the case of any emergency in a select agent lab. The Responsible Official will coordinate access and information issues with campus police, fire, and emergency responders.
- 12.4. If necessary, the Responsible Official will coordinate the emergency relocation of select agents to another secure location.

13. Site security and Control are described in detail in the Select Agent Security Plan

- 13.1. The laboratories are secured by a card reader and key. Sharing of key cards with other personnel is not permitted.
- 13.2. Individuals not authorized for access to select agents must be accompanied by approved personnel at all times while in the BSL-3 or ABSL-3 suites.
- 13.3. Data that could enable access to select agents by unauthorized personnel should be located on password-protected computers.

Appendix 1: Emergency telephone Numbers

Thomas A. Ficht	Office: 845-4118
Emergency	9-911
University Police	(979) 845-2345
College Station Police	(979) 764-3600
College Station Fire	(979) 764-3700
Environmental Health & Safety	(979) 845-2132
TAMU Area Maintenance (HVAC failure, steam leak, gas leak)	(979) 845-5542
TAMU Maintenance (24 hours)	(979) 845-4311
Radiological Emergencies	(979) 862-1111
Responsible University Officials	RO-Richard Ewing (979) 845-8585 business
	ARO-Angelia Raines (979) 847-9362 business
	Biosafety Officer-Brent Mattox (979) 845-2132 business
Building manager-Loren Skow	5-3194
ABSL-3	2-4778
TAF Lab	5-4185
<u>Neighboring labs to notify in case of simultaneous containment breach and spill outside BSC:</u>	
	8-3649
Templeton Lab	5-9813
	-xxxx
	5-9814

Binas Lab	8-4057
Busbee Lab	5-2050

Appendix 2: Decontamination Procedures for Spills of *Brucella* Cultures

1. Signal others in the BL3 labs of any spill outside the biological safety cabinet. All personnel should change out of contaminated clothing and wash any exposed skin with a disinfectant, such as Purell. Clothes must be removed within the BL3 area and will be autoclaved by those cleaning up.
2. Put on a clean scrub suit and go to the shower on the first floor animal facility. Shower thoroughly with soap.
3. Return to the lab for cleanup: Put on a full face respirator and tyvek suit (contained in the SPILL KIT). Put on double gloves and shoe covers.
4. Use paper towels to cover the spill. Prevent creation of contaminated aerosols.
5. Saturate all materials with 10% bleach solution (see previous section for description).
6. Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in autoclave bags.
7. Disinfect all exposed surfaces using 1X Wexcide or 1% Virkon (surface disinfectant solution).
8. Wipe surface of full-face respirator with 1% Virkon or 1X Wexcide, being careful to avoid skin contact with Wexcide.
9. Remove all clothing and place in autoclave bag.
10. Remove full face respirator and spray off all surfaces in the lab with 1% Virkon or 1X Wexcide.
11. Make sure that all contaminated material is autoclaved, surface-disinfected or incinerated.
12. Inform others not to work in the lab until the air handling system is able to clear any residual organisms from the air (3h).
13. Return to the lab after 3 hours and perform another decontamination of all lab surfaces with 1% Virkon or 1X Wexcide.
14. Report accident to Dr. Thomas A. Ficht.

Contents of spill kit located in BL-3 labs

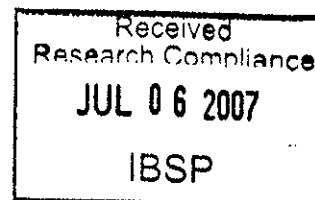
Full-face respirator, Tyvek suit, clean scrub suit, absorbent material, Purell skin disinfectant, towel, copy of decontamination procedures for spills.

INCIDENT RESPONSE PLAN

Dr. James E. Samuel

Reynolds Medical Building Room 419/420A-D

Texas A&M University, College Station, TX 77843



to ensure compliance with

42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

- 1.1. **General.** This is the incident response plan for the possession and use of *Coxiella burnetii* at Texas A&M University main campus (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121. This plan covers the use of these select agents when used in
- 1.2. This plan describe the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

- 2.1. **Principal Investigator.** The Principal Investigator, Dr. James E. Samuel, has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to Dr. James E. Samuel.
- 2.2. **Oversight by Responsible Official and Alternate Responsible Official.** Oversight of the select agent program is performed by the Responsible Official, the Alternate Responsible Official and the Biosafety Officer. Richard Ewing, Vice President for Research, is the Responsible Official at TAMU. The Alternate Responsible Official is Angelia Raines. The Biosafety Officer is Brent Mattox. Dr. James E. Samuel will report incidents, as required, to the Biosafety Officer and the Responsible Official or Alternate Responsible Official. Where required, the Responsible Official will report incidents to CDC.
- 2.3. **Annual Program Review.** The Responsible Official or Alternate Responsible Official will audit the incident response program on an annual basis. This review will include drills and exercises to ensure the effectiveness of the incident response plan. Based on the outcome of drills, exercises or reported incidents, this incident response plan may be updated.
- 2.4. **Contact Information.** The **Principal Investigator** may be contacted during business hours at 862-1684, at home and on their mobile phone at 220-8269. His email address is jsamuel@tamu.edu. The **Responsible Official**, Richard Ewing, may be contacted during normal business hours at (979) 845-8585 and at all other times at his email address is rewing@vprmail.tamu.edu. If the Responsible Official is unavailable, the **Alternate Responsible Official**, Angelia Raines, may be

contacted during normal business hours at (979) 847-9362 and at all other times at (770) 789-3456. Her email address is araines@vprmail.tamu.edu. The **Biosafety Officer, Brent Mattox** can be reached at (979) 845-2132 during business hours, and after hours at (979) 450-0662. His email address is bsmattox@neo.tamu.edu.

3. Description of Work

This plan covers all work being performed at TAMU. Each lab will be responsible for providing information specific to the work being performed as follows:

Lab	Work description	Unique features of Agent	Biosafety Level
	[REDACTED]		1
	Storage of Brucella spp. and C. burnetii	Locked freezer	3
	Inoculation of mice with Brucella spp. and C. burnetii and necropsy of infected animal	[REDACTED]	3
	Storage of Brucella spp. and C. burnetii	Locked freezer	3

Additional information concerning the laboratories and the select agent use is contained in the facility's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or Environmental Health and Safety Office.

4. Response to loss/theft:

- 4.1. Determination of Loss or Theft. Possible loss or theft of the select agent will be reported initially to the Principal Investigator if any of the following have occurred:
 - 4.1.1. The lock on the Select Agent storage area has been found open or appears to have been tampered with;
 - 4.1.2. Evidence of forced entry into the laboratory or storage areas has been found;
 - 4.1.3. A discrepancy in the Select Agent inventory has been identified;
 - 4.1.4. An employee reports cultures or samples missing;
 - 4.1.5. A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2;
 - 4.1.6. An infected animal is missing from its microisolator cage.
- 4.2. Investigation of Loss or Theft by the Principal Investigator. Upon receiving a report of possible loss or theft of the Select Agent(s), the Principal Investigator will immediately contact all personnel authorized for Select Agent access and call a meeting to determine whether the report of possible loss or theft can be explained by other means. For example, if an employee reports a malfunctioning lock, failure to note destruction of a strain in the inventory, or locates missing samples, the incident will be considered resolved and no further report will be made. A halt to all work on the select agent material associated with the incident will be halted until cleared by UPD or BSO.

- 4.2.1. Loss or Theft has not occurred: If the incident can be explained by means other than loss or theft (i.e. an employee reports having broken a lock or forgetting to record destruction of a culture, or has replaced the culture in the wrong location), the incident will be considered resolved and internal laboratory report will be filed. Procedures will be reviewed with laboratory personnel to prevent re-occurrence of the incident.
- 4.2.2. Loss or Theft has occurred: If no alternative explanation for the possible loss or theft of select agent can be found, the Principal Investigator will notify the Responsible Official for assistance in filing CDC Form 3, Report of Loss or Theft of select agent.
- 4.3. Release of a Select Agent or Toxin. Possible release of the agent or toxin will be reported initially to the Principal Investigator if any of the following has occurred:
 - 4.3.1. A package containing the Select Agent or toxin that has been received, which has been damaged in transit, such that the primary containment vessel appears to have been compromised;
 - 4.3.2. Simultaneous complete power failure of the Biosafety cabinet and negative pressure in the BSL-3 suite during work in the Biosafety cabinet with open cultures;
 - 4.3.3. Simultaneous spill of cultures outside the Biosafety cabinet and failure of negative pressure in the Biosafety Level 3 suite (In case of a spill, a spill kit containing absorbent material and disinfectant will be located in a designated lab for each Principal Investigator.);
 - 4.3.3.1. Personnel should be advised to immediately leave the lab after removing any contaminated clothing and to return in Tyvek suits with full face respirators after the air has been scrubbed clean by air handlers (approx. one hour).
 - 4.3.4. In case release of the Select Agent or toxin outside the BSL-3 laboratory is suspected, the Principal Investigator will notify laboratories, as well as the Responsible Official, the building manager and the BSO.
- 4.4. Exposure of laboratory personnel to cultures. The following incidents may result in unintentional exposure to the Select Agent that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to TAMU Occupational Health, where they will be given the option to initiate post-exposure prophylaxis. The exposure will be reported by the Principal Investigator, then to the Responsible Official, who will notify CDC of the exposure. The following are examples of unintentional exposure:
 - 4.4.1. A spill of live culture outside the Biosafety cabinet;
 - 4.4.2. Failure of the Biosafety cabinet during work with the Select Agent;
 - 4.4.3. Needle stick or cut with sharps contaminated with *Coxiella burnetii* and *Brucella* spp. ;
 - 4.4.4. If a bite from an infected animal penetrates the double gloves and breaks the skin;
 - 4.4.5. A centrifuge accident that results in aerosolization of the Select Agent.

5. **Security Breach:**

- 5.1. A security breach will be determined to have occurred if any of the following are observed:

- 5.1.1. The access control system has failed, leaving the BSL-3 suite accessible to unauthorized persons;
- 5.1.2. An unauthorized person is observed unaccompanied in the BSL-3 suite;
- 5.1.3. A lost or stolen card was used to access the BSL-3 laboratory;
- 5.1.4. An unauthorized person has accessed the computer used to control entry to the BSL-3 suite;
- 5.1.5. An unexpected or suspicious package arrives in the laboratory.

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the Responsible Official of the security breach and take steps to correct the problem. Corrective procedures will be secured immediately, but no later than 24 hours, an inventory will be performed of all samples in the laboratory and in Select Agent storage. Any missing select agent samples will be reported to CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator and the Responsible Official will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

6. Severe weather or natural disasters. The most likely occurrences in this area are severe thunderstorms, floods or tornadoes.

- 6.1. If severe weather (thunderstorms or flooding) is predicted, experiments with Select Agents should be suspended until the severe weather has passed to avoid power outages during the work. All samples should be secured inside the locked -80°C freezer or the locked +4°C storage.
- 6.2. If an earthquake is felt, workers should immediately leave the building--if possible, shedding gloves and lab coat on the way out of the BSL-3 suite. Cleanup, if necessary, can be performed once it is safe to re-enter the building.
- 6.3. Power to the BSL-3 suite may be affected if the emergency generator is flooded. In this case, all samples should be secured inside the -80°C freezer. If the vivarium is threatened by flooding, animal cages should be fastened shut, put into secondary containers (biohazard bag or large Tupperware) and transported to LARR (CMP) for secure holding until the threat of flooding has passed. If it becomes necessary to evacuate the College Station area, all animal experiments will be terminated before evacuation by euthanizing the animals and storing the carcasses in the secure select agent storage in room.
- 6.4. In case of a power outage, if there is no immediate danger to the building, secure all infectious samples inside a -80°C freezer, the +4°C refrigerator, or the incubators. The Biosafety cabinets and air handling system of the BSL-3 suite are on emergency backup power, which will prevent exposure to infectious samples in case of a power outage. Follow standard procedures for leaving the laboratory and return once the power has been restored to resume work.

7. Fire, Gas leak, Steam leak, Explosion, Bomb threat:

- 7.1. If work is being performed in the Biosafety cabinet, cap all samples, dispose of gloves and outer laboratory coat, and leave the laboratory immediately. If the fire is within the BSL-3 laboratory, and the worker feels (s)he can safely extinguish the fire, then the fire extinguisher located in the interior hall may be used. If a worker feels his or her safety threatened, (s) he should leave the laboratory immediately without stopping to decontaminate or secure any work, using the designated escape routes of the building. Upon leaving the building, personnel should assemble outside the laboratory

location in the Rm 419/420A-D and report to the Lab Director or designee for attendance.

- 7.2. Notify the appropriate emergency responders: Fire **9-911** or **911** from mobile phones, the Principal Investigator and the Biosafety Officer. For steam and gas leaks, notify TAMU Operations and Maintenance.
- 7.3. In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police should be notified immediately by calling the emergency number, **9-911** or **911**. Also inform the Principal Investigator and Responsible Official. Always be sure to give the name of the building, room number, your name and telephone extension number.

- 7.3.1. The University Police Department will assign personnel to investigate the call and take whatever police action they may deem necessary and reasonable for the safety of the campus community. The University Police will conduct a search of the building, or of specific locations in or around the building. When judged prudent and feasible to do so, the search will be conducted with the assistance and cooperation of the Principal Investigator and/or Responsible Official. After an evaluation/assessment of the content of the bomb threat, the decision to evacuate or close building shall be made jointly, whenever possible, by the Police and the Principal Investigator and/or Responsible Official.

- 7.3.2. Any unusual or suspicious object should be reported immediately to the University Police or to any immediate supervisor or administrative officer. Suspected objects or materials should **NOT** be touched or disturbed. Every bomb threat or incident of a suspected explosive device should be considered valid until all reasonable precautions for public safety have been taken or until the danger to life and property is terminated.

8. **Failure of Select Agent Storage Freezer:**

- 8.1. If the -80°C freezer in Rm 420D that is used to store *Coxiella burnetii* and *Brucella spp.* strains fails, the strains will be moved to a temporary backup location, which is either the other -80°C Revco freezer located in Rm 420B, or in secure freezer in a locked BSL-2 laboratory. This freezer will be locked in order to limit access to personnel authorized to work with select agents.

9. **Workplace violence:**

- 9.1. Incidents of disruptive or threatening behavior on the part of an employee, student or visitor should be reported immediately to the Principal Investigator, who will report the incident to the Department Head, the Responsible Official and the Workplace Violence Response Team, as proscribed by the TAMU Personnel and Procedures manual section 290-09. If the individual accused of disruptive or threatening behavior is authorized for access to select agents, this person's access will be suspended pending the results of an investigation by the Workplace Violence Response Team. If an act of violence or a physical assault has occurred, or the threatening activity occurs within the BSL-3 laboratory, the person feeling threatened should call the police immediately to report the incident. If the person accused of violence has access to select agents, the person's access will be suspended pending the outcome of the investigation. Suspension of select agent access will be reported to the Responsible Official and a suspended individual's access will be inactivated within 24 hours.

10. **Entry of emergency responders into the BSL-3 laboratory.**

- 10.1. In a case in which a life-threatening injury or medical condition (i.e. heart attack) occurs inside the BSL-3 laboratory, emergency responders will be allowed to enter the laboratory. If possible, upon feeling ill the laboratory worker should immediately exit the suite to facilitate treatment by emergency responders. Personnel protective equipment, including Tyvek suits, N95 masks, HEPA-filtered respirators and gloves, are located inside the entries (locker rooms) to the BSL-3 suite. A spill kit containing absorbent materials and disinfectant is located under the bench in each of the labs. A First Aid kit is located inside the lab. If responders are required to enter an area where a spill has occurred, they will be referred to Scott and White Clinic and offered post-exposure prophylaxis.
 - 10.1.1. Entry procedure for the BSL-3 laboratory: Dress yourself in a Tyvek suit, gloves, shoe covers and respiratory protection (N95 mask) before entering laboratories.
 - 10.1.2. Providing first aid and emergency medical treatment in the BSL-3 laboratory: A person working inside the Biosafety hood is not considered to be contagious unless a spill has occurred. The person's gloves may be contaminated, and may be removed to facilitate treatment. If there is no space within the labs to put the person on the floor, move the person to the interior hallway to administer treatment.
 - 10.1.3. Exit procedure from the BSL-3 laboratory: Emergency responders should remove Tyvek suit, mask, shoe covers and gloves before exiting and leave them behind in the BSL-3 laboratory. Hands should be washed immediately upon exit from the BSL-3 laboratory.
 - 10.1.4. Decontamination procedures for medical equipment and clothing: Emergency responders should decontaminate equipment before leaving the laboratory by one of the following methods:
 - 10.1.4.1. Autoclaving. Autoclaves are located in Rm 420A.
 - 10.1.4.2. ~~Specific methods and products of decontamination in lab.~~

11. Incident Response Plan Testing (Drills)

- 11.1. Drills or tabletop exercises will be conducted annually to test the effectiveness of the biosafety plan. The drills or exercises will be coordinated with the TAMU Police Department and will include, but not be limited to, the Principal Investigator or designee, EH&S Biosafety Officer, TAMU Fire Department representative and the Campus Emergency Planner.
- 11.2. The drill or exercise will include, but not be limited to, accessibility to restricted space, attempted or unauthorized entry into restricted spaces challenge, animal room security, staff knowledge of hazard/emergency protocols for their work location(s) and other situations that are deemed appropriate for each work location.
- 11.3. Following the drill or exercise, which will test the various components of the incident response plan for completeness, those involved will critique their findings for each drill/exercise location. The Principal Investigator working with the Responsible Official and Biosafety Officer will implement changes as necessary changes to the plan. Results of the drill or exercise will be reviewed by the Biological Safety Administrative Advisory Committee (Institutional Biosafety Committee).

12. Texas A&M University Crisis Management Plan

- 12.1. The entity crisis management plan is contained in a separate document and is referenced in the individual laboratory emergency response plan.
 - 12.2. Additional information concerning the laboratory emergency response plan is contained in the laboratory's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or the Environmental Health & Safety Department.
 - 12.3. The Responsible Official and Biosafety Officer should be contacted immediately in the case of any emergency in a select agent lab. The Responsible Official will coordinate access and information issues with campus police, fire, and emergency responders.
 - 12.4. If necessary, the Responsible Official will coordinate the emergency relocation of select agents to another secure location.
13. **Site security and control are described in detail in the Select Agent Security Plan**
- 13.1. The laboratories are secured by a card reader and key. **Sharing of key cards with other personnel is not permitted.**
 - 13.2. Individuals not authorized for access to Select Agents must be accompanied by approved personnel at all times while in the BSL-3 or ABSL-3 suites.
 - 13.3. Data that could enable access to select agents by unauthorized personnel should be located on password-protected computers.
 - 13.4. If approved personnel are observed violating security or Biosafety procedures, this observation should be reported immediately to the Principal Investigator. The Principal investigator will investigate the allegation and determine whether the violator should have his/her Select Agent access suspended or revoked. Suspension of Select Agent access will be reported to the Responsible Official and the individual's key card access will be terminated within 24 hours.
14. **Inventory Discrepancies:**
- 14.1. Inventory discrepancies will be documented on the agent access form.
 - 14.2. All discrepancies will be immediately reported to the Principal Investigator.
 - 14.3. If the discrepancy is believed to be a result of loss or theft, the incident response procedures for loss or theft and release will be followed.
 - 14.4. If the discrepancy is a result of a transfer, the transfer form will be documented.
15. **References**
- 15.1. 42 CFR Part 73
 - 15.2. 7 CFR Part 331
 - 15.3. 9 CFR Part 121
 - 15.4. Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention, National Institutes of Health, Fourth Edition, May 1999
 - 15.5. Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents (Revised BMBL, Appendix F), published in Morbidity and Mortality Weekly Report, December 6, 2002.

Emergency Telephone Numbers

Dr. James E. Samuel	Office: 862-1684
Emergency	9-911
University Police	(979) 845-2345
College Station Police	(979) 764-3600
College Station Fire	(979) 764-3700
Environmental Health & Safety	(979) 845-2132
TAMU Area Maintenance (HVAC failure, steam leak, gas leak)	(979) 845-5542
TAMU Maintenance (24 hours)	(979) 845-4311
Radiological Emergencies	(979) 862-1111
Responsible University Officials:	
RO-Richard Ewing	Work: (979) 845-8585
ARO-Angelia Raines	Work: (979) 847-9362
Biosafety Officer/ARO -Brent Mattox	Work: (979) 845-2132
Building Manager	
George Martin	Work: 845-7902
Dr. James E. Samuel Lab	863-1683
Neighboring labs to notify in case of simultaneous containment breach and spill outside BSC:	
Lab (Dr.Skare Lab Rm417)	845-0886

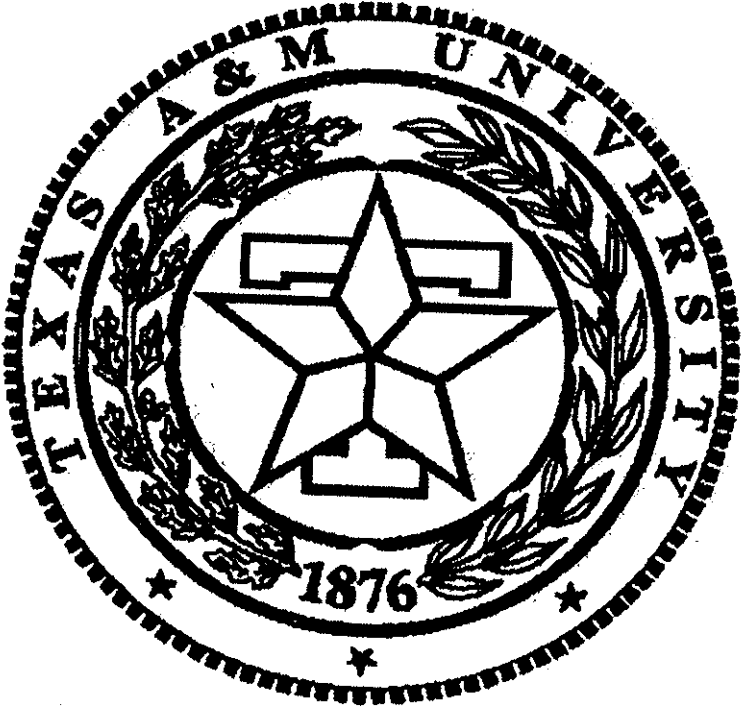
Decontamination Procedures for Spills of Cultures
(Please customize for specific laboratories.)

1. Signal others in the BL3 labs of any spill outside the biological safety cabinet. All personnel should change out of contaminated clothing and wash any exposed skin with a disinfectant, such as Purell. Clothes must be removed within the BL3 area and will be autoclaved by those cleaning up.
2. Put on a clean scrub suit and go to the shower on the first floor animal facility. Shower thoroughly with soap.
3. Return to the lab for cleanup: Put on a full face respirator and Tyvek suit (contained in the SPILL KIT). Put on double gloves and shoe covers.
4. Use paper towels to cover the spill. Prevent creation of contaminated aerosols.
5. Saturate all materials with 10% bleach solution (see previous section for description).
6. Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in autoclave bags.
7. Disinfect all exposed surfaces using 1X Wexcide or 1% Virkon (surface disinfectant solution).
8. Wipe surface of full-face respirator with 1% Virkon or 1X Wexcide, being careful to avoid skin contact with Wexcide.
9. Remove all clothing and place in autoclave bag.
10. Remove full face respirator and spray off all surfaces in the lab with 1% Virkon or 1X Wexcide.
11. Make sure that all contaminated material is autoclaved, surface-disinfected or incinerated.
12. Inform others not to work in the lab until the air handling system is able to clear any residual organisms from the air (3h).
13. Return to the lab after 3 hours and perform another decontamination of all lab surfaces with 1% Virkon or 1X Wexcide.
14. Report accident to the Principal Investigator, who will report it to other officials.

Contents of spill kit located in BL-3 labs:

Full-face respirator, Tyvek suit, clean scrub suit, absorbent material, Purell skin disinfectant, towel, copy of decontamination procedures for spills.

TAMU CRISIS MANAGEMENT PLAN



Crisis Management Plan

Texas A&M University
Crisis Management Plan

Submitted By: Christopher M. Meyer, Assistant Vice President
Office of Safety and Security

Associate Vice President for University Risk and Compliance

Date

Vice President for Facilities

Date

Associate Executive Vice President

Date

Executive Vice President and Provost

Date

Chief of Staff

Date

President

Date

CRISIS MANAGEMENT PLAN

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SECTION 1: AUTHORITY

These guidelines apply to Texas A&M University. The organizational and operational concepts set forth in these guidelines are promulgated under the following authorities:

A. FEDERAL

1. Federal Civil Defense Act of 1950, PL 81-920 as amended.
2. The Disaster Relief Act of 1974, PL 93-288 as amended.
3. Robert T. Stafford Disaster Relief and Emergency Assistance Act, PL 100-707
4. Emergency Management and Assistance, Code of Federal Regulations, Title 44.
5. Superfund Amendments and Reauthorization Act of 1986, PL 99-499 (Title III, "Emergency Planning and Community Right-to-Know Act of 1986").
6. Comprehensive Environment Response Compensation and Liability Act of 1980, PL 96510 (CERCLA or "Superfund").
7. Clean Water Act, (Section 311 of USC 1251).
8. Clean Air Act, (40 CFR Part 51).
9. Resource Conservation and Recovery Act (RCRA).
10. Public Health Security and Bioterrorism Preparedness and Response Act (42 CFR Part 73)
11. Agricultural Bioterrorism Protection Act of 2002; Possession, Use and Transfer of Biological Agents and Toxins (7 CFR Part 331 and 9 CFR Part 121)

B. STATE

1. Vernon's Texas Civil Statutes, Sections 7, 8, and 10, Article 5890e.
2. The Texas Disaster Act of 1975, V.T.C.A. Government Code, Title 4, Chapter 418.
3. Executive Order by the Governor, Executive Order RP-01 or current version.
4. Attorney General Opinion MW-140.
5. Hazard Communication Act, Title 83 Article 51826.
6. Texas Hazardous Substances Spill Prevention and Control Act, Chapter 26, Subchapter G. Texas Water Code.
7. State Solid Waste Disposal Act, Texas Civil Statutes Article 4477-7.
8. State of Texas Emergency Management Plan (Disaster Plan).

C. LOCAL

1. Texas A&M University Rule 34.07.99M2, Crisis Management
2. Brazos County Interjurisdictional Emergency Management Plan.

SECTION 2: PURPOSE

Texas A&M University is subject to emergencies or disasters resulting from major incidents or natural phenomena. This plan provides guidance and procedures to enable the university to effectively respond to and recover from major incidents, natural disasters or other emergencies on the campus. Response must be timely, vigorous, and directed toward containing the situation, minimizing the loss of life and property, averting undue hardship or suffering, and maintaining the maximum operational capabilities of the University. Only by annual review and regular exercise of this plan will rescue and recovery actions be effective in protecting human life and health and in preserving TAMU property and resources. The President, Texas A&M University, is the responsible authority to direct all training and exercises. This plan will be in support of the Brazos County Interjurisdictional Emergency Management Plan. This plan is written using as its basis the Incident Command System as defined by the Emergency Management Institute.

The purpose of these guidelines is to:

1. Provide guidance for emergency operations and the utilization of all available TAMU and government resources for the protection of lives, property, and the continuance of University operations in the event of a natural or man-made disaster or a national emergency including weapons of mass destruction attacks or threats thereof.
2. Outline the duties and responsibilities of departments and/or individuals during University emergency operations.
3. Establish guidelines for emergency planning and coordination of activities relating to disaster prevention and mitigation, preparedness, response, and recovery as related to local, county, state and federal governments.
4. Assign responsibilities for specific duties and activities related to emergency operations and disaster recovery.
5. Objectives of Emergency Operations are to:
 - a. **Provide emergency services** including medical assistance, rescue, fire protection, and police protection for life and property within the disaster area.
 - b. **Restore utilities** within the stricken area in an orderly and timely manner.
 - c. **Maintain fire, police, and utility services** during emergency operations.
 - d. **Facilitate, provide, and coordinate shelter and mass care** during and after the emergency in cooperation with the Red Cross and other organizations.
 - e. **Keep the public informed** of the current status of emergency operations in a timely manner.
 - f. **Promote the process of recovery** from the effects of disaster situations.

SECTION 3: DEFINITIONS

1. Area Command. An organization established to a) oversee the management of multiple incidents that are each being handled by an incident command system organization; or b) oversee the management of a very large incident that has multiple incident management teams assigned to it. Area command has the responsibility to set overall strategy and priorities,

allocate assigned resources based on priorities, ensure that incidents are properly managed, and ensure that objectives are met and strategies followed.

2. Centers for Disease Control (CDC). The CDC includes 11 centers, an institute, and offices whose mission is to promote health and quality of life by preventing and controlling disease, injury, and disability. See: <http://www.cdc.gov>.
3. The Chemical Emergency Transportation Center (CHEMTREC). A centralized, toll-free telephone service (800-424-9300) which has been set up to provide immediate advice on the nature of the product and steps to be taken in handling the early stages of transportation emergencies where hazardous chemical are involved. CHEMTREC promptly contacts the shipper of the material involved for more detailed information and appropriate follow-up action including on-scene assistance when feasible. See: <http://www.chemtrec.com>.
4. Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA). The original Superfund Act, primarily aimed at hazardous waste site identification and clean up.
5. CSFD. College Station Fire Department.
6. CSPD. College Station Police Department.
7. Crisis Management Plan. The plan that each jurisdiction has and maintains for responding to appropriate hazards. It establishes the specific procedures and approaches to be used in the management of an emergency situation.
8. Texas Division of Emergency Management (DEM). A division of the Texas Department of Public Safety. See: <http://www.txdps.state.tx.us/dem/>
9. Disaster District. Disaster Districts are regional state emergency management organizations mandated by the Executive Order of the Governor relating to Emergency Management whose boundaries parallel those of Highway Patrol Districts and Sub-Districts of the Texas Department of Public Safety.
10. Disaster District Committee (DDC). The DDC consists of a Chairperson (the local Highway Patrol Captain or Command Lieutenant) and representatives of the state agencies and volunteer groups represented on the State Emergency Management Council with resources in the district. The DDC Chairperson, supported by committee members, is responsible for identifying, coordinating the use of, committing and directing state resources within the district to respond to emergencies.
11. Disaster Recovery Center (DRC). The Disaster Recovery Center is established by FEMA in partnership with state and local emergency management offices. Representatives from federal, state, local, and volunteer agencies are there to explain the assistance available and to assist victims in procuring it.
12. Emergency Alert System (EAS). A network of broadcast stations and interconnecting facilities which have been authorized by the Federal Communications Commission to operate in a controlled manner during a war, state of public peril or disaster, or other

national emergency – as provided by the emergency broadcast system plan. Supercedes EBS (Emergency Broadcast System).

13. Emergency Management (EM). A framework for organizing and managing emergency protection efforts. There are four phases – mitigation, preparedness, response, and recovery – in the all-hazards approach.
14. Emergency Management Authority (EMA). Emergency management authority is derived from the Texas Disaster Act of 1975 and assigned to the chief elected official of each political jurisdiction within the state. In most cases this authority is delegated to an Emergency Management Coordinator.
15. Emergency Management Coordinator (EMC). Each of the local jurisdictions has assigned this responsibility as indicated:

Brazos County	Emergency Management Coordinator
City of Bryan	Director, Community Services Department
City of College Station	Director, Parks and Recreation Department
City of Wixon Valley	Mayor
Texas A&M University	Assistant Vice President, Office of Safety and Security
16. Emergency Management Director (EMD). The chief executive of each jurisdiction assumes the duties of emergency management director at the emergency operations center during an emergency. At Texas A&M, the EMD is the Vice President for Facilities. This is the senior decision making position in the EOC.
17. EOC Controller. The EOC Controller is responsible for the operations of the EOC when it is activated. EOC Controller is the Emergency Management Coordinator.
18. Emergency Operations Center (EOC). Specially equipped facilities from which government officials exercise direction and control and coordinate necessary resources in an emergency situation.
19. Emergency Public Information (EPI). Information that is disseminated to the public via the news media before, during and/or after an emergency or disaster.
20. Emergency Situation. As used in this plan, this term is intended to describe a range of situations, from an incident to a major disaster. It includes the following:
 - Incident. An incident is a situation that is limited in scope and potential effects.
 - Emergency. An emergency is a situation that is larger in scope and more severe in terms of actual or potential effects than an incident.
 - Disaster. A disaster involves the occurrence or threat of significant casualties and/or widespread property damage that is beyond the capability of the local government to handle with available local resources.
21. Federal Emergency Management Agency (FEMA). The federal agency charged with development of an integrated emergency management system and with supporting emergency management and disaster assistance efforts at all levels of government. See: <http://www.fema.gov>.
22. Field Command Post. Facility at a safe distance from an accident site where the incident commander, responders and technical representatives can make response decisions,

deploy manpower and equipment, maintain liaison with the media and handle communications.

23. Hazardous Material (HAZMAT). A substance in a quantity or form posing an unreasonable risk to health, safety and/or property when manufactured, stored or transported. The substance, by its nature, containment and reactivity, has the capability for inflicting harm during an accidental occurrence. It may be toxic, corrosive, flammable, reactive, an irritant, a strong sensitizer and poses a threat to health and the environment when improperly managed. Included are toxic substances, certain infectious agents, radiological materials and other related materials such as oil or other petroleum products, and industrial solid waste substances.
24. Incident Commander (IC). The person responsible for the management of all incident operations. The IC is in charge of the incident site.
25. Incident Command System (ICS). The combination of facilities, equipment, personnel, procedures, and communications operating with a common organizational structure, with responsibility for the management of assigned resources to effectively accomplish stated objectives pertaining to an incident and/or event.
26. Immediately Dangerous to Life or Health (IDLH). A measure of toxicity of a substance, the concentration of a toxin that is capable of causing irreparable injury or death.
27. Local Emergency Planning Committee (LEPC). A group of representatives of government and private industry who coordinate response plans for emergency conditions.
28. Liaison Officer. A member of the command staff responsible for interacting with representatives from cooperating and assisting agencies.
29. Logistics Section. The section responsible for providing facilities, services, and materials for the incident.
30. Medical Command Officer. Officer responsible for the coordination of all medical branch officers.
31. Medical Unit. The functional unit within the service branch of the logistics section responsible for the development of the medical emergency plan, and for providing emergency medical treatment of incident personnel.
32. Material Safety Data Sheet (MSDS). Document containing specific information on the safe handling of chemicals in the workplace.
33. Multijurisdiction Incident. An incident requiring action from multiple agencies that have a statutory responsibility for incident mitigation. In ICS, these incidents will be managed under unified command.
34. Mutual-Aid Agreements. Written agreements between organizations, either public or private, for reciprocal aid and assistance in case of disasters too great to be dealt with unassisted.

35. Nuclear Regulatory Commission. The U.S. Nuclear Regulatory Commission (NRC) is an independent agency established by the congress under the Energy Reorganization Act of 1974 to ensure adequate protection of the public health and safety, the common defense and security, and the environment in the use of nuclear materials in the United States. <http://www.nrc.gov>.
36. National Weather Service (NWS). To provide weather and flood warnings, public forecasts and advisories for all of the United States, its territories, adjacent waters and ocean areas, primarily for the protection of life and property. NWS data and products are provided to private meteorologists for the provision of all specialized services. See: <http://www.nws.noaa.gov>.
37. Public Information Officer (PIO). A member of the command staff responsible for interfacing with the media or other appropriate agencies requiring information directly from the incident. There is only one information officer per incident.
38. Radio Amateur Civil Emergency Service (RACES). A radio communication service conducted by volunteer licensed amateur radio operators, for providing emergency radio communications to local, regional, or state emergency management organizations. FCC 97.163(a).
39. Radiological Monitor (RM). A person who can operate radiation detection instruments and report results of radiation levels from peacetime or attack emergency to the Radiological Officer (RO).
40. Radiological Officer (RO). The Texas A&M Radiological Safety Officer serves as the Radiological Officer for the Brazos County Interjurisdictional Emergency Management Plan.
41. Reception Area. A specified area designated for reception and care of evacuees that is unaffected by the disaster or hazard, or in the case of possible nuclear attack, is relatively unlikely to experience direct weapons effects (blast of 2 PSI or more, heat, and initial nuclear radiation).
42. Resources Conservation and Recovery Act of 1976 (RCRA). Provides for the proper handling, use, and disposal of chemicals manufactured and used in the country. Commonly referred to as "cradle to grave" tracking of chemicals.
43. Resources List. A current list of all resources (equipment, personnel, supplies), which can be used by emergency services in response to local disaster/emergencies.
44. Safe Zone. A geographical region beyond the warm zone where there is no suspected product contamination; often referred to as the cold zone or the outermost zone.
45. Salvation Army (SA). The Salvation Army, an international movement, is an evangelical part of the universal Christian Church. Its message is based on the Bible. Its ministry is motivated by the love of God. Its mission is to preach the gospel of Jesus Christ and to meet human needs in His name without discrimination. See: www.salvationarmyusa.org
46. Self Contained Breathing Apparatus (SCBA). Supplemental oxygen breathing equipment used primarily by firefighters and divers.

47. Shelter-In-Place. A procedure that advised people to stay indoors and to attempt to reduce the airflow into a structure. This strategy is used when it has been recognized that people could not be evacuated from an area prior to the arrival of a toxic cloud.
48. Sheriff Office (SO). Brazos County Sheriff's Office.
49. Staging Area (SA). A pre-selected location having large parking areas and cover for equipment, vehicle operators, and other personnel such as a major shopping area, schools, etc. The SA provides a base for coordinated emergency operations, assembly of persons to be moved by public transportation to reception jurisdictions, a rally point for mutual aid, or a debarking area for returning evacuees.
50. State Coordinating Officer (SCO). The person designated by the Governor to serve as the on-scene representative for the Division of Emergency Management and to work in concert with the federal coordinating officer in administering state and federal assistance to disaster victims.
51. State Disaster District 6C. A multi-county region in central Texas so designated by the Texas Division of Emergency Management. A Regional Liaison Officer (RLO) and Disaster District Chairman (DDC) are appointed for each disaster district. A captain in the Bryan district headquarters of the DPS is assigned as the State Disaster District Chairman for Disaster District 6C. See: <http://www.txdps.state.tx.us/dem/>
52. Unified Command. In ICS, Unified Command is a unified team effort that allows all agencies with responsibility for the incident, either geographical or functional, to manage an incident by establishing a common set of incident objectives and strategies. This is accomplished without losing or abdicating agency authority, responsibility, or accountability. The operations section chief is responsible for implementing the incident action plan.

SECTION 4: SITUATION AND ASSUMPTIONS

A. GENERAL

1. Any employee of Texas A&M University may be tasked by this plan.
2. The local police and fire departments will respond, where support agreements or mutual aid agreements exist.
3. TAMU is included in the Brazos County 911 District. Dial 9-911 from campus telephones to access emergency services.
4. Most emergencies on the TAMU campus will involve multiple responding agencies including but not limited to, University Police, Physical Plant, Environmental Health and Safety, University Emergency Medical Services, College Station Fire Department and other appropriate University, city, county and state agencies.
5. All emergency responses will utilize the Incident/Unified Command System as required by the National Incident Management System (NIMS).
6. In most cases, fire department or law enforcement personnel will assume Incident Command, depending on the type of emergency.

7. Beutel Health Center is a freestanding, ambulatory care facility with no emergency room. It is not equipped to receive patients from mass casualty incidents. Casualties will be transported to local area hospitals.
8. Other TAMUS agencies operating on the TAMU campus shall coordinate their emergency actions with this plan.

B. SITUATION

Because of its geographic location, population concentration, high-rise buildings, rail, air and highway traffic, and other risk factors, Texas A&M University is exposed to many hazards, some of which have the potential for disrupting the University community and causing widespread damage and casualties.

Possible natural hazards include, but are not limited to tornadoes, floods, fires, winter storms, and hurricanes. There is also the threat of terrorism related activities associated with biological, nuclear, incendiary, chemical, and explosive weapons. Other disaster situations could develop from a hazardous materials accident, conflagration, major transportation accident, civil disorder, disease or other unknown or unpredictable occurrences.

Also, Brazos County, including Texas A&M is a designated reception area to receive evacuees from coastal areas in the event of threatening conditions from hurricanes or other disasters. It is possible that the area could be the recipient of evacuees from any other nearby area in the event of a disaster in that area which overwhelms local resources.

C. ASSUMPTIONS

1. Texas A&M University will continue to be exposed to the hazards and situations noted above, as well as others that may develop in the future.
2. Outside assistance will be available in most emergency situations affecting the University. Although these guidelines define procedures for coordinating such assistance, it is essential for the University to be prepared to carry out disaster response and short-term actions on an independent basis.
3. It is possible for a major disaster to occur any time and any place in or near the University. In some cases, timely dissemination of warnings and increased readiness measures may be possible. However, many disasters and events can, and will, occur with little or no warning.
4. University officials and representatives must recognize their responsibilities for the safety and well-being of students, employees, and visitors; and assume their responsibilities in the implementation of this emergency plan.
5. Proper implementation of these guidelines will reduce or prevent disaster-related losses.
6. Regardless of the threat or type of emergency, it is possible that the following results may be encountered:
 - a. Death or injury to people and animals.
 - b. Interruption or disruption to transportation.
 - c. Interruption or disruption to normal communications.
 - d. Interruption or disruption to utilities and other essential services.
 - e. Congregation of large numbers of people at the scene, at central locations, at shelters, etc.

- f. Significant numbers of people being displaced, requiring some or all of the following: evacuation, shelter, feeding, welfare, and other assistance.
- g. Structural damage to streets, buildings, utilities, and other property.
- h. Contamination of food, water, personnel, vehicles, property, and other substances.
- i. Shortages of essential items.
- j. Periods of civil unrest or disorder, including looting, rioting, mob scenes, violence, etc.
- k. Initial confusion of the affected population, with probable delays in University response due to disaster events.
- l. Extensive need for public information.
- m. Disruption of business activities.
- n. Other matters of minor to serious impact or inconvenience.

SECTION 5: CONCEPT OF OPERATIONS

A. GENERAL

It is the responsibility of the University to protect life and property from the effects of hazardous events within its own jurisdiction. Texas A&M has the primary responsibility for initial emergency management activities. These guidelines are based upon the concept that the emergency functions of various agencies/organizations involved in emergency management will generally parallel normal day-to-day functions or operations. To the maximum extent possible, the same personnel and material resources will be employed in both cases. Day-to-day functions that do not contribute directly to the emergency may be suspended for the duration of any emergency. The efforts that would normally be required for those functions will be redirected to the accomplishment of emergency tasks by the department, division, or agency concerned.

B. DECLARATION

The President may declare a campus state of disaster or emergency. The effect of the declaration is to activate the recovery and rehabilitation aspects of the plan and to authorize furnishing aid and assistance. When the needs for the emergency exceed local capability to respond, outside assistance will be requested from neighboring jurisdictions and/or the state government.

1. Texas A&M University has the responsibility for emergency disaster operations within its jurisdiction. Other local government agencies responding to a request for assistance will normally be under the direction and control of the University.
2. Whenever a large-scale emergency occurs within any of the emergency management cooperating jurisdictions and it is determined necessary that all resources in the county area are required, a joint university/cities/county operation will generally be initiated.
3. The services of the Brazos County Emergency Management Coordinator will normally be available to each political subdivision, whether the disaster is localized or countywide. He/she may serve as advisor to either City Mayor, County Judge, TAMU President, or other local government agency upon request, and will function in an advisory or other role, on staff in the Emergency Operations Center (EOC) operations, if requested.

4. Emergency response activities will employ the Incident/Unified Command System (ICS) to the maximum, practicable extent. A standard Emergency Operations Center organization is discussed later in this manual.
5. The University assumes no liability for injury or death of volunteers in the performance of their duties as volunteers except that which is imposed by State Law. University employees assigned to duty as part of the Guidelines for Emergency Operations shall retain all the rights, privileges, and immunities of University employees.

C. PHASES OF MANAGEMENT

These guidelines are predicated on an all-hazard approach and acknowledge that most responsibilities and functions performed during an emergency are not hazard specific. Likewise, these guidelines account for activities before and after, as well as during emergency operations; consequently, all phases of emergency management are addressed as discussed below.

1. **Mitigation** – Mitigation activities are those which eliminate or reduce the probability of a disaster occurring. Also included are those long-term activities, which lessen the undesirable effects of unavoidable hazards.
2. **Preparedness** – Preparedness activities serve to develop the response capabilities needed in the event an emergency should arise. Planning and training are among the activities conducted under this phase.
3. **Response** – Response is the actual provision of emergency services during a crisis. These activities help to reduce casualties and damage, and speed recovery. Response activities include warning, fire, evacuation, rescue, and other similar operations.
4. **Recovery** – Recovery is both a short-term and long-term process. Short-term operations seek to restore vital services to the University and provide for the basic needs of employees, students, and visitors. Long-term recovery focuses on restoring the University to its normal pre-disaster, or an improved, state of affairs. The recovery period is also an opportune time to institute future mitigation measures, particularly those related to the recent emergency. Examples of recovery actions would be provision of temporary housing and food, identification of damaged areas with assessment of needs, restoration of non-vital University services, application for disaster assistance, reconstruction of damaged areas, and similar required actions.

D. INCREASED READINESS CONDITONS

1. Most emergencies follow some recognizable build-up period during which actions can be taken to achieve an appropriate state of maximum readiness. General departmental actions are detailed in the appropriate sections of these guidelines; however, it is **acknowledged that disasters are unique occurrences, which require specific actions dependent upon the type, nature, and extent of the emergency. In this regard, this document is not all-inclusive, nor does it limit or restrict reasonable or prudent actions.**
2. The following conditions of increasing readiness will be used as a means of delineating the University alert posture.
 - a. **Condition 4:** The term “Condition 4” will be used to *denote a situation that causes a higher degree of readiness than is normally present.* Employees should review emergency plans and check supplies and equipment. “Condition 4” actions will be

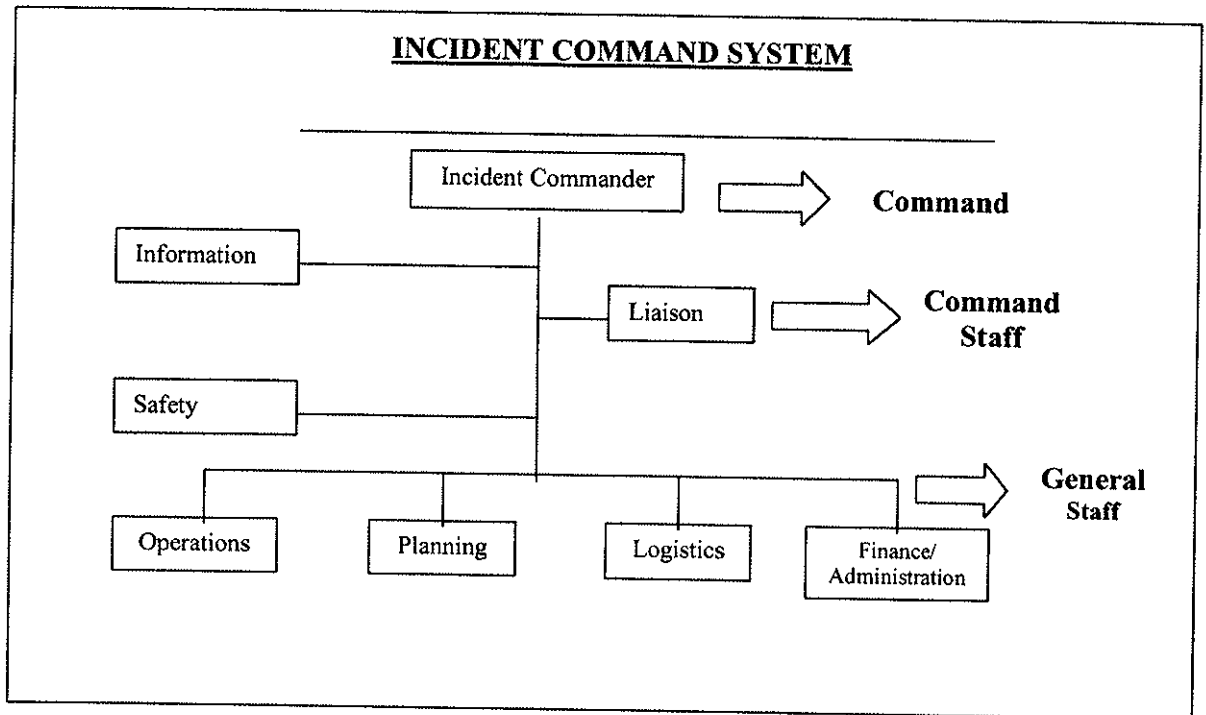
triggered by the onset of particular hazard vulnerability seasons such as tornado season, flash flood season, fire threats due to severe drought conditions, hurricane season, etc., the potential for local civil unrest, or an increase in international tensions.

- b. **Condition 3:** The term “Condition 3” will be used to *refer to a situation which presents a greater potential threat than “Condition 4”, but poses no immediate threat to life and/or property, that is, that threats are possible.* This condition includes situations that could develop into a hazardous condition such as tornado watches, hurricane watch, small-scale civil unrest, or possible enemy attack. Departments should begin preparing contingency plans for possible emergency response. “Condition 3” actions could be generated when the international situation has deteriorated to the point that enemy attack is a possibility. Declaration of “Condition 3” by the Emergency Management Director/Coordinator will require the initiation of the increased readiness activities.
- c. **Condition 2:** The term “Condition 2” will be used to *signify hazardous conditions in which the significant potential and probability of causing loss of life or extensive damage to property are probable.* This condition will require some degree of warning to personnel and will be triggered by severe weather warning information issued by the National Weather Service. A *Tornado Warning* will be issued when a tornado has actually been sighted in the area or is indicated by radar, and may strike in the vicinity. A *Flash Flood Warning* will be issued to alert persons that flash flooding is imminent or occurring on specified streams or designated areas, and that immediate action should be taken. *Civil Disorder* will be issued when there is relatively large-scale, localized violence, and/or when the international situation has deteriorated to the point that enemy attack is probable. This condition may/may not allow sufficient time for an orderly evacuation. Departments should place essential personnel on standby status and the EOC may be activated.
- d. **Condition 1:** The term “Condition 1” will be used to *signify that hazardous conditions are imminent.* This condition denotes a greater sense of danger and urgency than associated with a “Condition 2” event, and includes: a tornado has been sighted close to the University; wide-spread flooding is occurring; civil disorder precipitates large-scale violence; or an enemy attack is imminent based upon the evaluation of intelligence data. This warning (attack warning) will be declared and disseminated by the FEMA National Warning Center over the FEMA National Warning System (NAWAS). Departments will activate emergency personnel and respond to the situation, the EOC will be activated, and non-essential services may be suspended.

E. TASKS

1. See specific annexes for tasks/actions. Tasked departments/agencies will complete actions required by this plan. These departments will provide personnel for the following response teams as required. When this plan is implemented and response teams are activated, team members will be relieved of other duties and their response duty will become their primary duty.
 - a) Incident Command (IC) is established at the Field Command Post (FCP) and is most often directed and staffed mainly by College Station Fire Department

personnel. However, TAMU must be prepared and trained to execute this plan with or without the assistance or direction of outside agencies. TAMU personnel shall serve in Incident Command if directed to do so by the Incident Commander, regardless whether TAMU personnel or others run the IC. Incident Command is typically configured as shown below though the Incident Commander need not staff all positions shown if it is not deemed to be warranted for a specific incident.



Ref: Emergency Management Institute

- b) An Incident/Unified Command System shall be utilized for all multi-agency emergency responses.

2. In support of Incident Command, the following departments shall designate Primary and Secondary Response Teams as follows and shall train and equip them to respond to the incident scene when requested:

- a) Primary Response Team members shall report directly to the Entry Control Point and assist the Incident Commander with action at the site. The Primary Response Team shall consist of:

- University Police Representative
- Physical Plant Representative
- Environmental Health and Safety Representative
- Marketing and Communications Representative
- Transportation Services Representative

College Station Fire Department
Emergency Medical Services
Utilities Representative

- b) Secondary Response Team consists of other University personnel that may be requested by the Incident Commander to assist in activities at the Incident Site. The Secondary Response Team shall consist of but is not limited to the following:

Critical Incident Response team (CIRT)
Employee Assistance Program Representative (Human Resources)
Legal Representative
Contracting Representative
Dining Services Representative
Photographer
Airport Representative
Human Resources Representative
TAMUS Risk Management Representative
Representative(s) of affected TAMUS Agency(s)

F. ALERT PROCEDURES

1. General

- a. A terminal for the National Warning System is located in Austin, at the Texas Department of Public Safety (DPS), District 6B. A national emergency declaration and warning of nuclear attack or enemy action will come from this source through the University's or County's emergency management organizations.
 - b. Notification of severe weather, tornado, and flood watches and warnings emanate from NOAA, through the Texas Department of Public Safety office (DPS) in Bryan, as well as from the National Weather Service (NWS) in Galveston.
2. Alert Notification: Critical personnel notification will be in accordance with the following procedures:
- a. Weather emergency notification will be in accordance with procedures contained in Annex A, Weather Emergency.
 - b. Other emergency notifications will be in accordance with procedures contained in Appendix A, Crisis Communications.
 - c. Department and/or section heads, managers, and supervisors shall relay threat information, warnings, and readiness preparedness condition information to ensure all employees are notified. Departments shall initiate departmental notification plans and react according to their Guidelines for Emergency Operations.

SECTION 6: ORGANIZATION

A. GENERAL

The President, as Chief Executive Officer, and the Vice President for Facilities, as University Emergency Management Director, are responsible for emergency

management planning and operations for the University. Any department within the University may have emergency functions in addition to their normal duties; however, the particular role is situation dependent. Key departments are responsible for developing and maintaining their own Guidelines for Emergency Operations. General emergency management responsibilities are outlined in individual sections of this document.

B. CONCEPT

1. **The Vice President for Facilities is responsible for directing all emergency measures** with the University, as well as coordinating with College Station, Brazos County, and Bryan for mutual support.
2. **Crisis Management Plan (CMP) -**
 - a. The CMP shall be reviewed annually and modified as necessary. Results of the reviews and any changes to the CMP shall be reported to the President for approval before being submitted to the Chancellor of the A&M System.
 - b. Biannual exercises shall be held to train response personnel and evaluate the adequacy of the CMP. Reports of exercises shall be prepared and submitted to the President or designee.
 - c. Each unit or department identified as having a role in this CMP is responsible for communicating the content of the CMP to its staff.
 - d. The Assistant Vice President for Safety and Security shall serve as the TAMU Emergency Management Coordinator (EMC), shall ensure that the University's Crisis Management Plan is consistent and compatible with the County's Emergency Management Plan, and shall coordinate the CMP with the Brazos County Emergency Management Planning Office. The TAMU EMC shall also be responsible for ensuring the annual review of the CMP, documenting approved changes to the plan and planning and coordinating biannual emergency exercises.
3. **Crisis Management Planning Committee -**
 - a. Acts under the authority of and reports directly to the Vice President for Facilities.
 - b. Assists with the annual review of the CMP.
 - c. Assists with the planning and execution of biannual emergency drills.
3. Existing departments or agencies of local government (police, fire, etc.) will be primarily responsible for performing their normal functions during emergency operations. They will also perform additional duties as stated in these procedures and as the situation dictates.
4. The basic function of University officials is to coordinate all response activities through the EOC and request additional resources from College Station, Brazos County, Bryan, the disaster district, the State, and other organizations and agencies as required.
5. Departments will maintain the integrity of normal work crews whenever possible.
6. Initial reaction to a major disaster may require extended operations with work crews operating in shifts. Department heads should plan accordingly, from the disaster onset, to provide adequate time for personnel and crew rest while maintaining continuous relief efforts.
7. Hazardous conditions will likely follow any major disaster thereby increasing the risk of injuries and death.

8. Supervisors at all levels must constantly emphasize safety of students, employees, visitors, and the public.
9. A project number will be issued by Financial Management Services for the incident response effort, and will be disseminated to, and used by, all departments participating. This project number will be utilized in conjunction with the applicable accounting code to document all response and recovery costs associated with any disaster or emergency that requires a substantial response effort.

C. EMERGENCY OPERATIONS CENTER (EOC)

The EOC is the centralized communication and coordination facility for emergency response. It is the central meeting and gathering location for critical management and support personnel, and serves as an incident support operations and resource center. It will typically be organized in a manner that mirrors the Incident/Unified Command System (ICS), as much as the situation permits. Under the ICS, specific functions, responsibilities, and lines of communication and coordination are established.

THE EOC IS LOCATED IN ROOM 212 OF 1111 RESEARCH PARKWAY BUILDING IN THE RESEARCH PARK ON THE WEST CAMPUS.

THE ALTERNATE EOC IS ROOM 124 IN THE PHYSICAL PLANT BUILDING (#1156) ON AGRONOMY ROAD ON THE WEST CAMPUS.

When the Emergency Operations Center is activated, department heads (and other cognizant managers, as assigned) will direct the efforts of their departments or organizations from the EOC according to their respective Guidelines for Emergency Operations or Standard Operating Procedures for Emergency Management. Laptop computers and essential daily operating supplies will be brought to the EOC by each department at the time of activation, or as soon thereafter as possible. See Appendix D, EOC Operations Procedures.

EOC FUNCTIONS:

1. Coordinates all activities through the Field Command Post (FCP) for operating units.
2. Provides support, assistance, and supply for operating units.
3. Provides a communications base.
4. Obtains local, state, and federal assistance as needed.
5. Provides public information services and coordinates activities with the on-scene PIO.
6. Provides a centralized coordination and communications point, and an administrative and operational decision center for the University's response effort.

EOC STAFFING/RESPONSIBILITIES:

The Vice President for Facilities is responsible for directing all emergency measures with the University, as well as coordinating with College Station, Brazos County and Bryan for mutual support.

The Assistant Vice President for Safety and Security (TAMU Emergency Management Coordinator) is responsible for coordinating EOC operations to effect orderly evacuation, rescue, cleanup, or other operations as required.

1. Director of Security and University Police – has the responsibility of furnishing and directing staffing and equipment to cordon and maintain security in the affected area; conduct search and rescue operations; maintain crowd control; and direct large-scale evacuations.
2. Vice President for Facilities – has the responsibility for serving as liaison with the President’s Office and for authorizing mutual support needs.
3. Designee of Vice President for Student Affairs – has the responsibility of serving as the liaison with student officers; evacuation and relocation of students; and establishment of an emergency telephone information center to handle calls from parents.
4. Designee of Provost and Executive Vice President for Academic Affairs – has the responsibility of informing and assigning responsibility to the faculty.
5. Designee of Vice President for Finance and Controller – has the responsibility for coordinating financial resources for response and recovery operations.
6. Assistant Vice President for Safety and Security, TAMU Emergency Management Coordinator (EMC) – serves as Coordinator of EOC and serves as liaison to the Bryan, College Station, and/or Brazos County Emergency Management Organization and will coordinate needed outside resources.
7. Assistant Vice President of Physical Plant – has the responsibility of furnishing and directing manpower and equipment for restoring buildings to functional use; performing damage assessment and determining if buildings are structurally sound before being occupied. The Assistant VP will also have the responsibility of furnishing and directing manpower and equipment in setting up cleanup operations.
8. Executive Director of Marketing and Communications or Designee – has the responsibility for coordinating the needs of the outside media and for providing news releases to the Public and for coordination with the on-scene PIO. See Appendix A, Crisis Communications.
9. Director of Transportation Services – has the responsibility of furnishing equipment and directing manpower in setting up barricades and in supporting evacuation efforts. The Director will also be responsible for establishing traffic flow routes and assisting with traffic control.
10. Brazos County Emergency Management Coordinator (as requested) – will be responsible for assisting the TAMU EOC in acquiring local resources and resources which may be required from state and federal agencies. The Coordinator may be headquartered at the Brazos County Emergency Operations Center.
11. College Station/Bryan Fire Chief – serves as liaison for emergency operations and coordinates activities with UPD and TAMU Emergency Management Coordinator.
12. Administrative staff – provides support during EOC operations.

EOC Activation:

Upon notification of EOC activation, the members will report to the EOC located in room 212, 1111 Research Parkway in the University Police Department. The Secondary location will be in the Physical Plant Building (#1156) on Agronomy Road, Room 124.

The EOC shall activate when:

- a. The President, Vice President for Facilities, or their representative elect to activate the entire EOC or only those elements deemed necessary for response and recovery.
- b. The TAMU Emergency Management Coordinator or Director of Security and Police requests activation.
- c. The College Station EOC is activated in response to an on-campus incident.

- d. The Incident Commander requires its activation.

The EOC will:

Have as its primary responsibility to provide support to the Incident Commander and maintain constant contact with the Field Command Post and Unit Control Centers.

The priority of work in activating the EOC is as follows:

1. Establish radio communications with University departments in accordance with *Appendix E, EOC Activation Checklist*.
2. Establish communications with the Field Command Post and provide resources as requested.
3. Establish radio and/or telephone communications with Brazos County Emergency Management (phone: 361-4140/4141) and the City of College Station (phone: 764-6201/6216/6225). Notify R.A.C.E.S. and request assistance with communications support (phone: 845-6385/696-9494).
4. Establish internal telephone communications.
5. Notify DPS Bryan (776-3101/3103) of current status and submit an *Initial Disaster Report* to the DPS in Bryan (FAX: 776-3169) and the Division of Emergency Management (DEM) in Austin (Fax: 512-424-2444/7160). See *Appendix F, TAMU Initial Disaster Report* for report format.
6. Establish computer network links.
7. Set up maps, charts, and aerial photos as required.
8. Alert the Director of Marketing and Communications to establish the media center/press room, and notify news media through official news releases as necessary.
9. Perform other duties as required by the situation.

D. UNIT CONTROL CENTERS (UCC):

Unit Control Centers support operations, provide a focal point within an organization to monitor unit resources and response capability and coordinate their activities during disasters. UCC will assemble and dispatch resources to support this plan. Unit Control Centers will maintain detailed logs of their activities.

- a. Physical Plant
- b. EMS/Beutel Health Center
- c. University Police
- d. Transportation Services
- e. Telecommunications
- f. Human Resources
- g. Easterwood Airport
- h. Environmental Health and Safety
- i. Finance and Contracting
- j. Dining Service
- k. Student Affairs
- l. Marketing and Communications

E. FIELD COMMAND POST (FCP)

The Field Command Post (FCP) conducts all operations using the Incident/Unified Command System (ICS). Command is usually established prior to activation of the EOC. The Field Command Post provides the initial securing of the perimeter of the area, coordinates the actions of the operating units, and remains operational during the field actions (rescue, response, recovery, etc.) phases, as required.

1. Incident Commander:
 - a. The Incident Commander determines the location of the FCP, determines the need for EOC activation if not already activated, which streets are to be cleared, access routes to and from the site, and any specific transportation issues (such as helicopter landing zones, EMS locations, morgue location, etc., as appropriate). The Incident Commander also determines security boundaries, notifies Public Safety Dispatch of needs, including personnel recall from other departments as required, and sets up the FCP.
 - b. The Incident Commander commands all activities.
 - 1) The Fire Department initially controls all emergencies except those specifically assigned to Police Department.
 - 2) The Police Department controls all civil disturbances, bomb incidents, and terrorist activity operations.
 - c. The Incident Commander, through the Incident/Unified Command System, coordinates the actions of Fire, Police, Physical Plant, and all other units responding to the scene.
 - d. The Incident Commander performs other duties as required by the situation.
2. Transportation Services will:
 - a. Provide barricades and/or fencing to assist Police and Fire with area cordon.
 - b. Provide resource and logistical support for public safety operations.
 - c. Assist with evacuation efforts.
 - d. Support search and rescue operations, and coordinate with other operating units through the Police, Fire, and Incident Field Commanders.
 - e. Perform other duties as required by the situation.