

Pages 1 through 21 redacted for the following reasons:

Other Agency Record



TEXAS A&M UNIVERSITY
Environmental Health & Safety Department

August 23, 2007

Bruce Whitney, Ph.D.
Senior Biosafety and Outreach Specialist
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985

SUBJECT: Response to Information Request

Please find attached information you requested concerning elevated titers in Dr. Samuels working group. Normally this information would be provided by the Office of Research Compliance; however I am providing the information at your request.

1. Copies of IBC meeting minutes
2. Copies of Dr. Samuel's biosafety SOPs/manuals
3. Copies of 2006 and 2007 biosafety laboratory inspections for Dr. Samuel's laboratory
4. At the time the elevated titers were discovered, TAMU performed baseline and annual titers on employees using *C. burnetii*. If elevated titers were discovered the employee was contacted (as described below) and the circumstances within the laboratory were reviewed. TAMU still follows this policy today. We have drafted a new SOP for Occupational Health. This policy will be finalized upon completion of a review of all occupational health data from Dr. Samuel's lab.
5. Copies of correspondence are attached. It should be noted that TAMU does not have direct correspondence with the local health department. However because Scott & White Hospitals and Clinics, Occupational Medicine group, utilizes the Texas Department of State Health Services Laboratory to perform analysis of Q Fever and Brucella titers, they are also involved for any high titers. Whenever an "elevated" titer is detected by the TDSHS Laboratory, they immediately report the information to the local health department(s) where the infection is reported from. In our case, that is the Brazos County Health Department. Unfortunately, this notification frequently is transmitted to the local health department(s) faster than either Scott and White or Texas A&M Occupational Health find out the results. On several occasions, the Brazos County Health Department has contacted the individual with the elevated titer before Scott and White does, and prior to Scott and White informing TAMU Occupational Health. This results in the individual with the

elevated titer being contacted three times. We are aware that Brazos County Health Department has been notified by confirmation with the individual, and by unrelated conversations with Brazos County Health Department Epidemiologists. In keeping with patient confidentiality guidelines, Brazos County will not release the names of the individuals they contact, although we eventually find out.

All three of the groups (Brazos County Health Department, Scott & White, and TAMU Occupational Health) ask basically the same questions and provide the same information. (1) explanation of elevated titer and meaning of titer (2) ascertain if patient has or is suffering any illness, (3) availability of prophylaxis. In addition, Scott and White and TAMU Occupational Health also retest the employee in a few weeks, and continue monitoring

6. The researcher provides specific biosafety training for the select agent. In addition, EHSD provides voluntary laboratory safety training. These documents are attached.

As always, please feel free to contact me with any questions that you may have by telephone at (979) 862-8116 or by electronic mail at jmsalsman@tamu.edu.

Respectfully,

A handwritten signature in black ink, appearing to read "B. S. Mattox", with a stylized flourish at the end.

Brent S. Mattox
Environmental Safety Manager

Cc Central File

*IBC meeting minutes where the protocol for this research
was reviewed and approved,
as well as where the incident was described.*

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

WEDNESDAY, JUNE 27, 2007

MINUTES

MEMBERS PRESENT	VPR STAFF PRESENT	MEMBERS NOT PRESENT	GUESTS
Elizabeth Browder Tom Ficht Brent Mattox Susan Payne Vernon Tesh Angelia Raines (non-voting) Frank Stein Jan Faber (non-voting)	Tiffany Agnew Olivia Ash Kena Rogers Susan Wolff	George Booz (non-voting) Tiffany Inbody (non-voting) Patricia Klein Conrell Lockett, III *Victor Pantusa (alternate) Jon Skare Peter Tarlow	John Salsman
CALL TO ORDER	The meeting of the Institutional Biosafety Committee was called to order at 11:55 a.m. by Tiffany Agnew, with 6 voting members present.		
AGENDA ITEM	DISCUSSION/ ISSUES RAISED	RECOMMENDATIONS/ACTIONS/ FOLLOW-UP	
Introductory Comments	<ul style="list-style-type: none"> Tiffany stated for the record that quorum was present. Tiffany announced to the committee that Dr. Thomas Ficht has resigned as chair of the IBC committee. She articulated that Dr. Ficht has been a tremendous leader and the committee thanked him for his contribution to the committee over the years. Tiffany mentioned that VPR will be hosting a special event to thank Dr. Ficht for his years of dedication. It was also stated that he will remain an active member of the Institutional BioSafety Committee. Tiffany announced the visitors that were present: Kevin Rougas is the IBC new student and will be assisting Tiffany with the IBSP program; Kena Rogers is from the Animal Protection Program and was in attendance to assist with the minutes for the meetings; Olivia Ash is the Program Coordinator for the Animal Protection Program and was in attendance to discuss animal issues that were brought forth to the IBC; and Josh Andreas who is the new Administrative Coordinator for the 	<ul style="list-style-type: none"> The review of the minutes was postponed until after the review of the new rDNA protocols. 	

	<p>Office of Research Compliance and was in attendance to obtain more information on how the IBC function.</p> <ul style="list-style-type: none"> • Tiffany presented the April and May meeting minutes for the committee to review. 	
<p>rDNA Protocols</p> <p><u>2006007-Long</u></p>	<ul style="list-style-type: none"> • Dr. Payne presented information regarding this renewal application submission with the following information: Dr. Long produces cell lines and transgenic animals in which specific genes have been targeted for silencing via RNA interference. The short hairpin RNAs used for gene silencing are delivered to cells using commercially available and previously described lentiviral vector systems. Dr. Long attaches descriptions of the vectors he proposes to use. He states that all manipulations of the vector are performed under BSL2 conditions and that packaging cells are bleached and autoclaved. He notes that no endogenous human lentiviruses are known, minimizing the possibility of generating new replication competent lentiviruses should the particles infect human cells. Dr. Long also notes that media from cells infected with replication incompetent particles will be tested for the presence of replicating particles by plating onto fresh non-infected cells however he does not state what assay will be used to assay for replication competent particles. While it appears that Dr. Long understands the potential (albeit low) risks of using a lentivirus vector for gene delivery there are some items that require modification. (1) Dr. Long should note that the IBC recommends that liquids be decontaminated using a final concentration of 10% household bleach (not 1%) if bleach is to be used for decontamination. Although 	<ul style="list-style-type: none"> ▪ Dr. Payne motioned to approve the application at BSL2 containment, PENDING satisfactory response. Dr. Browder seconded the motion. There was no further discussion. Motion passed with 6 ayes, 0 nays, and 0 abstentions. (<i>Jan Faber entered after the vote; however, he is represented as a non-voting member</i>)

	<p>Dr. Long states that all items will also be autoclaved, he should clarify this decontamination protocol to note the understanding that 1% bleach treatment alone is not adequate prior to disposal of any liquids or solids. (2) In section VI B (Biological containment) please include the university building numbers in the table and note the BSL levels for these rooms. (3) In section VIA #3 (Target systems) please note the BSL level that will be in use for target systems treated with transducing particles. Note that all of the rooms for propagation and used of lentiviral vectors should be BSL2. Please provide evidence that the facilities and procedures meet BSL2 recommendations. (4) Please state the assay(s) that will be used to test for the release of replicating particles from transduced cells. While the risk of generating replication competent recombinant particles is very low, it is not zero, and exogenous lentiviruses of humans and animals might provide opportunities for recombination. Testing of transduced cells for the release of replication competent particles should be performed regularly if it is anticipated that any animals or cells will be released in the future. Dr. Payne indicated that she supports pending approval of this application, at BSL2, upon clarification of the items listed above.</p> <ul style="list-style-type: none"> • Dr. Browder added that the PI stated that he will use proper containment methods; however, the containment procedures should be specified. Dr. Browder asked that the PI describe the containment procedures for animals. • The Committee recommended approval of this protocol, with the understanding that the Investigator provides the following information: (1) If you wish to house animals at BSL1, please provide assurance that you will test stocks ahead of time to ensure no replication; (2) Animal 	<ul style="list-style-type: none"> ▪ Tiffany will follow up on the Animal Use Protocols (AUP) associated with the IBC permit and note them on the application accordingly.
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	<p>Attachment Section I.D. Please specify where animals will be housed and under what BSL containment they will be housed (3) Animal Attachment A Section IV: Please indicate the measure in place to ensure proper containment of the animals; (4) Please note that Global Genetics is no longer an approved site for animals. Please remove this location from you application; (5) Please indicate the BS on al rooms and all animal housing sites to be used. Please note that work with viral vectors must be completed; (6) Please remember to complete Attachment D; (7) Page 12 of 19: Please specify if you will use 1/10 dilution of household bleach; (8) Pate 16 or 19. Please modify Section D to include IACUC approved, as opposed to "ULACC accredited"; (9) Page Section 5: Please include Biodigestion as a final disposition</p> <ul style="list-style-type: none"> • Dr. Tesh presented the details of the new submission with the following information: This is an IBC application from Dr. James Samuel, to study the virulence mechanisms of Coxiella burnetii. Long term research goals include the development of animal models to study the agent, and the production of a phylogenetically diverse collection of C. burnetii strains to be stored and administered by the ATCC. C. burnetii is a HHS designated select agent. Dr. Samuel is DOJ approved to possess and use this agent and is a registrant with the CDC DSAT. Studies will be conducted under BSL3/ABSL3 conditions. The obligate intracellular organism will be cultured in embryonated eggs, human cells, or in animals (mice and guinea pigs). In vitro work will be carried out in class II B1/B2 biological safety cabinets that have been certified to be operational. In the proposal, the investigator plans to introduce antibiotic resistance markers into C. 	<ul style="list-style-type: none"> ▪ Dr. Browder motioned to approve the application at BSL2 and BSL3 containment, PENDING satisfactory response to the questions posed. Dr. Tesh seconded the motion. There was no further discussion. Motion passed with 6 ayes, 0 nays, and 0 abstentions.
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2007036-Samuel

	<p>burnetii. The antibiotics to be used (ampicillin, chloramphenicol, kanamycin, rifampin) are not effective in treating Q-fever in humans. Work with <i>C. burnetii</i> poses medical risks. <i>C. burnetii</i> pre-exposure titers are determined prior to starting work with the agent and an annual serological survey is in place. A training protocol for work with the agent under BSL3 conditions is in place. All wastes will be autoclaved prior to disposal. The investigator checked all the rDNA exemption boxes on the application form; this work does not qualify for rDNA exemption. In Part IV, Section A.1, the investigator lists "various" genes to be cloned into <i>C. burnetii</i> or <i>E. coli</i> K12 strains. In the past, the committee has not accepted "various genes" as a sufficiently detailed response on the rDNA form. The PI claims there will be no cloning of toxic products or medical risks associated with the rDNA work. Mice and guinea pigs will be administered <i>C. burnetii</i> via ip, oral and aerosol routes. The animal experiments will be carried out in ABSL3 facilities in LARR and the Reynolds Medical Building. The investigator proposes to use MyD88 K/O mice, however, the source of these mice is unclear. The investigator proposes to infect "human cells" with the organism, but the types of cells to be used are not clear. Personnel training records appear to be in order. Dr. Tesh recommended approval at BSL3/ABSL3 pending clarification of the <i>C. burnetii</i> genes to be cloned into expression vectors and a listing of the "human cells" to be employed in the study.</p> <ul style="list-style-type: none"> • John Salsman recommended that the approval of the permit should be contingent upon training and fit testing for respiratory gear. • The Committee recommended approval of this protocol, with the understanding that the Investigator 	<ul style="list-style-type: none"> ▪ Angelia indicated Josh will set up a meeting to discuss what is needed between IBC & IACUC in terms of animals housing, ▪ The Office of Research Compliance shall verify
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<p><u>2007040-Leibowitz</u></p>	<p>provides the following information: (1) Please specify the antibiotic drug resistance markers in the Research Objectives; (2) Please provide documentation of fit testing for the use of respirator; (3) Page Section 5: Please include Biodigestion as a final disposition; (4) Please provide more clarification regarding the genes to be used (page 14 of 39). "Various" is insufficient; (5) Clarify the use of MYD-88 knockout mice (research objectives)</p> <ul style="list-style-type: none"> • Dr. Ficht questioned Attachment D. He recommended that there is a distinction between which personnel are working with BSL1-2 agents and toxins and who will be working with BSL3 agents, who shall be DOJ approved. • Dr. Tesh presented the details of the IBC application submission with the following information: This is a complex protocol submitted for IBC approval by Dr. Julian Leibowitz, Department of Microbial and Molecular Pathogenesis in the College of Medicine. The investigator studies the replication and virulence of coronaviruses using several virus model systems including Theiler's murine encephalitis virus and mouse hepatitis virus (MHV). Note that the investigator is not proposing to use replication competent SARS coronavirus in any of these studies. Dr. Leibowitz proposes to do work under BSL2 conditions using a certified class IIA biological safety cabinet. Recombinant Semliki Forest viruses expressing structural proteins from SARS will be used to generate virus-like particles to monitor virus release from, and gene expression in, mammalian cells. Replication deficient adenoviruses will be used to express GFP as a control in these experiments. A concern is that in Part III,B,3 (p. 10/30), the investigator notes that rMHV expressing SARS genes may show enhanced virulence 	<p>training of personnel, and verify that Biosafety and Security Plans are current.</p> <ul style="list-style-type: none"> ■ Dr. Payne motioned to approve the application at BSL2 containment, PENDING satisfactory response to the questions posed. Dr. Browder seconded the motion. There was no further discussion. Motion passed with 6 ayes, 0 nays, and 0 abstentions. ■ The Office of Research Compliance shall request the Occupational Health Program to ensure vaccinia virus vaccination.
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	<p>in the MHV mouse model of SARS. Would these recombinant viruses likely pose increased risks for humans, and if so, should the experiments be performed under BSL3 conditions? Treatment options available following exposure to any of the viral agents are listed by the investigator. Pre-exposure blood draws have been taken, even though no work with SARS is proposed. The investigator does plan to transport stock MHV and recombinant baculoviral strains to off-campus collaborators. Regarding disposal, if chemical treatments (bleach or Wescodyne) are used as the sole agent, what are the treatment conditions, and what is the evidence that these conditions are effective? Mice will be administered MHV and rMHV strains via ip, intracranial and aerosol routes. Training records look OK. I recommend clarification from the investigator regarding the medical risks associated with some of the rMHV constructs, and clarification of chemical decontamination efficacy. I also recommend that an IBC member with expertise in the multitude of viral vectors used in these experiments (Dr. Payne) also be consulted regarding issues of personnel safety.</p> <ul style="list-style-type: none"> • The Committee recommended approval of this protocol, with the understanding that the Investigator provides the following information: (1) Please provide clarification of the increased risk to humans associated with the modification of the MHV; (2) Please clarify the reason of housing of mice in the ABSL3 Suite in the LARR facility; (3) Page Section 5: Please include Biodigestion as a final disposition; (4) Page 15 of 30. Please provide the conditions of decontamination and evidence of efficacy of Wescodyne; (5) Please ensure you seek assistance from EHSD regarding the shipping of your materials; (6) Page 11 of 30: Please provide written assurance that 	
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<p><u>2007042-Hendrix</u></p>	<p>opening sealed centrifugation tubes and sonication and will occur under a BioSafety Cabinet</p> <ul style="list-style-type: none"> • Dr. Tesh presented the details of the IBC application submission with the following information: This is an IBC application from Dr. Laura Hendrix in the Department of Microbial and Molecular Pathogenesis in the College of Medicine. Dr. Hendrix studies the interaction of the intracellular pathogen <i>Bartonella bacilliformis</i> with hematopoietic cells to better understand the host response to the pathogen. <i>B. bacilliformis</i> causes profound anemia and immunosuppression in humans. Dr. Hendrix categorizes <i>B. bacilliformis</i> as a RG3 agent, but because of the lack of risk for aerosol transmission, she proposes to carry out studies at BSL2. Other lower virulence <i>Bartonella</i> species (<i>henselae</i> and <i>quintana</i>) are available to the investigator, presumably to be used in comparative analyses. Work will be done in a class IIA biological safety cabinet that is currently overdue for annual certification. In Part III,B,3 (p. 8/28), the PI states "Experiments are planned which would introduce kanamycin resistance which has been approved for use in <i>Bartonella</i>." Presumably this means that kanamycin is not approved for use in treatment of bartonellosis. All wastes are to be autoclaved prior to disposal. The investigator checked all the rDNA exemption boxes although the protocol is probably not exempt. The investigator proposes to clone "various" genes into <i>E. coli</i> K12 and <i>Bartonella</i> strains. In the past, the IBC has not considered "various genes" to be a sufficiently detailed response. The PI declares no cloning of toxic products, medical risks or intention to transport agents. In Attachment A, the investigator ticks no use of toxins with live animals 	<ul style="list-style-type: none"> ▪ Dr. Payne motioned to Table the application until the PI provide information on use of live animals. Dr. Browder seconded the motion. There was no further discussion. Motion passed with 6 ayes, 0 nays, and 0 abstentions. (<i>Dr. Browder left the meeting after the vote; quorum was no longer present</i>) ▪ Tiffany will contact Environmental Health and Safety to verify the BioSafety Cabinets certification.
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	<p>(Part I), no use of pathogens with live animals (Part II), and no use of genetically modified animals (Part III), yet animals are to be disposed of by autoclaving or incineration - the reviewer is unclear precisely what is to be done with animals in these experiments. Training records look O.K. Prior to approval, this reviewer recommends: 1) check certification status of the biological cabinets that will be employed in these studies; 2) request a complete listing of the "various genes" to be cloned and expressed in this project; and 3) request clarification on the use of animals in this project.</p> <ul style="list-style-type: none"> • The Committee recommended the Investigator provide the following information for further consideration: (1) Please provide written assurance that opening sealed centrifugation tubes and sonication will occur under a BioSafety Cabinet. 	
<p>Old Business</p> <p>a. Repairs in Bldg 972 (LARR) – BSL3 Suite Update-Inspection Report</p>	<ul style="list-style-type: none"> • Brent indicated that animal house can be used; however, no experimentation can be involved in the BSL2 Suite of LARR. Brent reported that the Hepa-Filtration system has been repaired • Angelia articulated that the Inspection Process is currently as follows: Environmental Health and Safety Office will inspect the labs. The certifications are then sent to the IBC. If there are any deficiencies the EHS report to the IBC any unsatisfactory inspection findings. Facility should respond to the IBC indicating all corrective actions planned to resolve the deficiencies. 	
<p>b. Investigative Report on Q-Fever Update</p>	<ul style="list-style-type: none"> • The IBC will send documentation to PI regarding indicating that he/she did not follow his/her Standard Operating Procedure. The person with possible exposure was an employee and should have been titer testing prior to 	

	<p>use. Brent articulated that University Rules indicate all visitors and employees must be drawn before entering a BSL3 laboratory. Any outside inspectors must provide proof of baseline titers before entering a BSL3 lab.</p>	
<p>c. Alleged S19 Exposure Update</p>	<ul style="list-style-type: none"> • It was articulated that a charge needs to be conducted to the committee indicating the responsibilities under its purview. • Brent indicated that he has communicated with Principal Investigator and it appears no exposure has occurred. Should an exposure have actually occurred, NIH would have been notified as an adverse event. 	
<p>d. Genetically Modified Animals</p>	<ul style="list-style-type: none"> • Olivia prepared a list of questions for the IACUC committee regarding the review of genetically modified animals. She asked that the committee consider what types of genetically modified animals require review by the IBC. • It was recommended that this topic be added to the Institutional BioSafety Committee's Retreat agenda. 	
<p>New Business</p>		
<p>a. Expectations of the IBC- Increase Membership?</p>	<ul style="list-style-type: none"> • Dr. Tesh articulated that the roles of the IBC are expanding and the need for additional members is present. • Angelia recommended that a person with scientific background be made available to review and determine if a permit should be forwarded to the committee or if it is deemed exempt. She articulated that the expedited review process will be internally viewed and communicated to the committee before the retreat. • Dr. Tesh asked that the committee members assist Tiffany in expediting the review of permits by formally 	

<p>b. SBAT Training Update</p>	<p>detailing the results of their review in IGPS. Additionally, it was requested that research objectives in IGPS be reviewed as it is not needed. Research objectives can be found in the write complete reviews.</p> <ul style="list-style-type: none"> • Tiffany reported that in the last committee meeting Dr. Bazer indicated there would be opportunities for training in June. She reported that currently on 9 individuals out of 100 still need to attend the training; however, she also indicated that this number may be lower. • Tiffany to create reports to the committee indicating what activi 	
<p>Date of Next Meeting a. Meeting Calendar</p>	<ul style="list-style-type: none"> • Next Meeting Date: Tuesday, July 3, 2007 11:30 a.m. – 4:00 p.m. 	
<p>ADJOURNMENT</p>	<p>The meeting was adjourned at 2:50 p.m.</p>	

Biosafety SOPs/Manuals

**STANDARD OPERATING PROCEDURES FOR
BIOSAFETY LEVEL 3 SUITE,**

Rooms

Not public information

Not public information

COLLEGE STATION, TX

Entry Procedures

Sign up to use the BSL-3 by writing your name, date, and time of entry into the suite on the dry erase board located in Dr. Samuel's BSL-2 laboratory, room Public Inform. Before entering the facility, the operator must first enter all details required in the log-in book outside the anteroom (name, date, time in).

Once inside the ante-room the operator dons a laboratory gown/coat and 2 pairs of gloves.

Biosafety Cabinet Use

Before working in the biosafety cabinet, the UV light is turned off, the fluorescent light is switched on, and a biohazard bag, a paper towel, a Wexide squeeze bottle and a fresh absorbent sheet (if needed) are placed in the cabinet.

All materials needed to complete the experiment are placed in the cabinet to limit the number of times hands pass through the air barrier. Equipment is not to be placed on the intake grills at the front of the cabinet, nor blocking the exhaust opening at the back of the cabinet.

The outer (second) pair of gloves is always removed before withdrawing hands from the biosafety cabinet. A new outer pair of gloves is then donned before proceeding with other work in the BSL-3.

A biohazard bag should be present in the cabinet. Absorbent material (such as paper towels) is placed in the bottom of the biohazard bag. This bag is used for discarding solid waste (gloves, plastic waste, pipette tips). Once the bag is full, it is closed, wiped with Wexide and taken out of the cabinet to be collected into a larger covered waste container next to the cabinet.

Liquid waste should be put into a special container inside the biosafety cabinet with sufficient concentrated hypochlorite bleach to achieve a final concentration of not less than 10% and allowed to react overnight before disposal. Wipe the outside of the container with Wexide or 10% chlorine bleach before removing it from the cabinet. The liquids are then disposed of down the sink using large amounts of water.

Contaminated pipettes and plastic inoculating loops should be submerged in a container filled with the appropriate concentration of Wexide solution. The contaminated pipette tray must remain in the hood until the operator is ready to autoclave it.

Anything removed from the BSC during the work session is to be decontaminated by wiping with Wexide while still in the BSC. Ethanol (70%) is then used to remove the Wexide.

At the end of each work session, culture tubes, DNA tubes, racks and other material to be removed from the cabinet are decontaminated by wiping with Wexide while still within the cabinet. Ethanol (70%) is then used to remove the Wexide.

The absorbent sheet and other absorbent materials used during cleaning along with the gloves are placed into a biohazard bag while still within the cabinet. The bag is closed with autoclave tape while still in the cabinet. Wipe the outside of the bag with Wexide. Do not twist or tie the bag as it will blow open in the autoclave. Place the bag into a larger covered waste container next to the cabinet.

A fresh pair of gloves is donned and the hood is now wiped down completely with Wexide followed by 70% ethanol (the ethanol serves to remove the Wexide). Nothing should be left in the Biosafety cabinet when leaving the facility.

All tissue or cell culture related materials should be disposable whenever possible. Only disposable plastic pipettes and plastic inoculating loops are to be used in the BSL-3 lab.

Exiting Procedures

If autoclaving is necessary, the operator is to follow autoclaving procedures detailed below.

Once done with working outer gloves are removed and put in the general biohazard container. The inner pair of gloves must be removed in the ante-room. Finally, you must wash and dry your hands with microbicidal soap before exiting the anteroom.

The operator exits through the outer door and notes his/her time out in the log book.

Decontamination Procedures

All waste material leaving the BSL-3 facility must first be autoclaved for at least an hour except for the liquids decontaminated with bleach as noted above.

A double-door autoclave is located in the laboratory next to the ante-room.

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

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

Decontamination Procedures for Spills

- Allow aerosols to settle in the room
- Dress in protective clothing (e.g., lab coat, gloves)
- Gently cover spill with paper towels and apply 1% sodium hypochlorite (bleach), starting at perimeter and working towards the center
- Allow sufficient contact time (30-60 min) before clean up
- Decontaminate all wastes before disposal: **autoclave**
- Spill procedure notice displayed in suite

Personnel Protective Equipment

1. When in the BSL-3, Suite SA worker must wear protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls. Any clothing that is reusable must be decontaminated before being laundered. Clothing must be changed when overtly contaminated.
2. Gloves must be worn in Suite SA when handling any materials, animals, and equipment contaminated with *Coxiella burnetii*.
3. It is recommended that when in BSL-3, Suite SA personnel frequently change their gloves, along with hand washing. Disposable gloves must never be reused.
4. In BSL-3, Suite SA all manipulations of materials infected with *Coxiella burnetii*, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, etc., are conducted in a Class II or Class III biological safety cabinet.
5. When a procedure or process in BSL-3, Suite SA cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirators, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) must be used.
6. Personnel working in Suite SA are required to utilize respiratory and face protection when in rooms containing infected animals.

Long-term Inventory Records

All long term inventory records will be kept on the document Access Log, which will be maintained in the laboratory.

Special Practices

All doors are kept locked.

Dr. Samuel controls access to the suite.

Laboratory personnel receive appropriate training and instruction on the potential hazards associated with work in the suite and necessary precautions.

As part of an Occupational Health Plan, workers with access to *C. burnetii* will participate in a periodic serologic analysis for response to *C. burnetii*. A serologic sample will be taken prior to work with virulent *C. burnetii* as a baseline sample. Scott and White Clinics, the Occupational Health Plan provider, will notify workers of reportable serologic responses. Personnel will be advised of the opportunity to consult with Scott and White clinicians about the relationship between serological titer, clinical disease, and treatment options. Personnel reporting to the PI with clinical symptoms consistent with acute Q fever will be advised of the opportunity to consult Scott and White clinicians.

All personnel working with *Coxiella burnetii* in the BSL-3 have demonstrated proficiency in standard microbiological practices and techniques as well as practices specific to the suite.

STANDARD OPERATING PROCEDURES - BIOSAFETY PLAN

**for
LEVEL 3 SUITE, room** SA

Not public information

COLLEGE STATION, TX

PI: James Samuel

The Department of Health and Human Services (HHS) has issued a final rule regarding possession, use, and transfer of Select Agents and toxins (42 CFR Part 73). The final rule implements provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and is designed to protect public health and safety.

42 CFR 73 requires that an individual or entity required to register, must develop and implement a written safety plan. The plan must be written in a manner that is commensurate with the risk of the agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures.

The biosafety and containment procedures must be sufficient to contain the select agent or toxin (*e.g.*, physical structure and features of the entity, and operational and procedural safeguards).

The CDC/NIH publication, Biosafety in Microbiological and Biomedical laboratories, including all appendices. Will be used when developing safety plans.

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.

This safety plan will be reviewed 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.

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

Revised: 5/15/06

Entry Procedures:

Sign up to use the BSL-3 by writing your name, date, and time of entry into the suite on the dry erase board located in Dr. Samuel's BSL-2 laboratory, room SA

Before entering the BSL-3 (SA) suite, the operator must first enter all details required in the Facility access log-in book outside the anteroom (name, date, time in).

Once inside the anteroom the operator dons a laboratory gown/coat and 2 pairs of gloves.

Biosafety Cabinet Use:

Before working in the biosafety cabinet, the UV light is turned off, the fluorescent light is switched on, and a biohazard bag, a paper towel, a Wexide squeeze bottle and a fresh absorbent sheet (if needed) are placed in the cabinet.

All materials needed to complete the experiment are placed in the cabinet to limit the number of times hands pass through the air barrier. Equipment is not to be placed on the intake grills at the front of the cabinet, nor blocking the exhaust opening at the back of the cabinet.

The outer (second) pair of gloves is always removed before withdrawing hands from the biosafety cabinet. A new outer pair of gloves is then donned before proceeding with other work in the BL-3.

A biohazard bag should be present in the cabinet. Absorbent material (such as paper towels) is placed in the bottom of the biohazard bag. This bag is used for discarding solid waste (gloves, plastic waste, pipette tips). Once the bag is full, it is closed, wiped with Wexide and taken out of the cabinet to be collected into a larger covered waste container next to the cabinet.

Liquid waste should be put into a special container inside the biosafety cabinet with sufficient concentrated hypochlorite bleach to achieve a final concentration of not less than 10% and allowed to react overnight before disposal. Wipe the outside of the container with Wexide or 10% chlorine bleach before removing it from the cabinet. The liquids are then disposed of down the sink using large amounts of water.

Contaminated pipettes and plastic inoculating loops should be submerged in a container filled with the appropriate concentration of Wexide solution. The contaminated pipette tray must remain in the hood until the operator is ready to autoclave it.

Anything removed from the BSC during the work session is to be decontaminated by wiping with Wexide while still in the BSC. Ethanol (70%) is then used to remove the Wexide.

At the end of each work session, culture tubes, DNA tubes, racks and other material to be removed from the cabinet are decontaminated by wiping with Wexide while still within the cabinet. Ethanol (70%) is then used to remove the Wexide.

The absorbent sheet and other absorbent materials used during cleaning along with the gloves are placed into a biohazard bag while still within the cabinet. The bag is closed with autoclave tape while still in the cabinet. Wipe the outside of the bag with Wexide. Do not twist or tie the bag as it will blow open in the autoclave. Place the bag into a larger covered waste container next to the cabinet.

A fresh pair of gloves is donned and the hood is now wiped down completely with Wexide followed by 70% ethanol (the ethanol serves to remove the Wexide). Nothing should be left in the Biosafety cabinet when leaving the facility.

All tissue or cell culture related materials should be disposable whenever possible. Only disposable plastic pipettes and plastic inoculating loops are to be used in the BSL3 lab.

Exiting Procedures:

If autoclaving is necessary, the operator is to follow autoclaving procedures detailed below.

Once done with working outer gloves are removed and put in the general biohazard container. The inner pair of gloves have to be removed in the anteroom. Finally, you must wash and dry your hands with microbicidal soap before exiting the anteroom.

The operator exits through the outer door and notes his/her time out in the log book.

Decontamination Procedures:

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.

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

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

On a monthly basis, Wex-cide 128 (1 gal) will be poured down floor drains to ensure periodic decontamination. A record of this activity will be documented and maintained by the laboratory manager.

Decontamination Procedures for Spills

- Allow aerosols to settle in the room
- Dress in protective clothing (e.g., lab coat, gloves)
- Gently cover spill with paper towels and apply 1% sodium hypochlorite (bleach), starting at perimeter and working towards the center
- Allow sufficient contact time (30-60 min) before clean up
- Decontaminate all wastes before disposal: autoclave
- Spill procedure notice displayed in suite

Personnel Protective Equipment

1. When in the BSL-3, Suite SA worker must wear protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls. Any clothing that is reusable must be decontaminated before being laundered. Clothing must be changed when overtly contaminated.
2. Gloves must be worn in Suite SA when handling any materials, animals, and equipment contaminated with *Coxiella burnetii*.
3. It is recommended that when in BSL-3, Suite SA personnel frequently change their gloves, along with hand washing. Disposable gloves must never be reused.
4. In BSL-3, Suite SA all manipulations of materials infected with *Coxiella burnetii*, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, etc., are conducted in a Class II or Class III biological safety cabinet.
5. When a procedure or process in BSL-3, Suite SA cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirators, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) must be used.
6. Personnel working in Suite SA are required to utilize respiratory and face protection when in rooms containing infected animals.

Long-term Inventory Records:

All long term inventory records will be kept on the document Access Log, which will be maintained in the laboratory.

Special Practices:

All doors are kept locked.

Dr. Samuel controls access to the suite.

Laboratory personnel receive appropriate training and instruction on the potential hazards associated with work in the suite and necessary precautions.

As part of an Occupational Health Plan, workers with access to *C. burnetii* will participate in a periodic serologic analysis for response to *C. burnetii*. A serologic sample will be taken prior to work with virulent *C. burnetii* as a baseline sample. Scott and White Clinics, the Occupational Health Plan provider, will notify workers of reportable serologic responses. Personnel will be advised of the opportunity to consult with Scott and White clinicians about the relationship between serological titer, clinical disease, and treatment options. Personnel reporting to the PI with clinical symptoms consistent with acute Q fever will be advised of the opportunity to consult Scott and White clinicians.

All personnel working with *Coxiella burnetii* in the BSL-3 have demonstrated proficiency in standard microbiological practices and techniques as well as practices specific to the suite.

Incident Response:

The incident response plan will be utilized in conjunction with the university crisis management plan in the event of an emergency.

STANDARD OPERATING PROCEDURES FOR BIOSAFETY LEVEL 3

Not public information

COLLEGE STATION, TX

Although these procedures have been written specifically for the BSL3 suite in Building 1504 (SA and SA A-D) they are applicable to experiments in building972 (room 143) except where explicitly indicated otherwise

Entry Procedures:

Sign up to use the BL3 by writing your name, date, and time of entry into the suite on the dry erase board located in Dr. Samuel's BL-2 laboratory, room 414. Before entering the facility, the operator must first enter all details required in the log-in book outside the anteroom (name, date, time in).

Once inside the anteroom the operator dons a laboratory gown/coat and 2 pairs of gloves.

Biosafety Cabinet Use

Before working in the biosafety cabinet, the UV light is turned off, the fluorescent light is switched on, and a biohazard bag, a paper towel, a Wexide squeeze bottle and a fresh absorbent sheet (if needed) are placed in the cabinet.

All materials needed to complete the experiment are placed in the cabinet to limit the number of times hands pass through the air barrier. Equipment is not to be placed on the intake grills at the front of the cabinet, nor blocking the exhaust opening at the back of the cabinet.

The outer (second) pair of gloves is always removed before withdrawing hands from the biosafety cabinet. A new outer pair of gloves is then donned before proceeding with other work in the BL-3.

A biohazard bag should be present in the cabinet. Absorbent material (such as paper towels) is placed in the bottom of the biohazard bag. This bag is used for discarding solid waste (gloves, plastic waste, pipette tips). Once the bag is full, it is closed, wiped with Wexide and taken out of the cabinet to be collected into a larger covered waste container next to the cabinet.

Liquid waste should be put into a special container inside the biosafety cabinet with sufficient concentrated hypochlorite bleach to achieve a final concentration of not less than 10% and allowed to react overnight before disposal. Wipe the outside of the container with Wexide or 10% chlorine bleach before removing it from the cabinet. The liquids are then disposed of down the sink using large amounts of water.

Contaminated pipettes and plastic inoculating loops should be submerged in a container filled with the appropriate concentration of Wexide solution. The contaminated pipette tray must remain in the hood until the operator is ready to autoclave it.

Anything removed from the BSC during the work session is to be decontaminated by wiping with Wexide while still in the BSC. Ethanol (70%) is then used to remove the Wexide.

At the end of each work session, culture tubes, DNA tubes, racks and other material to be removed from the cabinet are decontaminated by wiping with Wexide while still within the cabinet. Ethanol (70%) is then used to remove the Wexide.

The absorbent sheet and other absorbent materials used during cleaning along with the gloves are placed into a biohazard bag while still within the cabinet. The bag is closed with autoclave tape while still in the cabinet. Wipe the outside of the bag with Wexide. Do not twist or tie the bag as it will blow open in the autoclave. Place the bag into a larger covered waste container next to the cabinet.

A fresh pair of gloves is donned and the hood is now wiped down completely with Wexide followed by 70% ethanol (the ethanol serves to remove the Wexide). Nothing should be left in the Biosafety cabinet when leaving the facility.

All tissue or cell culture related materials should be disposable whenever possible. Only disposable plastic pipettes and plastic inoculating loops are to be used in the BSL3 lab.

Exiting Procedures

If autoclaving is necessary, the operator is to follow autoclaving procedures detailed below.

Once done with working outer gloves are removed and put in the general biohazard container. Enter changing room and remove gloves outside to inside. Finally, you must wash and dry your hands with microbicidal soap before exiting the anteroom.

The operator exits through the outer door and notes his/her time out in the log book. Wash hands in Rm 414 for hygiene to remove residue from microbicidal soap.

Decontamination Procedures

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.

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

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

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

Decontamination Procedures for Spills

- Allow aerosols to settle in the room
- Dress in protective clothing (e.g., lab coat, gloves)
- Gently cover spill with paper towels and apply wex-cide, starting at perimeter and working towards the center
- Allow sufficient contact time (30-60 min) before clean up
- Decontaminate all wastes before disposal: autoclave
- Spill procedure notice displayed in suite

AEROSOL CHALLENGES

1 Intra-entity transfer forms must be filled out at least one day prior to performance of any transfer between buildings.

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

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 143.

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.

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.

5 At the CMP facility, animals will be transported to room 143 in microisolator cages and removed in the biological safety cabinets and loaded into cages for challenges.

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.

6 Madison Chamber preparation and use (building Not public information)

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. 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 Nebulizer jars are filled with inoculum under the safety cabinet.

6.6 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.

6.7 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.

6.8 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.

6.9 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.

6.10 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.

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 143 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 143. 5/17/07

7.7 The tyvek suits are removed in the hall outside room 143 and placed in approved containers to be autoclaved by CMP personnel. The animal rack is transported back to the animal holding room.

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

8 The inoculums and extracted tissues are returned to building 1504 in approved containers

8.1 Animals may either be sacrificed at CMP (building 972) or moved back to animal holding facilities in building by CMP personnel.

8.2 Tissues are harvested as early immediately post exposure to one week, and up to one-year post inoculation and homogenized in PBS.

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.

1.1 Outer packaging is used to transport the material back to the originating lab

Special Practices

All doors are kept locked.

Dr. Samuel controls access to the suite.

Laboratory personnel receive appropriate training and instruction on the potential hazards associated with work in the suite and necessary precautions.

As part of an Occupational Health Plan, workers with access to *C. burnetii* will participate in a periodic serologic analysis for response to *C. burnetii*. A serologic sample will be taken prior to work with virulent *C. burnetii* as a baseline sample. Scott and White Clinics, the Occupational Health Plan provider, will notify workers of reportable serologic responses. Personnel will be advise of the opportunity to consult with Scott and White clinicians about the relationship between serological titer, clinical disease, and treatment options. Personnel reporting to the PI with clinical symptoms consistent with acute Q fever will be advised of the opportunity to consult Scott and White clinicians.

All personnel working with *Coxiella burnetii* in the BL-3 have demonstrated proficiency in standard microbiological practices and techniques as well as practices specific to the suite.

STANDARD OPERATING PROCEDURES FOR BIOSAFETY LEVEL 3

REYNOLDS MEDICAL BUILDING COLLEGE STATION, TX

Although these procedures have been written specifically for the BSL3 suite in Building 1504 (room SA and SA A-D) they are applicable to experiments in Building 972 (room 143) except where explicitly indicated otherwise

1. ACCESS TO BSL3

1.1 Access is limited to areas working with SBAT is regulated by CDC/DOJ.

- Only approved personnel may work with SBAT in registered areas.
- Personnel are issued a key card requiring fingerprint activation when you have been assigned a CDC/DOJ approval number and successfully completed all training requirements under the direction of the PI or designee.
- Passcards are not to be transferred between individuals or shared.
- In order to maintain the accuracy of access logs cards may not be borrowed. In this event access may only be gained with the assistance of the PI.

1.2 Non-approved personnel must be escorted by approved personnel and are not permitted to work with or gain access to SBAT. Access is defined as "at any point in time in which has possession of the agent (example carries, uses or manipulates) or has the ability to gain possession of the select agent or toxin".

- Non-approved personnel must be escorted at all times in the BSL3 and sign a certificate of training to acknowledge the laws governing access to SBAT.
- It is the responsibility of the escort to maintain contact with the trainee and to correctly and completely fill in the Facility Access Log.

2. SAFETY EQUIPMENT (PRIMARY BARRIERS): BIOSAFETY LEVEL 3

2.1 Properly maintained biological safety cabinets are used (Class II or III) for all manipulation of infectious materials.

2.2 Outside of a biological safety cabinet, appropriate combinations of personal protective equipment are used (e.g., special protective clothing, masks, gloves, face protection, or respirators), in combination with physical containment devices (e.g., centrifuge safety cups, sealed centrifuge rotors, or containment caging for animals).

2.3 This equipment must be used for manipulations of cultures and of those clinical or environmental materials which may be a source of infectious aerosols; the aerosol challenge of experimental animals; harvesting of tissues or fluids from infected animals and embryonated eggs, and necropsy of infected animals.

2.4 Face protection (goggles and mask, or faceshield) is worn for manipulations of infectious materials outside of a biological safety

cabinet.

- 2.5 Respiratory protection is worn when aerosols cannot be safely contained (i.e., outside of a biological safety cabinet), and in rooms containing infected animals.
- 2.6 Protective laboratory clothing such as solid-front or wraparound gowns, scrub suits, or coveralls must be worn in, and not worn outside, the laboratory. Reusable laboratory clothing is to be decontaminated before being laundered.
- 2.7 Gloves must be worn when handling infected animals and when hands may contact infectious materials and contaminated surfaces or equipment. Disposable gloves should be discarded when contaminated, and never washed for reuse.
- 2.8 Working in the different labs warrants different levels of biocontainment. Any work within the biological safety cabinet (BSC) may be performed without any additional protective gear.

3. PROCEDURES WHILE WORKING IN THE BSL3 SUITE

- 3.1 The following specimens should be considered contaminated:
- all items or liquids known to contain infectious agents.
 - If there is any question about a substance, it should be considered contaminated.
- 3.3 Handling sharp objects
- Sharp objects include:
 - syringe needles,
 - glass Pasteur pipets (or any thin glass tubing),
 - broken glass,
 - knife (scalpel) blades, and
 - anything else that could puncture human skin.
 - Whenever possible, avoid the use of sharp objects and glass objects. Substitute plasticware for glassware.
 - Never re-cap, bend, or break a hypodermic needle.
 - Never handle broken glass, use tweezers or tongs. Use a dustpan and broom to clean up broken glass.
- 3.4 When using the biological safety cabinets:
- Minimize the number of items inside the biological safety cabinet. The only items should be those that are immediately required for the experiment. Too many items in the cabinet disrupt laminar airflow and reduce the level of protection provided by the cabinet.
 - Never obstruct the vents in the cabinet. These include:
 - the vent in the front of the cabinet (covered by the grill),
 - the vents on the left and right sides of the cabinet, and

the vent in the back of the cabinet.

3.5 The telephones in the BSL3 suite are for emergency use only, to provide additional safety for you. Remember that you are holding potentially contaminated latex gloves very close to your face, that these gloves are touching the receiver, which is very close to your face and mouth, and that someone else will be using the receiver after you. Remove the outer pair of latex exam gloves before picking up the receiver.

- Decontaminate the receiver immediately after every use.
- Do not give the BSL3 phone number to friends. They can leave a message, and you can return their calls when you leave the BSL3 suite. If there is an emergency, laboratory or office staff can transfer the call or come into the BSL3 suite to give you the message.

4. Biosafety Cabinet Use

Before working in the biosafety cabinet, the UV light is turned off, the fluorescent light is switched on, and a biohazard bag, a paper towel, a Wexide squeeze bottle and a fresh absorbent sheet (if needed) are placed near the cabinet.

All materials needed to complete the experiment are placed in the cabinet to limit the number of times hands pass through the air barrier. Equipment is not to be placed on the intake grills at the front of the cabinet, nor blocking the exhaust opening at the back of the cabinet.

A biohazard bag should be present in the cabinet. This bag is used for discarding solid waste (gloves, plastic waste, pipette tips). Once the bag is full, it is closed, wiped with Wexide and taken out of the cabinet to be collected into a larger covered waste container next to the cabinet.

Liquid waste should be put into a special container inside the biosafety cabinet with sufficient concentrated hypochlorite bleach to achieve a final concentration of not less than 10% and allowed to react overnight before disposal. Wipe the outside of the container with Wexide or 10% chlorine bleach before removing it from the cabinet. The liquids are then autoclaved prior to disposal down the sink using large amounts of water.

Anything removed from the BSC during the work session is to be decontaminated by wiping with Wexide while still in the BSC. Ethanol (70%) is then used to remove the Wexide.

At the end of each work session, culture tubes, DNA tubes, racks and other material to be removed from the cabinet are decontaminated by wiping with Wexide while still within the cabinet. Ethanol (70%) is then used to remove the Wexide from metal surfaces.

The autoclave bag is closed with autoclave tape while still in the cabinet. Wipe the outside of the bag with Wexide. Do not twist or tie the bag as it will blow open in the autoclave. Place the bag into a larger covered waste container next to the cabinet.

The hood is now wiped down completely with Wexide followed by 70% ethanol (the ethanol serves to remove the Wexide).

All tissue or cell culture related materials should be disposable whenever possible. Only disposable plastic pipettes and plastic inoculating loops are to be used in the BSL3 lab.

5. ROUTINE CLEANING AND DECONTAMINATION PROCEDURES

5.2 At the very minimum, all laboratory surfaces should be disinfected before and after work. The following disinfectants may be used:

- 70% ethanol or isopropyl alcohol
- Wexide® (diluted 1:256, or 15 ml per gallon of water)
- 10% household bleach (diluted 100 ml per liter of water)

5.3 All material to be autoclaved are stored in leak proof pans.

5.4 All other (non-sharp) waste and trash generated in the laboratories are placed in biosafety bags and autoclaved.

- Decontamination
 - When a biohazard waste bag is approximately 2/3-full, it should be autoclaved.
 - Place the bag in a leak-proof pan before carrying the bag into the hallway (to prevent possible leakage of liquid onto the floor).
 - Autoclave using the "Gravity" program for trash (solid). Bacterial plates are autoclaved using the liquid cycle for spent media.
 - Test tape is used to close the bag.
- When the bin is full these bags are transferred to the general trash (dumpster).
- All autoclave runs are recorded and the autoclaves are certified weekly using thermotolerant spores (commercial supplier).
- Autoclaves are operated as described on the EHSD web page (<http://finance.tamu.edu/ehsd/resources/biosafety.asp>) using conditions recommended by NIH and described in the IBC application form.

5.5 Disposal of liquid waste:

- Large volumes of liquid waste are kept in autoclaveable containers less than 3/4-full, and autoclaved in pans to catch any spills.
- Decontamination with appropriate dilution of bleach may also be used (section 4.2 above).
- Smaller cultures in disposable plasticware are placed inside biohazard bags and placed in autoclaveable pans (for double-containment) before autoclaving.

- Liquid waste is autoclaved on the "Liquid" as described on the Environmental Health and Safety web page and the IBC application form.
- When the cycle is complete, open the autoclave door about 2 inches and wait at least 10 minutes before removing the liquids. (Follow directions given by the messages on the autoclave).
- After 10 minutes, take the bottles out of the autoclave. If the autoclaved waste contains no coagulated solids, it may be poured down the sink. Bottles with coagulated solids must be sealed and placed directly in the dumpster outside the building.

5.6 Floors are mopped quarterly with either:

- Wexcide® (as described above), or
- Commercial bleach (1:10 dilution in water)

6. DECONTAMINATION PROCEDURES FOR SPILLS

6.1 Immediately hold your breath. DON'T TAKE A DEEP BREATH!!

6.2 Signal others in the BSL3 labs of any spill outside Class IIa biological safety cabinet. All other personnel must exit and shower profusely with disinfectant soap and shampoo. Clothes must be removed within the BSL3 area and will be autoclaved by those cleaning up. Place a sign on the lab door to indicate unsafe condition.

6.3 Exit the lab and shower to remove any aerosol contamination.

6.4 Wait one hour to allow the room to evacuate any aerosol and put on a fullface respirator with HEPA cartridges and double gloves.

6.5 Use a polyzorb adsorbent pillow (one-liter) or paper towels to cover The spill. Prevent creation of contaminated aerosols.

6.6 Saturate all materials with disinfectant solution (see previous section For description).

6.7 Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in double autoclave bags.

6.8 Disinfect all exposed surfaces using any of the surface disinfecting agent (Wexcide, bleach) in aerosolizer.

6.9 Wipe surface of full face respirator with disinfectant, being careful to Avoid skin contact with disinfectant.

6.10 Remove all clothing and shoes and place in double autoclave bag. Have a bag outside the room to transfer all contaminated material

from room.

- 6.11 Remove full-face respirator and place in double plastic bag for Ethylene oxide sterilization.
- 6.12 Continue sterilization of BSL3 area using aerosolizer with 1X Wexcide.
- 6.13 Make sure that all contaminated material is autoclaved or ethylene Oxide sterilized.
- 6.14 Put on a clean wrap-around to go to locker room and shower profusely with disinfectant soap and shampoo.

7. PROCEDURE IN THE EVENT OF ACCIDENT

- 7.1 In the case of a spill proceed as described above and then report the accident to Dr. James Samuel (979-862-1684 or 979-220-8269) or your immediate supervisor and departmental administrator (979-845-1314).
- 7.2 In the event that you have an accident that causes a break in the skin (broken glass, etc) be sure to disinfect the area carefully using alcohol
 - 2.1 Always be certain to disinfect yourself carefully before leaving the BSL3 lab.
- 7.3 Make an appointment to see your physician or the Occupational Health Program Physicians at Scott & White clinic (979-691-3072).
 - 3.1 Follow the incident report and contact the biosafety officer, University Police and the Office of Research Compliance.
 - 3.2 Students (especially those on fellowship) should be sure to mention that this accident is covered by Occupational Health and not Workman's Compensation

8. SPECIAL PRACTICES: BIOSAFETY LEVEL 3

- 8.1 Laboratory doors are kept closed when experiments are in progress.
- 8.2 The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. Persons who are at increased risk of acquiring infection or for whom infection may be unusually hazardous are not allowed in the laboratory or animal rooms.
The director has the final responsibility for assessing each

circumstance and determining who may enter or work in the laboratory.

- 8.3 The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures, enter the laboratory or animal rooms.
- 8.4 When infectious materials or infected animals are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.
- 8.5 As part of an Occupational Health Plan, workers with access to *C. burnetii* will participate in a periodic serologic analysis for response to *C. burnetii*. A serologic sample will be taken prior to work with virulent *C. burnetii* as a baseline sample. Scott and White Clinics, the Occupational Health Plan provider, will notify workers of reportable serologic responses. Personnel will be advise of the opportunity to consult with Scott and White clinicians about the relationship between serological titer, clinical disease, and treatment options. Personnel reporting to the PI with clinical symptoms consistent with acute Q fever will be advised of the opportunity to consult Scott and White clinicians.
- 8.6 Baseline serum samples are collected and stored for all laboratory and other at-risk personnel
- 8.7 A biosafety manual is prepared or adopted. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.
- 8.8 Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.
- 8.9 The laboratory director is responsible for ensuring that, before Working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the

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

8.11 All manipulations involving infectious materials are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench.

8.12 Laboratory equipment and work surfaces should be decontaminated with an appropriate disinfectant on a routine basis, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination with infectious materials.

Contaminated equipment should also be decontaminated before it is sent for repair or maintenance or package for transport in accordance with applicable local, state, or federal regulations, before removal from the facility. Plastic-backed paper toweling used on non-perforated work surfaces within biological safety cabinets facilitates clean-up.

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

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

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

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

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

9. EXIT PROCEDURES

9.1 Any time you move away from the biosafety cabinet:

1.1 Remove the outer pair of gloves.

1.2 Disinfect the inner pair of gloves with 70% ethanol.

9.2 Before leaving the Procedure Laboratories

- 2.1 Decontaminate all surfaces with appropriate disinfectant.
- 2.2 Turn on the ultraviolet light in the biosafety cabinet.
Leave the fan motor running in the biosafety cabinet (It requires a 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

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.

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

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

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

Decontamination Procedures for Spills

- Allow aerosols to settle in the room
- Dress in protective clothing (e.g., lab coat, gloves)
- Gently cover spill with paper towels and apply wex-cide, starting at perimeter and working towards the center
- Allow sufficient contact time (30-60 min) before clean up
- Decontaminate all wastes before disposal: autoclave
- Spill procedure notice displayed in suite

11. Special Protocols: AEROSOL CHALLENGES

- 11.1 Intra-entity transfer forms must be filled out prior to performance of any transfer between buildings.
- 11.2 *Coxiella* suspensions used for inoculations are prepared and loaded into conical tubes in rooms SA of building 1504 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 143.
 - 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 room 143 in microisolator cages and removed in the biological safety cabinets and loaded into cages for challenges.
 - 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 972 room 143)
 - 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. 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 Nebulizer jars are filled with inoculum under the safety cabinet.

6.6 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.

6.7 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.

6.8 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.

6.9 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.

6.10 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 143 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 143.5/17/07

7.7 The tyvek suits are removed in the hall outside room 143 and placed in approved containers to be autoclaved by CMP personnel. The animal rack is transported back to the animal holding room.

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 1504 in approved containers

8.1 Animals may either be sacrificed at CMP (building 972) or moved back to animal holding facilities in building by CMP personnel.

8.2 Tissues are harvested as early immediately post exposure to one week, and up to one-year post inoculation and homogenized in PBS.

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.

2007 Biosafety Laboratory Inspection Reports

TEXAS A&M UNIVERSITY

VICE PRESIDENT FOR RESEARCH - OFFICE OF RESEARCH COMPLIANCE

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Institutional Biosafety Committee

Institutional Animal Care and Use Committee

Institutional Review Board

MEMORANDUM

TO: Dr. James Samuel
Medical Microbiology and Immunology
MS 1114

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

DATE: February 2, 2007

REG.: Annual IBC Inspection of Select Agent Facilities- Building 1504 (Samuel)

At 10:15 a.m. (CST) on January 10, 2007, the following individuals completed the Annual IBC Inspection of the Select Agent Facilities- Building 1504(Samuel):

Ms. Angelia Raines- IBC Member/Director, ORC
Dr. Thomas Ficht- IBC Member (Chair)
Mr. Brent Mattox- IBC Member/EHS
Ms. Nancy Eaker- EHS
Ms. Tiffany Agnew- IBSP Coordinator

The aforementioned team utilized the combined checklist from Environmental Health and Safety and the Office of Research Compliance to complete the inspection of the facilities. The use of this combined checklist marks the combined inspection by both offices, to reduce duplicated efforts for identical information. In accordance with CFR 42 § 73.9, inspection of Select Agent Facilities at Texas A&M University have been conducted in December. However, in an attempt to give the Select Agent investigators an opportunity to review the combined checklist, the inspections of all Select Agent Facilities were scheduled to be completed in January. The inspection for Building 1504 was originally scheduled to take place on Wednesday, January 10, 2007; however, due to inclement weather, the University was closed on this day. The inspection was rescheduled for the aforementioned date.

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

1. As a result of the **Facility Assessment** of the *Laboratory Facilities (Secondary Barriers)*, the following was noted in respect of the interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination:
 - a. SA
 - i. Penetration(s) in wall(s) next to the autoclave unit
 - ii. Cracks in the paint
 - b. SA
 - i. Airflow alarm sounding (Air balance was verified to be good, but the sensor was inoperable.)
 - ii. Fire extinguisher has not been serviced since 2004 (Others in suite should be serviced/checked as well.)
 - iii. Cracks in paint
 - iv. Hole in wall near door needs to be filled
 - v. Coving where it meets the wall needs to be sealed; gaps noted
 - vi. No door sweep on the door

- c. SA
 - i. No door sweep on the door
 - ii. Cracks in paint
 - iii. Hole in wall near door needs to be filled
 - iv. Coving where it meets the wall needs to be sealed
 - d. SA
 - i. UV light on Biosafety Cabinet (BSC) needs to be repaired. (EHS will notify contractor.)
 - ii. Cracks in paint
 - iii. Coving where it meets the wall needs to be sealed
 - iv. Glass containers noted on the floor
2. As a result of the **Program Assessment** in regards to *Training*, the following was noted:
- a. Several training certificates were not signed.
3. As a result of the **Program Assessment** in regards to *records*, the following was noted:
- a. There was no updated Emergency Contact list in records. (Records reflect investigator who is no longer at institution.)
4. As a result of the **Program Assessment** in regards to the Agent Access Log, the following was noted:
- a. Improper use of the Agent Access Log; entries were not complete and there were many inconsistencies.
 - b. Members of the team suggested PI provide additional training to personnel in the correct usage of the log.

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

If you have any additional questions or concerns, please contact our office as soon as possible.

cc: IBC
Department head
IBC files

IBC INSPECTION REPORT

BSL3/ABSL3 SBAT FACILITIES & Entity Program

Date: January 10, 2007

Principal Investigator/Lab Director: Dr. James Samuel

Location: Building Number -1504 Room (s) SA B, C, & D

Inspection Team:

Angelia Raines, Tom Ficht
Brent Mattox, Nancy Eaker

Section I - Facility Assessment (PI)

A. Safety Equipment (Primary Barriers)

- ☒ Yes ☐ No Protective laboratory clothing, such as solid-front or wrap-around gowns, scrub suits, or coveralls, are worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overly contaminated.
- ☒ Yes ☐ No Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.
- ☒ Yes ☐ No Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.
- ☒ Yes ☐ No All activities with recombinant DNA molecules, manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, or other potential aerosol producing activities, are conducted in a Class II or Class III biological safety cabinet.
- ☒ Yes ☐ No When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirator, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.
- ☒ Yes ☐ No Respiratory and face protection are used when in rooms containing infected animals.

B. Laboratory Facilities (Secondary Barriers)

- ☒ Yes ☐ No The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.
- ☒ Yes ☐ No Each laboratory contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.
- ☐ Yes ☒ No The interior surfaces of walls, floors, and ceilings of areas where BLS-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and

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

- ☒ Yes ☐ No Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.
- ☒ Yes ☐ No Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.
- ☒ Yes ☐ No Windows in the laboratory are closed and sealed.
- ☒ Yes ☐ No A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.
- ☒ Yes ☐ No Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.
- ☐ Yes ☒ No A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.
- ☒ Yes ☐ No HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.
- ☒ Yes ☐ No Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.
- ☒ Yes ☐ No Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).
- ☒ Yes ☐ No An eyewash facility is readily available inside the laboratory.
- ☒ Yes ☐ No Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.
- ☒ Yes ☐ No The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as

modified by operational experience.

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

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

C. Standard Microbiological Practices

- ☒ Yes ☐ No Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.
- ☒ Yes ☐ No Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.
- ☒ Yes ☐ No Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.
- ☒ Yes ☐ No Mechanical pipetting devices are used; mouth pipetting is prohibited.
- ☒ Yes ☐ No Policies for the safe handling of sharps are instituted.

- ☒ Yes ☐ No All procedures are performed carefully to minimize the creation of aerosols.
- ☒ Yes ☐ No Work surfaces are decontaminated at least once a day and after any spill of viable material.
- ☒ Yes ☐ No All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.
- ☒ Yes ☐ No Persons under 16 years of age are not allowed to enter a BL3 laboratory.
- ☒ Yes ☐ No If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.
- ☒ Yes ☐ No An insect and rodent control program is in effect.

D: Special Practices

- ☒ Yes ☐ No Laboratory doors are kept closed when experiments are in progress.
- ☒ Yes ☐ No The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.
- ☒ Yes ☐ No The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements (e.g., immunization), and who comply with all entry and exit procedures enter the laboratory or animal rooms.
- ☒ Yes ☐ No When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.
- ☒ Yes ☐ No Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled.
- ☒ Yes ☐ No Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.
- ☒ Yes ☐ No A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.
- ☒ Yes ☐ No Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure

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

☒ Yes ☐ No

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

☒ Yes ☐ No

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

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

☒ Yes ☐ No

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

☒ Yes ☐ No

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

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

☒ Yes ☐ No

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

☒ Yes ☐ No

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

☒ Yes ☐ No

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

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

☒ Yes ☐ No

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

☒ Yes ☐ No

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

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

- ☒ Yes ☐ No An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with Select Agents at this facility:
If yes: IBC approved the work proposed for this facility on: 4/21/04 (date).
- ☒ Yes ☐ No 2. **Training:** Site specific and safety training is provided to individuals with access to areas where Select Agents are handled or stored:
- Is provided prior to individuals beginning to work with Select Agents: ☒ Yes ☐ No
 - Is provided: ☒ Annually ☐ Biannually ☐ Other (specify frequency):
Records indicate training completed May 2, 2006 (reflected changes in facility entry).
 - Written records of individuals are kept: ☒ Yes ☐ No
 - Personnel demonstrate proficiency in laboratory procedures prior to working with Select Agents: ☒ Yes ☐ No
 - Unannounced visits by EH&S and follow up by supervisory personnel: ☐ Yes ☐ No
3. Provide a brief explanation of the system in place to detect loss or theft of select agent(s):
within the Incident Response Plan
4. **Inventory:** Individual responsible for inventory of select agent(s): **Dr. Samuel/ Eunhee Lee (designee)**
- How often is the inventory record reconciled? **12/09/05 (Indicated in SOP as Annually)**
 - How is access to the inventory log limited? **In locked cabinet and on secure file on computer; PI and designee only have access keys and password**
 - Inventory tracking includes the following information (list):
5. **Security:** There is a site-specific Security Plan for this laboratory: ☒ Yes ☐ No
- Building with Select Agent has self-closing doors: ☒ Yes ☐ No
 - Means to limit access to buildings with laboratories with Select Agent:
Guard station at the facility entrance: ☐ Yes ☒ No
Card access system or locks: ☒ Yes ☐ No
6:00 a.m.-6:00 p.m. Monday-Friday, 24 hours on weekends
Security alarm system in the laboratory building: ☒ Yes ☐ No
Other (describe): **Alarm will sound if door is held open too long.**
 - Means to limit access to laboratories with Select Agent once inside the building:
Door to laboratory is locked: ☒ Yes ☐ No
Doors to BSL3 locked 24 hours. These doors are magnetic on both sides of the door, with dual key card and fingerprint ID system.
Card access system or locks: ☒ Yes ☐ No
Other (describe): _____
 - Means to limit access to select agents once inside the laboratory:
Locked incubators, refrigerators, freezers, etc.: ☒ Yes ☐ No
Locked freezers only; locks are only on inventory items.
Security alarm system that directly monitors the laboratory: ☒ Yes ☐ No
Other (describe): **Hawkeye System used; reports filter into the radio room on campus. Only DOJ approved personnel have access to BSL3 Suite.**
 - Means to limit access to select agents in storage:
Storage area door locked: ☒ Yes ☐ No
Lock boxes: ☒ Yes ☐ No
Freezer has padlock. Lock box within freezer that only Dr. Tesh has key an authorization to access.
Security alarm system that directly monitors the laboratory: ☐ Yes ☒ No
Other (describe): _____
 - Means to monitor unauthorized entry into the laboratory where select agents are used or stored: **Facility Access Log**
Electronic logs of card access system entries are reviewed for unusual activity:
☒ Yes ☐ No
Manual sign in and out logs are kept and monitored: ☒ Yes ☐ No
Video camera surveillance: ☐ Yes ☒ No

- j. The laboratory is secured when no one is present during regular working hours: ☒ Yes ☐ No
- k. Number of people with access: **all those listed on 4B table**
- l. Individuals not directly involved in research activities have access to Select Agent: ☒ Yes ☐ No
If yes, please explain: **George Martin (building manager- DOJ approved)**
- m. Non-laboratory personnel (visitors, including janitorial and facility maintenance personnel) have access to the laboratory with select agents: ☒ Yes ☐ No
If yes, are they allowed into the laboratory unescorted? ☐ Yes ☒ No
6. Decontamination: All cultures, stock and other regulated wastes are decontaminated before disposal by an approved decontamination method: ☒ Yes ☐ No
If yes, describe method: **Noted in Standard Operational Procedures (Biosafety Plan)**

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

- ☒ Yes ☐ No 1. The facility has an Institutional Biosafety Committee that has approved work with recombinant DNA or has approval pending.
New submission will need to be before: April 21, 2007
- ☒ Yes ☐ No 2. The biosafety level listed in the *Application for IBC Permit* for this laboratory meets NIH Guidelines.
3. Will you be possessing, using, or transferring the following:
a. Select Agent nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that are capable of infection and/or replication: ☐ Yes ☒ No
b. Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids are in a vector or host chromosome and/or are expressed *in vivo* or *in vitro*: ☐ Yes ☒ No
c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. ☒ Yes ☐ No
4. Are you intending to conduct the following experiments:
a. Experiments utilizing recombinant DNA techniques that involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture: ☐ Yes ☒ No
b. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxin molecules lethal for vertebrates at an LD50 < 100 ng/kg body weight: ☐ Yes ☒ No
c. Provide a brief description of the recombinant constructs and any associated expression control of elements, including what the recombinant DNA encodes for, if known:
Noted in *Application for IBC Permit*
d. Give an estimate of range of length of recombinant DNA to be used:
Less than 20

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

1. List species of small animals that are used: **mice, and guinea pigs**
2. Describe route of infection: **oral, nasal, aerosolization, and i.p.**
3. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☒ Yes ☐ No
If yes, describe method: **autoclave**
4. The facility requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this facility? ☒ Yes ☐ No
If yes, the proposed work with Select Agents has been approved by the IACUC: ☒ Yes ☐ No

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

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

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

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

Sink location:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Eyewash locations:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Biosafety cabinet (BSC) locations:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Fume hood locations:	<input type="checkbox"/> Yes <input type="checkbox"/> No
HVAC supply and exhaust locations:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Freezer/refrigerator locations:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Other large equipment locations (incubators, centrifuges, etc):	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Plan provides a description of the HVAC system (check all that are appropriate):

<input type="checkbox"/> Single-pass	<input type="checkbox"/> Re-circulated	<input type="checkbox"/> Dedicated exhaust	<input type="checkbox"/> Shared exhaust
<input type="checkbox"/> Constant air volume	<input type="checkbox"/> Variable air volume	<input type="checkbox"/> Redundant exhaust fans	<input type="checkbox"/> Emergency power back-up
7. Plan provides information on the biosafety cabinets in use (attach additional sheets if needed):
Class of cabinet:

<input type="checkbox"/> I	<input type="checkbox"/> II, Type A1	<input type="checkbox"/> II, Type A2 (formerly II, B3)	<input type="checkbox"/> II, B1	<input type="checkbox"/> II, B2	<input type="checkbox"/> III
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 Biosafety cabinet connection to the HVAC system:

<input type="checkbox"/> Hard duct	<input type="checkbox"/> Thimble	<input type="checkbox"/> Re-circulating	<input type="checkbox"/> Other (explain): _____
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 Define certification period: ☐ Annual ☐ Biannual
 Does user verify air flow during BSC use? ☐ Yes ☐ No

Section III – Entity Program (IBSP)

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

Section IV – Inspection Summary

1. As a result of the **Facility Assessment** of the *Laboratory Facilities (Secondary Barriers)*, the following was noted in respect of the interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination:
 - a. SA
 - i. Penetration(s) in wall(s) next to the autoclave unit
 - ii. Cracks in the paint
 - b. SA
 - i. Airflow alarm sounding (Air balance was verified to be good, but the sensor was inoperable.)
 - ii. Fire extinguisher has not been serviced since 2004 (Others in suite should be serviced/checked as well.)
 - iii. Cracks in paint
 - iv. Hole in wall near door needs to be filled
 - v. Coving where it meets the wall needs to be sealed; gaps noted
 - vi. No door sweep on the door
 - c. SA
 - i. No door sweep on the door
 - ii. Cracks in paint
 - iii. Hole in wall near door needs to be filled
 - iv. Coving where it meets the wall needs to be sealed
 - d. SA
 - i. UV light on Biosafety Cabinet (BSC) needs to be repaired. (EHS will notify contractor.)
 - ii. Cracks in paint
 - iii. Coving where it meets the wall needs to be sealed
 - iv. Glass containers noted on the floor
2. As a result of the **Program Assessment** in regards to *Training*, the following was noted:
 - a. Several training certificates were not signed.
3. As a result of the **Program Assessment** in regards to *records*, the following was noted:
 - a. There was no updated Emergency Contact list in records. (Records reflect investigator who is no longer at institution.)
4. As a result of the **Program Assessment** in regards to the Agent Access Log, the following was noted:
 - a. Improper use of the Agent Access Log; entries were not complete and there were many inconsistencies.
 - b. Members of the team suggested PI provide additional training to personnel in the correct usage of the log.

TEXAS A&M UNIVERSITY
LABORATORY INSPECTION / CERTIFICATION
FOR RESEARCH INVOLVING
INFECTIOUS AGENTS and/or RECOMBINANT DNA

Principal Investigator: Jim Samuel

Lab Contact Person: Eunhee Lee

Email address: jsamuel@tamu.edu

Department: MMPA

Office Phone Number 2-1684

Lab Phone Number: 2-1683

Lab location - Bldg: 1504 - Reynolds Medical Science Bldg

Room: Not public information

Biological agents used:

☐ Recombinant DNA

☒ Human pathogens - list:

Coxiella burnetii

☒ Animal pathogens - list:

Coxiella burnetii

☐ Plant pathogens - list:

☐ Human tissues or body fluids

☒ Non-pathogenic biological materials

Biosafety level: ☒ BL2 ☐ BL3

Results: ☒ Meets criteria at appropriate biosafety level
 ☐ Does not meet criteria

Date of Inspection: 2/16/2007

Environmental Health & Safety Inspector: Walker

NIH BIOSAFETY LEVEL 2 CRITERIA

A. Standard Microbiological Practices

- Y 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.
- Y 2. Persons wash their hands after they handle viable materials and animals, after removing gloves, and before leaving the laboratory.
- Y 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the work areas. Food is stored outside the work area in cabinets or refrigerators designated for this purpose only.
- Y 4. Mouth pipetting is prohibited; mechanical pipetting devices are used
- Y 5. Policies for the safe handling of sharps are instituted.
- Y 6. All procedures are performed carefully to minimize the creation of splashes or aerosols.
- Y 7. Work surfaces are decontaminated on completion of work or at the end of the day and after any spill or splash of viable material with disinfectants that are effective against the agents of concern.
- Y 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method, such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are to be placed in a durable, leakproof container and closed for transport from the laboratory. Materials to be decontaminated at off-site from the laboratory are packaged in accordance with applicable local, state, and federal
- Y 9. Experiments of lesser biohazard potential can be conducted concurrently in carefully demarcated areas of the same laboratories.

Comments:

B. Special Practices

- Y 1. Access to the laboratory is limited or restricted by the laboratory director when work with infectious agents or organisms containing recombinant DNA molecules is in progress. In general, persons who are at increased risk of acquiring infection or for whom infection may be unusually hazardous are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The laboratory director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.
- Y 2. The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet specific entry requirements (e.g., immunization) enter the laboratory or animal rooms.
- Y 3. A biohazard sign must be posted on the entrance to the laboratory when infectious agent(s) or organisms containing recombinant DNA molecules in use. Appropriate information to be posted includes the agent(s) in use, the biosafety level, the required immunizations, the investigator's name and telephone number, any personal protective equipment that must be worn in the laboratory, and any procedures required for exiting the laboratory.
- N/A 4. Laboratory personnel receive appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing).
- N/A 5. When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel are collected and stored. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the facility.
- Y 6. Biosafety procedures are incorporated into standard operating procedures or in a biosafety manual adopted or prepared specifically for the laboratory by the laboratory director. Personnel are advised of special hazards and are required to read and to follow instruction on practices and procedures.

- Y 7. The laboratory director ensures laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural or policy changes.
- Y 8. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels
- Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
 - Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of infectious materials or organisms that contain recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
 - Syringes which re-sheath the needle, needle-less systems, and other safe devices should be used when appropriate.
 - Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass are decontaminated before disposal, according to any local, state, or federal regulations.
- Y 9. Cultures, tissues, specimens of body fluids, or potentially infectious wastes are placed in a container with a cover that prevents leakage during collection, handling, processing, storage, transport, or shipping.
- Y 10. Laboratory equipment and work surfaces should be decontaminated with an effective disinfectant on a routine basis, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination by infectious materials. Contaminated equipment must be decontaminated according to any local, state, or federal regulations before it is sent for repair or maintenance or packaged for transport in accordance with applicable local, state, or federal regulation, before removal from the facility.
- Y 11. Spills and accidents which result in overt exposures to infectious materials are immediately reported to the laboratory director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.
Spills and accidents which result in overt exposures to organisms that contain recombinant DNA are immediately reported to Institutional Biosafety Committee and NIH/OBA. Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985, (301) 496-9638, (301) 496-9839 (fax).
- Y 12. Animals not involved in the work being performed are not permitted in the lab.
- Y 13. An insect and rodent control program is in effect.

Comments:

C. Safety Equipment

- Y 1. Properly maintained biological safety cabinets, preferably Class II, or other appropriate personal protective equipment or physical containment devices are used whenever:
- Procedures with a potential for creating aerosols or splashes are conducted. These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of infectious/recombinant DNA materials whose internal pressures may be different from ambient pressures, inoculating animals intranasally, and harvesting infected tissues from animals or embryonate eggs.
 - High concentrations or large volumes of infectious agents or organisms that contain recombinant DNA molecules are used. Such materials may be centrifuged in the open laboratory if sealed rotor heads or centrifuge safety cups are used, and if these rotors or safety cups are opened only in a biological safety cabinet.

- Y 2. Face protection (goggles, mask, face shield or other splatter guards) is used for anticipated splashes or sprays of infectious or other hazardous materials to the face, when the microorganisms must be manipulated outside the
- Y 3. Protective laboratory coats, gowns, smocks, or uniforms designated for lab use are worn while in the laboratory. This protective clothing is removed and left in the laboratory before leaving for non-laboratory areas (e.g., cafeteria, library, administrative offices). All protective clothing is either disposed of in the laboratory or laundered by the institution; it should never be taken home by personnel.
- Y 4. Gloves are worn when handling infected animals and when hands may contact infectious materials, organisms containing recombinant DNA molecules, contaminated surfaces or equipment. Wearing two pairs of gloves may be appropriate. Gloves are disposed of when overtly contaminated, and removed when work with infectious materials is completed, or when the integrity of the glove is compromised. Disposable gloves are not washed, reused, or used for touching "clean" surfaces (keyboards, telephones, etc.), and they should not be worn outside the lab. Alternative to powdered latex gloves should be available. Hands are washed following removal of gloves.

Comments:

D. Laboratory Facilities (Secondary Barriers)

- Y 1. Provide lockable doors for facilities that house restricted agents (as defined in 42 CFR 72.6).
- Y 2. Consider locating new laboratories away from public areas.
- Y 3. Each laboratory contains a sink for hand washing.
- Y 4. The laboratory is designed so that it can be easily cleaned. Carpets and rugs in laboratories are inappropriate. .
- Y 5. Bench tops are impervious to water and resistant to moderated heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate the work surfaces and equipment.
- Y 6. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.
- Y 7. Install biological safety cabinets in such a manner that fluctuations of the room supply and exhaust air do not cause the biological safety cabinets to operate outside their parameters for containment. Locate biological safety cabinets away from doors, from windows that can be opened, from heavily traveled laboratory areas, and from other potentially disruptive equipment so as to maintain the biological safety cabinets' air flow parameters for containment.
- Y 8. An eyewash station is readily available.
- Y 9. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.
- N/A 10. There are no specific ventilation requirements. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory. If the laboratory has windows that open to the exterior, they are fitted with fly screens.

Comments:

**2006 Inspection Report
1504**

(Inspections conducted 01/06)

TEXAS A&M UNIVERSITY

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

Principal Investigator
Lab Contact Person
Department
Office Phone Number
Lab Phone Number
Lab Location - Bldg

1504- not public information Room

Biological agents used:

☐ Recombinant DNA

☒ Human pathogens - list: *Coxiella burnetii*
Bruella abortus

☐ Animal pathogens- list:

☐ Human tissues or body fluids

☐ Non-pathogenic biological materials

Biosafety Level: ☐ BL2 ☒ BL3

Results: ☒ Meets criteria at appropriate biosafety level
☐ Does not meet criteria

Comments:

*Too much clutter in shower area!
Everything else looks good.*

Date of Inspection: 1-9-06

Environmental Health & Safety Inspector:

B.S. Mays

NIH BIOSAFETY LEVEL 3 CRITERIA

A. Standard Microbiological Practices

- ☒ 1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.
- ☒ 2. Persons wash their hands after handling infectious materials and animals, after handling organisms containing recombinant DNA molecules, after removing gloves, and when they leave the laboratory.
- ☒ 3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for that purpose only.
- ☒ 4. Mechanical pipetting devices are used; mouth pipetting is prohibited.
- ☒ 5. Policies for the safe handling of sharps are instituted.
- ☒ 6. All procedures are performed carefully to minimize the creation of aerosols.
- ☒ 7. Work surfaces are decontaminated at least once a day and after any spill of viable material.
- ☒ 8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.
- ☒ 9. Persons under 16 years of age are not allowed to enter a BL3 laboratory.
- ☒ 10. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.
- ☒ 11. An insect and rodent control program is in effect.

B. Special Practices

- ☒ 1. Laboratory doors are kept closed when experiments are in progress.
- ☒ 2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.
- ☒ 3. The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements (e.g., immunization), and who comply with all entry and exit procedures enter the laboratory or animal rooms.
- ☒ 4. When infectious materials, infected animals, or organisms containing recombinant DNA molecules are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.
- ☒ 5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for

the agent being handled.

6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.
7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.
8. Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.
9. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.
10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.
 - a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
 - b. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of infectious materials or organisms containing recombinant DNA molecules. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be promptly placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
 - c. Syringes which re-sheath the needle, needle-less systems, and other safe devices should be used when appropriate.
 - d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.
11. All open manipulations involving infectious materials or organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.
12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant after work with infectious materials or organisms containing recombinant DNA molecules is finished and especially after overt spills, splashes, or other contamination with infectious materials.
 - a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.
 - b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.
13. Cultures, tissues, specimens of body fluids or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.
14. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories and animal rooms are decontaminated before disposal or reuse.
15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

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

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

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

Animals housed in separate room

C. Safety Equipment (Primary Barriers)

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

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

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

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

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

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

D. Laboratory Facilities (Secondary Barriers)

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

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

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

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

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

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

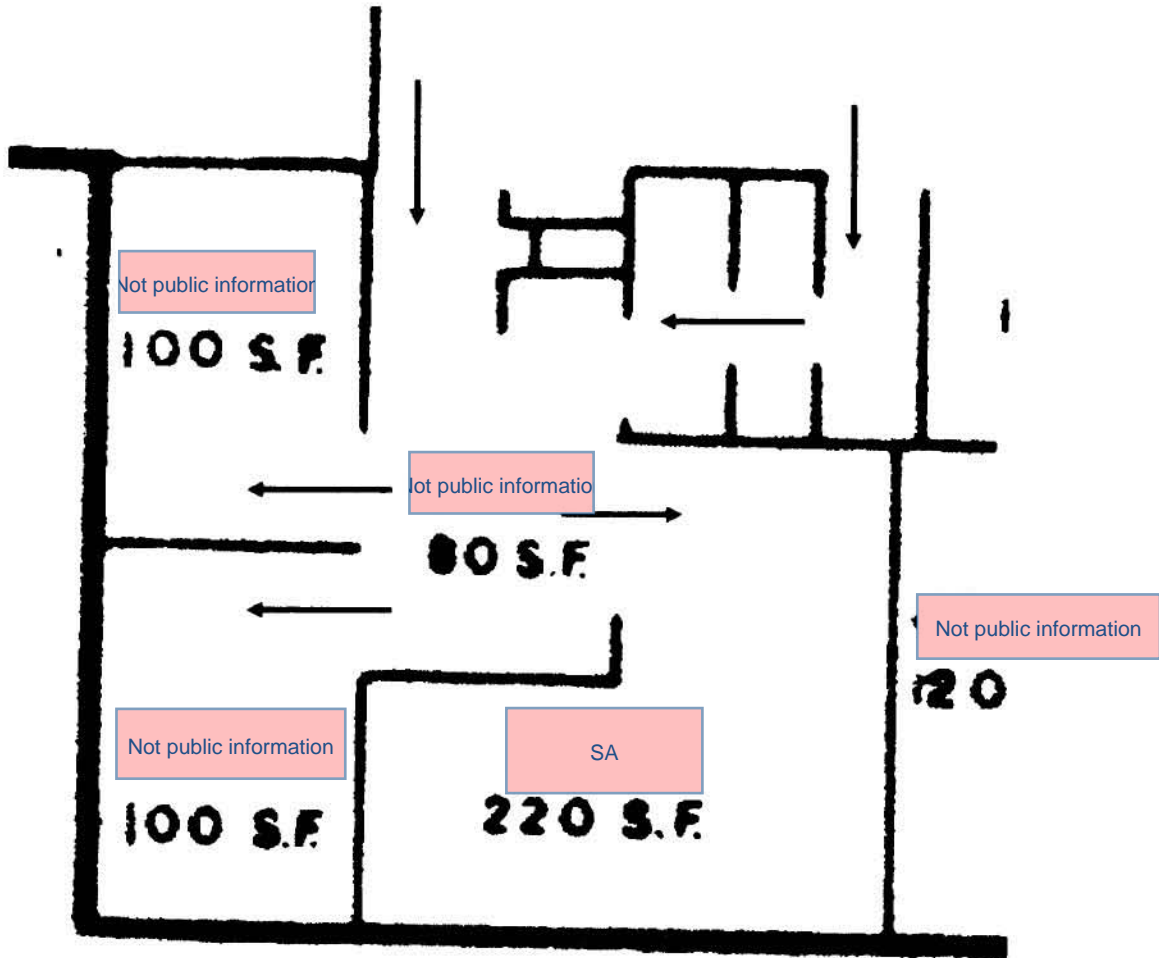
✓ 7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the

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

- ✓ 8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas. *As much as possible*
- ✓ 9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.
- ✓ 10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from the Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.
- ✓ 11. Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.
- ✓ 12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).
- ✓ 13. An eyewash facility is readily available inside the laboratory.
- ✓ 14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.
- ✓ 15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.
- ✓ 16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

Not public information

Center / 1504



Occupational Health Requirements for Workers

DRAFT

DRAFT

Occupational Health Program Blood Drawing Requirements for Select Agents

The Occupational Health Program may, in consultation with the health care provider, require baseline serum or titers prior to entry into areas where certain organisms may be present. The organisms and/or facilities requiring baselines will be determined on a case by case basis. Currently, the Program is requiring baseline serum and/or titers for the following organisms prior to entry into facilities utilizing the agents:

All *Brucella* species, including select agent exempt strains

Coxiella burnetii

Pre-exposure tuberculosis (TB) tests performed within the last year plus post-exposure testing where applicable

Retesting

In consultation with the health care provider, repeat testing will be performed at the request of an attending physician or whenever signs or symptoms of illness occur. Frequency of testing will be determined by the health care provider.

Enrollment

All individuals working with animals or who may be working with infectious agents are required to enroll in the Occupational Health Program. Individuals may decline to participate in the medical evaluation portion of the program, but may be denied access to certain facilities or agents.

Visitors

As a general practice, visitors will not be required to have baseline titers or serums collected prior to visiting laboratories. However, depending on the length of stay, the particular agent in use, or the operations being conducted at the time of visit (e.g. aerosol experiments), specific baseline tests may be required. Contractors who spend a significant amount of time in the facilities will normally be required to have baselines. TB tests are required for all visitors to the Laboratory Animal Facility (Building 972). TB tests must have been conducted within the last year, with no known exposures occurring since the test.

Results

Results of baseline titers or any subsequent testing are maintained by the health care provider. Occupational Health does not interpret titers. The attending physician or the health care provider will determine the significance, if any, of titer results. In the event of an abnormal titer, the following actions will be taken:

Health Care Provider

In the event of an abnormal titer, the health care provider will notify the patient directly, and offer follow-up treatment and prophylaxis where appropriate. The health care provider will also notify the Occupational Health Program.

Occupational Health Program

The Occupational Health Program will immediately inform the Office of Research Compliance of any abnormal results reported to it by the health care provider if select agents are involved. The Occupational Health Program will follow up with the patient(s) and conduct an investigation, if appropriate. If select agents are involved, a copy of the investigative report will be provided to the Office of Research Compliance. The Occupational Health Program will determine if appropriate safety procedures were in place and followed, if personal protective equipment was appropriate and properly used, and verify with the patient(s) and health care provider that appropriate follow up and prophylaxis has been provided and made available, and whether or not any clinical manifestations of disease have occurred. Currently, Scott & White (Health Care Provider) utilizes the Texas Department of State Health Services (TDSHS) Laboratory for titer results. The State Laboratory notifies the Brazos County Health Department automatically, but the Occupational Health Program will contact the Brazos County Health Department as a matter of courtesy.

Patient Confidentiality

The health care provider may disclose to the Occupational Health Program an individual's protected health information for the purposes of workplace medical surveillance or the evaluation of work-related illness and injuries to the extent the employer needs the information to comply with OSHA, MSHA, or the requirements of other Federal or State laws having a similar purpose. The information disclosed must be limited to the provider's findings regarding such medical surveillance or work-related injury. The covered health care provider must provide the individual with written notice that the information will be disclosed to his or her employer (or the notice may be posted at the worksite if that is where the service will be provided).

The Occupational Health Program will only disclose information received from the health care provider to principal investigators or supervisors when necessary to comply with applicable regulations, conducting post-exposure assessments, or when necessary to protect employee health and safety. For further information, please contact Occupational Health at 845-2132, or the health care provider.

*Correspondence between TAMU and any other
local, state, or federal agencies, concerning this incident*

From: Angelia Raines
To: Agnew, Tiffany
Date: 8/22/2007 5:35:05 PM
Subject: Fwd: Reporting of Elevated Titers

for the NIH/OBA package.

>>> "Mattox, Brent S" <bsmattox@tamu.edu> 8/22/2007 5:32 PM >>>
Angelia:

The following paragraphs summarize how State and Local health Agencies are notified with an elevated titer.

Scott & White hospitals and Clinics, Occupational Medicine group, utilizes the Texas Department of State Health Services Laboratory to perform analysis of Q Fever and Brucella titers. Whenever an "elevated" titer is detected by the TDSHS Laboratory, they immediately report the information to the local health department(s) where the infection is reported from. In our case, that is the Brazos County Health Department. Unfortunately, this notification frequently is transmitted to the local health department(s) faster than either Scott and White or Texas A&M Occupational Health find out the results. On several occasions, the Brazos County Health Department has contacted the individual with the elevated titer before Scott and White does, and prior to Scott and White informing TAMU Occupational Health. This results in the individual with the elevated titer being contacted three times. We are aware that Brazos County Health Department has been notified by confirmation with the individual, and by unrelated conversations with Brazos County Health Department Epidemiologists. In keeping with patient confidentiality guidelines, Brazos County will not release the names of the individuals they contact, although we eventually find out.

All three of the groups (Brazos County Health Department, Scott & White, and TAMU Occupational Health) ask basically the same questions and provide the same information. (1) explanation of elevated titer and meaning of titer (2) ascertain if patient has or is suffering any illness, (3) availability of prophylaxis. In addition, Scott and White and TAMU Occupational Health also retest the employee in a few weeks, and continue monitoring. Based on the current plan, only baseline titers will be collected in the future, with additional tests being conducted upon signs or symptoms of exposure, or known releases or uncontrolled exposures with intervals determined by Occupational Medicine at Scott and White. TAMU Occupational health will continue to track all individuals enrolled in the program.

If you have any questions, please let me know.

Sincerely,

Brent S. Mattox, CIH
Manager, Occupational Health

cac ??

Biosafety Training
(prior to incident)

Biosafety Level 3 Procedures Training Examination for *Coxiella burnetii*

You may consult the literature to find the answers

Please determine if the following statements are **TRUE** or **FALSE**.

1. It is OK to open tubes containing live *C. burnetii* outside the biosafety hood in the BL-3 if you are wearing a mask. *false*
2. Used disposable needles must be recapped before disposal in a puncture-resistant container designated for sharps disposal. *false*
3. *Coxiella burnetii* is reported to be susceptible to sodium hypochlorite (bleach), formalin, and phenols. *true*

Please respond to the following questions with a **SHORT ANSWER**.

1. What are the initial symptoms of Q fever and how long after exposure do they usually occur?
headache, flu-like symptoms after 2 to 3 weeks after exposure in acute cases; manifestation as endocarditis or hepatitis in chronic cases
2. What is the recommended treatment for Q fever?
treatment with antibiotics such as tetracycline and new quinolones

3. What is the proper way to decontaminate non-radioactive *C. burnetii* waste before removing them from the BL-3 laboratory?

by autoclaving with liquid or solid waste cycle

4. Describe the procedure to be followed in the case of an uncontained spill of live *C. burnetii* outside the biosafety hood.

- hold breath and allow aerosols to settle
- warn other lab members and leave room, take off all clothes, shower out
- after appropriate time put on required personal protection and cover spill with paper towels and bleach
- let sit for \approx 30 min
- clean up and autoclave waste

I, Not public information, have received training and instruction in regard to proper handling procedures for *Coxiella burnetii* as well as operating procedures for the BL-3 laboratory. I agree to work in accordance with the regulations and procedures outlined therein.

Signature

Not public information

Date 23. Feb. 2004

Texas A&M University

Facilities and Research Laboratories With Select Agents

By my signature below, I certify that I have read and understand the laboratory security and emergency policies and procedures for working with *Coxiella burnetii* and *Rickettsia prowazekii* in laboratory room(s) Not public information and the select agent storage facility in room Not public information under the direction of Dr. James E. Samuel. This includes the following recent modifications:

A. Procedures for securing the area when individuals approved under part 73.8 include individual key card and thumb print secured entry. B. Each individual approved under 73.8 is required not to share with any other person, his or her unique means of accessing the area or SelectAgent or Toxin."

I further certify that I understand the hazards of working with *Coxiella burnetii* and *Rickettsia prowazekii*; 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 <2 or 3> work; and the standard operating procedures for this laboratory.

Not public information

Printed Name

Not public information

04/08/04

Date

Supervisor

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. UNIVERSITY 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 in laboratory room(s) _____ and the select agent storage facility in room _____ under the direction of _____.

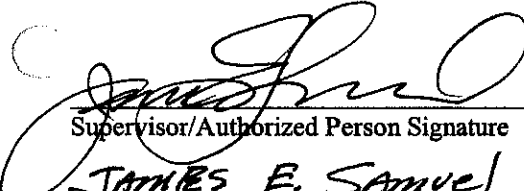
I further certify that I understand the hazards of working with _____; the indications of infection or intoxication by this agent; the reporting system for potential exposure and accidents; how to seek evaluation and therapy; the standard microbiological practices for this laboratory; the special Biosafety 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.

Not public information

02/08/05
Date

Printed name of Person Receiving Training


Supervisor/Authorized Person Signature

2/8/05
Date

JAMES E. SAMUEL
Printed Name of Authorized Person Providing Training

(Reproduce this document as needed to cover all personnel)

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

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Not public information

12/05/2005
Date

Printed name of Person Receiving Training


Supervisor/Authorized Person Signature

12/5/05
Date

James E. Samuel

Printed Name of Authorized Person Providing Training

(Reproduce this document as needed to cover all personnel)

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Security and Safety Training Certificate
For
Authorized Persons who have Access to Areas or Facilities and Research Laboratories
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- 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. UNIVERSITY EMERGENCY RESPONSE PROCEDURES

Please refer to:

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

CERTIFICATION

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 and Rickettsia prowazekii in laboratory room(s) Not public information and the select agent storage facility in room Not public information under the direction of Dr. James E. Samuel.

I further certify that I understand the hazards of working with Coxiella burnetii and Rickettsia prowazekii; 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.

Not public information

03/08/07
Date

Printed name of Person Receiving Training


Supervisor/Authorized Person Signature

3/8/07
Date

James E. Samuel

Printed Name of Authorized Person Providing Training

(Reproduce this document as needed to cover all personnel)

Select Agent Program Training

Personnel Information (Please Print)

Last Name:

Not public information

First Name:

Not public information

Middle Initial:

Email:

Not public information

Principal Investigator (PI)

Check (√) all that apply:

☐ PI Adams

☐ Comparative Medicine Program (CMP)

☐ PI Davis

☐ PI Ficht

☒ PI Samuel

☐ PI Tesh

☐ N/A

Home Address:

Personal Info

☒ Yes ☐ No

I understand the Select Agent Approval Process

I understand that access to a Select Agent is **prohibited** unless the individual is approved by the IBC and CDC.

Before accessing an agent, the individual must be IBC/CDC approved and must be trained on safety and security procedures for the lab.

☒ Yes ☐ No

I understand that entering a Select Agent facility is **prohibited** unless the individual is approved by the IBC and CDC **or** escorted at all times. The individual must also be trained on safety and security procedures for the lab.

Individuals who are being escorted **MAY NOT** have access to any Select Agent.

The facility Access log **must** be used to document all individuals entering a Select Agent lab and whether the individual is being escorted.

☒ Yes ☐ No

I understand the Safety and Security training I received for Selects Agents used or stored in

Not public information

☒ Yes ☐ No

I understand the Safety and Security training I received for Selects Agents used or stored in

Not public information

☒ Yes ☐ No

I understand the Safety and Security training I received for Selects Agents used or stored in

Not public information

☒ Yes ☐ No

I understand the Safety and Security training I received for Selects Agents used or stored in

Not public information

By signing below, I certify that I received safety and security training for Select Agents used in the following labs. Check (√) all that apply:

Not public information

Signature

Not public information

Date

June 01, 2007

Biosafety Level 3 Procedures Training Examination for *Coxiella burnetii*

You may consult the literature to find the answers

Please determine if the following statements are **TRUE** or **FALSE**.

1. It is OK to open tubes containing live *C. burnetii* outside the biosafety hood in the BL-3 if you are wearing a mask. *False*
2. Used disposable needles must be recapped before disposal in a puncture-resistant container designated for sharps disposal. *False*
3. *Coxiella burnetii* is reported to be susceptible to sodium hypochlorite (bleach), formalin, and phenols. *True*

Please respond to the following questions with a **SHORT ANSWER**.

1. What are the initial symptoms of Q fever and how long after exposure do they usually occur?

Flu-like disease, pneumonia, hepatitis in acute cases and endocarditis in chronic cases. 2 or 3 weeks after exposure

2. What is the recommended treatment for Q fever?

Antibiotic drugs like tetracyclines or new quinolones are recommended for treatment.

3. What is the proper way to decontaminate non-radioactive *C. burnetii* waste before removing them from the BL-3 laboratory?

The proper way to decontaminate non-radioactive *C. burnetii* waste is by autoclaving.

4. Describe the procedure to be followed in the case of an uncontained spill of live *C. burnetii* outside the biosafety hood.

1. allow aerosols to settle
2. cover with paper towels and apply 1% Sodium hypochlorite
3. Let dry for 30-60 min
4. clean it up
5. Autoclave waste

I, Not public information have received training and instruction in regard to proper handling procedures for *Coxiella burnetii* as well as operating procedures for the BL-3 laboratory. I agree to work in accordance with the regulations and procedures outlined therein.

Signature

Not public information

Date 8/24/04

Received
Research Compliance

SEP 15 2004

IBC

Texas A&M University
Facilities and Research Laboratories with Select Agents or Toxins

By my signature below, I certify that I have read and understand the laboratory security and emergency policies and procedures for working with C. burnetii & R. prowazekii in laboratory room(s) Not public information and the select agent storage facility in room Not public information under the direction of James E. Samuel.

I further certify that I understand the hazards of working with C. burnetii and R. prowazekii; 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 BSL-3 work according to the Biosafety in Microbiological and Biomedical Laboratories guidebook; and the standard operating 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 Office of the Vice President for Research and the TAMU Office of Environmental Health and Safety; and that the detailed records of information necessary to account for all activities related to this agent will be maintained.

Not public information

9/12/04

Date

Not public information

Printed name

research assistant

Position/Title

Are you a US citizen?

☒ Yes. ☐ No.

Country of your citizenship (if not USA)

Have you undergone training in safety, security, and emergency response?

☒ Yes. ☐ No.

9/13/04 NMMIM

Date and location of training

Personal Info

Social security number

Personal Info

Date of birth

Not public information

Email address

Supervisor's signature

James E. Samuel

Supervisor's printed name

9/14/04

Date

(Reproduce this page as needed to cover all personnel.)

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. UNIVERSITY 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 and Rickettsia prowazekii laboratory room(s) Not public information and the select agent storage facility in room Not public information for the direction of Dr. James E. Samuel.

I further certify that I understand the hazards of working with Coxiella burnetii & Rickettsia prowazekii; 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.

Not public information

2/8/05
Date

Printed name of Person Receiving Training

Supervisor/Authorized Person Signature

2/8/05
Date

James E. Samuel
Printed Name of Authorized Person Providing Training

(Reproduce this document as needed to cover all personnel)

**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;
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- is a fugitive from justice;
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- 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.

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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.

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Please refer to:

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

CERTIFICATION

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* and *Rickettsia prowazekii* in laboratory room(s) 420 Reynolds and the select agent storage facility in room 420 Reynolds under the direction of Dr. James E. Samuel.

I further certify that I understand the hazards of working with *Coxiella burnetii* and *Rickettsia prowazekii*; 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.

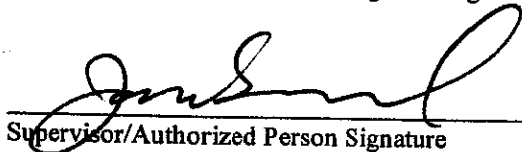
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Not public information

12/5/05

Date

Printed name of Person Receiving Training


Supervisor/Authorized Person Signature

12/5/05

Date

James E. Samuel

Printed Name of Authorized Person Providing Training

(Reproduce this document as needed to cover all personnel)

Texas A&M University

Facilities and Research Laboratories With Select Agents

By my signature below, I certify that I have read and understand the laboratory security and emergency policies and procedures for working with Coxiella burnetii and Rickettsia prowazekii in laboratory room(s) Not public information and the select agent storage facility in room Not public information under the direction of Dr. James E. Samuel. This includes the following recent modifications:

A. Procedures for securing the area when individuals approved under part 73.8 include individual key card and thumb print secured entry. B. Each individual approved under 73.8 is required not to share with any other person, his or her unique means of accessing the area or SelectAgent or Toxin."

I further certify that I understand the hazards of working with Coxiella burnetii and Rickettsia prowazekii; 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 <2 or 3> work; and the standard operating procedures for this laboratory.

JAMES E. Samuel
Printed Name

James E. Samuel
Signature

4/8/04
Date

James E. Samuel
Supervisor

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

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- 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)

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VII. REPORTING

Campus Police

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

CERTIFICATION

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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.



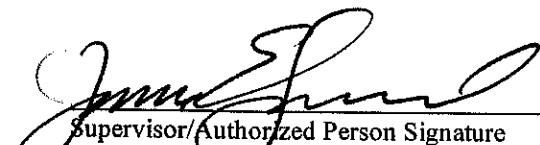
Signature of Person Receiving Training

2/8/05

Date

JAMES E. SAMUEL

Printed name of Person Receiving Training



Supervisor/Authorized Person Signature

2/8/05

Date

James E. Samuel

Printed Name of Authorized Person Providing Training

(Reproduce this document as needed to cover all personnel)

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.

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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. UNIVERSITY EMERGENCY RESPONSE PROCEDURES

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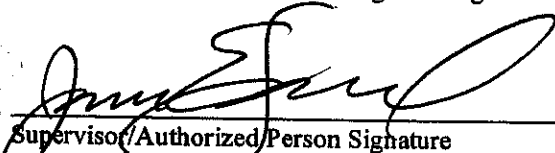
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12/5/05

Date

JAMES E. Samuel

Printed name of Person Receiving Training



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12/5/05

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3/8/17
Date

JAMES E. Samuel
Printed name of Person Receiving Training


Supervisor/Authorized Person Signature

3/8/17
Date

James E. Samuel

Printed Name of Authorized Person Providing Training

(Reproduce this document as needed to cover all personnel)

Select Agent Program Training

Personnel Information (Please Print)

Last Name:

SAMUEL

First

Name: JAMES

Middle Initial:

E

Email: JSAMUEL@TAMHSC.EDU

Principal Investigator (PI)

Check (√) all that apply:

☐ PI Adams

☐ Comparative Medicine Program (CMP)

☐ PI Davis

☐ PI Ficht

☒ PI Samuel

☐ PI Tesh

☐ N/A

Home Address::

5505 Trotter LN

College Station, TX 77845

☒ Yes ☐ No

I understand the Select Agent Approval Process

I understand that access to a Select Agent is **prohibited** unless the individual is approved by the IBC and CDC.

Before accessing an agent, the individual must be IBC/CDC approved and must be trained on safety and security procedures for the lab.

☒ Yes ☐ No

I understand that entering a Select Agent facility is **prohibited** unless the individual is approved by the IBC and CDC **or** escorted at all times. The individual must also be trained on safety and security procedures for the lab.

Individuals who are being escorted **MAY NOT** have access to any Select Agent.

The facility Access log **must** be used to document all individuals entering a Select Agent lab and whether the individual is being escorted.

☐ Yes ☐ No

I understand the Safety and Security training I received for Selects Agents used or stored in Not public information

☒ Yes ☐ No

I understand the Safety and Security training I received for Selects Agents used or stored in Not public information

☒ Yes ☐ No

I understand the Safety and Security training I received for Selects Agents used or stored in Not public information

☒ Yes ☐ No

I understand the Safety and Security training I received for Selects Agents used or stored in Not public information

By signing below, I certify that I received safety and security training for Select Agents used in the following labs. Check (√) all that apply: Not public information

Signature

Date

6/1/07

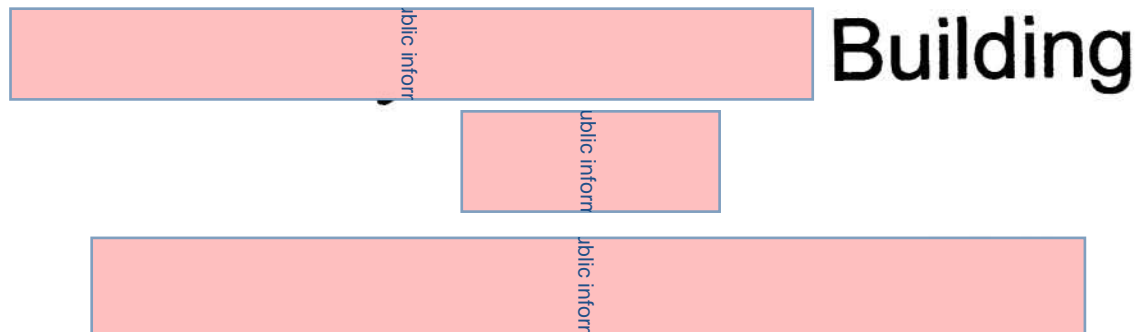
Biosafety Training
(after the incident)

Texas A&M University
Select Biological Agent and Toxins Program Training
Houston Building - Auditorium
June 1, 2007
9:00 a.m. – 1:00 p.m.

Agenda

Time	Topic	Presenter(s)
9:00 a.m.	Opening Remarks	Fuller Bazer
9:05 a.m.	Agenda Review	Angelia Raines
9:10 – 9:40	Process for New submissions, Amendments and Annual reviews (including risk assessment process and medical surveillance process)	Vernon Tesh/Thomas Ficht and Brent Mattox
9:40 – 9:45	Approval process prior to accessing an SBAT Agent -	Angelia Raines
9:45-9:50	Approval process prior to accessing a facility	Angelia Raines
9:50-10:20	Occupational Health Program including blood borne pathogen training	Brent Mattox
10:20-10:30	Break	
10:30 – 11:10	Research Specific Safety Plan /SOPs	Jim Samuel Thomas Ficht –
11:10-12:00	Overview of the Requirement for Personal Protection Equipment (PPE) including handouts on the Respiratory Protection Program	Brent Mattox
12:00 – 12:10	Intra-Facility Transfers	Brent Mattox
12:00 – 12:20	Inter-facility transfers	Tiffany Agnew
12:20 – 12:50	Incident Response process	Bert Kretzschmar and Brent Mattox
12 :50 -12:55	Bi-monthly monitoring	Angelia Raines
12:50 p.m.	Closing Remarks	Fuller Bazer

Standard Operating Procedures



Access

(section 1)

- Personnel are allowed access to the BL-3 suite after they receive official DOJ clearance
- Doors to locker rooms are secured with a key lock as well as electronic card mechanism.
 - Cards and keys are not to be transferred or shared
 - Everyone must swipe their card upon entry
 - If a card is left at home, access can only be obtained through the assistance of the P.I.
- Doors to individual labs, equipment rooms, airlock, and animal housing are secured with a Cipher code door lock.
- Doors are to be secured at all times and checked by personnel.

Entry Procedures (section 2)

- Let someone know where you will be
- All personnel must sign the facility access log located in the outer changing room (in first locker Vet Med Park)
 - Also sign facility access log when entering airlock from outside
- Street clothes are kept in the clean changing area
- In inner changing room put on scrubs, booties, clogs, facemask, gloves
- When working in BSC add second pair of gloves, tyvek sleeves, lab coat

Procedures while working (section 3)

- Contaminated materials kept in double containers outside of BSC
- sharps
- Spill procedures have been posted

Cleaning and decontamination (section 4)

- Approved disinfectants:
 - 70% ethanol, Wexcide, 10% bleach, 1% virkon-S
- Autoclaving: record all activity
 - Cover biohazard sign with autoclave tape
 - Liquid versus gravity cycles
 - Autoclaved trash is placed inside a non-biohazard bag and thrown out in general trash
- Weekly cleaning

Cleaning and decontamination (section 4)

- Transfer of trash from Not public information
 - all trash, surgical utensils, empty feed bags, etc. are bagged and sprayed with bleach before removal and transport to the autoclave.
 - Animal carcasses are triple bagged (bleach sprayed between layers) and brought to the vet school incinerator.

Radioactivity (section 5)

- Treatment of radioactive waste prior to removal
 - All treated waste is plated to ensure non-viability prior to addition to general radiation waste

Decontamination: Spills (section 6)

- Hold breath; signal to others in lab
- Remove clothing and leave in room; post sign on door “hazardous conditions...do not enter”
- Shower
- Notify P.I.
- Wait 1 hour; return to clean

Accidents (section 7)

- In case of spill proceed as previously described
- Notify the P.I.
- Accidents causing breaks in skin: disinfect area with 1% virkon-S
- Make appointment to go to Scott and White
- Notify biological safety officer; file incident report

Exit procedures (section 11)

- When exiting the BSC: remove tyvek sleeves, outer gloves/spray inner gloves with bleach or virkon-S
- Clean all surfaces
- Inner locker room: remove scrubs, facemask, inner gloves. Wash hands
- Outer locker room: put on clothes.
- Sign out facility access log

Storage/Inventory (section 12)

- The -80°C in room public inform is locked at all times.
- All entry and removal of select agent must be properly recorded on the agent access log.
 - Destruction or complete use of a tube must be recorded and immediately reported to the P.I.
- Notebooks must show record of the number of plates grown and date of destruction.
- Electronic copies of the freezer inventory are maintained by the P.I., indicating all strains as well as their box/slot location.
- Entire inventory is reconciled annually
- Inventory reconciliation during yearly IBC/EHSD inspection
- Discrepancies in inventories **MUST** be immediately reported to the P.I. for investigation

Intrafacility transfer (section 13)

- Correct permits must be obtained prior to shipping or receiving any agent and EHSD must be contacted for approval
- SBAT may be transferred only in IATA approved containers.
- EHSD must approve the packaging prior to shipping any samples.
- Intrafacility transfer forms must be filled out and faxed to EHSD

Experimental protocols (section 14)

- Centrifugation, bacterial growth, tissue culture, mutant construction, microencapsulation, DNA isolation
- Animal infections

Aerosol Infection (section 15)

- File intra-entity transfer forms
- Transport in approved containers
- PAPR and tyvek
- Animal handling
- Decontamination
- Other routes of infection

Electronic Security

- All computers must be password protected
- Passwords should be changed routinely and should contain a combination of letters and numbers/symbols

Incident reporting/security breaches

- Emergency contact numbers are located by the phones in the BL-3 as well as the doors to all laboratories.
- Upon discovery, immediately notify the P.I. of any theft, loss, or release of agent.
 - Theft or loss is reported to UPD; releases (i.e. infections) are reported to EHSD.
 - All research is halted during investigation

Standard Operating Procedures

[redacted]
Room [redacted]
(Also building [redacted])

Access

- Personnel are only allowed unescorted access to the BL-3 suite after they receive official DOJ clearance
- Doors to locker room is secured with a card lock and finger print.
 - Cards are not to be transferred or shared
 - If a card is left at home, access can only be obtained through the assistance of the P.I.
- Doors to individual labs, equipment rooms, airlock, and animal housing are secured with a Cipher code door lock.
- Doors are to be secured at all times and checked by personnel.

Entry Procedures

- Let someone know where you will be: sign up on board rm Not public information
- All entering personnel must sign the facility access log located in the changing room
Not public information
- In changing room put on scrubs, booties, facemask, gloves
- When working in BSC add second pair of gloves, tyvek sleeves, lab coat

Procedures while working

- All work should be tailored to be performed in BSC, if possible
- Follow SOP for specific protocols when applicable
- sharps
- Spill procedures have been posted

Cleaning and decontamination

- Approved disinfectants:
 - 70% ethanol, Wexcide, 10% bleach

Autoclaving

– Liquid versus trash

- Monthly cleaning of floor drain using 1 gal wex-cide. Log of activity maintained by facilities manager

Decontamination: Spills

- Allow aerosols to settle in the room
- Dress in protective clothing (e.g., lab coat, gloves)
- Gently cover spill with paper towels and apply wex-cide, starting at perimeter and working towards the center
- Allow sufficient contact time (30-60 min) before clean up
- Decontaminate all wastes before disposal: atuoclave
- Spill procedure notice displayed in suite

Accidents

- Notify the P.I.
- PI will notify biological safety officer; file incident report

Exit procedures

- Prior to exiting the BL3: remove tyvek sleeves, lab coat, shoe covers, outer gloves
- Enter locker room
- Locker room: remove facemask, inner gloves outside to inside.
- Wash hands with microbical soap before exit.
- Sign out facility access log
- Return to Rm public informat and wash hands with soap and water to remove microbicical soap residue

Storage/Inventory

- The -80°C in room SA B and D are locked at all times.
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- Animal infections: aerosol experiments conform to CMP protocol

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ANIMAL BIOSAFETY LEVEL 3

Working in ABSL-3
areas.



Working in ABSL-3 Areas

Biosafety is a priority when working in ABSL-3 areas.

- Eating, Drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use is **strictly prohibited**.
- Animals not involved in the work being performed are not permitted into ABSL-3 areas (to include transition areas).



Working in ABSL-3 Areas

- ◆ Access to ABSL-3 areas is restricted to personnel who have been advised of the potential hazard and who need to enter the area for program or service purposes when infected animals are present.
- ◆ Be sure to sign in and out on the entry/exit log.
- ◆ **Always** check the doors after entry/exit to ensure that they remain secured/locked.



Working in ABSL-3 Areas

- ◆ Persons who are at increased risk of acquiring infection, or for whom infection might be unusually hazardous, should confer with an occupational medicine physician prior to entering an ABSL-3 area.
- Persons at increased risk may include:
 - Children
 - Pregnant woman
 - Immunodeficient/Immunosuppressed individuals



Working in ABSL-3 Areas

- Biological Warning signs are posted on the access doors to the ABSL-3 animal area.
 - Agent information and emergency contact information are included on the signs
- Laboratory personnel will need to receive appropriate immunizations or tests for the agents handled or potentially present in the work area (e.g., TB skin testing).



Working in ABSL-3 Areas

- ◆ Be aware that you are in an area in which you are placed at risk.
- Anyone that is lax about the procedures followed in this area is creating risk to not only himself/herself, but also to other individuals and animals therein.
- ◆ Your health and safety are dependant not only on your behavior, but that of all individuals using the area.



Working in ABSL-3 Areas

- ◆ Be sure to work in a manner which will assure both containment of the hazardous agent and safety of personnel.
- ◆ Do not enter any room in which you have not been authorized to enter.
- ◆ Adhere to all safety protocols regarding appropriate attire, sanitation, animal handling and material disposal.



Working in ABSL-3 Areas

- ◆ Should any questions arise while working in the biohazard area always consult with the area supervisor.
- ◆ Report any breaks in protocol that you commit or observe to the area supervisor.
 - Reporting is intended to ensure the safety of all personnel.



Select Agents in ABSL-3 Areas

- ◆ All individuals entering into an ABSL-3 area where select agents are used/stored must be:

1. Cleared by the IBC and CDC and be select agent cleared by the Department of Justice (DOJ).
2. Cleared to access the facility in which the agent is kept.

Note: If the individual has not been cleared to work with the agent or has not been cleared to access the facility, then that individual must be with (AT ALL TIMES) an individual who has been cleared to work with the agent and has been cleared to access the facility.

- ◆ Personnel who have been cleared to work with select agents will be issued a personal access card and codes for each select agent ABSL-3 area.



Select Agents in ABSL-3 Areas

- Access cards and codes are only to be used by the person to which they have been assigned.
- The loss of an access card to a select agent biohazard area is to be immediately reported to the area supervisor and to the University Police Department (UPD).



Working in ABSL-3 Areas

- ◆ Personal protective equipment is used for all activities involving manipulations of infectious materials or infected animals.
- ◆ All persons entering the ABSL-3 area are required to wear a Tyvek suit (with scrubs underneath), appropriate face/eye protection, appropriate respiratory protection, 2 pair of latex gloves and a pair of approved, area maintained foot wear.



Working in ABSL-3 Areas

- ◆ If using a biological safety cabinet:
 - Turn the blower and light switches to the “ON” position.
 - Clean the biological safety cabinet with an appropriate disinfectant solution prior to using (be sure to wait proper contact time).
- Begin your tasks.



Working in ABSL-3 Areas

- ◆ All animals will be housed in cages topped with a filtered micro-isolator lid.
- ◆ Always ensure that the micro-isolator lid rests securely on the cage top (no gaps between lid and cage).
- ◆ Be sure that the lid filter is clean and free of debris, rips or holes.



Working in ABSL-3 Areas

- ◆ Cages are to be opened and/or changed out inside of an operating certified Class I or Class II biological safety cabinet.
- ◆ Avoid quick or sudden movements that may cause increased aerosolization when working with infected animals or biological agents in a biological safety cabinet.



Working in ABSL-3 Areas

- ◆ All items placed inside of an operating biological safety cabinet are to be disinfected before being removed from the cabinet.
- ◆ Equipment and work surfaces are to be decontaminated with an appropriate disinfectant, especially after overt spills, splashes, or other contamination by infectious material.



Working in ABSL-3 Areas

When finished:

- ◆ The biological safety cabinet is to be cleaned and disinfected (to include underneath the work platform).
- Once cleaned and disinfected, be sure to turn both the blower switch and light switch to the “OFF” position.
- ◆ Be sure to wipe down work surfaces with disinfectants before leaving.
- ◆ Disinfectant will be poured down floor drains by CMP daily.



Working in ABSL-3 Areas

- ◆ Cultures, tissues, or specimens of body fluids are to be placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.
- ◆ Contaminated material is disinfected (autoclave or chemical) before disposal.



Working in ABSL-3 Areas

- ◆ A high degree of precaution must always be taken with any contaminated sharp items such as:
 - Needles
 - Syringes
 - Scalpels
 - Glass items



Working in ABSL-3 Areas

- ◆ All used needles and syringes are to be placed into a designated sharps container (do not recap needles).
- ◆ Broken glassware must not be handled by hand, but must be removed by mechanical means (e.g., brush and dust pan) and placed into a designated sharps container.



Working in ABSL-3 Areas

- ◆ When ready to leave the area, be sure to spray yourself down (head to foot) with an appropriate disinfectant.
- ◆ Un-suit (be sure to follow proper un-suited procedures for the area).
- ◆ Scrubs worn under the Tyvek suit will be placed in a biohazard laundry bag (in 2nd transition room) and autoclaved later.
- ◆ Showering is required for CMP personnel and recommended for all other personnel.



TUBERCULOSIS

Primary Risks:

- ◆ *Mycobacterium Tuberculosis* is a highly infectious agent that usually affects the lungs. It can become airborne and inhaled by personnel and very few organisms may be required to cause infection. A vaccine has been developed but its use is not recommended in the United States.



TUBERCULOSIS

Routs of Exposure:

- ◆ Inhalation of infectious aerosols is the most likely source of infection to laboratory and animal personnel. Experimentally infected Guinea pigs and mice do not pose the same problem since droplet nuclei are not produced by coughing in these species. Always make efforts to reduce or eliminate aerosols while handling infected animals and bedding.



TUBERCULOSIS

Medical Treatment:

- ◆ A tuberculin skin test is used for finding out if an individual is infected. A baseline skin test should take place before an individual begins working in the ABSL-3 area. However, it does not tell whether or not an individual has TB disease. Seek medical attention for evaluation and possible treatment if you have been exposed to the agent and/or experience symptoms associated with Tuberculosis.

ANY QUESTIONS?

**Working in ABSL-3
areas.**

Personal Protective Equipment: Selection and Use



Brent S. Mattox, RS, CIH

Texas A&M University

Permissible Practice

- ☞ Use Respiratory Protection ONLY when Engineering Controls are not Feasible or during Implementation.
- ☞ Respirators Provided when Necessary to Protect Employee Health.
- ☞ Respirators Must be Applicable & Suitable.
- ☞ Establishment of Respiratory Protection Program

Respiratory Protection Program

☞ Must Contain the Following:

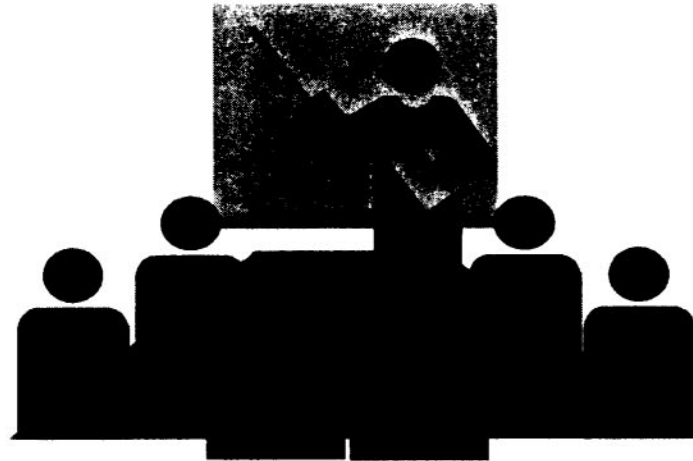
- Procedures for selecting respirators for use in the workplace
- Medical Evaluations of employees required to use respirators
- Fit testing procedures for tight-fitting respirators
- Procedures for use of respirators in emergencies (foreseeable and routine)

Respiratory Program (cont.)

- Procedures and schedules for cleaning, disinfection, storing, inspecting, repairing, discarding, and otherwise maintaining respirators
- Procedures to assure adequate air quality, quantity, and flow for atm. supplying respirators
- Training of employees in the respiratory hazards to which they may be exposed

Program (cont.)

- Training in the proper use of respirators, including putting on and removing, any limitations of use, and their maintenance
- Procedures for regularly evaluating the effectiveness of the program.



Where Respirator Use is Not Required

- ☞ Provide at request to employees ONLY When Use will not create a hazard.
- ☞ The Employer must establish and implement those elements of a written program to assure employee is medically qualified, and on use, storage, etc..
- ☞ NOTE: No written program required for employees using dust masks (voluntary)
N95 respirators ARE NOT DUST MASKS

Key Aspects

- ☞ All respirators must be NIOSH certified, Including N95 Disposable Respirators.
- ☞ For gases and vapors supplied air must be used or an air-purifying respirator provided that:
 - It is equipped with an end-of-service-life indicator (ESLI).
 - If no ESLI, cartridges must be replaced on a schedule based on objective information

Key Aspects (cont.)

- ☞ Medical Evaluations must be provided prior to fit-testing and usage.
- ☞ Medical Evaluations must be performed by a physician or other licensed health care professional (PLHCP).
- ☞ Follow-up examinations to be determined by PLHCP, change in exposure, or symptoms of overexposure.

Key Aspects (cont.)

- ☞ Qualitative fit testing can be used only with negative pressure respirators requiring a fit factor of 100 or less.
- ☞ Quantitative fit is passed when fit factor is 100 or above for negative pressure respirators and 500 or above for full face respirators (all tight fitting).

Key Aspects (cont.)

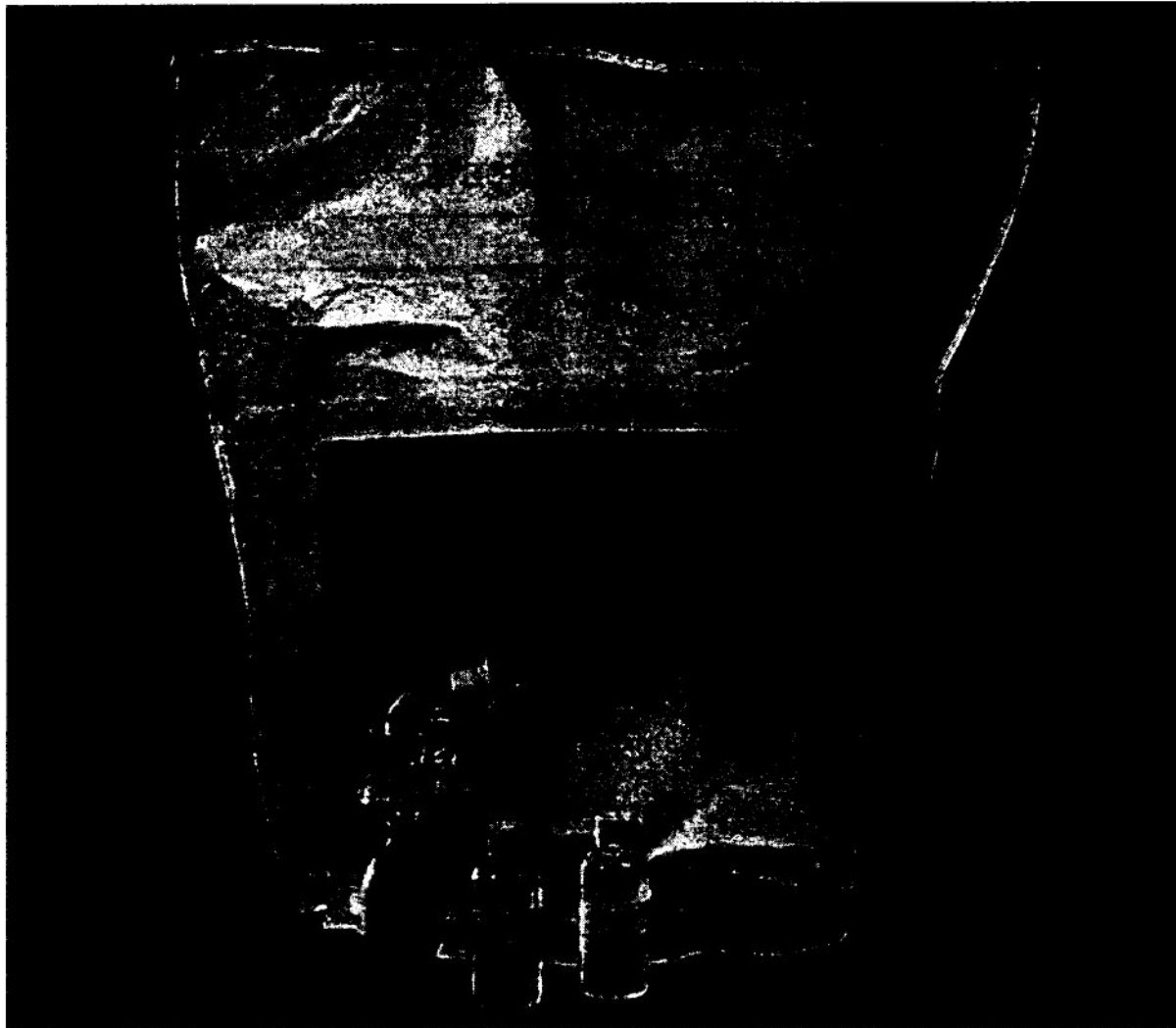
- ☞ A Medical Questionnaire MUST be completed prior to fit testing.
- ☞ Medical Questionnaires must be evaluated prior to fit testing
- ☞ Training must be provided prior to actual use of respiratory protection.

Fit Testing of Respirators

- ☞ Qualitative (isoamyl acetate, irritant smoke)
 - Inexpensive
 - Provides Qualitative Data Only
 - If Done Correctly, Time Consuming
 - Some Workers can't Smell



Qualitative Testing (Bitrex)

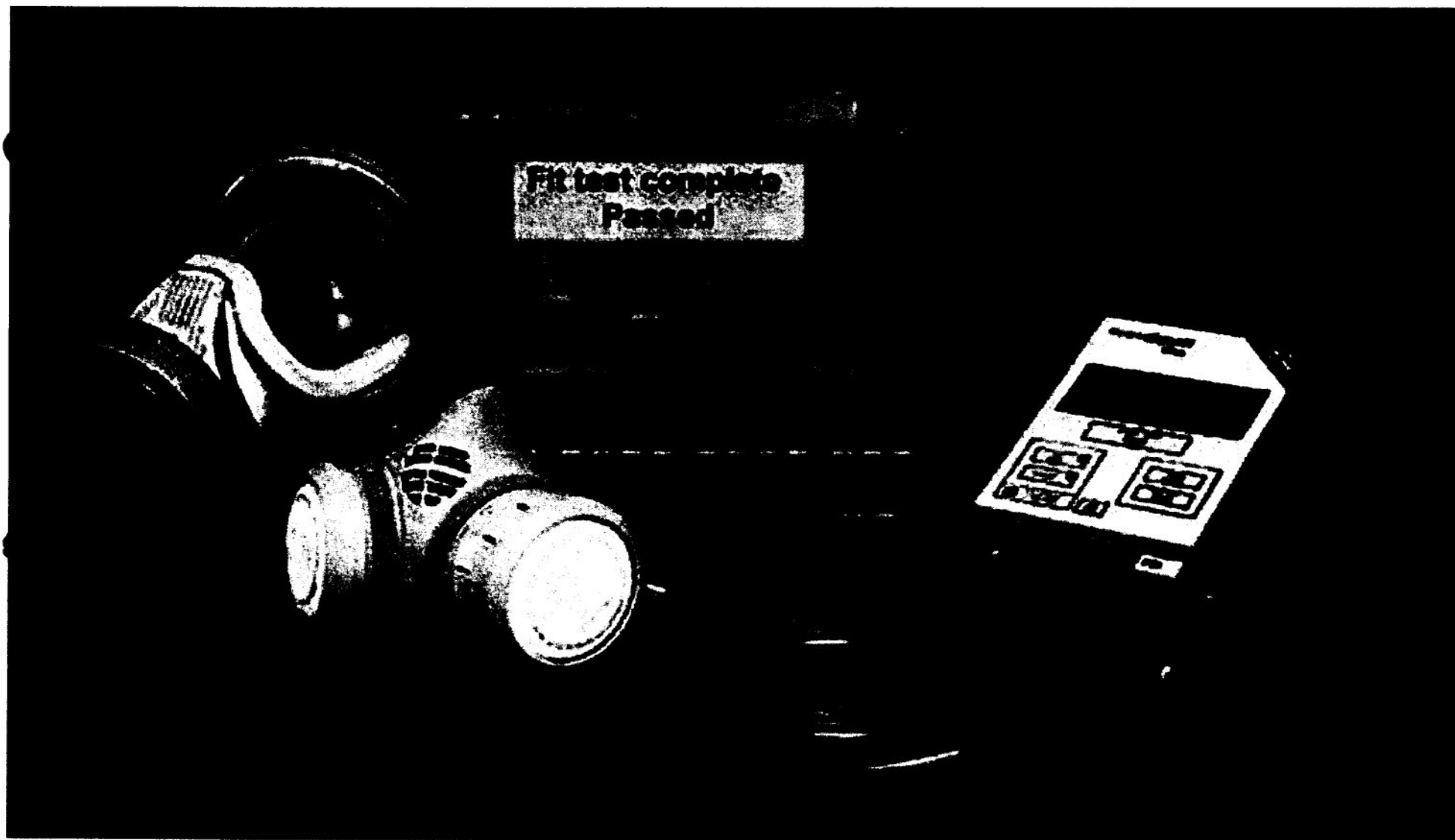


Fit Testing of Respirators

- ☞ Quantitative (Test Booth, Portacount)
 - High Initial Cost
 - Requires Maintenance
 - May Require Training in Operation
 - Advantage in Providing Quantitative Information on Fit.



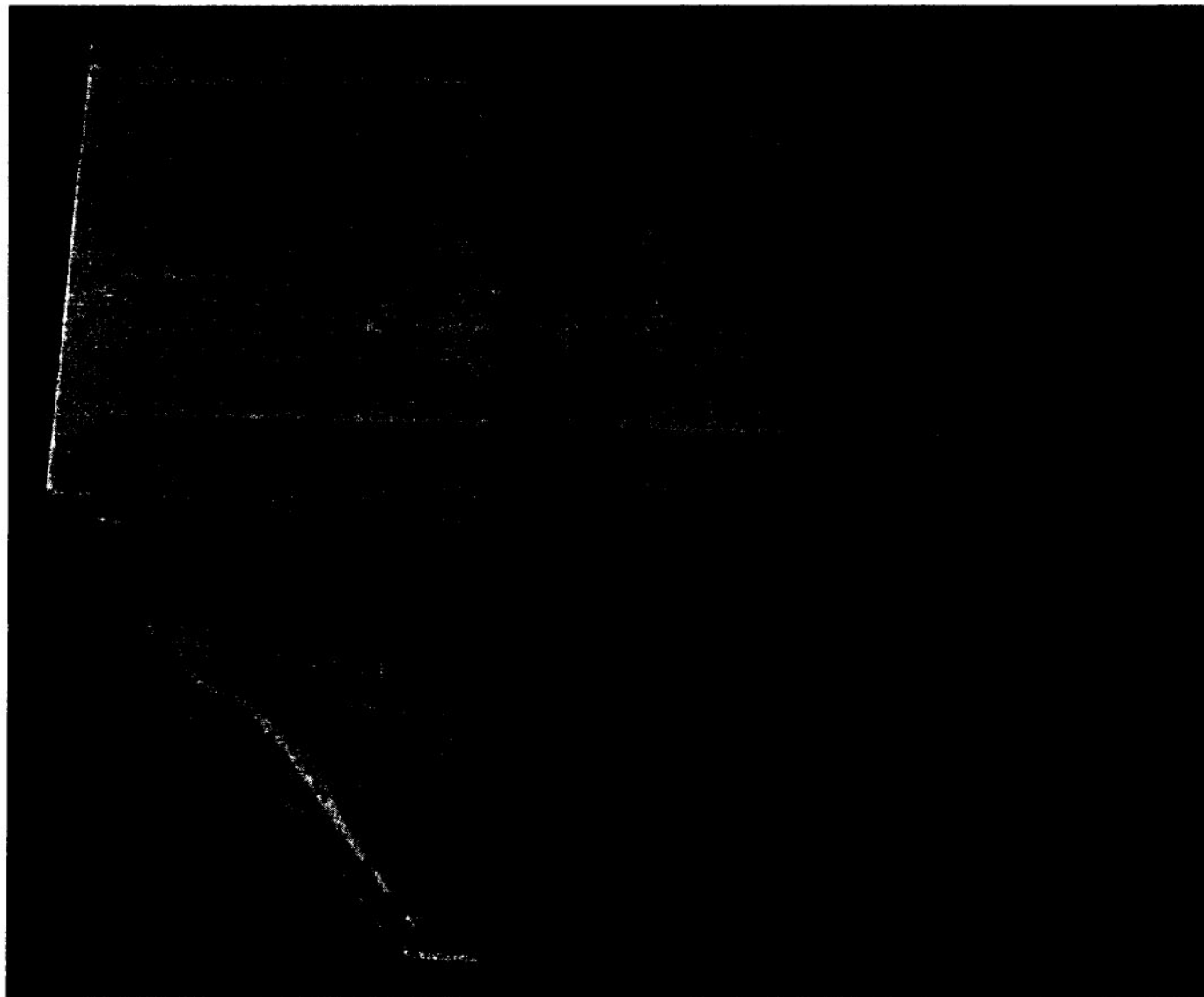
Portacount™ Fit Tester



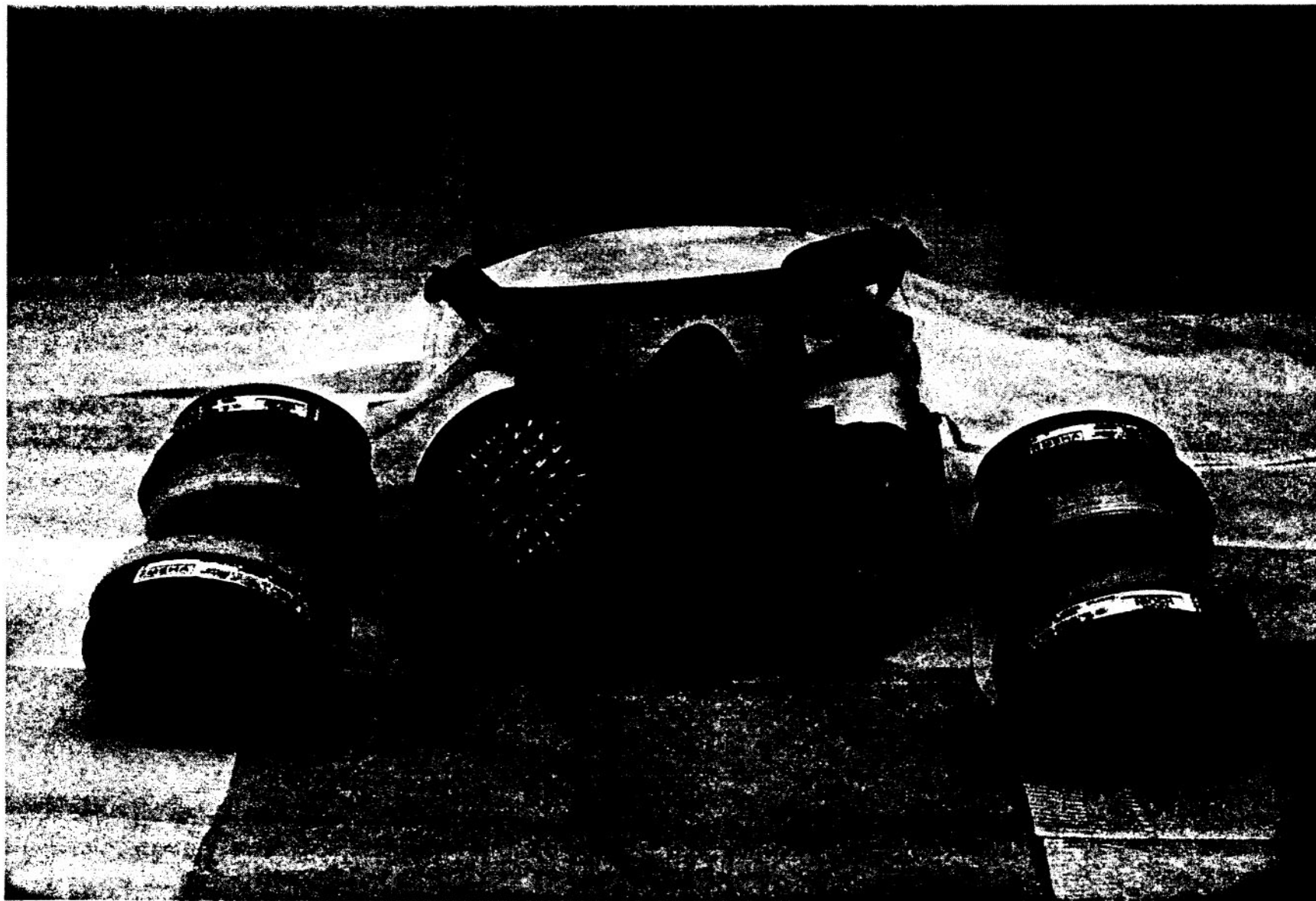
N95 Respirators/Masks



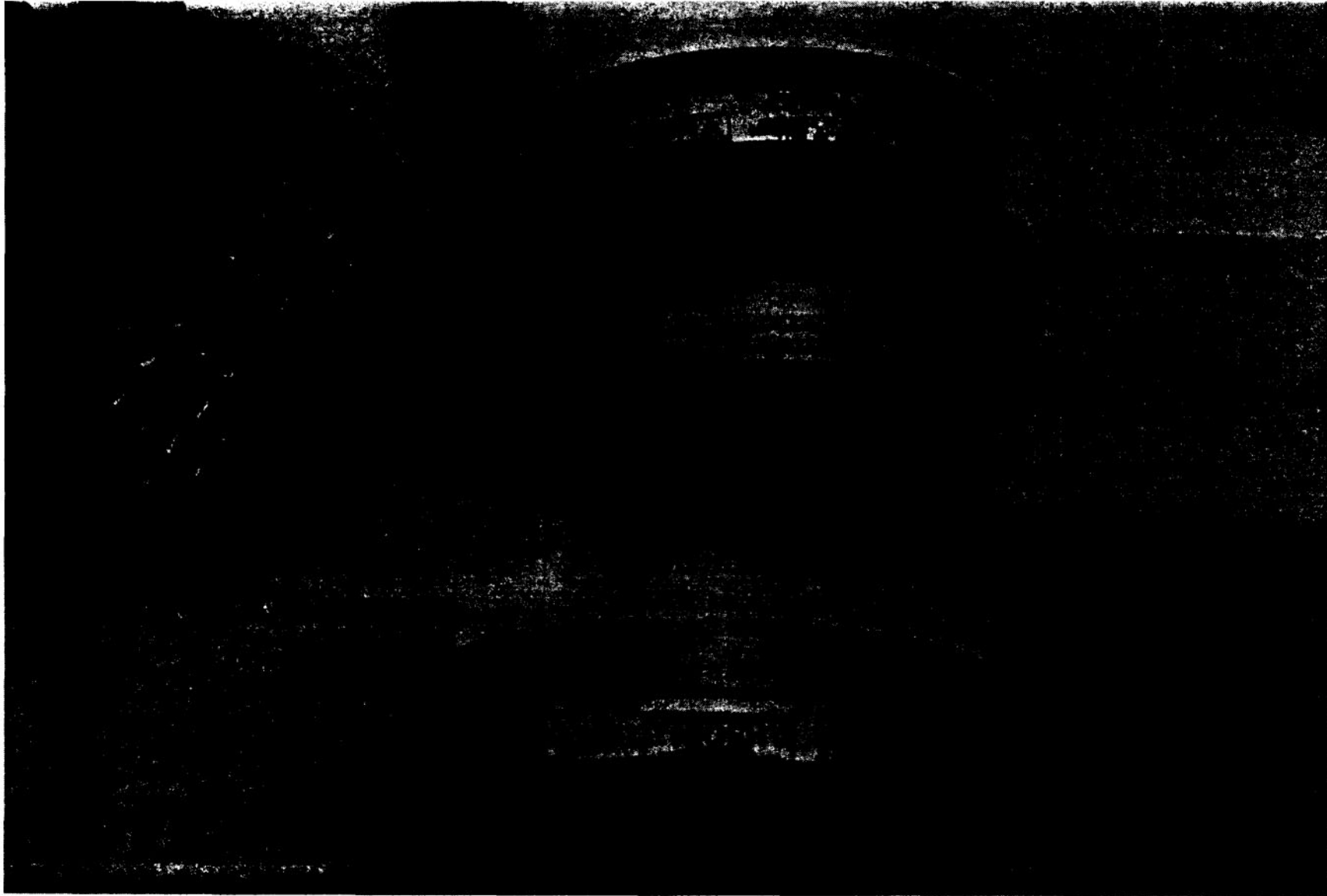
N95 Respirators/Masks



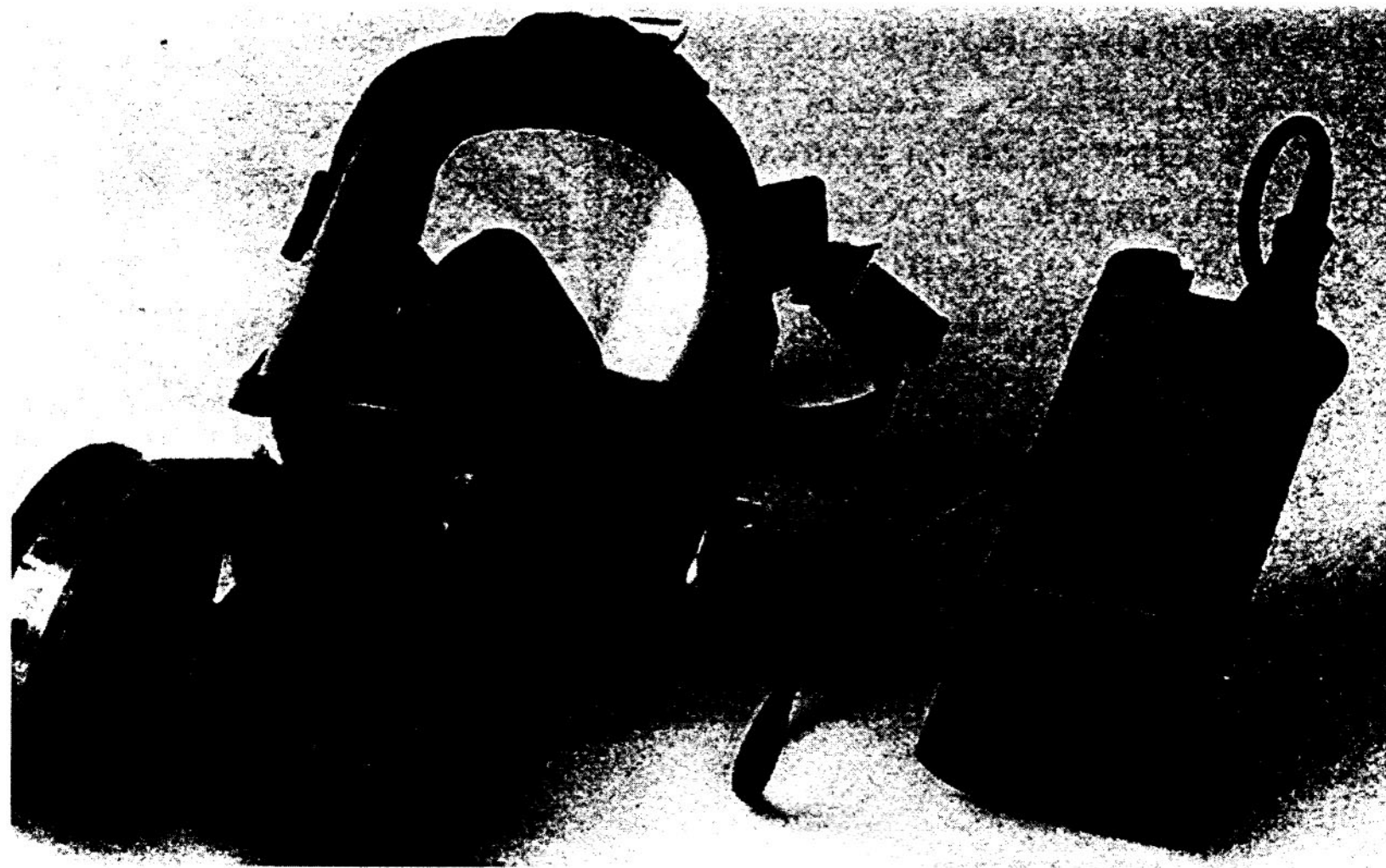
Air Purifying Respirators



APRs Work by Filtering Air



Powered Air Purifying Respirator



AAD#07124

2071
P95 Filter2076*
HF/P95 Filter2078**
P95 Filter2091
P100 Filter2098***
P100 Filter2097****
P100 Filter7093
P100 Filter

Filter Retainers & Adapters



502 Filter Adapter

501 Filter Retainer
AAD#070545N11
N95 Filter5P71
P95 Filter
AAD#07194

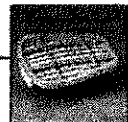
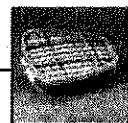
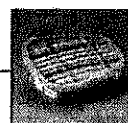
* P95 filter with hydrogen fluoride and nuisance level acid gas relief.

** P95 filter with nuisance level organic vapor/acid gas relief.

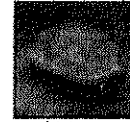
*** P100 filter with nuisance level acid gas relief.

**** P100 filter with nuisance level organic vapor relief.

AAD#07046

6001
OV6002
AG6003
OV/AG6004
AM/MA6005
Form6006
Multi Gas6009
Merc

AAD#07047

60921
P100/OV60922
P100/AG60923
P100/OV/AG60924
P100/AM/MA60925
P100/Form60926
P100/Multi Gas60929
P100/Merc

Other Automotive Aftermarket Products Available:

Paint Spray

Packouts (S, M, L):

#07177; #07178;

#07179

Bodyman and Brake

Packouts (S, M, L):

#07181; #07182;

#07183

Full Facepiece

6000 Series OV/P95

Packouts (S, M, L):

#07161; #07162;

#07163

R-6022

Replacement

Packouts OV/P95

(S, M, L): #07195

60928
P100/OV/AG

3M recommended for
methylbromide or
radioiodine up to
5 ppm with daily
cartridge change

NEW

Full Face APR



BL3 Respirator Usage

- ☞ Respiratory AND Face Protection Are to be Used When in Rooms Containing Infected Animals {Including Labs Where Animals are Temporarily Located for Experimentation}

BL3 Usage

- ☞ ALL Manipulations of Infectious Materials, Necropsies of Infected Animals, harvesting of Tissues or Fluids From Infected Animals or Embryonate Eggs, etc., are Conducted in a Biological Safety Cabinet (BSC)
- ☞ IF NOT in a BSC . . .

BL3 Usage

- ☞ Use Appropriate Combinations of PPE and Physical Containment Devices (sealed rotors, etc.)
- ☞ Based on a Risk Assessment by PI with Assistance/Input/Review by Biological Safety Officer

Personal Protective Clothing



BL3 PPE Guidelines

- ☞ Solid Front or Wrap-Around Gowns, Scrub Suits or Coveralls are Worn by Workers
- ☞ Protective Clothing is Not Worn Outside (carried out) Of the Laboratory
- ☞ Reusable Clothing is Decontaminated Before Laundering
- ☞ Clothing is Changed When Overtly Contaminated

BL3 PPE (cont.)

- ☞ Gloves Must be Worn When handling Infectious Materials, Infected Animals, and When Handling Protective Equipment.
- ☞ Frequent Changing of Gloves Accompanied by Handwashing is Recommended
- ☞ Disposable Gloves are Not Reused

BL3 PPE

- ☞ Avoid Using Natural Latex Gloves
- ☞ Avoid using Powdered Gloves
- ☞ If Using Chemicals, Use Nitrile or other Suitable Gloves
- ☞ Disposable Clothing Should be Tyvek or Spun Bound Polypropylene

Questions?



Brent S. Mattox, RS, CIH

Environmental Health and
Safety Department

Texas A&M University

(409) 845-2132




Report of Theft, Loss, or Release from SBAT Facilities

Bert Kretzschmar,
University Police Department

Brent Mattox,
Environmental Health and Safety Department

June 1, 2007



What is a Theft or Loss?

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

If a Theft or Loss Occurs...

- Immediately notify the University Police Department (UPD).
- Immediately stop all work so that UPD can investigate. Do not resume work until UPD gives you clearance to do so.

UPD Investigation

- The purpose of the investigation is to understand what happened and recommend changes that can be taken to prevent the incident from happening again.
- UPD will lead the investigation with input from the Principal Investigator and the Environmental Health and Safety Department.
- UPD will issue an investigation report that includes an assessment of the security risk and changes to lab plans or procedures, if needed.

What is a Release?

- **Release**

- Occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area.

If a Release Occurs...

- Immediately notify the Environmental Health and Safety Department (EHSD) or UPD (if the release occurs between 5:00 p.m. and 8:00 a.m.).
- Immediately stop all work so that EHSD can investigate. Do not resume work until EHSD gives you clearance to do so.

EHSD Investigation

- The purpose of the investigation is to understand what happened and recommend changes that can be taken to prevent the incident from happening again.
- EHSD will lead the investigation with input from the Principal Investigator and the UPD.
- EHSD will issue an investigation report that includes an assessment of the safety risk and changes to lab plans or procedures, if needed.

Conclusion

- Safety and security procedures must always be followed when working with Select Agents.

If a Theft, Loss or Release is discovered...
IMMEDIATELY REPORT IT!


It is everyone's responsibility!



Bi-monthly Program Inspections

Angelia Raines,
Institutional Biosafety Committee
Office of Research Compliance

June 1, 2007



Purpose of Inspections

- Assist the PI in complying with regulations related to SBAT activities
- Increase personnel safety and laboratory security
- Help resolve problems
- Develop best practices

Who will inspect?

- The inspection team will consist of the Environmental Health and Safety Department (EHSD), and the Institutional Biosafety Committee (IBC), with input from the Principal Investigator/Laboratory Director (PI),
- The team will use an inspection checklist

Inspections

- Program inspections will occur every other month beginning in August.
 - August – 1197 and Not public information
 - September – 1504 and Not public information
- Inspection findings will be communicated to the PI with a date of correction.
- Serious deficiencies may cause research to be suspended.
- Richard Ewing, Texas A&M SBAT Responsible Official (RO) will receive a program report based on the results of the inspections

Conclusion

- **The goal of Bi-monthly inspections is to increase safety, security and compliance**

It is everyone's responsibility!

Bloodborne Pathogen Training

Texas A&M University
Environmental Health & Safety
Occupational Health

What are bloodborne pathogens?

- Bloodborne pathogens are microorganisms that are present in human blood and bodily fluids and can cause disease in people.
- Can include:
 - Hepatitis A, B, C
 - Human Immunodeficiency Virus (HIV)

Transmission

- Bloodborne pathogens transmitted through contact with infected human blood and other fluids that contain blood:
 - Blood
 - Semen
 - Vaginal Secretions
 - Cerebrospinal Fluid
 - Amniotic Fluid
 - Saliva
 - Any bodily fluid that is visibly contaminated with blood

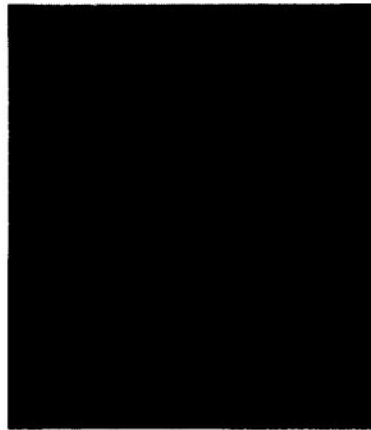


Natural Barrier

- Unbroken skin provides a barrier against bloodborne pathogens.
- Infected blood can enter your system through:
 - Open sores
 - Cuts
 - Abrasions
 - Acne
 - Damaged or broken skin, such as blisters

Mucous Membranes

- Bloodborne pathogens may be transmitted through mucous membranes:
 - Eyes
 - Nose
 - Mouth



What is HIV?

- The Human Immunodeficiency Virus (HIV) causes Acquired Immunodeficiency Syndrome (AIDS), a severe illness which suppresses the body's immune system.
- No known cure or immunization which can prevent seroconversion from HIV to AIDS.
- HIV has been isolated in almost all body organs, tissues, and fluids.

HIV

- Can be transmitted through needlesticks with contaminated needles and mucous membrane or non-intact skin exposure to infected blood, tissue, blood products, and bodily fluids.
- Most occupational infections have been the result of needlesticks.
 - The risk of seroconversion after an HIV-contaminated needlestick is ~0.3%.

What is Hepatitis A?

- Hepatitis A is an acute (short-term), viral liver disease. Symptoms include jaundice, fatigue, nausea, abdominal pain, and fever.
- No chronic, long-term infection
- High incidence in IV drug users
- Vaccine available but only recommended for high-risk groups

What is Hepatitis B?

- Hepatitis B Virus (HBV) causes an infection of the liver. Symptoms can include flu-like symptoms and jaundice and may not appear until 2-6 months after infection.
- HBV is 100 times more infectious than HIV.
 - HIV ~0.3%, or 3 in 1,000
 - HBV ~30%, or 300 in 1,000

HBV

- Transmitted in many of the same ways as HIV, by needlesticks or mucous membrane exposures to infected bodily fluids.
- HBV can survive for *up to 7 days outside of the host in dried blood*.
- 1.25 million people in the U.S. are considered “chronic carriers” of the virus.
- Vaccine available FREE of charge through Occupational Health Program.

What is the TAMU Occupational Health Program?

- Provide pre-exposure prophylaxis (such as Hepatitis B vaccine), medical evaluations, and post-exposure evaluation and treatment at no cost to you
- Scott & White Department of Occupational Health & Environmental Medicine
- Fill out Occupational Health Program Enrollment Form and return to EHSD
- Follow instructions on form to contact Scott & White for appointments, vaccines, etc.
- Call 862-4042 with questions

What is Hepatitis C?

- Hepatitis C (HCV) causes infection of the liver, potentially liver disease, cirrhosis, or liver cancer. Symptoms like those of HBV.
- Less infectious than HBV, but more than HIV
 - HIV ~0.3%, or 3 in 1,000
 - HBV ~30%, or 300 in 1,000
 - HCV ~10%, or 100 in 1,000
- Most commonly transmitted through needlestick exposures.
- 4 million “chronic carriers” in U.S.
- No vaccine

Protecting Yourself From Bloodborne Pathogens

- Follow Standard Precautions (formerly Universal Precautions)
- Use Personal Protective Equipment (PPE)
- Use mechanical devices such as sharps containers

Standard Precautions

- Minimum control procedures based on the principle that *all blood, body fluids, and people are potentially infectious*.
- Include:
 - Routine use of protective equipment to prevent skin and mucous membrane exposure
 - Handwashing
 - Use soap and water
 - Lather 10-15 seconds
 - Wash all surfaces
 - Rinse with warm water
 - Towel dry



Personal Protective Equipment (PPE)

- **Gloves**

- Always check for tears, punctures, etc. before wearing
- If you have sores, blisters, cuts, etc. on hands, cover with bandage before wearing gloves
- Latex allergy issues
 - Use powder-free gloves with reduced protein content, or nitrile
 - Wash hands immediately after removing latex gloves



- **Goggles/Eyewear**

- **Masks**

Always wash hands after removing any potentially contaminated PPE

Emergency Procedures

- For needlesticks, splashes, other potential exposures:
 - Dispose of needle properly in sharps container.
 - Wash area with soap and water for at least 15 minutes.
 - If blood/fluid splashed in eye, mouth, or nose, flush affected area with running water for at least 15 minutes.
 - Notify supervisor.
 - Report to TAMU Occupational Health Program and Scott & White Occupational Medicine.
 - Scott & White will offer post-exposure evaluation and follow-up.

Blood/Bodily Fluid Spills

- Custodial will clean up small blood and bodily fluid spills, indoors only.
- If you feel comfortable cleaning the size/type of spill in question, you may do so.
- If not, call Environmental Health & Safety to clean blood, large spills, and incidents outdoors.

Spill Clean Up Procedures

- Wear PPE (gloves, goggles, etc.)
- Remove any sharp objects carefully before cleaning spill. Use forceps, tweezers, etc.
- Use 10-15% Clorox solution to disinfect (~1 1/2 cups bleach to 1 gallon water)
- Circle spill with disinfectant, place paper towel on top, then saturate entire spill
- Let stand 10-15 minutes
- Wipe up spill and dispose of paper towel
- Wipe again with solution to clean area

Summary

This has been an introduction to bloodborne pathogen safety. A DVD is available from EHS with more information, in English and Spanish formats. People potentially exposed to bloodborne pathogens are strongly encouraged to view the video.



Questions? Contact Environmental Health & Safety

- Spill Response
- Occupational Health

(979) 845-2132
ehsd@tamu.edu
TAMU 4472



Access to a Select Agent or SBAT facility

Angelia Raines,
Institutional Biosafety Committee
Office of Research Compliance

June 1, 2007



Access...

- IBC/CDC approval is required before accessing an agent or before unescorted access to a facility.
- Everyone is responsible...

What is access to an Agent?

- any point in time if the individual has possession of a select agent or toxin (*e.g.*, ability to carry, use, or manipulate) or
- the ability to gain possession of a select agent or toxin.

Agent Access requirements...

- IBC/CDC approval
- Safety, Security and Incident response training
- Each individual with access to select agents or toxins must have the appropriate education, training, and/or experience to handle or use such agents or toxins.

Remember...

No access to any Select Agent until...

APPROVAL AND TRAINING IS VERIFIED!

Access to a facility

- Individual must be approved for access to a particular facility and particular room.
- If not approved for facility access - MUST be escorted at all times.
- Current approval list is enclosed

Access to a facility

- Everyone MUST sign the access log
- Escorts sign in and complete the escort section of for unapproved individuals signing in.
- Training is required for employees and visitors – before entering an SBAT facility

Remember...

- Remember...If not approved for facility access - MUST be escorted at all times.
- If not approved by IBC/CDC – NO ACCESS TO AGENT

Conclusion

- **In order to ensure safety and security, access to Select Agents and to facilities must be controlled...**

It is everyone's responsibility!

Online Hazard Communication Training Course

**E
H
S
D**

**HAZARD
COMMUNICATION IN
THE LABORATORY**



ENVIRONMENTAL
HEALTH AND SAFETY
DEPARTMENT

Welcome to Hazard Communication Training!

- This online training course is designed to satisfy the Hazard Communication Training requirements for working with hazardous chemicals at Texas A&M University. The Program is divided into four parts, as described in the next slide.

CONTENTS

- SECTION ONE
 - HAZARD COMMUNICATION
- SECTION TWO
 - GENERAL SAFETY
- SECTION THREE
 - CHEMICAL SAFETY
- SECTION FOUR
 - EMERGENCY RESPONSE



SECTION ONE: HAZARD COMMUNICATION

- RULES & REGULATIONS
- RIGHT TO KNOW



WHAT IS THE PURPOSE OF HAZARD COMMUNICATION?

TO ENSURE THAT EMPLOYERS AND EMPLOYEES KNOW ABOUT WORK HAZARDS AND HOW TO PROTECT THEMSELVES SO THAT THE INCIDENCE OF ILLNESSES AND INJURIES DUE TO HAZARDOUS CHEMICALS IS REDUCED.



SECTION ONE -

WHO IS COVERED BY THE TEXAS HAZARD COMMUNICATION LAW?

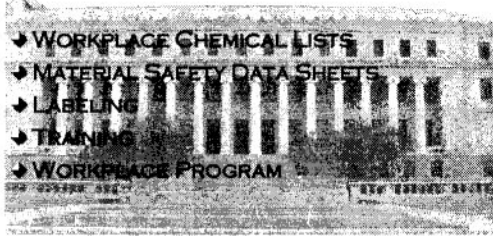


APPLIES TO ALL EMPLOYEES WORKING FOR THIS STATE WHO MAY BE EXPOSED TO HAZARDOUS CHEMICALS UNDER NORMAL OPERATING CONDITIONS OR FORESEEABLE EMERGENCIES



SECTION ONE -
HAZCOM

WHAT ARE THE TEXAS A&M REQUIREMENTS?



SECTION ONE -
HAZCOM

RESEARCH LABORATORIES ARE REQUIRED TO PROVIDE THE FOLLOWING:

- SUPERVISION
- TRAINING
- MATERIAL SAFETY DATA SHEETS (MSDSs)
- PRIMARY CONTAINER LABELING
- PERSONAL PROTECTIVE EQUIPMENT

EXEMPTIONS

- INVENTORIES
- SECONDARY CONTAINER LABELS

SECTION ONE -
HAZCOM

RESEARCH LABS ARE REQUIRED TO TRAIN EMPLOYEES WHEN:

- THEIR ASSIGNMENT BEGINS
- WHENEVER A NEW HAZARD IS INTRODUCED



SECTION ONE -
TRAINING

WHAT GENERAL SAFETY TRAINING IS REQUIRED?

- INFORMATION ON MSDSS (MATERIAL SAFETY DATA SHEETS) AND HOW TO OBTAIN THEM
- INFORMATION ON LABELS
- GENERIC INFORMATION ON HAZARDOUS CHEMICALS
- FIRST AID
- PPE (PERSONAL PROTECTIVE EQUIPMENT)
- CHEMICAL SPILL CLEAN-UP
- CHEMICAL WASTE DISPOSAL

SECTION ONE -
TRAINING

WORK AREA SPECIFIC TRAINING IS REQUIRED ON:



- INFORMATION ON HAZARDOUS CHEMICALS
- LOCATION OF MSDSS
- PPE
- FIRST AID
- SPILL CLEAN-UP
- CHEMICAL WASTE DISPOSAL

SECTION ONE -
TRAINING

MATERIAL SAFETY DATA SHEETS REQUIREMENTS

- MSDSS MUST BE READILY ACCESSIBLE
 - CAN BE KEPT IN A WORK AREA FILE
 - CAN BE PROVIDED BY THE MANUFACTURER/DISTRIBUTOR
 - CAN BE OBTAINED FROM EHSD 979.845.2132
- MSDSS MUST BE CURRENT!



SECTION ONE - MSDS

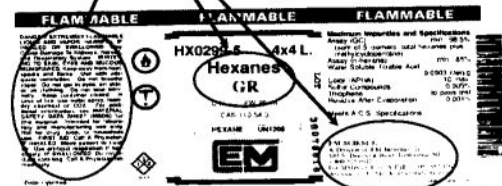
MSDSs CONTAIN THE FOLLOWING INFORMATION:

- ➔ IDENTIFICATION
- ➔ MANUFACTURER NAME AND ADDRESS
- ➔ PHYSICAL AND CHEMICAL CHARACTERISTICS
- ➔ PHYSICAL HAZARDS
- ➔ HEALTH HAZARDS
- ➔ ROUTES OF ENTRY
- ➔ EXPOSURE LIMITS
- ➔ CARCINOGENICITY
- ➔ SAFE HANDLING
- ➔ EMERGENCY AND FIRST-AID

SECTION ONE - MSDS

PRIMARY CONTAINERS MUST BE LABELED AND CONTAIN THE FOLLOWING:

- ➔ IDENTITY
- ➔ HAZARDS
- ➔ MANUFACTURER



SECTION ONE -

LABELING SECONDARY CONTAINERS MUST CONTAIN:

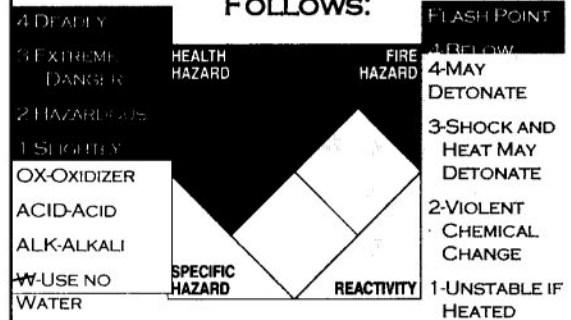
- ➔ IDENTITY
- ➔ HAZARDS



(IN LABORATORY, CHEMICALS MUST BE READILY IDENTIFIABLE)

SECTION ONE - LABELING

N.F.P.A. 704 LABELS ARE OFTEN USED TO CONVEY HAZARDS AS FOLLOWS:



SECTION ONE -

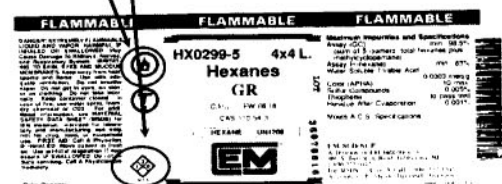
TRANSPORTATION LABELING Will Be Found ON OUTER SHIPPING PACKAGES



SECTION ONE - LABELING

MANUFACTURERS MAY INCORPORATE LABELING SYSTEMS

- ➔ N.F.P.A.
- ➔ D.O.T.



SECTION ONE -

SECTION TWO: GENERAL SAFETY TRAINING



Content:

- CONCEPTS
- PHYSICAL HAZARDS
- CHEMICAL STORAGE
- PERSONAL PROTECTION
- HAZARDOUS WASTE
- RESOURCE

SAFETY CONCEPTS

➤ HAZARD

- THE SOURCE OF DANGER (CHEMICAL, ELECTRICAL, HOT SURFACE, ETC.)

● RISK

- THE LIKELIHOOD OF OCCURRENCE (CHEMICAL EXPOSURE, SHOCK, BURN)

➤ CONSEQUENCE

- OUTCOME & IMPACT

SECTION TWO -
CONCEPTS

PHYSICAL HAZARDS

- ELECTRICAL
- CUTS & PUNCTURE WOUNDS
- MECHANICAL
- NOISE
- TEMPERATURE
- PROJECTILES
- HOUSEKEEPING
- RADIATION



SECTION TWO - PHYSICAL

COMPRESSED GASES



- GASES - TOXIC, CORROSIVE, FLAMMABLE, EXPLOSIVE
- HAZARDS
 - WEIGHT
 - SUDDEN RELEASE OF PRESSURE
- REGULATORS
- LEAKS
- IDENTIFICATION
- HANDLING AND USE
- EMPTY CYLINDERS

SECTION TWO - PHYSICAL
HAZARDS

CHEMICALS SHOULD BE STORED BY:



- HAZARD CLASS
- SEPARATE INCOMPATIBLES
- KEEP FROM HEAT/SUNLIGHT
- PROPERLY LABEL
- MINIMIZE QUANTITIES
- NO FLAMMABLES IN HOUSEHOLD REFRIGERATOR
- PROTECT AGAINST SPILLS
- DISPOSE OF OUTDATED, QUESTIONABLE OR UNNEEDED

SECTION TWO - CHEMICAL
STORAGE

Shipping Hazardous Chemicals

- Only Authorized Individuals may Ship Hazardous Chemicals! Check With EHSD at 845-2132 to Determine Who May Ship Hazardous Materials in Your Area.
- NEVER CARRY OR CHECK HAZARDOUS CHEMICALS ONTO AN AIRPLANE!
- IF Unsure of the Hazard, Contact EHSD!

PERSONAL PROTECTION CAN BE ACHIEVED BY TWO MEANS:

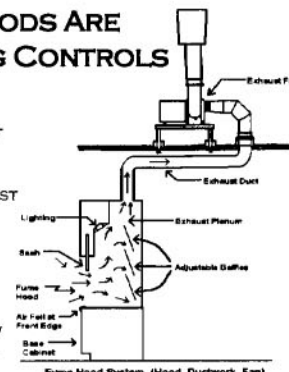
- ↓ ENGINEERING CONTROLS, SUCH AS:
 - GENERAL VENTILATION
 - LOCAL EXHAUST
- ↓ PPE
 - ↓ ONLY WHEN ENGINEERING CONTROLS ARE NOT POSSIBLE



SECTION TWO — PERSONAL PROTECTION

FUME HOODS ARE ENGINEERING CONTROLS

- ↓ KEEP SASH CLOSED
- ↓ RAISE LARGE EQUIPMENT SO GAPPED ON THE BOTTOM
- ↓ KEEP EQUIPMENT AT LEAST 6" FROM FACE
- ↓ KEEP CLEAN
- ↓ NOT FOR STORAGE
- ↓ NO PERCHLORIC ACID
- ↓ DO NOT MODIFY
- ↓ DO NOT BLOCK AIRFLOW
- ↓ AVOID RAPID MOVEMENT



Fume Hood System (Hood, Ductwork, Fan)

SECTION TWO — PERSONAL PROTECTION

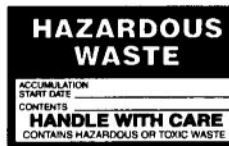
PERSONAL PROTECTIVE EQUIPMENT (PPE)

- ↓ EYES
 - GLASSES, GOGGLES, FULL FACE SHIELD
- ↓ HANDS
 - APPROPRIATE TYPE OF GLOVES
- ↓ BODY
 - LAB COAT, APRON, OTHER APPROPRIATE CLOTHING
- ↓ RESPIRATORY
 - DUST MASK, FULL AND HALF FACE RESPIRATORS, SCBA



SECTION TWO — PERSONAL PROTECTION

HAZARDOUS WASTE MUST BE PROPERLY HANDLED!



- ↓ USE ONLY APPROPRIATE CONTAINERS
- ↓ DO NOT MIX "INCOMPATIBLE WASTE"
- ↓ ALLOW FOR EXPANSION
- ↓ KEEP CONTAINER CLOSED
- ↓ LABEL CONTAINER AS "HAZARDOUS WASTE"
- ↓ IDENTIFY CONTENTS ON LABEL

SECTION TWO — HAZARDOUS WASTE

HAZARDOUS WASTE DISPOSAL

- ↓ DEFACE ORIGINAL CONTAINER LABEL
- ↓ COMPLETE HAZARDOUS WASTE TAG
 - AVAILABLE FROM EHSD
- ↓ MAIL COMPLETED LOWER TAG TO EHSD, MS4472

SECTION TWO — HAZARDOUS WASTE

WASTE CHEMICALS COST MONEY! TO REDUCE THE COST OF WASTE:



- ↓ AVOID UNKNOWN
- ↓ RETURN GAS CYLINDERS
- ↓ AVOID REACTIVES
- ↓ REDUCE VOLUME
- ↓ RETURN UNUSED TO SOURCE

DO NOT POUR HAZARDOUS CHEMICALS DOWN THE DRAIN OR EVAPORATE UP THE FUME HOOD.

SECTION TWO — HAZARDOUS WASTE

OTHER RESOURCES FOR SAFETY:

- ➔ SAFETY IN ACADEMIC LABORATORIES, 7TH EDITION, ISBN 0-8412-3863-4 & 0-8412-3864-2, AMERICAN CHEMICAL SOCIETY, 800-227-5558, OSS@ACS.ORG

SECTION THREE: CHEMICAL SAFETY

- ➔ CORROSIVES
- ➔ REACTIVES
- ➔ FLAMMABLES
- ➔ TOXINS



WHAT ARE CORROSIVES?



- ➔ MATERIALS THAT CAN DESTROY TISSUE AT THE POINT OF CONTACT. EXAMPLES ARE:
 - ACIDS
 - BASES
 - DEHYDRATING AGENTS
 - STRONG OXIDIZING AGENTS

SECTION THREE -

WORKING WITH CORROSIVES



- PROTECT EYES AND SKIN
- ➔ WORK IN HOOD
- ➔ LARGE QUANTITIES
 - WEAR PROTECTIVE CLOTHING
- ➔ ACID TO WATER DILUTION

SECTION THREE -

WHAT IF I GET CORROSIVES ON ME?



- ➔ RINSE IN SAFETY SHOWER OR EYEWASH FOR 15 MINUTES
- ➔ SEEK MEDICAL ATTENTION

SECTION THREE -
CORROSIVES

WHAT ARE REACTIVES?

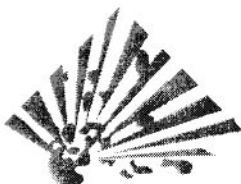
- ➔ REACTIVES ARE AGENTS THAT UNDERGO VIOLENT REACTION UNDER CERTAIN CONDITIONS
 - EXPLOSIVE
 - READILY POLYMERIZE
 - WATER REACTIVE
 - AIR REACTIVE
 - STRONG OXIDIZERS



SECTION THREE -
REACTIVES

WORKING WITH REACTIVES

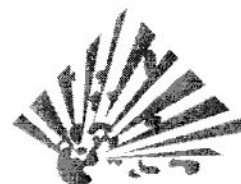
- ➔ ISOLATE FROM CAUSE OF REACTION
- ➔ STORAGE
 - SEPARATE FROM OTHER CHEMICALS
 - COOL/ DRY AREA
 - OUT OF SUNLIGHT



SECTION THREE -

WHEN REACTIVES REACT

- ➔ EMERGENCY EQUIPMENT
 - FIRE EXTINGUISHER
 - RESPIRATORY EQUIPMENT
- ➔ CONTACT
 - FLUSH FOR 15 MINUTES (EXCEPT WITH WATER REACTIVES)



SECTION THREE -
REACTIVES

WHAT ARE FLAMMABLES?



- BURNS READILY
 - FLASH POINT – TEMPERATURE AT WHICH A MATERIAL WILL FLASH IF PROVIDE AN IGNITION SOURCE
 - AUTO-IGNITION TEMPERATURE – WILL IGNITE EVEN IF NO IGNITION PROVIDED
 - FLAMMABILITY LIMITS – RANGE OF CONCENTRATION IN WHICH A GAS WILL BURN IN AIR
- ➔ NEEDS
 - FUEL
 - OXIDIZER
 - IGNITION SOURCE

SECTION THREE -
FLAMMABLES

WORKING WITH FLAMMABLES



- ➔ REMOVE IGNITION SOURCE
- ➔ STORAGE
 - WELL VENTILATED AREA
 - LAB-SAFE REFRIGERATOR
 - ISOLATED

SECTION THREE -

WHEN THERE IS A FIRE



- ➔ FIRE EXTINGUISHERS
- ➔ ACTIVATE OR OBEY BUILDING ALARMS
- ➔ FOLLOW BUILDING EVACUATION PROCEDURES

SECTION THREE -

WHAT ARE TOXINS?

- ➔ TOXINS CAUSE ILLNESS OR INJURY BY UPSETTING BIOLOGICAL FUNCTIONS OR DAMAGING BIOLOGICAL STRUCTURES
- ➔ DOSE-RESPONSE RELATIONSHIP



SECTION THREE - TOXINS

FACTORS AFFECTING TOXICITY

- ↓ DOSAGE
- ↓ DURATION OF EXPOSURE
- ↓ EXPOSURE TO OTHER CHEMICALS
- ↓ ROUTES OF ENTRY
- ↓ PHYSICAL HEALTH
- ↓ INHERITED PARAMETERS
- ↓ SENSITIVITY TO THE CHEMICAL



SECTION THREE - TOXINS

TYPES OF TOXINS

- ↓ CARCINOGENS
 - CAUSE GROWTH OF ABNORMAL TISSUE
- ↓ REPRODUCTIVE TOXINS
 - INTERFERE WITH REPRODUCTION OF ADULT
- ↓ TERATOGENS
 - INTERFERE WITH EMBRYO/FETUS DEVELOPMENT



SECTION THREE - TOXINS

TYPES OF TOXINS

- ↓ MUTAGENS
 - ALTERS DNA
- ↓ NEUROTOXINS
 - DAMAGE NERVOUS SYSTEM



SECTION THREE - TOXINS

WORKING WITH TOXINS

- ↓ KNOW WHAT'S IN MIXTURES
- ↓ SAFE LEVELS OF EXPOSURE
 - PEL - 8 HOUR
 - STEL - 15 MIN.
- ↓ USE HOOD
- ↓ USE PROPER PROTECTIVE GEAR
- ↓ NO FOOD OR DRINKS IN LAB



SECTION THREE - TOXINS

WORKING WITH TOXINS

- ↓ WHEN IN DOUBT, CONTACT EHSD FOR:
 - INFORMATION
 - MONITORING
 - RECOMMENDATIONS



SECTION THREE - TOXINS

SECTION FOUR: EMERGENCY RESPONSE

- ↓ FIRST AID
- ↓ SPILL
- ↓ FIRE



FIRST AID FOR CHEMICAL EXPOSURE



- ➔ REMOVE CONTAMINATED CLOTHING
- ➔ FLUSH WITH WATER (15 MINUTES)
- ➔ CHEMICAL SPECIFIC FIRST AID
- ➔ MEDICAL ATTENTION

SECTION FOUR – FIRST AID

WHAT IF I SPILL A CHEMICAL?



- ➔ PROTECT YOURSELF
- ➔ NOTIFY OTHERS
- ➔ ATTEND TO INJURED OR EXPOSED
- ➔ IDENTIFY CHEMICAL
- ➔ DEVELOP PLAN OF ACTION

● CONTACTS

- CONTAIN SPILL
- CLEAN AREA
- DECONTAMINATE AREA

- EMERGENCY 9-911
- EHSD 5-2132
- AFTER HOURS 5-4311

SECTION FOUR – SPILL

FIRE SAFETY: WHEN TO USE AN EXTINGUISHER

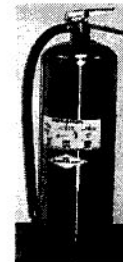


- ➔ SMALL CONTAINED
- ➔ KNOW EXTINGUISHER
- ➔ WHEN IN DOUBT, SOUND THE ALARM AND EVACUATE!

SECTION FOUR – FIRE

TYPES OF FIRE EXTINGUISHERS

- ➔ WATER EXTINGUISHER
 - LARGE SILVER CYLINDER
 - CLASS A FIRES ONLY (COMBUSTIBLES SUCH AS PAPER)
 - 2 1/2 GALLONS OF WATER
 - STREAM CAN SHOOT ABOUT 20-30 FEET
 - DANGEROUS ON CLASS B OR C FIRES (LIQUID OR ELECTRICAL)



SECTION FOUR – FIRE

FIRE EXTINGUISHERS

- ➔ MULTIPURPOSE EXTINGUISHER
 - DRY CHEMICAL
 - MAY BE CLASS ABC TYPE OR BC TYPE
 - WORKS BY COATING THE MATERIAL TO PREVENT RE-IGNITION
 - DISCHARGE TIME - 15-30 SECONDS, 6-10 FEET RANGE



SECTION FOUR – FIRE

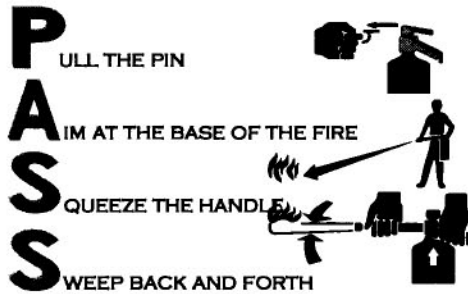
FIRE EXTINGUISHERS

- ➔ CARBON DIOXIDE EXTINGUISHER
 - CO₂ LIQUID UNDER PRESSURE - BECOMES A GAS WHEN DISCHARGED
 - WORKS BY DISPLACING THE OXYGEN IN THE FIRE TRIANGLE
 - OPERATING RANGE 3-6 FEET
 - DOES NOT WORK WELL OUTSIDE



SECTION FOUR – FIRE

USING AN EXTINGUISHER



This Concludes the Online Portion of Hazard Communication!

- A Training Document Will Be Mailed to You. This Should Be Completed by Your Supervisor and Placed in Your Personnel File.
- If You Have Any Questions, Please Feel Free To Contact EHSD for Information. EHSD Industrial Hygiene Can Be Reached At 845-2132.

Introduction to Laboratory Safety (Classroom Course)


**E
H
S
D**

**HAZARD
COMMUNICATION AND
LABORATORY SAFETY**



NANCY EAKER
PRESENTER

CONTENTS



- SECTION ONE
 - SAFETY ON CAMPUS
- SECTION TWO
 - HAZARD COMMUNICATION
- SECTION THREE
 - GENERAL SAFETY
- SECTION FOUR
 - CHEMICAL SAFETY
- SECTION FIVE
 - EMERGENCY RESPONSE

SAFETY ON CAMPUS

SECTION ONE

- CONTACTS
- EHSD
- REPORTING ACCIDENTS



SAFETY CONTACTS

- SAFETY HOTLINE
 - 862-SAFE
- EMAIL
 - EHSD@TAMU.EDU
- EMERGENCY (FD, PD, EMS)
 - 9911
- UPD (NON-EMERGENCY)
 - 845-2345
- EHSD (8-5)
 - 845-2132
- MAINTENANCE, EHSD (AFTER HOURS)
 - 845-4311

**EMERGENCY
9-911**

**ENVIRONMENTAL HEALTH &
SAFETY PROGRAMS**

➤ CHEMICAL SAFETY	➤ HAZARD COMMUNICATION
➤ BIOLOGICAL SAFETY	➤ SAFETY INSPECTIONS
➤ RADIOLOGICAL SAFETY	➤ FUME HOOD TESTING
➤ FIRE & LIFE SAFETY	➤ BIOL. SAFETY CABINET CERT.
➤ INDUSTRIAL HYGIENE	➤ SAFETY TRAINING
➤ LABORATORY SAFETY	➤ CONSTRUCTION PLAN REVIEW
➤ HAZARDOUS WASTE	➤ PROTOCOL REVIEW
➤ SPILL RESPONSE	
➤ LASER SAFETY	

REPORTING ACCIDENTS

- Actual Accidents and Injuries: Report Immediately

FIRST REPORT OF INJURY
Completed by Supervisor

FORMS: Dept. Office or HR Homepage

- Near Accidents: Inform Supervisor & EHSD
- Hazardous Conditions: Inform Supervisor

HAZARD COMMUNICATION

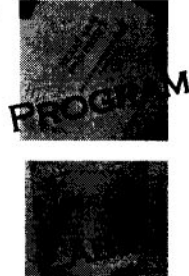
SECTION
Two

- ➔ RULES & REGULATIONS
- ➔ RIGHT TO KNOW



PURPOSE OF HAZARD COMMUNICATION

TO ENSURE THAT EMPLOYERS AND EMPLOYEES KNOW ABOUT WORK HAZARDS AND HOW TO PROTECT THEMSELVES SO THAT THE INCIDENCE OF ILLNESSES AND INJURIES DUE TO HAZARDOUS CHEMICALS IS REDUCED.



TEXAS HAZARD COMMUNICATION



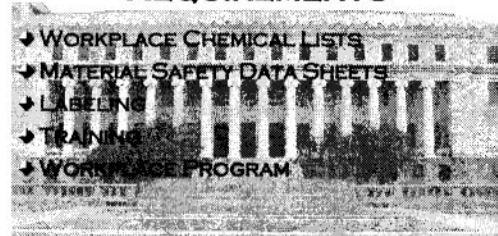
APPLIES TO ALL EMPLOYEES WORKING FOR THIS STATE WHO MAY BE EXPOSED TO HAZARDOUS CHEMICALS UNDER NORMAL OPERATING CONDITIONS OR FORESEEABLE EMERGENCIES

EMPLOYEES MAY BE SUBJECT TO ADMINISTRATIVE PENALTIES AND CIVIL OR CRIMINAL PENALTIES FROM \$50 TO \$5,000 FOR EACH VIOLATION OF THIS ACT.
FOR MORE INFORMATION, SEE THE COMPLAINT FORM.



TEXAS A&M REQUIREMENTS

- ➔ WORKPLACE CHEMICAL LISTS
- ➔ MATERIAL SAFETY DATA SHEETS
- ➔ LABELING
- ➔ TRAINING
- ➔ WORKPLACE PROGRAM

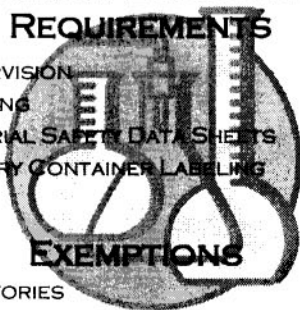


RESEARCH LABORATORY REQUIREMENTS

- ➔ SUPERVISION
- ➔ TRAINING
- ➔ MATERIAL SAFETY DATA SHEETS
- ➔ PRIMARY CONTAINER LABELING
- ➔ PPE

EXEMPTIONS

- ➔ INVENTORIES
- ➔ SECONDARY CONTAINER LABELS



TRAINING REQUIREMENTS

- ➔ WHEN ASSIGNMENT BEGINS
- ➔ WHENEVER NEW HAZARD IS INTRODUCED



TRAINING GENERAL SAFETY

- INFORMATION ON MSDS AND HOW TO OBTAIN THEM
- INFORMATION ON LABELS
- GENERIC INFORMATION ON HAZARDOUS CHEMICALS
- FIRST AID
- PPE
- CHEMICAL SPILL CLEAN-UP
- CHEMICAL WASTE DISPOSAL

TRAINING WORK AREA SPECIFIC



- INFORMATION ON HAZARDOUS CHEMICALS
- LOCATION OF MSDSS
- PPE
- FIRST AID
- SPILL CLEAN-UP
- CHEMICAL WASTE DISPOSAL

MATERIAL SAFETY DATA SHEETS REQUIREMENTS

- READILY ACCESSIBLE
 - WORK AREA FILE
 - MANUFACTURER/DISTRIBUTOR
 - EHS 979.845.2132
- CURRENT



MATERIAL SAFETY DATA SHEETS INFORMATION

- IDENTIFICATION
- MANUFACTURER NAME AND ADDRESS
- PHYSICAL AND CHEMICAL CHARACTERISTICS
- PHYSICAL HAZARDS
- HEALTH HAZARDS
- ROUTES OF ENTRY
- EXPOSURE LIMITS
- CARCINOGENICITY
- SAFE HANDLING
- EMERGENCY AND FIRST-AID

LABELING PRIMARY CONTAINER

- IDENTITY
- HAZARDS
- MANUFACTURER

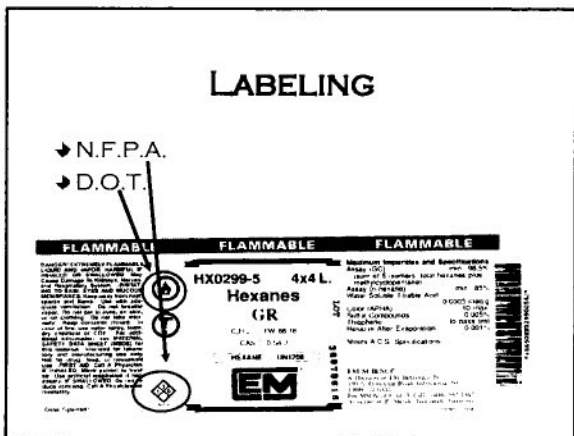
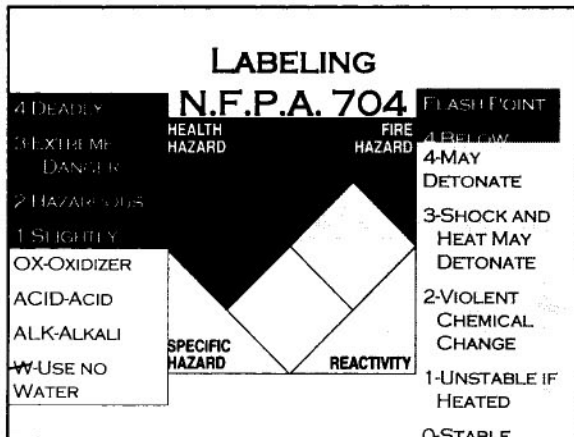


LABELING SECONDARY CONTAINERS

- IDENTITY
- HAZARDS



(IN LABORATORY, CHEMICALS MUST BE READILY IDENTIFIABLE)



GENERAL SAFETY

SECTION THREE

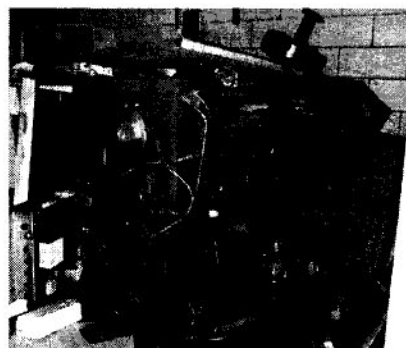
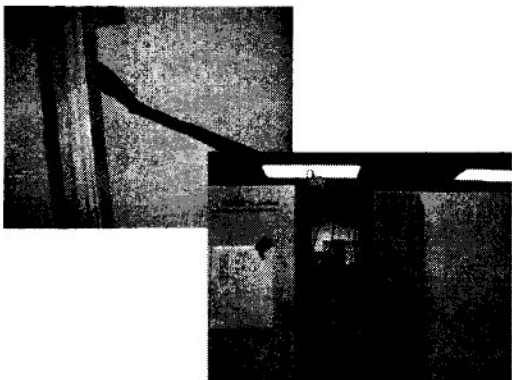
- ↓ CONCEPTS
- ↓ PHYSICAL HAZARDS
- ↓ CHEMICAL STORAGE
- ↓ PERSONAL PROTECTION
- ↓ WASTE DISPOSAL
- ↓ SHIPPING

SAFETY CONCEPTS

- ↓ HAZARD
 - THE SOURCE OF DANGER (CHEMICAL, ELECTRICAL, HOT SURFACE, ETC.)
- ↓ RISK
 - THE LIKELIHOOD OF OCCURRENCE (CHEMICAL EXPOSURE, SHOCK, BURN)
- ↓ CONSEQUENCE
 - OUTCOME & IMPACT

PHYSICAL HAZARDS

- ↓ ELECTRICAL
- ↓ CUTS & PUNCTURE WOUNDS
- ↓ MECHANICAL
- ↓ NOISE
- ↓ TEMPERATURE
- ↓ PROJECTILES
- ↓ HOUSEKEEPING



COMPRESSED GASES



- GASES - TOXIC, CORROSIVE, FLAMMABLE, EXPLOSIVE
- HAZARDS
 - WEIGHT
 - SUDDEN RELEASE OF PRESSURE
- REGULATORS
- LEAKS
- IDENTIFICATION
- HANDLING AND USE
- EMPTY CYLINDERS

LIQUID CRYOGENS

- CRYOGENS, SUCH AS LIQUID NITROGEN, OXYGEN, AND HELIUM ARE EXTREMELY COLD LIQUIDS THAT CAN PRODUCE A PAINFUL BURN.
- CRYOGENS CAN EXPAND RAPIDLY AND MUST NEVER BE CONTAINED IN A CLOSED SYSTEM.
- EYES AND BARE SKIN CAN BE INJURED IMMEDIATELY IF THEY COME INTO CONTACT WITH CRYOGENS.

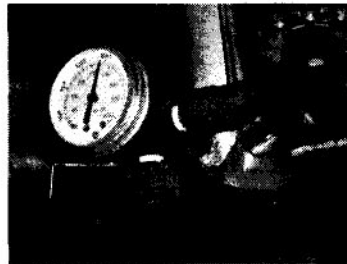
LIQUID NITROGEN BURN TO THE HAND



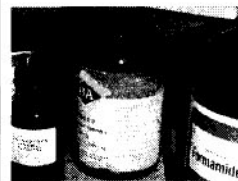
WHAT SHOULD I LOOK FOR ON CYLINDERS?

- CYLINDERS SHOULD BE TESTED EVERY FIVE (5) YEARS. CONTACT EHSD AT 845-2132 FOR DETAILS.
- LOOK FOR SWELLING (RIBBING) OF THE EXTERNAL TANK. IF EVIDENCE EXISTS, CONTACT EHSD IMMEDIATELY.
- REPORT ANY EXCESSIVE VENTING OR LEAKAGE TO THE VENDOR AND EHSD.
- ALWAYS CHECK THAT A PRESSURE RELIEF VALVE AND RUPTURE DISC ARE PRESENT ON THE CYLINDER PRIOR TO FILLING OR USAGE.

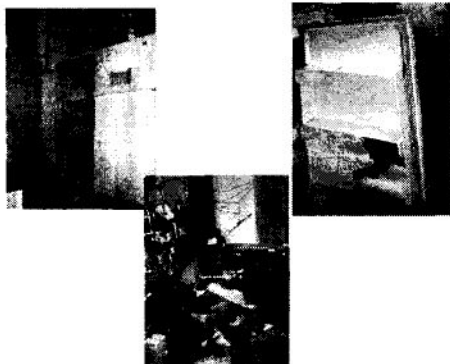
PRESSURE RELIEF VALVE AND RUPTURE DISC



CHEMICAL STORAGE



- BY HAZARD CLASS
- SEPARATE INCOMPATIBLES
- KEEP FROM HEAT/SUNLIGHT
- PROPERLY LABEL
- MINIMIZE QUANTITIES
- NO FLAMMABLES IN HOUSEHOLD REFRIGERATOR
- PROTECT AGAINST SPILLS
- DISPOSE OF OUTDATED, QUESTIONABLE OR UNNEEDED



PERSONAL PROTECTION

- ENGINEERED CONTROLS
 - GENERAL VENTILATION
 - LOCAL EXHAUST
- PPE



CHEMICAL FUME HOOD

- ➔ KEEP SASH CLOSED
- ➔ RAISE LARGE EQUIPMENT
- ➔ KEEP EQUIPMENT AT LEAST 6" FROM FACE
- ➔ KEEP CLEAN
- ➔ NOT FOR STORAGE
- ➔ NO PERCHLORIC ACID
- ➔ DO NOT MODIFY
- ➔ DO NOT BLOCK AIRFLOW
- AVOID RAPID MOVEMENT

Fume Hood System (Hood, Outwork, Fan)



PERSONAL PROTECTIVE EQUIPMENT

- ➔ EYES
 - GLASSES, GOGGLES, FULL FACE SH
- ➔ HANDS
 - APPROPRIATE TYPE OF GLOVES
- ➔ BODY
 - LAB COAT, APRON, OTHER APPROPRIATE CLOTH
- ➔ RESPIRATORY
 - DUST MASK, FULL AND HALF FACE RESPIR. SCBA

HAZARDOUS WASTE

- ➔ USE APPROPRIATE CONTAINER
- ➔ NO "INCOMPATIBLE WASTE"
- ➔ ALLOW FOR EXPANSION
- ➔ KEEP CLOSED
- ➔ LABEL "HAZARDOUS WASTE"
- ➔ IDENTIFY CONTENTS

HAZARDOUS WASTE

- ➔ DEFACE CONTAINER LABEL
- ➔ COMPLETE HAZARDOUS WASTE TAG
 - AVAILABLE AT EHSD

HAZARDOUS MATERIALS SHIPPING

- ➔ DEFACE CONTAINER LABEL
- ➔ COMPLETE HAZARDOUS WASTE TAG
 - AVAILABLE AT EHSD

CHEMICAL SAFETY

SECTION
FOUR

- ➔ CORROSIVES
- ➔ REACTIVES
- ➔ FLAMMABLES
- ➔ TOXINS



CORROSIVES



- ➔ DESTROY TISSUE AT THE POINT OF CONTACT
 - ACIDS
 - BASES
 - DEHYDRATING AGENTS
 - STRONG OXIDIZING AGENTS

WORKING WITH CORROSIVES



- ➔ PROTECT EYES AND SKIN
- ➔ WORK IN HOOD
- ➔ LARGE QUANTITIES
 - WEAR PROTECTIVE CLOTHING
- ➔ A-W DILUTION

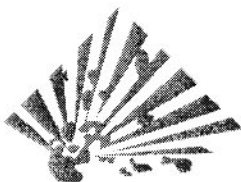
CONTACT WITH CORROSIVES



- ➔ RINSE IN SAFETY SHOWER OR EYEWASH FOR 15 MINUTES
- ➔ MEDICAL ATTENTION

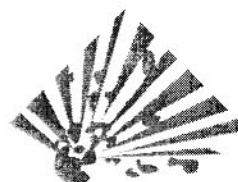
REACTIVES

- ➔ UNDERGO VIOLENT REACTION UNDER CERTAIN CONDITIONS
 - EXPLOSIVE
 - READILY POLYMERIZE
 - WATER REACTIVE
 - AIR REACTIVE
 - STRONG OXIDIZERS



WORKING WITH REACTIVES

- ➔ ISOLATE FROM CAUSE OF REACTION
- ➔ STORAGE
 - SEPARATE FROM OTHER CHEMICALS
 - COOL/DRY AREA
 - OUT OF SUNLIGHT



WHEN REACTIVE REACT

- EMERGENCY EQUIPMENT
 - FIRE EXTINGUISHER
 - RESPIRATORY EQUIPMENT
- CONTACT
 - FLUSH FOR 15 MINUTES (EXCEPT WITH WATER REACTIVES)



FLAMMABLES

- BURNS READILY
 - FLASH POINT
 - IGNITION TEMPERATURE
 - FLAMMABILITY LIMITS
- NEEDS
 - FUEL
 - OXIDIZER
 - IGNITION SOURCE



WORKING WITH FLAMMABLES

- REMOVE IGNITION SOURCE
- STORAGE
 - WELL VENTILATED AREA
 - LAB-SAFE REFRIGERATOR
 - ISOLATED



WHEN THERE IS A FIRE

- FIRE EXTINGUISHERS
- BUILDING ALARMS
- BUILDING PROCEDURES



TOXINS

- CAUSE ILLNESS OR INJURY BY UPSETTING BIOLOGICAL FUNCTIONS OR DAMAGING BIOLOGICAL STRUCTURES
- DOSE-RESPONSE RELATIONSHIP



"SOLA DOSIS FACIT
VENENUM"
-PARACELSUS

FACTORS AFFECTING TOXICITY

- DOSAGE
- DURATION OF EXPOSURE
- EXPOSURE TO OTHER CHEMICALS
- ROUTES OF ENTRY
- PHYSICAL HEALTH
- INHERITED PARAMETERS
- SENSITIVITY TO THE CHEMICAL



TYPES OF TOXINS

- ↓ CARCINOGENS
 - CAUSE GROWTH OF ABNORMAL TISSUE
- ↓ REPRODUCTIVE TOXINS
 - INTERFERE WITH REPRODUCTION OF ADULT
- ↓ TERATOGENS
 - INTERFERE WITH EMBRYO/FETUS DEVELOPMENT



TYPES OF TOXINS

- ↓ MUTAGENS
 - ALTERS DNA
- ↓ NEUROTOXINS
 - DAMAGE NERVOUS SYSTEM



WORKING WITH TOXINS

- ↓ MIXTURES
- ↓ SAFE LEVELS OF EXPOSURE
 - PEL - 8 HOUR
 - STEL - 15 MIN.
- ↓ USE HOOD
- ↓ PROPER PROTECTIVE GEAR
- ↓ NO FOOD OR DRINKS IN LAB



WORKING WITH TOXINS

- ↓ WHEN IN DOUBT, CONTACT EHSD
 - INFORMATION
 - MONITORING
 - RECOMMENDATIONS



EMERGENCY RESPONSE

SECTION FIVE

- ↓ CONTACTS
- ↓ FIRST AID
- ↓ SPILL
- ↓ FIRE



CONTACT PHONE NUMBERS



- ↓ EMERGENCY
 - 9-911
- ↓ EHSD
 - 845-2132
- ↓ AFTER-HOURS
 - 845-4311

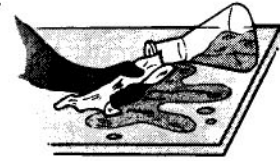
FIRST AID



- ➔ REMOVE CONTAMINATED CLOTHING
- ➔ FLUSH WITH WATER (15 MINUTES)
- ➔ CHEMICAL SPECIFIC FIRST AID
- ➔ MEDICAL ATTENTION

CHEMICAL SPILL CLEAN-UP

- ➔ PROTECT YOURSELF
- ➔ NOTIFY OTHERS
- ➔ ATTEND TO INJURED OR EXPOSED
- ➔ IDENTIFY CHEMICAL
- ➔ DEVELOP PLAN OF ACTION
 - CONTAIN SPILL
 - CLEAN AREA
 - DECONTAMINATE AREA

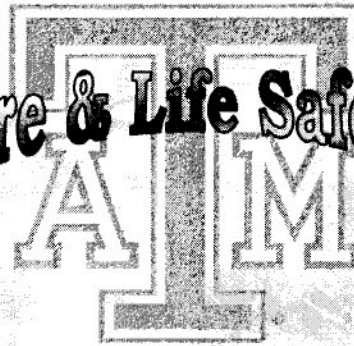


FIRE & LIFE SAFETY



• JOHN W. FELLERS

Fire & Life Safety



John Fellers

Fire Safety & Prevention

- IF YOU HEAR THE FIRE ALARM SOUND, EVACUATE IMMEDIATELY!
- CHECK DOOR FOR HEAT WITH THE BACK OF YOUR HAND.
- CLOSE DOORS BEHIND YOU TO PREVENT FIRE & SMOKE SPREAD
- KEEP STORAGE 24" FROM THE CEILING

Fire Safety & Prevention Cont.

- DO NOT USE EXTENSION CORDS AS PERMANENT WIRING
- USE POWER STRIPS WITH SURGE PROTECTION.
 - POWER STRIPS MUST BE PLUGGED DIRECTLY INTO AN OUTLET.
 - DO NOT PLUG EXTENSION CORD INTO POWER STRIPS OR CONNECT IN SERIES.
- WHEN ON CAMPUS DIAL **9-911** IN AN EMERGENCY!



- 9-911 WILL DIAL BRAZOS COUNTY 911 DISTRICT
- 911 WILL TRANSFER CALL TO APPROPRIATE DISPATCH
 - UNIVERSITY POLICE
 - BRYAN FIRE DEPARTMENT
 - COLLEGE STATION FIRE DEPARTMENT
 - A&M EMERGENCY MEDICAL SERVICE



What Helps To Keep Us Safe?

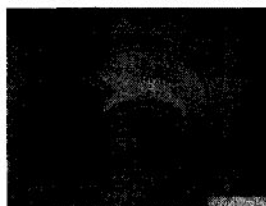
- FIRE ALARM SYSTEMS
- SPRINKLER SYSTEMS
- FIRE EXTINGUISHERS
- EVACUATION PLANS



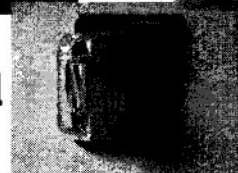
Fire Alarm Systems

- A FAS CONSISTS OF:
 - FIRE ALARM CONTROL PANEL
 - DETECTION DEVICES
 - MANUAL PULL STATIONS
 - AUDIO/VISUAL DEVICES
- FAP ALERTS CAMPUS DISPATCH

Smoke Detector Manual Pull Station



Audio/Visual



How it Works...

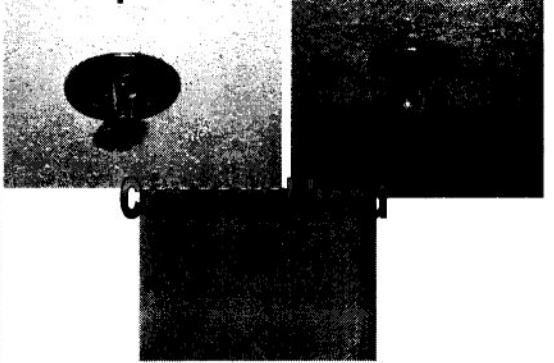
- DEVICE ACTIVATED & ALARM SOUNDS
- RADIO SIGNAL SENT TO UPD & PHYSICAL PLANT RADIO ROOM
- RADIO ROOM CALLS FIRE DEPARTMENT
- FIRE DISPATCH SENDS TRUCKS

Sprinkler Systems

- SPRINKLER HEADS HAVE A SPECIFIC HEAT RATING
- ONCE THAT TEMPERATURE IS REACHED THE SPRINKLER HEAD WILL "POP" AND WATER WILL DISCHARGE
- DO ALL SPRINKLER HEADS POP AT THE SAME TIME?
- KEEP STORAGE AT LEAST 18" BELOW THE BOTTOM OF A SPRINKLER HEAD

Quick response head

Head with thermal link



Fire Extinguishers

- TYPES OF FIRES
 - CLASS A - COMMON COMBUSTIBLES
 - CLASS B - FLAMMABLE LIQUIDS
 - CLASS C - ENERGIZED ELECTRICAL
 - CLASS D - COMBUSTIBLE METALS

Fire Extinguishers Cont.

TYPES OF FIRE EXTINGUISHERS

- CLASS A - COMMON COMBUSTIBLES
 - WATER
 - DRY CHEMICAL
- CLASS B - FLAMMABLE LIQUIDS
 - CO²
 - DRY CHEMICAL

Types of Extinguishers cont...

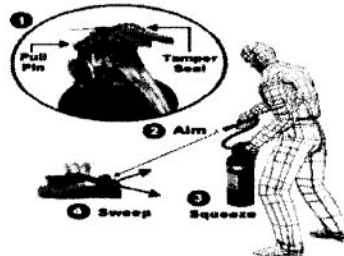
- CLASS C - ENERGIZED ELECTRICAL
 - DRY CHEMICAL
 - CO²
- CLASS D - COMBUSTIBLE METALS
 - DRY CHEMICAL

Fire Extinguishers

- SHOULD
 - BE USED ON THE CLASS OF FIRE FOR WHICH THEY ARE DESIGNED.
 - BE USED BY THOSE TRAINED IN THE PROPER USE OF EXTINGUISHERS.*
 - BE WITHIN 75 FEET TRAVEL DISTANCE..

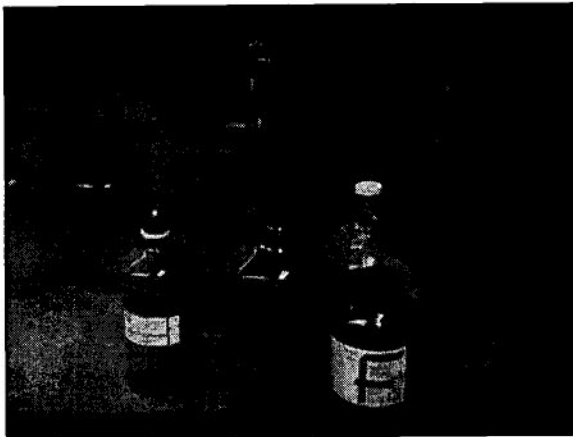
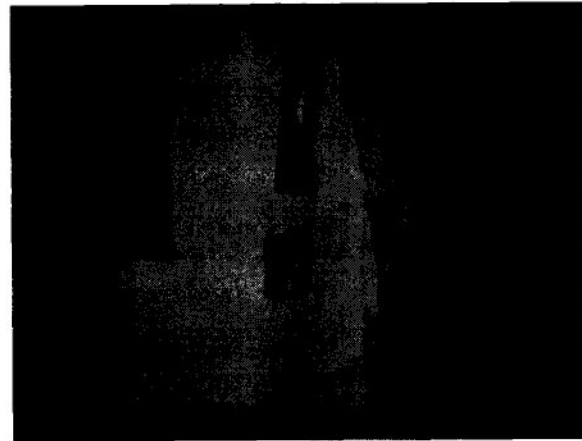
* EHSD offers hands-on training on the proper use of portable fire extinguishers

P.A.S.S.



Fire Extinguishers

- SHOULD NOT...
 - BE BLOCKED BY CHEMICALS OR OTHER ITEMS.
 - BE USED WHEN THE FIRE IS LARGE.
 - BE USED AS COAT RACKS.



Evacuation Plans

- Specific for each building
- Contain
 - Responsibilities
 - Evacuation procedures
 - Emergency reporting procedures
 - Fire drill policy
 - Emergency contact phone numbers

TABLE OF CONTENTS

INTRODUCTION	1
CONTACT PERSONNEL	2
FLOOR PROCTOR LIST	3
FIRE REPORTING PROCEDURES	4
FIRE MARSHAL RESPONSIBILITIES	5
OCCUPANT RESPONSIBILITIES	6
FLOOR PROCTOR RESPONSIBILITIES	7
FLOOR PROCTOR EVACUATION PROCEDURE	8
FIRE DRILL POLICY	9
EMERGENCY FLOOR PLANS	10-1
FLOOR PROCTOR ENTRANCE ASSIGNMENTS	7
EMERGENCY PHONE NUMBERS	7

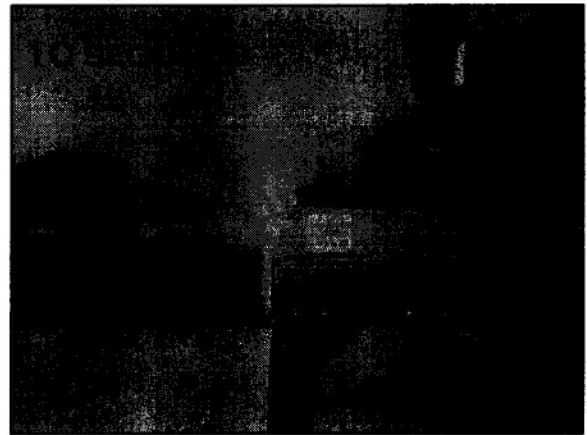
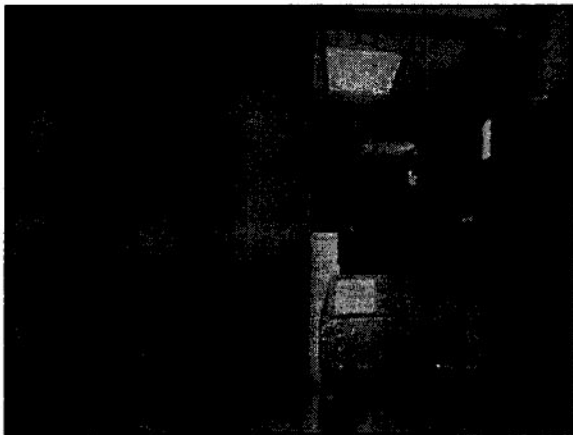
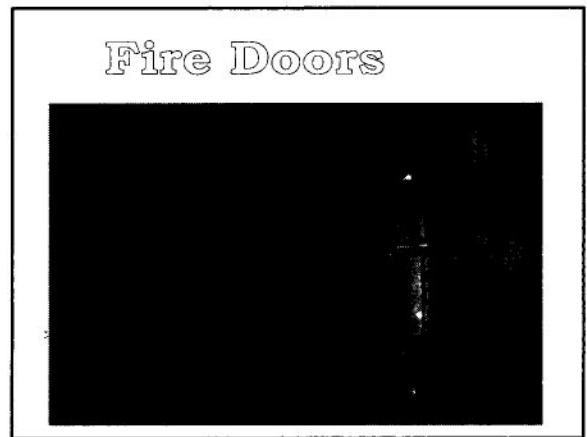
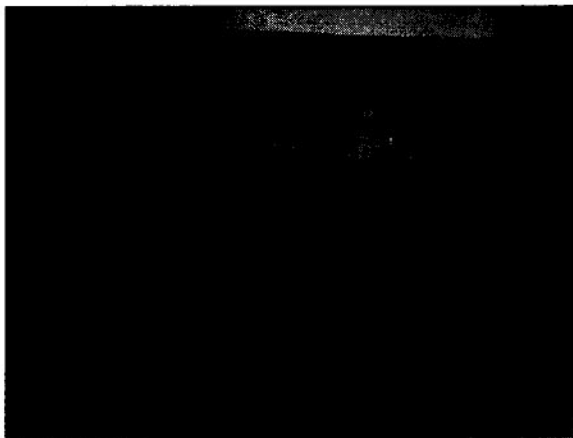
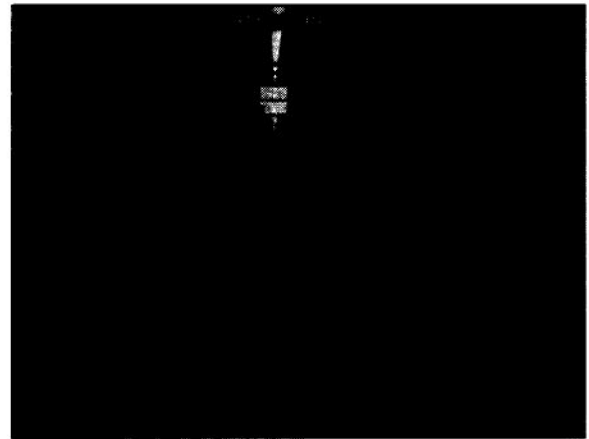
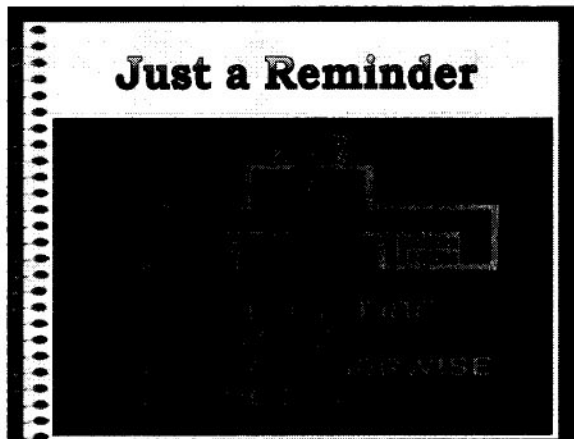
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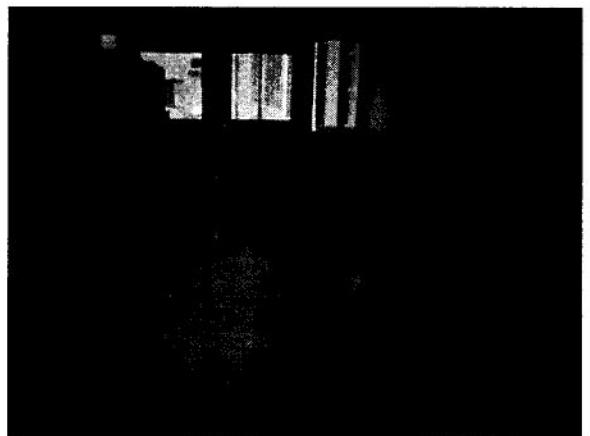
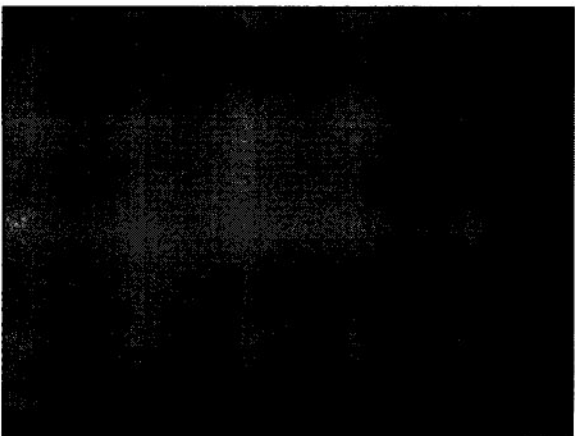
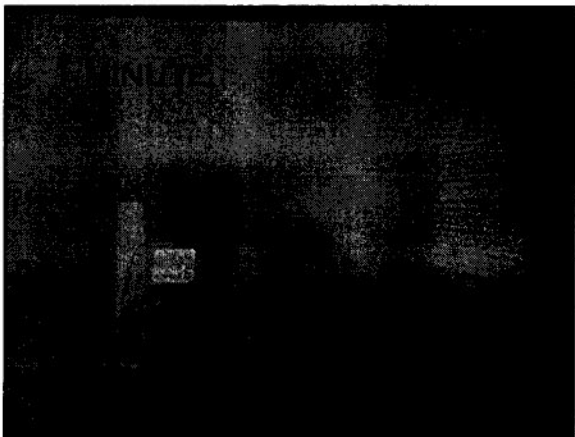
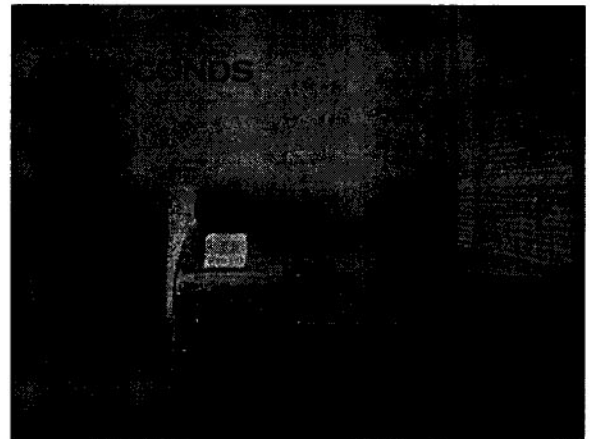
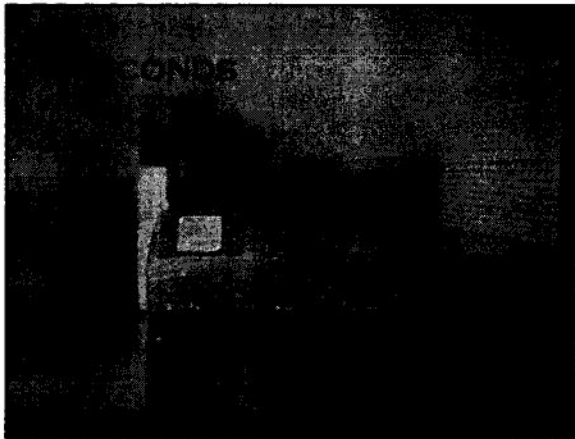
Fire Drill Policy

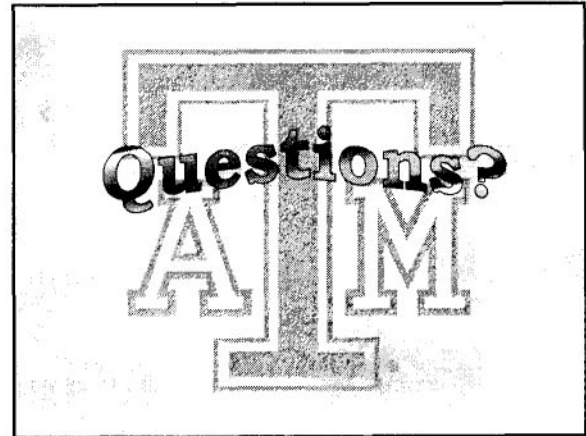
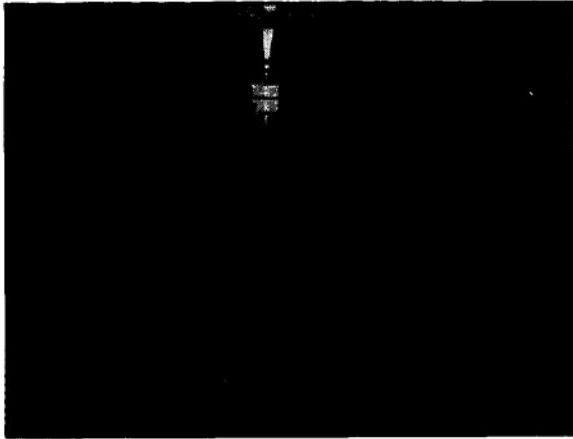
NFPA 101 (Life Safety Code)

Section 4.7.2

- Emergency egress and relocation drills...shall be held with sufficient frequency to familiarize the occupants with the drill procedure and to establish conduct of the drill as a matter of routine.....







BIO SAFETY TRAINING

BRENT MATTOX

ASEPTIC TECHNIQUES AND PROCEDURES

- PRIOR TO MANIPULATION
 - USE STERILE COMPONENTS
 - USE ENGINEERED CONTROLS WHEN APPROPRIATE (BSC)
 - ENSURE COMPONENTS ARE PRESENT IN BSC
- DURING MANIPULATION
 - OPEN VESSEL FOR MINIMUM TIME REQUIRED
 - AVOID CROSS CONTAMINATION (E.G., USING A LOOP THAT HAS CONTACTED THE OUTSIDE OF THE VESSEL)

ASEPTIC TECHNIQUES AND PROCEDURES

- USE UNIVERSAL PRECAUTION
- NO MOUTH PIPETTING
- NO FOOD, DRINK, TOBACCO PRODUCTS
- DO NOT APPLY COSMETICS OR REMOVE CONTACTS
- WORK SURFACES SHOULD BE DECONTAMINATED EVERY DAY AND AFTER ANY SPILL
- WASH HANDS:
 - AFTER WORKING WITH A BIOHAZARD
 - AFTER REMOVING PPE
 - BEFORE LEAVING LAB
- DO NOT TOUCH FACE WHILE WORKING WITH BIOLOGICAL MATERIAL
- DO NOT WEAR PPE OUTSIDE THE LAB

UNIVERSAL PRECAUTIONS

- ASSUME THAT ALL SAMPLES ARE INFECTIOUS
- USE GOOD LABORATORY PRACTICES
- USE PROTECTIVE BARRIERS
- WASH HANDS AND EXPOSED SKIN
- AVOID SKIN PUNCTURES
- AVOID CONTACT WITH SKIN OPENINGS
- IMMUNIZATIONS

BIOLOGICAL SAFETY LEVELS

- BSL-1
 - GENERAL BIOLOGY
- BSL-2
 - PATHOGENS — NOT AIRBORNE
- BSL-3
 - HIGHLY INFECTIOUS OR AIRBORNE
- BSL-4
 - EXTREME HAZARDS (FULL CONTAINMENT)

BIOLOGICAL WASTE DISPOSAL

LIQUIDS:	DECONTAMINATE → SEWER
SOLIDS:	AUTOClave → TRASH
ANIMALS:	INCINERATE
SHARPS:	ENCAPSULATE → TRASH

DISINFECTION

- CHOOSE DISINFECTANT
 - CONSIDER ORGANISM
 - CHARACTERISTICS OF AREA
- FREQUENTLY DISINFECT SURFACES AND EQUIPMENT



CHOOSING A DISINFECTANT

ALCOHOLS	ETHYL OR ISOPROPYL ALCOHOL AT 70-80% CONCENTRATION IS A GOOD GENERAL PURPOSE DISINFECTANT; NOT EFFECTIVE AGAINST BACTERIAL SPORES
PHENOLS	EFFECTIVE AGAINST VEGETATIVE BACTERIA, FUNGI, AND VIRUSES CONTAINING LIPIDS; UNPLEASANT ODOR
FORMALDEHYDE	CONCENTRATION OF 5-8% FORMALIN IS A GOOD DISINFECTANT AGAINST VEGETATIVE BACTERIA, SPORES, AND VIRUSES; KNOWN CARCINOGEN; IRRITATING ODOR
QUATERNARY AMMONIUM COMPOUNDS	CATIONIC DETERGENTS ARE STRONGLY SURFACE ACTIVE; EXTREMELY EFFECTIVE AGAINST LIPOVIRUSES; INEFFECTIVE AGAINST BACTERIAL SPORES; MAY BE NEUTRALIZED BY ANIONIC DETERGENTS (I.E. SOAPS)
CHLORINE	LOW CONCENTRATIONS (50-500PPM) ARE ACTIVE AGAINST VEGETATIVE BACTERIA AND MOST VIRUSES; HIGHER CONCENTRATIONS (2500PPM) ARE REQUIRED FOR BACTERIAL SPORES; CORROSIVE TO METALS; MUST BE PREPARED FRESH
IODINE	NOT RECOMMENDED FOR GENERAL USE; EFFECTIVE AGAINST VEGETATIVE BACTERIA AND VIRUSES; LESS EFFECTIVE AGAINST BACTERIAL SPORES

WET HEAT STERILIZATION



- OCCURS WHEN CONTAMINATE REACHES
 - 15 PSI
 - 250F
 - 30 MIN
- POTENTIAL PROBLEMS
 - DENSE LOADS
 - POOR HEAT CONDUCTORS (E.G. PLASTICS)
 - CONTAINERS PREVENTING STEAM PENETRATION (SOME PLASTIC BAGS, DOUBLE BAGGING)

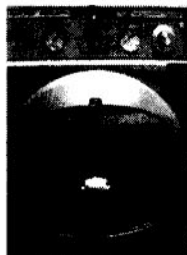
WET HEAT STERILIZATION



- TESTING LOADS
 - AUTOCLAVE TAPE
 - VERIFIES TEMPERATURE
 - BIOLOGICAL INDICATOR
 - MOST EFFECTIVE
 - TEST SHOULD BE CONDUCTED AS NORMALLY USED

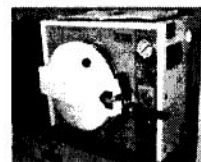
AUTOCLAVE (PACKAGING)

- DO NOT DOUBLE BAG OR TIGHTLY SEAL
- DO NOT PLACE SHARP OBJECTS IN BAG
- SHALLOW METAL PANS ARE MORE EFFECTIVE THAN TALL PLASTIC TUBS
- VESSELS WITH LIQUID SHOULD NOT BE CAPPED
- ADD WATER TO DRY WASTE BAGS



AUTOCLAVE (REMOVING WASTE)

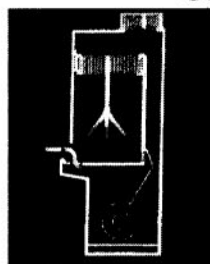
- ENSURE AUTOCLAVE IS "OFF" BEFORE OPENING
- ENSURE STEAM PRESSURE IS DOWN
- OPEN DOOR (NO MORE THAN .5 INCH) SLOWLY KEEPING HEAD AND HANDS FROM OPENING
- WAIT AT LEAST 10 MINUTES (OR MANUFACTURERS RECOMMENDATION) BEFORE REMOVING ANYTHING
- WEAR HEAT RESISTANT GLOVES
- CLEAN ANY SPILL IMMEDIATELY
- TAKE BAG TO DUMPSTER



ENCAPSULATION

- | | |
|---|--|
| <ul style="list-style-type: none"> • METAL SHARPS <ul style="list-style-type: none"> — USE RIGID CONTAINER — ENCAPSULATE (PLASTER OF PARIS) — LABEL "ENCAPSULATED SHARPS" — PLACE IN DUMPSTER | <ul style="list-style-type: none"> • GLASS SHARPS <ul style="list-style-type: none"> — DECONTAMINATE — SEAL IN PUNCTURE RESISTANT CONTAINER — LABEL "NON-CONTAMINATED GLASSWARE" — PLACE IN DUMPSTER |
|---|--|

BIOLOGICAL SAFETY CABINET



- AIRFLOW + HEPA FILTRATION
- KEEP CLEAN
- SET-UP BEFORE USE WITH BIOHAZARDS
- INSPECTED/CERTIFIED
 - INITIALLY
 - AFTER RELOCATION OR REPAIR
 - SEMIANNUALLY OR ANNUALLY

BIOLOGICAL SAFETY CABINET



- PREPARATION:
 - TURN OFF UV LIGHT
 - WIPE WORK SURFACE WITH APPROPRIATE DISINFECTANT
 - PLACE ONLY NEEDED ITEMS IN CABINET
 - SEGREGATE ITEMS FOR CLEAN AND DIRTY MATERIALS
 - PROVIDE WASTE CONTAINER INSIDE CABINET
 - RESTRICT ENTRY INTO LAB AND MOVEMENT IN LAB

BIOLOGICAL SAFETY CABINET



- USE:
 - WEAR LAB COAT AND GLOVES
 - KEEP WORK AT LEAST 4" FROM GLASS VIEW PANEL
 - LIMIT ARM MOVEMENT
 - LIMIT USE OF BURNER
 - PLACE DISINFECTANT-SOAKED TOWEL ON THE WORK SURFACE TO CONTAIN SPILL
 - CONTROL TISSUE AND LOOSE PAPER

BIOLOGICAL SAFETY CABINET



- COMPLETION:
 - DECONTAMINATE SURFACE OF OR ENCLOSE ITEMS WHICH CAME IN CONTACT WITH BIOHAZARD
 - COVER WASTE CONTAINER
 - ALLOW CABINET TO OPERATE 5 MIN WITHOUT ACTIVITY

BIOLOGICAL SPILLS

- IMMEDIATE ACTIONS:
 - WARN OTHERS
 - LEAVE THE ROOM; CLOSE THE DOOR
 - REMOVE CONTAMINATED GARMENTS
 - WASH HANDS
 - NOTIFY SUPERVISOR
 - SEEK MEDICAL ATTENTION, IF NECESSARY

BIOLOGICAL SPILL

- CLEAN UP PROCEDURE
 - WAIT FOR AEROSOLS TO SETTLE
 - PUT ON PROTECTIVE CLOTHING
 - COVER WITH TOWELS; ALLOW CONTACT TIME
 - APPLY DISINFECTANT
 - WIPE UP; MOP FLOOR
 - AUTOCLAVE WASTES

NEW EMPLOYEES

- TRAINING
- SUPERVISED WORK

RECORDS

- METAL SHARPS — DATE OF TREATMENT, QUANTITY, METHOD, NAME OF PERSON (PRINTED) (MAINTAIN 3 YEARS)
- AUTOCLAVE —
 - DATE OF TREATMENT, QUANTITY, METHOD, NAME OF PERSON (PRINTED)
 - DATE OF VERIFICATION TEST, RESULTS

TRANSPORTING INFECTIOUS MATERIALS

- ON CAMPUS
 - USE LEAK-PROOF CONTAINER
 - PLACE PRIMARY CONTAINER INTO SEALED LEAK-PROOF SECONDARY CONTAINER
 - USE RIGID TRANSPORT CONTAINER
 - LABEL TRANSPORT CONTAINER WITH BIOHAZARD SYMBOL, MATERIAL, EMERGENCY CONTACTS
 - SECURE TRANSPORT CONTAINER IN VEHICLE

TRANSPORTING INFECTIOUS MATERIALS

- OFF CAMPUS
 - FOLLOW FEDERAL AND INTERNATIONAL REGULATIONS
 - ONLY BE TRAINED EMPLOYEES OR
CONTACT EHSD @ 845-2132

Copies of emergency
plans for handling
accidental spills and
personnel
contamination



Biological Safety

TOPIC	PAGE
Biosafety Principle	12-2
General Biosafety Guidelines	12-3
CDC and NIH Biosafety Levels	12-5
Recombinant DNA Research	12-9
Disinfection and Sterilization	12-10
Biological Safety Cabinets	12-14
Clean Benches	12-18
Importing and Shipping Biological Materials	12-18
Biological Spill Response	12-18
Biological Waste Disposal	12-20
Bloodborne Pathogens	12-27

Biosafety Principle

The primary principle of biological safety (i.e., biosafety) is containment. The term *containment* refers to a series of safe methods for managing infectious agents in the laboratory. The purpose of containment is to reduce or eliminate human and environmental exposure to potentially harmful agents.

Primary and Secondary Containment

There are two levels of biological containment — primary and secondary. Primary containment protects people and the immediate laboratory environment from exposure to

infectious agents. Good microbial techniques and safety equipment provide sufficient primary containment. Examples of primary barriers include safety equipment such as biological safety cabinets, enclosed containers, and safety centrifuge cups. Occasionally, when it is impractical to work in biological safety cabinets, personal protective equipment, such as lab coats and gloves may act as the primary barrier between personnel and infectious materials.

Secondary containment protects the environment external to the laboratory from exposure to infectious materials. Good facility design and operational practices provide secondary containment. Examples of secondary barriers include work areas that are separate from public areas, decontamination facilities, handwashing facilities, special ventilation systems, and airlocks.

Elements of Containment

Ultimately, the three key elements of biological containment are laboratory practices, safety equipment, and facility design. To ensure minimal exposure, employees must assess the hazards associated with their work and determine how to apply the biosafety principle appropriately.

IMPORTANT:

Employees working with infectious agents or potentially infectious materials must be aware of the hazards associated with their work. These workers must be trained and proficient in biosafety procedures and techniques.

General Biosafety Guidelines

Biohazardous materials require special safety precautions and procedures. Follow these guidelines when working with infectious agents:

Personal Hygiene Guidelines:

- Wash your hands thoroughly, as indicated below:
 - After working with any biohazard
 - After removing gloves, laboratory coat, and other contaminated protective clothing
 - Before eating, drinking, smoking, or applying cosmetics
 - Before leaving the laboratory area
 - Do not touch your face when handling biological material
 - Never eat, drink, smoke, or apply cosmetics in the work area

Clothing Guidelines:

- Always wear a wrap-around gown or scrub suit, gloves, and a surgical mask when working with infectious agents or infected animals.
- Wear gloves *over* gown cuffs.
- Never wear contact lenses around infectious agents.
- Do not wear potentially contaminated clothing outside the laboratory area.
- To remove contaminated clothing, follow these steps:
 - 1. Remove booties from the back.
 2. Remove head covering from the peak.
 3. Untie gown while wearing gloves.
 4. Remove gloves by peeling them from the inside out.
 5. Remove the gown by slipping your finger under the sleeve cuff of the gown.

Handling Procedures:

- Use mechanical pipetting devices.
- Minimize aerosol production.
- Add disinfectant to water baths for infectious substances.
- Use trunnion cups with screw caps for centrifuging procedures. Inspect the tubes before use.
- Use secondary leak-proof containers when transporting samples, cultures, inoculated petri dishes, and other containers of biohazardous materials.

Syringes:

Avoid using syringes and needles whenever possible. If a syringe is necessary, minimize your chances of exposure by following these guidelines:

- Use a needle-locking or disposable needle unit.
- Take care not to stick yourself with a used needle.

- Place used syringes into a pan of disinfectant without removing the needles.
- Do not place used syringes in pans containing pipets or other glassware that require sorting.
- Do not recap used needles.
- Dispose of needles in an approved sharps container.

Work Area:

- Keep laboratory doors shut when experiments are in progress.
- Limit access to laboratory areas when experiments involve biohazardous agents.
- Ensure that warning signs are posted on laboratory doors. These signs should include the universal biohazard symbol and the approved biosafety level for the laboratory.
- Ensure that vacuum lines have a suitable filter trap.
- Decontaminate work surfaces daily and after each spill.
- Decontaminate all potentially contaminated equipment.
- Transport contaminated materials in leak-proof containers.
- Keep miscellaneous material (i.e., books, journals, etc.) away from contaminated areas.
- Completely decontaminate equipment before having maintenance or repair work done.

Universal Precautions:

Clinical and diagnostic laboratories often handle specimens without full knowledge of the material's diagnosis; these specimens may contain infectious agents. To minimize exposure, observe universal precautions when handling any biological specimen. Consider all specimens to be infectious and treat these materials as potentially hazardous.

CDC and NIH Biosafety Levels

The Centers for Disease Control (CDC) and the National Institutes of Health (NIH) have established four biosafety levels consisting of recommended laboratory practices, safety equipment, and facilities for various types of infectious agents. Each biosafety level accounts for the following:

- Operations to be performed

- Known and suspected routes of transmission
 - Laboratory function
-

Biosafety Level 1

Biosafety Level 1 precautions are appropriate for facilities that work with defined and characterized strains of viable organisms that do not cause disease in healthy adult humans (e.g., *Bacillus subtilis* and *Naegleria gruberi*). Level 1 precautions rely on standard microbial practices without special primary or secondary barriers. Biosafety Level 1 criteria are suitable for undergraduate and secondary education laboratories.

Biosafety Level 2

Biosafety Level 2 precautions are appropriate for facilities that work with a broad range of indigenous moderate-risk agents known to cause human disease (e.g., Hepatitis B virus, salmonellae, and *Toxoplasma* spp.). Level 2 precautions are necessary when working with human blood, body fluids, or tissues where the presence of an infectious agent is unknown. The primary hazards associated with level 2 agents are injection and ingestion. Most TAMU research laboratories should comply with Biosafety Level 2 criteria.

Biosafety Level 3

Biosafety Level 3 precautions apply to facilities that work with indigenous or exotic agents with the potential for aerosol transmission and lethal infection (e.g., *Mycobacterium tuberculosis*). The primary hazards associated with level 3 agents are autoinoculation, ingestion, and inhalation. Level 3 precautions emphasize primary and secondary barriers. For primary protection, all laboratory manipulations should be performed in a biological

safety

cabinet or other enclosed equipment. Secondary protection should include controlled access to the laboratory and a specialized ventilation system.

Biosafety Level 4

Biosafety Level 4 precautions are essential for facilities that work with dangerous and exotic agents with a high risk of causing life-threatening disease, the possibility of aerosol transmission, and no known vaccine or therapy (e.g., Marburg or Congo-Crimean viruses).

Level 4 agents require complete isolation. Class III biological safety cabinets or full-body

air-supplied positive-pressure safety suits are necessary when working with level 4 agents. In

addition, isolated facilities, specialized ventilation, and waste management systems are

required. There are no Biosafety Level 4 facilities at TAMU.

Biosafety Summary

Animal Biosafety

Four biosafety levels are also described for infectious disease work with laboratory animals.

Safety practices, equipment, and facilities are designated by Animal Biosafety Levels 1, 2, 3, and 4.

Refer to the Laboratory Safety chapter for more information regarding the use of hazardous materials with laboratory research animals.

For More Information

A copy of the CDC/NIH criteria for laboratory and animal biosafety levels is

available from
the Environmental Health & Safety Department.

Recombinant DNA Research

As an institute that receives NIH funding, TAMU is obligated to ensure that all recombinant

DNA (rDNA) work conducted by its faculty and staff conforms with Federal rDNA guidelines. This task falls jointly to the Institutional Biosafety Committee (IBC) and the

Environmental Health & Safety Department. The IBC reviews all protocols involving rDNA,

rules on the appropriateness of proposed containment procedures, and sets suitable biosafety levels. The Environmental Health & Safety Department inspects individual laboratories and verifies that practices and facilities meet the requisite biosafety level assigned by the IBC.

The Federal rDNA guidelines define rDNA as "... molecules which are constructed outside

of living cells by joining natural or synthetic DNA segments to DNA molecules that can

replicate in a living cell." The Federal definition also includes the replicated progeny of these

molecules as well as cells, plants, and animals that harbor such molecules. Transgenic plants

and animals also come under the guidelines, even if the transgenic DNA was not cloned prior to introduction.

Investigators who possess rDNA in any form must file an rDNA protocol with the IBC. A

copy of the TAMU Policies and Procedures for Research Involving Recombinant DNA is

available from the Environmental Health & Safety Department.

Disinfection and Sterilization

Biological safety depends on proper cleanup and removal of potentially harmful agents.

Disinfection and sterilization are two ways to help ensure biological safety in the laboratory.

- **Disinfection:**

Reduction of the number of pathogenic organisms by the direct application of physical or chemical agents.

- **Sterilization:**

Total destruction of all living organisms.

The following sections discuss guidelines and procedures for biological disinfection and sterilization.

General Guidelines

Choosing the best method for disinfection and sterilization is very important. The proper method depends on the following:

- Target organisms to be removed
- Characteristics of the area to be cleaned

Once you have chosen the proper method for disinfection or sterilization, follow these guidelines to ensure laboratory safety:

- Frequently disinfect all floors, cabinet tops, and equipment where biohazardous materials are used.
 - Use autoclavable or disposable materials whenever possible. Keep reusable and disposable items separate.
 - Minimize the amount of materials and equipment present when working with infectious agents.
 - Sterilize or properly store all biohazardous materials at the end of each day.
 - Remember that some materials may interfere with chemical disinfectants — use higher concentrations or longer contact time.
 - Use indicators with autoclave loads to ensure sterilization.
 - Clearly mark all containers for biological materials (e.g., *BIOHAZARDOUS - TO BE AUTOCLAVED.*).
-

Types of Disinfectant

Use the following table to aid in the selection of disinfectants:

Disinfectant	Uses
Alcohols	Ethyl or isopropyl alcohol at 70-80% concentration is a good general purpose disinfectant; not effective against bacterial spores.
Phenols	Effective against vegetative bacteria, fungi, and viruses containing lipids; unpleasant odor.
Formaldehyde	Concentration of 5-8% formalin is a good disinfectant against vegetative bacteria, spores, and viruses; known carcinogen; irritating odor.
Quaternary Ammonium Compounds	Cationic detergents are strongly surface active; extremely effective against lipoviruses; ineffective against bacterial spores; may be neutralized by anionic detergents (i.e., soaps).
Chlorine	Low concentrations (50-500 ppm) are active against vegetative bacteria and most viruses; higher concentrations (2,500 ppm) are required for bacterial spores; corrosive to metal surfaces; must be prepared fresh; laundry bleach (5.25% chlorine) may be diluted and used as a disinfectant.
Iodine	Recommended for general use; effective against vegetative bacteria and viruses; less effective against bacterial spores; Wescodyne diluted 1 to 10 is a popular disinfectant for washing hands.

NOTE:

See the Radiation Safety chapter for information pertaining to the use of ultraviolet lights as a method of disinfection.

Sterilization Methods

There are three common methods for sterilizing laboratory materials: wet heat, dry heat, and ethylene oxide gas.

WET HEAT

When used properly, the damp steam heat from an autoclave effectively sterilizes biohazardous waste. Sterilization occurs when contaminated materials reach 15 psi pressure at 250°F or 121°C for at least 30 minutes.

IMPORTANT:

For the autoclave process to be effective, sufficient temperature, time, and direct steam contact are essential.

Every TAMU department that autoclaves biohazardous waste should have written documentation to ensure the waste is sterile. Parameters for sterilization and standard operating procedures should include requirements for verifying sterilization.

Potential problems with wet heat sterilization and autoclaves include the following:

- Heavy or dense loads require higher temperature for sterilization.
- Poor heat conductors (e.g., plastic) take longer to sterilize.
- Containers may prevent steam from reaching the materials to be sterilized.
- Incomplete air removal from the chamber can prevent contact between the steam and the load.
 - Deep trays can interfere with air removal.
 - Tightly stacked loads can impede steam circulation and air removal.
- Double-bagging will impede steam penetration.
- Carcasses do not allow steam penetration.
- Some bags and containers rated as *autoclavable* have thermal stability but they do not allow steam penetration.

To ensure that all materials are sterile, always test autoclave loads. Remember, however, that some sterilization indicators are incomplete. Autoclave tape, for example, verifies sufficient

external temperature exposure, but it does not indicate internal equipment temperature, exposure time, or steam penetration. Thermocouples or other instrumentation can also indicate temperature, but they do not verify sterility. A biological indicator is the most effective monitor to ensure sterility. Commercially available strips or vials of *Bacillus* species endospores, for example, are suitable biological indicators.

DRY HEAT

Dry heat is less effective than wet heat for sterilizing biohazardous materials. Dry heat requires more time (two to four hours) and a higher temperature (320–338°F or 60–170°C) to achieve sterilization. A *Bacillus* species biological indicator can verify dry heat sterilization.

ETHYLENE OXIDE GAS

Ethylene oxide gas is lethal to all microorganisms. Because it is also a known carcinogen and potentially explosive (freon and carbon dioxide mixtures are stable), minimize your exposure and use extreme care when working with this gas. Ethylene oxide sterilizers and aerators must be properly vented. Ethylene oxide gas is most effective with heat-resistant organisms and heat sensitive equipment. The effectiveness of ethylene oxide gas may be affected by the following:

- Temperature:
 - The antimicrobial activity of ethylene oxide increases with increased temperature. Normal sterilization temperature is 120–140°F or 49–60°C.
 - Ethylene Oxide Concentration:
 - Sterilization time decreases with increased gas concentration. Normal concentration is 500–1000 mg/L.
 - Humidity:
 - Relative humidity of 30–60% is necessary.
 - Exposure Time:
 - Follow the manufacturer's recommendations.
-

Biological Safety Cabinets

A biological safety cabinet is a primary barrier against biohazardous or infectious agents.

Although biological safety cabinets surround the immediate workspace involving an agent,

they do not provide complete containment (i.e., aerosols can escape). Therefore, careful

work practices are essential when working with agents that require a biological safety cabinet.

NOTE:

A biological safety cabinet is often referred to by other names such as: biohood, tissue culture hood, or biological fume hood.

All biological safety cabinets contain at least one High Efficiency Particulate Air (HEPA)

filter. These cabinets operate with a laminar air flow (i.e., the air flows with uniform velocity,

in one direction, along parallel flow lines).

Biological safety cabinets must be inspected and certified:

- When newly installed
- After filter or motor replacement
- After being moved
- Annually

Contact the Environmental Health & Safety Department for more information about inspections.

The following sections discuss safety procedures and guidelines for working with various

types of biological safety cabinets.

Types of Cabinets

The following table outlines various types of biological safety cabinets:

Type of Cabinet	Operation and Use
	Only exhaust air is filtered. The user and environment are protected but

Class I	the experiment is not. Operator's hands and arms may be exposed to hazardous materials inside the cabinet. This cabinet may be used with low to moderate-risk biological agents.
Class II:	Vertical laminar air flow with filtered supply and exhaust air. The user, product, and environment are protected.
Type A	Recirculates 70% of the air inside the cabinet. Do not use with flammable, radioactive, carcinogenic, or high-risk biological agents.
Type B1	Recirculates 30% of the air inside the cabinet and exhausts the rest to the outside. May be used with low to moderate-risk agents and small amounts of chemical carcinogens or volatiles.
Type B2	Offers total exhaust with no recirculation.
Type B3	Same as Class II Type A, but vented to the outside of the building.
Class III or Glovebox	Gas-tight and maintained under negative air pressure. Used to work with highly infectious, carcinogenic, or hazardous materials. All operations are conducted through rubber gloves attached to entry portals.

Using Biological Safety Cabinets

Follow these guidelines for using biological safety cabinets properly:

Preparation:

- Leave safety cabinets on at all times. Otherwise, turn the blower on and purge the air for at least five minutes before beginning work.
- Never turn off the blower of a biological safety cabinet that is vented to the outside.
- Turn off the UV light if it is on. Never work in a unit with the UV light illuminated. (UV light will damage your eyes.)
- Do not depend on the UV germicidal lamp to provide a sterile work surface; wipe down the surface with a disinfectant (70% alcohol is usually suitable).

NOTE:

For more information on ultraviolet lights, refer to the Radiation Safety chapter.

- Place everything needed for your procedure inside the cabinet prior to beginning work. Arrange the equipment in logical order.
- Provide a container for wastes inside the cabinet. (Remember, nothing should pass through the air barrier until the entire procedure is complete.)
- Never place any items on the air-intake grilles.
- Place a disinfectant-soaked towel on the work surface to contain any splatters or spills that occur.
- Keep the laboratory door shut and post signs stating "CABINET IN USE" on all the

doors. Restrict activities that will disturb the cabinet's airflow, such as entry, egress, and walking traffic.

Cabinet Use:

- Conduct work at least four inches from the glass view panel. The middle third area is ideal.
- Limit arm movement and avoid motions that could disturb airflow.
- If a burner is necessary, use the *Touch-O-Matic* type with a pilot light. Since flames cause air turbulence, place burners to the rear of the workspace.
- Never use flammable solvents in a biological safety cabinet unless it is a total-exhaust cabinet (e.g., Class II B2).

Experiment Completion:

- Enclose or decontaminate all equipment that has been in direct contact with the infectious agent.
- Cover all waste containers.
- To purge airborne contaminants from the work area, allow the cabinet to operate for five minutes with no activity inside the cabinet.
- Remove all equipment from the cabinet.
- Decontaminate interior work surfaces.

IMPORTANT:

Biological safety cabinets are not a substitute for good laboratory practices. Because aerosols can escape, take precautions to minimize aerosol production and to protect yourself from contamination.

Clean Benches

A clean bench has horizontal laminar air flow. The HEPA-filtered air flows across the work surface towards the operator, providing protection for the product, but no protection for the user. Because clean benches offer no protection, use a clean bench only to prepare sterile media. Do not use clean benches when working with pathogenic organisms, biological materials, chemicals, or radioactive materials.

Importing and Shipping Biological Materials

The Public Health Service provides Foreign Quarantine regulations for importing etiologic

agents and human disease vectors. Other regulations for packaging, labeling, and shipping,

are administered jointly by the Public Health Service and the Department of Transportation.

The U.S. Department of Agriculture regulates the importation and shipment of animal

pathogens. It prohibits the importation, possession, and use of certain animal disease agents

that pose a serious threat to domestic livestock and poultry.

Biological Spill Response

The exact procedure for responding to a biological spill depends on the material, amount,

and location of the spill.

In general, follow these steps immediately after a biological spill occurs:

1. Warn others.
2. Leave the room; close the door.
3. Remove contaminated garments.
4. Wash your hands.
5. Notify your supervisor.

Follow these steps to clean up a biological spill:

1. Wait for any aerosols to settle.
2. Put on protective clothing, as appropriate.
3. Apply disinfectant to the contaminated area.
4. Cover the area with paper towels to absorb the disinfectant.

5. Wipe up the towels and mop the floor.
6. Autoclave all contaminated wastes.

NOTE:

Spill cleanup must be appropriate for the hazards involved. Call the Environmental Health & Safety Department for assistance.

If a spill occurs inside a biological safety cabinet, follow these steps:

1. Decontaminate materials while the cabinet is operating to prevent contaminants from escaping.
2. Spray or wipe all affected equipment with an appropriate disinfectant. (Wear gloves while doing this.)
3. If the spill is large, flood the work surface with disinfectant and allow it to stand for 10 to 15 minutes before removing it.

Biological Waste Disposal

The Texas Department of Health (TDH) and the Texas Natural Resource Conservation

Commission (TNRCC) regulate the disposal of biohazardous waste. Waste that contains

infectious materials and waste that may be harmful to humans, animals, plants, or the environment is considered biohazardous. Examples of biohazardous waste include the

following:

- Waste from infectious animals
- Bulk human blood or blood products
- Microbiological waste (including pathogen-contaminated disposable culture dishes, and disposable devices used to transfer, inoculate, and mix pathogenic cultures)
- Pathological waste
- Sharps
- Hazardous rDNA and genetic manipulation products

TAMU's Biological Waste Disposal Program (available from the Environmental

Health &

Safety Department) stipulates that biohazardous waste meets strict safety requirements for the following:

- Segregation
- Treatment
- Labels
- Packaging
- Transportation
- Documentation

Biohazardous waste mixed with hazardous chemical or radioactive waste must be treated to

eliminate the biohazard prior to disposal. After treatment, manage the hazardous waste

through the Environmental Health & Safety Department.

IMPORTANT:

Disinfect all infectious material prior to disposal.

The following sections offer general safety guidelines and procedures for disposing of biological waste.

Segregation

Segregation is necessary when working with hazardous biological agents.

- Any waste that could cause a laceration or puncture must be disposed of as "Sharps." Sharps must be segregated from other waste.
 - Do not mix waste that requires incineration with glass or plastics.
 - Do not mix biological waste with chemical waste or other laboratory trash.
 - Segregate hazardous biological waste from nonhazardous biological waste.
-

Handling and Transport

Follow these guidelines for handling and transporting biohazardous waste:

- Properly trained personnel (not the custodial staff) are responsible for transporting treated biological waste to the dumpster or incinerator. Only properly trained technical personnel may handle untreated biohazardous waste.

- Contain and label all treated waste before transporting it to the incinerator or dumpster.
 - Avoid transporting untreated biohazardous materials and foul or visually offensive materials through non laboratory areas.
 - Do not use trash/laundry chutes, compactors, or grinders to transfer or process untreated biohazardous waste.
-

Labeling Biohazardous Waste

Follow these guidelines for labeling biohazardous waste:

- Clearly label each container of untreated biohazardous waste and mark it with the Biohazard Symbol.
 - Label containers intended for landfill disposal to indicate the method of treatment. Cover the Biohazard Symbol with this label.
 - Label autoclave bags with special tape that produces the word "AUTOCLAVED" upon adequate thermal treatment. Apply this tape across the Biohazard Symbol before autoclaving the bag.
 - Label all containers for sharps as "ENCAPSULATED SHARPS."
 - It is recommended to label nonhazardous biological waste as "NONHAZARDOUS BIOLOGICAL WASTE."
-

Disposal Methods

Different materials require different disposal methods to ensure safety. Follow these guidelines for physically disposing of biological waste.

- **Animal Carcasses and Body Parts:**
- Incinerate the materials or send them to a commercial rendering plant for disposal.
- **Solid Animal Waste:**
- All animal waste and bedding that is infectious or harmful to human, animals, or the environment should be treated by incineration, thermal disinfection, or chemical disinfection.
- **Liquid Waste:**
- Liquid waste, including bulk blood and blood products, cultures and stocks of etiological agents and viruses, cell culture material, and rDNA products should be disinfected by thermal or chemical treatment and then discharged into the sanitary sewer system.
- **Metal Sharps:**
- All materials that could cause cuts or punctures, must be contained, encapsulated, and disposed of in a manner that does not endanger other workers. Needles, blades, etc. are considered biohazardous even if they are sterile, capped, and in the original

container.

- Pasteur Pipets and Broken Glassware:

Place in a rigid, puncture resistant container. Disinfect by thermal or chemical treatment, if contaminated. Label the container as "Broken Glass" and place it in a dumpster.

NOTE:

If broken glass is commingled with metal sharps, encapsulation is required for disposal.

- Plastic Waste:

Contaminated materials must be thermally or chemically treated and placed in a properly labeled, leak-proof container for disposition in the dumpster. Materials that are not contaminated may be placed directly in the dumpster.

- Microbiological Waste:

Solids must be thermally or chemically treated and placed in a properly labeled, leak-proof container for disposition in the dumpster. Liquids must be thermally or chemically treated and then discharged into the sanitary sewer system.

- Human Pathological Waste:

Human cadavers and recognizable body parts must be cremated or buried. Other pathological waste from humans and primates must be incinerated.

- Genetic Material:

Materials containing rDNA or genetically altered organisms must be disposed of in accordance with NIH Guidelines and the TAMU Biological Waste Disposal Program.

Nonhazardous Biological Waste

Most biological waste that is not infectious or otherwise hazardous to humans, animals, plants, or the environment may be discarded as regular waste or sewage. The only exceptions are animal carcasses and body parts. These wastes must be incinerated or

sent to

a commercial rendering plant for treatment. In addition, there are no record-keeping requirements for nonhazardous biological waste.

Follow these guidelines for nonhazardous biological waste:

- It is recommended to autoclave or disinfect all microbial products, even if they are not biohazardous.
 - Avoid disposing of waste in a manner that could cause visual or odorous problems.
 - Do not label nonhazardous biological waste as hazardous (e.g., do not use the Biohazard Symbol, red bags, etc.). Instead, it is recommended to label the container as "NONHAZARDOUS BIOLOGICAL WASTE."
 - Use nonhazardous animal bedding and manure for compost or fertilizer when possible.
-

Recordkeeping Requirements

Each TAMU department that generates biohazardous waste must comply with the recordkeeping requirements of the TAMU Biological Waste Disposal Program and State

regulations. Written records must contain the following information:

- Date of treatment
- Amount of waste treated
- Method/conditions of treatment
- Name (printed) and initials of person performing the treatment

If a department generates more than 50 pounds per calendar month of biohazardous waste,

the records must also include a written procedure for the operation and testing of any equipment used and a written procedure for the preparation of any chemicals used in treatment. The records must also include either the results of a biological indicator or

a

continuous readout (e.g., strip chart) to demonstrate proper parameters for effective treatment.

Bloodborne Pathogens

Bloodborne pathogens are biological agents that cause human disease. Examples of bloodborne diseases include the following:

- Hepatitis

- Syphilis
- Malaria
- Human Immunodeficiency Virus (HIV)

Two significant and deadly bloodborne diseases are hepatitis B virus (HBV) and HIV. These

pathogens may be present in the following:

- Human blood
- Body fluids, such as saliva, semen, vaginal secretions, phlegm, and other body fluids visibly contaminated with blood
- Unfixed human tissues or organs other than intact skin
- HIV or HBV cultures
- Blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Bloodborne pathogens may enter the body and infect you through a variety of means, including the following:

- Accidental injury with a sharp object contaminated with infectious material.
- Open cuts, nicks, and skin abrasions that come into contact with infectious materials. Other potential sites of transmission includes acne sores and the mucous membranes of the mouth, nose, or eyes.
- Unprotected sexual activity with someone who is infected with the disease.
- Indirect transmission, such as touching a contaminated object and then transferring the pathogen to the mouth, eyes, nose, or open skin.

Currently, TAMU is not covered by Federal or State regulations concerning bloodborne

pathogens. If you suspect you have been exposed to a bloodborne pathogen, report the incident to your supervisor immediately.

MANAGEMENT AND DISPOSAL OF BIOLOGICAL WASTE
AT
TEXAS A&M UNIVERSITY

July 2003

MANAGEMENT AND DISPOSAL OF BIOLOGICAL WASTE AT TEXAS A&M UNIVERSITY

A. INTRODUCTION

The purpose of this document is to provide information, requirements, guidelines and procedures for the handling and disposal of hazardous and non-hazardous biological waste for all departments and units on the Texas A&M University campus in College Station and at the Riverside Campus.

In Texas, the disposal of biohazardous waste is regulated by the Texas Department of Health and the Texas Commission on Environmental Quality. Local regulations of the City of College Station also apply to all waste that will be disposed in the College Station Municipal Landfill (e.g., TAMU trash dumpsters and residual ash from the TAMU incinerators).

"BIOLOGICAL WASTE" means discarded biological material from teaching, clinical, and research laboratories and operations. This does not include household or office trash, waste from Food Services, Physical Plant, bedding and manure from normal agricultural operations or bedding and litter from noninfectious animals. **"BIOHAZARDOUS WASTE"**¹ means any solid or liquid biological waste that is hazardous because of its physical and/or biological nature. All waste that contains infectious material or which, because of its biological nature, may be harmful to humans, animals, plants or the environment is biohazardous waste. This includes: waste from infectious animals; bulk human blood or blood products; microbiological waste; pathological waste; sharps; and hazardous products of recombinant DNA biotechnology and genetic manipulation. Definitions of terms used in this document can be found in APPENDIX A.

Treatment of all laboratory biological waste prior to disposal is good laboratory practice, and is highly recommended, but biohazardous waste must be treated prior to disposal. Acceptable treatment methods include thermal or chemical disinfection, encapsulation (solidification), or incineration.

The key requirements for disposal of biohazardous waste are that it must be (1) segregated from other waste; (2) securely packaged; (3) specifically labeled to indicate the method of treatment; (4) transported to the point of treatment or disposal by appropriately trained personnel; (5) treated to eliminate the biological hazard; and (6) documented by maintenance of appropriate records.

Biohazardous waste that is mixed with hazardous chemical waste, radioactive waste, or both must be treated to eliminate the biohazard prior to disposal. After treatment, the waste must be managed as hazardous chemical waste through the Environmental Health and Safety Department (EHSD) or as radioactive waste through the Radiological Safety Division of EHSD.

TABLE 1 summarizes requirements for treatment and disposal of biohazardous waste at TAMU. TABLE 2 provides a model form for maintaining the record of treatment of biohazardous waste. Questions or requests for any variance from these procedures should be directed to the Environmental Health and Safety Department (845-2132, Mail Stop 4472).

B. RESPONSIBILITY

The Principal Investigator, faculty member or other person with operational responsibility shall assure compliance with these requirements within his/her laboratory or area of responsibility.

C. SEGREGATION

1. Any waste that could produce laceration or puncture injuries must be disposed of as "sharps". Sharps must be segregated from other waste. Metal sharps and broken glass may be commingled with each

¹Biohazardous Waste may also be called "medical waste", "special waste", "regulated waste", "red bag waste", "infectious waste", or "pathological waste". For simplicity, the present document will refer to all such material as "BIOHAZARDOUS WASTE". Definitions in this document are derived from Title 25, Texas Administrative Code, Chapter 1.

- other, but not with non-sharp waste.
2. Waste that is to be incinerated should not be commingled with glass or plastics.
 3. Biological waste must not be commingled with chemical waste or other laboratory trash.
 4. Biohazardous waste should be segregated from other biological waste.

D. CONTAINERS

Containers must: be appropriate for the contents; not leak; be properly labeled; and maintain their integrity if chemical or thermal treatment is used. Containers of biohazardous material should be kept closed.

1. LIQUIDS – Use leak-proof containers able to withstand thermal or chemical treatment.
2. METAL SHARPS – Use a rigid, puncture-resistant container (heavy-walled plastic is recommended) suitable for encapsulation and disposal. Container and encapsulated contents must withstand an applied pressure of 40 psi without rupture.
3. NON-HAZARDOUS SOLID BIOLOGICAL WASTE – Use heavy-duty plastic bags or other appropriate containers without a Biohazard Symbol. Red or orange biohazard bags or containers should not be used for non-hazardous material.
4. PASTEUR PIPETS and BROKEN GLASSWARE – Use a rigid, puncture-resistant container (e.g., plastic, heavy cardboard or metal) that can be sealed.
5. SOLID BIOHAZARDOUS WASTE – Use heavy-duty plastic "BIOHAZARD BAGS" (autoclave bags) or containers for solid biohazardous waste.

E. STORAGE

Biological waste may be held temporarily under refrigeration, prior to disposal, in a safe manner that does not create aesthetic (visual or odor) problems. Biohazardous waste should be treated and disposed of promptly and not allowed to accumulate. Containers holding biohazardous material must be clearly labeled, including the Biohazard Symbol. Temporary holding areas for biohazardous waste must be clean and orderly with no access to unauthorized persons (warning signs should be posted).

F. LABELING BIOHAZARDOUS WASTE CONTAINERS

1. Each container of untreated biohazardous waste must be clearly identified as such and must be labeled with the Biohazard Symbol.
2. Each container of treated biohazardous waste to be placed in a TAMU trash dumpster must be labeled to indicate the method of treatment and to cover biohazard markings.
3. Label autoclave bags with commercially available autoclave tape that produces the word "AUTOCLAVED" upon adequate thermal treatment. Apply this tape across the Biohazard Symbol on the bag before autoclaving.
4. All containers of encapsulated sharps must be labeled as "ENCAPSULATED SHARPS".

NOTE: It is not a requirement to label containers of non-hazardous biological waste, but it is recommended to label such containers as "NON-HAZARDOUS BIOLOGICAL WASTE".

G. HANDLING AND TRANSPORT

1. Only properly trained technical personnel can handle or transport untreated biohazardous waste.
2. Treated waste must also be transported by properly trained technical personnel (not custodial).
3. Avoid transporting untreated biohazardous materials or foul or visually offensive material through non-lab or populated areas.
4. Trash/laundry chutes, compactors, grinders cannot be used to transfer or process untreated biohazardous waste.

H. TREATMENT AND DISPOSAL METHODS (summarized in TABLE 1)

NOTE: Waste should be treated as near the point of origination as possible.

1. ANIMAL CARCASSES AND BODY PARTS may be incinerated, biodigested, landfilled, or rendered. (Exceptions: see H. 3 and H. 11) Animal carcasses or recognizable body parts may only go to the College Station (BVSWM) landfill using the TAMU Special Waste Permit from the Texas Commission on Environmental Quality (TCEQ). Contact EHSD regarding this permit before transporting carcasses to the BVSWM landfill. Carcasses of animals that die in the field may not be buried on site.
2. ANIMAL WASTE, SOLID (bedding, manure, etc):
 - a. BIOHAZARDOUS ANIMAL WASTE:
 - 1) Incinerate; OR
 - 2) Disinfect by thermal or chemical treatment; place in a TAMU trash dumpster; OR
 - 3) Alternative method, with approval of the University Veterinarian.
 - b. NON-HAZARDOUS ANIMAL WASTE: Use as compost or fertilizer whenever practical.
3. CHEMICAL WASTE: Biohazardous waste which also contains hazardous chemicals must be managed as hazardous chemical waste through the EHSD.
4. GENETIC MATERIAL: Disposal of materials containing recombinant DNA or genetically altered organisms must be consistent with applicable NIH Guidelines, in addition to complying with the requirements contained in this document.
5. HUMAN PATHOLOGICAL WASTE:
 - a. Human cadavers, recognizable body parts: dispose by cremation or interment.
 - b. Other solids – incinerate, or disinfect for disposal in TAMU trash dumpster.
 - c. Body fluids – disinfect by thermal treatment for disposal in TAMU trash dumpster, or by chemical treatment for discharge into the sewer system
6. METAL SHARPS: Discarded metal sharps **MUST** be contained, encapsulated and disposed of in a manner that prevents injury to laboratory, custodial and landfill workers. Needles, blades, etc., are considered BIOHAZARDOUS even if they are sterile, capped and in the original container. **Never place sharps in a trash container or plastic bag that might be handled by custodial staff.**
 - a. Place containers of encapsulated sharps in a TAMU trash dumpster.
 - b. Gas chromatography needles should be thoroughly rinsed to remove hazardous chemicals, then disposed with non-contaminated broken glassware.
 - c. Do not attempt to recap, bend, break or cut discarded needles.
7. MICROBIOLOGICAL WASTE:
 - a. Solid – Disinfect by thermal or chemical treatment; place in a TAMU trash dumpster.
 - b. Liquid – Disinfect by thermal or chemical treatment; discharge into the sewer system.
8. NON-HAZARDOUS BIOLOGICAL WASTE:
 - a. It is good laboratory practice to autoclave or chemically treat all microbial products prior to disposal, even if the material is not hazardous.
 - b. Solid – Place in a TAMU trash dumpster.
 - c. Liquid – Discharge into the sewer system.
9. PASTEUR PIPETS and BROKEN GLASSWARE:
 - a. CONTAMINATED WITH BIOHAZARDOUS MATERIAL:
 - 1) Disinfect by thermal or chemical treatment; place in a TAMU trash dumpster; OR
 - 2) Encapsulate and place in a TAMU trash dumpster. **NOTE: Encapsulation is required if metal sharps are commingled with glass sharps.**
 - b. NOT CONTAMINATED: Place in a TAMU trash dumpster.
 - c. **DO NOT INCINERATE GLASSWARE.**
10. PLASTIC WASTE:
 - a. CONTAMINATED WITH BIOHAZARDOUS MATERIAL: Disinfect by thermal or chemical treatment; place in a TAMU trash dumpster.
 - b. NOT CONTAMINATED: Place in a TAMU trash dumpster.
 - c. **DO NOT INCINERATE PLASTICS.**
11. RADIOACTIVE WASTE: Biological waste that contains radioactive material must be disposed according to the procedures of the Radiological Safety Division of EHSD.

TABLE 1. TREATMENT AND DISPOSAL OF BIOHAZARDOUS WASTE AT TEXAS A&M UNIVERSITY

TYPE OF WASTE		CONTAINER	TREATMENT METHOD	DISPOSAL METHOD
ANIMAL WASTE				
a.	Carcasses	B	D	O
		B	I	P
		B	-	Q
		B	-	R
b.	Tissue and Body Parts	B	D	O
		B	I	P
c.	Bulk blood and blood products	B	D	O
		B	E or G	K
d.	Animal bedding	A	D	O
		A	E or G	J
MICROBIOLOGICAL WASTE				
a.	Solid	A	D ¹	O
		A	E, F, or G	J
b.	Liquid	B	E or G	K
PATHOLOGICAL WASTE				
a.	Materials removed during surgery, labor and delivery, autopsy or biopsy including body parts, tissues and organs	B	D	O
		B	E or G	J
b.	Anatomical remains	B	G	L
c.	Bulk blood and blood products	B	D	O
		B	E	J
		B	G	K
SHARPS				
a.	Metal sharps including hypodermic needles, syringes with needles, scalpel blades, razor blades	C	H	N
b.	Pasteur pipets and broken glass	C	E, F, or G	J
		C	-	M

CONTAINER REQUIREMENTS

- A. Heavy duty plastic bag or other appropriate container such as BIOHAZARD BAGS.
- B. Heavy duty leak proof container.
- C. Puncture-resistant container.

TREATMENT METHODS

- D. Incinerate.
- E. Steam autoclave [120 C.; 15 psi; 30 min. (minimum)].
- F. Dry heat [160 C., 2 hr. (minimum)].
- G. Chemical disinfection - 10% hypochlorite or EPA-approved chemical disinfectant or sterilant used according to manufacturer's direction.
- H. Encapsulate in a solid matrix [e.g., plaster of Paris; or a commercial encapsulant (Isolyser)].
- I. Biodigestion

DISPOSAL METHODS

- J. Deposit treated waste in a TAMU trash dumpster.
- K. Discharge disinfected liquid into the sewer system (NOTE: Excess proteinaceous material can clump and cause drain clogging. Grinding treated waste may be necessary. Do not grind untreated biohazardous material.)
- L. Interment or cremation.
- M. Place in a puncture-resistant container and deposit in a TAMU trash dumpster.
- N. Place encapsulated sharps in a TAMU trash dumpster.
- O. Residual incinerator ash is disposed at the College Station landfill.
- P. Effluent is discharged to sanitary sewer.
- Q. Send to commercial rendering plant.
- R. College Station (BVSWMA) landfill using the TAMU Special Waste Permit issued by TCEQ.

LABELING REQUIREMENTS

Containers of biohazardous materials must be clearly identified and marked with the BIOHAZARD symbol. Containers of treated biohazardous waste must be labeled to indicate the method of treatment and to cover the Biohazard Symbol. Waste that is not biohazardous prior to treatment should not be placed in a "BIOHAZARD" container.

DO NOT INCINERATE GLASS OR PLASTIC LABWARE.

I. TRAINING AND HAZARD COMMUNICATION

The Principal Investigator or individual with primary supervisory responsibility must assure that all personnel who work with, or who may contact potentially biohazardous material are informed of the hazards and are trained in the proper procedures and equipment needed to avoid exposure, proper treatment and disposal of biohazardous wastes, and recognition of symptoms of infection or exposure.

J. WRITTEN PROCEDURES AND RECORDS

Each biohazardous waste generating entity at TAMU is required to maintain written records that, at a minimum, contain the following information:

1. Date of treatment
2. Quantity of waste treated
3. Method/conditions of treatment
4. Name (printed) and initials of the person performing the treatment.

If an entity generates more than fifty (50) pounds of biohazardous waste per calendar month, the records must also include:

1. A written procedure(s) for: the operation and testing of any equipment used; and the preparation of any chemicals used in treatment.
2. Documentation of efficacy. With processes for which the manufacturer documents compliance with specified performance standards (e.g., temperature, pressure, pH, etc.), and for processes which produce a continuous readout (e.g. strip chart or chart paper), routine parameter monitoring may used to verify efficacy. Otherwise, biological monitoring is required to document a 99.99% reduction using an appropriate biological indicator (*Bacillus* species) at the following intervals:
 - a. 50 - 100 pounds per calendar month requires testing once per month
 - b. 101 - 200 pounds per calendar month requires testing biweekly
 - c. more than 200 pounds per calendar month requires testing weekly.

Records must be maintained for at least 3 years for **EACH CONTAINER** of biohazardous waste treated (including sharps that are encapsulated).

See TABLE 2 for suggested format and model log sheet.

NOTE: There are no record requirements for non-hazardous biological waste.

K. REFERENCES:

1. Title 25 Texas Administrative Code, Chapter 1, 1.131-1.137. December 21, 1994. (Definition, Treatment and Disposition of Special Waste from Health Care Related Facilities).
2. Title 30 Texas Administrative Code, Chapter 330, 330.24, 330.136, 330. 641-643, 330.1001-1010. December 20, 1994. (Solid Waste Management Rules for Medical Waste Management, Disposal, Transportation, Collection, & Storage).
3. Centers for Disease Control / National Institutes of Health, Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, 1999.
4. "Management of Medical Waste", City of College Station, August 1993.

APPENDIX A. DEFINITION OF TERMS

1. **ANIMAL WASTE** includes carcasses; body parts; bulk whole blood and blood products, serum, plasma and other blood components; and bedding of animals.
2. **BIODIGESTION** is a heated alkaline hydrolysis tissue digestion system permitted by the TCEQ.
3. **BIOHAZARDOUS WASTE** is infectious or, because of its physical and/or biological nature, may be harmful to humans, animals, plants or the environment. Biohazardous waste includes:
 - a. Animal waste known or suspected of being contaminated with a pathogen
 - b. Bulk human blood or blood products
 - c. Microbiological waste
 - d. Pathological waste
 - e. Infectious waste
 - f. Waste products of recombinant DNA biotechnology and genetic manipulation
 - g. Sharps
4. **BIOLOGICAL INDICATOR** - Commercially available microorganism (e.g. spore strips or vials of *Bacillus* species) which can be used to verify the performance of waste treatment equipment and/or processes.
5. **BULK BLOOD AND BLOOD PRODUCTS** - Discarded bulk (>100 ml.) blood and blood products in a free draining, liquid state; body fluids contaminated with visible blood; and materials saturated or dripping with blood.
6. **CHEMICAL DISINFECTION** means the use of a chemical agent such as 10% bleach or EPA-approved chemical disinfectant/sterilant (used according to manufacturer's direction) to significantly reduce biological activity of biohazardous material.
7. **DISCHARGE INTO THE SEWER SYSTEM** means flushing treated liquid biological waste into the TAMU sanitary sewer system followed by copious quantities of water.
8. **ENCAPSULATION** is the treatment of sharps waste using a material such as Plaster of Paris (or a commercial product such as Isolyser) which when fully reacted, will encase the waste in a solid protective matrix. The encapsulating agent must completely fill the container. The container and solidified contents must withstand an applied pressure of 40 psi without disintegration.
9. **INCINERATION** means burning biological waste in an incinerator permitted by the Office of Air Quality, TCEQ.
10. **INFECTIOUS WASTE** is waste containing pathogens or biologically active material which because of its type, concentration, and quantity is capable of transmitting disease.
11. **MICROBIOLOGICAL WASTE:**
 - a. discarded cultures and stocks of infectious agents and associated biological material
 - b. discarded cultures of specimens from medical, pathological, pharmaceutical, research, and clinical laboratories
 - c. discarded live and attenuated vaccines
 - d. discarded used disposable culture dishes
 - e. discarded used disposable devices used to transfer, inoculate, and mix cultures

NOTE: in vitro tissue cultures that have not been intentionally exposed to pathogens are exempt from the definition of microbiological waste.
12. **PATHOGENS** includes any diseases that are transmissible to humans.
13. **PATHOLOGICAL WASTE** pertains to human materials and includes, but is not limited to:
 - a. human materials removed during surgery, labor, delivery, spontaneous abortion, autopsy or biopsy including: body parts; tissues and fetuses; organs; bulk blood and body fluids
 - b. laboratory specimens of blood, tissue or body fluids after completion of laboratory examination
 - c. anatomical remains.
14. **SHARPS** - Any device having acute rigid corners or edges, or projections capable of cutting or piercing, including:
 - a. hypodermic needles, syringes, and blades
 - b. glass pipets, microscope slides, and broken glass items.
15. **THERMAL TREATMENT** means:
 - a. autoclaving at a temperature of not less than 121° C., and a minimum pressure of 15 psi for at least 30 minutes (longer times may be required depending on the amount of waste, water content and the type of container used); or
 - b. subjecting biological material to dry heat of not less than 160° C., under atmospheric pressure for at least two hours.

(Exposure begins after the material reaches the specific temperature and does not include lag time).
16. **TREATMENT** refers to chemical, thermal or mechanical processes that significantly reduce or eliminate the hazardous characteristics, or that reduce the amount of a waste.

APPENDIX B. INFORMATION AND ASSISTANCE

1. INCINERATION or BIODIGESTION

Receptionist, 845-4654
Dr. John Edwards, 845-4608
Dr. Kenneth Turner, 862-3968
Department of Veterinary Pathobiology
College of Veterinary Medicine

2. UNIVERSITY VETERINARIAN

University Veterinarian
Laboratory Animal Resources and Research Facility (LARR)
845-7433

3. ENVIRONMENTAL HEALTH AND SAFETY DEPARTMENT

845-2132

4. FOR ASSISTANCE WITH AUTOCLAVES NOT ON SERVICE CONTRACT

Physical Plant, Area Maintenance 7
845-3125

Whitney, Bruce (NIH/OD) [C]

From: Mattox, Brent S [bsmattox@tamu.edu]
Sent: Monday, July 09, 2007 5:03 PM
To: Whitney, Bruce (NIH/OD) [C]
Cc: Bazer, Fuller; Raines, Angelia; Vernon Tesh; Ewing, Richard
Subject: Requested Response on Elevated Q Fever Titers.

Dr. Whitney:

Per your request, please see the attached report in pdf format. If you have any further questions, please let me know.

Sincerely,

Brent S. Mattox, CIH
Biosafety Officer

8/6/2007



TEXAS A&M UNIVERSITY
Environmental Health & Safety Department

Bruce Whitney, PhD.
Senior Biosafety and Outreach Specialist
Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive, Suite 150
Bethesda, MD 20892-7985

Dr. Whitney:

Thank you for providing Texas A&M University the opportunity to explain our actions concerning the elevated titers for *Coxiella burnetii*. As you are aware, three individuals had "elevated titers" for the organism, in March 2006. The following paragraphs and attachments summarize the institution's response, as well as providing background information on our Occupational Health Program.

Background Information – Occupational Health Program and medical Surveillance

The Occupational Health Program at Texas A&M University is operated administratively out of the Environmental Health and Safety Department (EHSD). EHSD utilizes the services of Scott & White Hospitals, Department of Occupational Medicine, to provide medical surveillance and medical support for the program. Occupational Medicine (Scott & White) is directed by a board certified occupational health physician. In 2004, a variety of individual contracts and surveillance programs on the campus were consolidated, with administration being charged to EHSD. Although the program was originally established to provide medical surveillance for all individuals working with animals, coverage has been extended to individuals working with infectious agents, including *Coxiella burnetii*. In the case of the Q fever research, titers are drawn annually, with baseline titers required of new employees.

Event Description and Response

As part of the routine monitoring program for infectious agents, titers were drawn for Q fever for all individuals working with the agent in March 7, 2006. Subsequently, Scott & White Occupational Medicine forwarded the samples to the Texas Department of State Health Services (TDSHS) for Q fever IFA titers. It should be noted that TDSHS follows the following guidelines when evaluating titer results:

A single Q fever IFA titer of greater than or equal to 1:256 is evidence of a prior infection, but it does not confirm that the infection was recent. The most

convincing evidence of recent infection is a four-fold rise in antibody titer between an acute serum and a convalescent serum. Reactions to both phase I and phase II antibodies are often seen in test sera. However, in acute Q fever the phase I and phase II antibody is usually higher than the phase I titer.

TSDSHS issued the laboratory results on March 17, with a follow-up letter to the three individuals dated March 22, 2006. Scott & White Occupational Medicine informed EHSD Occupational Health of the titer results on April 3, 2006. As institutional Biosafety officer, I immediately informed the Office of Research Compliance, the supporting group for the Institutional Biosafety Committee. The researcher was contacted by phone on April 4, 2006, and the laboratory was visited by Occupational health (Biosafety Officer). I also spoke with all three individuals who had received the elevated titer results, none of whom had any illness or recalled any incident in the laboratory where exposure could have occurred. I verified that all three individuals had been in contact with Scott & White and had been offered prophylaxis. In reviewing Dr. Samuel's protocols (the PI in charge of the Q fever laboratory) nothing was noted that seemed out of the ordinary or that had been changed from previous inspections. As a safety precaution, Dr. Samuel's BL3 laboratory was decontaminated by wiping down all surfaces (this was in addition to the weekly cleaning that takes place). Dr. Samuel's group does not utilize recombinant *Coxiella burnetii*, but does utilize *Escherichia coli* with a variety of *C. burnetii* genes cloned into them. All work is performed with the live organisms in biological safety cabinets which are certified on an annual basis. All cabinets utilized by Dr. Samuel were certified during this period. I have attached several emails and a letter from Dr. Samuel concerning the titers. One of the emails states that the information will be presented to the provost, a clear indication that Texas A&M takes employee safety and health very seriously. Additionally, all protocols involving recombinant DNA research or any work with pathogens must be reviewed and approved by the Institutional Biosafety Committee (IBC). The IBC has reviewed and approved all research involving Q fever, and was kept informed of this incident and the subsequent investigation.

Discussion and Summary

As you are no doubt aware, Q fever titers are not good indicators of recent infection. With the exception of Rattanasavanh, the individuals had a past history of positive titers. As mentioned earlier, TSDSHS utilizes an agglutination titer of 1:256 as evidence of a prior infection, but not as a recent infection. A fourfold increase in titers is more convincing of a recent infection, but since titers are taken on an annual basis and the previous tests were all indicative of prior exposures, coupled with no signs or symptoms of illness and no adverse events in the laboratory, the institution did not view the titers as either an exposure or an infection. However, as can be seen from our actions, the institution still took action to investigate and make changes, if they had been deemed appropriate. To date, Occupational Health has no knowledge that any of the individuals listed as suffering from clinical signs of illness. Two of the three individuals are still employed by Texas A&M University and remain in the monitoring program. As a complicating factor, Q fever is ubiquitous in nature, and outside exposures, particularly with our veterinarians, cannot be easily ruled out. For all of these reasons, A&M does not

believe that titers alone are good indicators of recent infection, particularly when patients are asymptomatic.

In conclusion, Texas A&M University takes the health and safety of its employees and the public very seriously, and welcomes any inquiries or input on occupational health. If you have any additional questions or concerns, please do not hesitate to contact us either through my office at (979) 845-2132, or the Office of Research Compliance at (979) 458-1467.

Sincerely,

A handwritten signature in black ink, appearing to read "B. S. Mattox", written in a cursive style.

Brent S. Mattox, CIH
Institutional Biosafety Officer

CC: Richard Ewing, Angelia Raines, John Salsman

03/29/2006 15:24

5124587533

DSHS LAB REPORTING

PAGE 23/24



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

EDUARDO J. SANCHEZ, M.D., M.P.H.
COMMISSIONER1100 W. 49th Street • Austin, Texas 78756
1-888-963-7111 • <http://www.dshs.state.tx.us>

* Page 1 of 2 *

Submitter copy to: ** DUPLICATE REPORT ** Date: 3/17/2006

SCOTT & WHITE HOSP MICRO LAB-01450132
2401 SOUTH 31ST STREET
TEMPLE, TX 76508Spec #: S06SM001138
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Address:

Personal Info

DOB:

Personal Info

Date Rcvd: 3/8/2006
Spec Type: SERUM

Test Reas: DIAGNOSIS

NEW REQUIREMENT: Due to regulatory (CLIA) requirements, effective February 14, 2005, all specimen forms must include the date of collection or the specimen will be rejected.

Final Results

Specimen Numbers: S06SM001138
Date Collected: 3/7/2006

BRUCELLA AGGLUTINATION <1:40

An agglutination titer of <1:40 is considered to be negative.

Q FEVER IFA **PHASE I <1:64
PHASE II 1:256

A single Q fever IFA titer of greater than or equal to 1:256 is evidence of a prior infection, but, it does not confirm that the infection was recent. The most convincing evidence of recent infection is a fourfold rise in antibody titer between an acute serum and a convalescent serum. Reactions to both phase I and phase II antibody are often seen in test sera. However, in acute Q fever the phase II antibody is usually higher than the phase I titer. In chronic Q fever phase I titers rise in later specimens while phase II titers fall or remain constant.

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TH

03/29/2006 15:24

5124587533

DSHS LAB REPORTING

PAGE 24/24



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COMMISSIONER1100 W. 49th Street • Austin, Texas 78756
1-888-963-7111 • <http://www.dshs.state.tx.us>* Page 2 of 2*
Submitter copy to: ** DUPLICATE REPORT ** Date: 3/17/2006SCOTT & WHITE HOSP MICRO LAB-01450132
2401 SOUTH 31ST STREET
TEMPLE, TX 76508Spec #: 806SM001138
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512) 458-7578

Patient

Patient Address:

Personal Info

DOB:

Personal Info

<< Q FEVER IFA is Reportable to Health Dept >>

Susan U. Neill, Ph.D., M.B.A.
Director, Laboratory Services Section
CLIA License Number 45D0660644
www.dshs.state.tx.us/lab

A handwritten signature in dark ink, appearing to be "Pm".



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

EDUARDO J. SANCHEZ, M.D., M.P.H.
COMMISSIONER1100 W. 49th Street • Austin, Texas 78756
1-888-963-7111 • <http://www.dshs.state.tx.us>Submitter copy to: ** DUPLICATE REPORT ** * Page 1 of 2 *
Date: 3/17/2006SCOTT & WHITE HOSP MICRO LAB-01450132
2401 SOUTH 31ST STREET
TEMPLE, TX 76508Spec #: S06SM001128
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Address:

Subj Specific Info, Personal Info

DOB:

Personal Info

COLLEGE STATION, TX

Date Rcvd: 3/8/2006
Spec Type: SERUM

Test Reas: DIAGNOSIS

NEW REQUIREMENT: Due to regulatory (CLIA) requirements, effective February 14, 2005, all specimen forms must include the date of collection or the specimen will be rejected.

Final Results

Specimen Numbers: S06SM001128
Date Collected: 3/7/2006

BRUCELLA AGGLUTINATION <1:40

An agglutination titer of <1:40 is considered to be negative.

Q FEVER IFA **PHASE I <1:64
PHASE II 1:256

A single Q fever IFA titer of greater than or equal to 1:256 is evidence of a prior infection, but, it does not confirm that the infection was recent. The most convincing evidence of recent infection is a fourfold rise in antibody titer between an acute serum and a convalescent serum. Reactions to both phase I and phase II antibody are often seen in test sera. However, in acute Q fever the phase II antibody is usually higher than the phase I titer. In chronic Q fever phase I titers rise in later specimens while phase II titers fall or remain constant.

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4676271

Dated
#2414618



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

EDUARDO J. SANCHEZ, M.D., M.P.H.
COMMISSIONER

1100 W. 49th Street • Austin, Texas 78756
1-888-963-7111 • <http://www.dsha.state.tx.us>

* Page 2 of 2 *

Submitter copy to: ** DUPLICATE REPORT ** Date: 3/17/2006

SCOTT & WHITE HOSP MICRO LAB-01450132
2401 SOUTH 31ST STREET
TEMPLE, TX 76508

Spec #: S06SM001128
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Address:

Personal Info

DOB: Personal Info

COLLEGE STATION, TX

<< Q FEVER IFA is Reportable to Health Dept >>

Susan U. Neill, Ph.D., M.B.A.
Director, Laboratory Services Section
CLIA License Number 45D0660644
www.dshs.state.tx.us/lab

03/29/2006 15:24 512400033

DSHS LAB REPORTING

PAGE 08/24

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TEXAS DEPARTMENT OF STATE HEALTH SERVICES

EDUARDO J. SANCHEZ, M.D., M.P.H.
COMMISSIONER1100 W. 49th Street • Austin, Texas 78756
1-888-963-7111 • <http://www.dshs.state.tx.us>Submitter copy to: ** DUPLICATE REPORT ** Page 1 of 2*
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2401 SOUTH 31ST STREET
TEMPLE, TX 76508Spec #: S06SM001127
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512) 458-7578

Patient

Patient Address:

Subj Specific Info, Personal Info

Date Rcvd: 3/8/2006
Spec Type: SERUM

Test Reas: DIAGNOSIS

NEW REQUIREMENT: Due to regulatory (CLIA) requirements, effective February 14, 2005, all specimen forms must include the date of collection or the specimen will be rejected.

Final Results

Specimen Numbers: S06SM001127
Date Collected: 3/7/2006

BRUCELLA AGGLUTINATION <1:40

An agglutination titer of <1:40 is considered to be negative.

Q FEVER IFA **PHASE I 1:64
PHASE II 1:1024

A single Q fever IFA titer of greater than or equal to 1:256 is evidence of a prior infection, but, it does not confirm that the infection was recent. The most convincing evidence of recent infection is a fourfold rise in antibody titer between an acute serum and a convalescent serum. Reactions to both phase I and phase II antibody are often seen in test sera. However, in acute Q fever the phase II antibody is usually higher than the phase I titer. In chronic Q fever phase I titers rise in later specimens while phase II titers fall or remain constant.

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9/15/06
fw

470 94.40
31



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

EDUARDO J. SANCHEZ, M.D., M.P.H.
COMMISSIONER

1100 W. 49th Street • Austin, Texas 78756
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Submitter copy to: ** DUPLICATE REPORT ** * Page 2 of 2 *
Date: 3/17/2006

SCOTT & WHITE HOSP MICRO LAB-01450132
2401 SOUTH 31ST STREET
TEMPLE, TX 76508

Spec #: S06SM001127
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Tel #: (512) 458-7578

Patient

Patient Address:

Subj Specific Info, Personal Info

<< Q FEVER IFA is Reportable to Health Dept >>

Susan U. Neill, Ph.D., M.B.A.
Director, Laboratory Services Section
CLIA License Number 45D0660644
www.dshs.state.tx.us/lab

9/15/06
fw

Mattox, Brent S

From: Mattox, Brent S
Sent: Monday, April 03, 2006 5:07 PM
To: Raines, Angelia
Cc: Salsman, John M
Subject: Elevated Titers for Q-Fever (Coxiella Burnetii)
Follow Up Flag: Follow up
Flag Status: Red

At approximately 2:30 PM, the Occupational Health Program received a call from Scott & White reporting high titers for Q-Fever had been received on three individuals from Dr. Samuel's Laboratory. Scott & White had already spoken with Dr. Samuel and had requested follow-up visits with the three individuals. Based on this information, your office (Office of Compliance) was informed. Since you were out of the Office, I also informed Dr. Van Wilson and Dr. Tom Ficht, co-chairs of the Institutional Biosafety Committee at around 3:30 PM.

As Institutional Biosafety Officer, the following are observations and recommendations.

1. Elevated titer indicates direct exposure to the organism *Coxiella burnetii*, indicating that laboratory precautions failed to isolate the organism from laboratory personnel. At present, we have no indication of any signs of illness among staff. Q-fever is rarely, if ever (Control of Communicable Diseases Manual, 18th ed., American Public Health Association, pg. 436). The disease is easily treatable with antibiotics. Therefore, there should be little or any risk to other individuals. Isolation or confinement of patients is unnecessary.
2. Follow-up with Scott & White is recommended.
3. The Laboratory should be carefully decontaminated and safety procedures reviewed, including the use of personal protective equipment.

In summary, follow-up with Scott & White or a personal Physician should be documented, laboratory procedures evaluated, and thorough decontamination of surfaces and any reusable protective equipment (lab coats or scrubs). EHSD will follow up with the IBC and the Principal Investigator to determine if any additional steps are necessary. Again, there is no evidence the organism has breached the BL3 Laboratory containment.

If you have any questions, I can be reached at 845-2132.

Sincerely,

Brent S. Mattox, CIH
Biological Safety Officer

7/9/2007

Mattox, Brent S

From: Mattox, Brent S
Sent: Friday, April 07, 2006 11:36 AM
To: Clark, Charley; Salsman, John M
Subject: FW: Elevated Titers for Q-Fever (Coxiella Burnetii)

Follow Up Flag: Follow up
Flag Status: Red

Attachments: Elevated Titers for Q-Fever (Coxiella Burnetii); Angelia Raines.vcf



Elevated Titers for Angelia Raines.vcf
Q-Fever (C... (521 B)

Latest on the titer issue.

Brent

-----Original Message-----

From: Angelia Raines [mailto:ARaines@vprmail.tamu.edu]
Sent: Friday, April 07, 2006 11:33 AM
To: jsamuel@medicine.tamhsc.edu
Cc: Van Wilson; Mattox, Brent S; ibc@tamu.edu; Thomas Ficht
Subject: Fwd: Elevated Titers for Q-Fever (Coxiella Burnetii)

Dr. Samuel:

Per our conversation, below are two recommendations from Brent Mattox, the Institutional Biosafety Officer (BSO), in regards to the elevated titers for the organism Coxiella burnetii associated with your lab.

1. Follow-up with Scott & White for all lab personnel, including yourself, with elevated titers.

During our conversation, you discussed your SOP for elevated titers and indicated the steps you have taken to ensure the safety of your staff. Please send a complete copy of your lab SOP, including the safety procedures, to my office along with documentation of the steps you have already taken. This information will be reviewed and if changes are needed, you will be notified.

2. The Laboratory should be carefully decontaminated and safety procedures reviewed, including the use of personal protective equipment.

You also indicated that you would have your lab cleaned but wished to avoid using an aerosol decontaminant at this time. Please note what steps you will take to clean your lab.

I will need a response as soon possible but no later than 4/11/06.

Thank you in advance for your assistance.

Angelia

Angelia Raines
Director, VPR Office of Research Compliance TAMU 1186 1500 Research Parkway Suite 150 B
(Centeq Building) College Station, Texas 77843-1186 araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax

Mattox, Brent S

From: Mattox, Brent S
Sent: Friday, April 07, 2006 7:49 AM
To: Mattox, Brent S; 'Van Wilson'
Cc: Raines, Angelia
Subject: RE: Elevated Titters for Q-Fever (Coxiella Burnetii)
Follow Up Flag: Follow up
Flag Status: Red

This information will be shared with the Provost this morning. Does anyone have anything they would like to add?

Brent

From: Mattox, Brent S
Sent: Thursday, April 06, 2006 4:58 PM
To: Van Wilson
Cc: Raines, Angelia; Salsman, John M
Subject: FW: Elevated Titters for Q-Fever (Coxiella Burnetii)

Dr. Wilson:

The following email is what was sent to the Office of Compliance regarding the titer issue. You may want to talk to Angelia about a response, but all I am looking for is some indication number three has been done (decontamination may mean surface decon of selected areas only, depending on the PI's findings) and that the College of Medicine has verified the individuals in the Lab have been informed.

Hope this helps,

Brent

From: Mattox, Brent S
Sent: Monday, April 03, 2006 5:07 PM
To: Raines, Angelia
Cc: Salsman, John M
Subject: Elevated Titters for Q-Fever (Coxiella Burnetii)

At approximately 2:30 PM, the Occupational Health Program received a call from Scott & White reporting high titers for Q-Fever had been received on three individuals from Dr. Samuel's Laboratory. Scott & White had already spoken with Dr. Samuel and had requested follow-up visits with the three individuals. Based on this information, your office (Office of Compliance) was informed. Since you were out of the Office, I also informed Dr. Van Wilson and Dr. Tom Ficht, co-chairs of the Institutional Biosafety Committee at around 3:30 PM.

As Institutional Biosafety Officer, the following are observations and recommendations.

1. Elevated titer indicates direct exposure to the organism *Coxiella burnetii*, indicating that laboratory precautions failed to isolate the organism from laboratory personnel. At present, we have no indication of any signs of illness among staff. Q-fever is rarely, if ever (Control of Communicable Diseases Manual, 18th ed., American Public Health Association, pg. 436). The disease is easily treatable with antibiotics. Therefore, there should be little or any risk to other individuals. Isolation or confinement of patients is unnecessary.

7/9/2007

2. Follow-up with Scott & White is recommended.
3. The Laboratory should be carefully decontaminated and safety procedures reviewed, including the use of personal protective equipment.

In summary, follow-up with Scott & White or a personal Physician should be documented, laboratory procedures evaluated, and thorough decontamination of surfaces and any reusable protective equipment (lab coats or scrubs). EHSD will follow up with the IBC and the Principal Investigator to determine if any additional steps are necessary. Again, there is no evidence the organism has breached the BL3 Laboratory containment.

If you have any questions, I can be reached at 845-2132.

Sincerely,

Brent S. Mattox, CIH
Biological Safety Officer

7/9/2007

Mattox, Brent S

From: Mattox, Brent S
Sent: Friday, April 07, 2006 11:36 AM
To: Clark, Charley; Salsman, John M
Subject: FW: Elevated Titers for Q-Fever (Coxiella Burnetii)

Follow Up Flag: Follow up
Flag Status: Red

Attachments: Elevated Titers for Q-Fever (Coxiella Burnetii); Angelia Raines.vcf



Elevated Titers for Angelia Raines.vcf
Q-Fever (C... (521 B)

Latest on the titer issue.

Brent

-----Original Message-----

From: Angelia Raines [mailto:ARaines@vprmail.tamu.edu]
Sent: Friday, April 07, 2006 11:33 AM
To: jsamuel@medicine.tamhsc.edu
Cc: Van Wilson; Mattox, Brent S; ibc@tamu.edu; Thomas Ficht
Subject: Fwd: Elevated Titers for Q-Fever (Coxiella Burnetii)

Dr. Samuel:

Per our conversation, below are two recommendations from Brent Mattox, the Institutional Biosafety Officer (BSO), in regards to the elevated titers for the organism Coxiella burnetii associated with your lab.

1. Follow-up with Scott & White for all lab personnel, including yourself, with elevated titers.

During our conversation, you discussed your SOP for elevated titers and indicated the steps you have taken to ensure the safety of your staff. Please send a complete copy of your lab SOP, including the safety procedures, to my office along with documentation of the steps you have already taken. This information will be reviewed and if changes are needed, you will be notified.

2. The Laboratory should be carefully decontaminated and safety procedures reviewed, including the use of personal protective equipment.

You also indicated that you would have your lab cleaned but wished to avoid using an aerosol decontaminant at this time. Please note what steps you will take to clean your lab.

I will need a response as soon possible but no later than 4/11/06.

Thank you in advance for your assistance.

Angelia

Angelia Raines
Director, VPR Office of Research Compliance TAMU 1186 1500 Research Parkway Suite 150 B
(Centex Building) College Station, Texas 77843-1186 araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax

Mattox, Brent S

From: Samuel, James [JSAMUEL@medicine.tamhsc.edu]
Sent: Friday, July 06, 2007 9:07 AM
To: Mattox, Brent S
Cc: Samuel, James
Subject: Re: Request for information

Brent,

The only recombinant organism expressing *C. burnetii* antigens we currently work with is *E. coli*. We have expressed the majority of the genes from *C. burnetii* in *E. coli*, so a list of individual genes would be rather artificial. There are ~2150 ORFs (genes) predicted for the *C. burnetii* genome.

Also specifically indicate to the NIH that we did not classify titer information as indication of either an exposure or an infection. Therefore, we did not fail to report an exposure event. This is the key issue that seems to be not clearly defined to agencies and the public.

JimS

On 7/6/07 8:28 AM, "Mattox, Brent S" <bsmattox@tamu.edu> wrote:

Dr. Samuel:

I have not heard ack from NIH, so I am making an assumption that the questions posed are on the individuals that had elevated titers. Let me have the list of "recombinant organisms" expressing *C. burnetii* antigens and we'll go from there. I need to get this report out today, so let me know. I will stress to NIH that there were no adverse events, no signs of illness, and that elevated titers are not useful as an indicator of exposure by themselves.

Brent

From: Mattox, Brent S
Sent: Tuesday, July 03, 2007 9:37 AM
To: 'Samuel, James'
Cc: 'whitneyb@mail.nih.gov'
Subject: RE: Request for information

I will ask and get back to you with a reply.

Thanks,

Brent

From: Samuel, James [mailto:JSAMUEL@medicine.tamhsc.edu]
Sent: Monday, July 02, 2007 6:18 PM
To: Mattox, Brent S
Subject: Re: Request for information

Brent,

This is actually two questions, one of which is a short answer that I have already replied to you about, and one which I have not been asked.

7/9/2007

We do not have recombinant *Coxiella burnetii*.

We do have a variety of *C. burnetii* genes cloned into *E. coli* K12 and express a variety of these antigens. I have a rather long list of cloned genes which we have expressed, either in the past or present. I believe particularly they refer to the research staff. Do they wish to know who the 3 individuals that had elevated titers were and if they were individually expressing a list of antigens. Or do they want a complete accounting of *C. burnetii* genes for which we have expressed protein in *E. coli*.

JImS

On 7/2/07 5:21 PM, "Mattox, Brent S" <bsmattox@tamu.edu> wrote:

Dr. Samuel:

here is the email from NIH. Help me with the rDNA usage issues, and feel free to add anything you feel as pertinent. I will then generate a report (within 5 days) and have you review it before it goes out.

Thanks,

Brent

From: Whitney, Bruce (NIH/OD) [C] [mailto:whitneyb@mail.nih.gov]
Sent: Monday, July 02, 2007 11:49 AM
To: Mattox, Brent S
Subject: Request for information

Dear Mr. Mattox,

Thank you for the information you provided to me in response to my call concerning the incident at Texas A&M University in which research staff were found to have high titers for *Coxiella burnetii*. So that we can better understand what occurred, OBA requests that you provide us with a written report of the incident. Among other facts, we wish to know if the research staff were working, at any time before the high titers were found, with either recombinant *Coxiella burnetii* or with any recombinant organism expressing *Coxiella burnetii* antigen(s). If so, how did such exposure occur? Please respond in 5 working days from receipt of this email.

Thank you for your assistance in this matter.

Bruce Whitney, Ph.D.
Senior Biosafety and Outreach Specialist (contractor)
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985
Tel: (301) 435-2149
Fax: (301) 496-9839

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7/9/2007

James E. Samuel, Professor
Department of Microbial and Molecular Pathogenesis
College of Medicine
Texas A&M Health Science Center
407 Reynolds Medical Building
College Station, TX 77843-1114
PHONE: (979) 862-1684
FAX: (979) 845-3479
e-mail: jsamuel@tamhsc.edu



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Department of Microbial and Molecular
Pathogenesis

MEMORANDUM

Date: April 7, 2006
To: Angelia Raines
Director, VPR Office of Research Compliance
From: James E. Samuel
Professor

The following information is provided in response to your query concerning "elevated titers for the organism *Coxiella burnetii* associated with my laboratory and our response to notification of these elevated titers". Please be advised that the description of these serological samples as "elevated titers" is not precise and I have included information to demonstrate this point. We participate in an annual serological survey as part of our occupational health plan. Three individuals were identified to me as having tested in a notifiable condition, as defined by The Health Department (Brazos County Health Department), which is the local response and evaluation arm of the National Center for Disease Control and Prevention that prepared this assay material and advises local agencies responses to interpretation of the assay. All three individuals received a notification from The Health Department in a letter dated March 22, 2006. I also received notification of the notifiable results from the Occupational Health group at Scott and White Health Clinic, the group that performed serological sampling, which was forwarded to The Health Department. As per our established protocol, I informed each individual that they could seek advice and treatment from Scott and White clinicians. [Subj Specific Info] elected to decline further advice and treatment based on the notifiable titers and knowledge of previous serological titers and occupational experiences. Upon your suggestion, Dr. [Subj Specific Info] myself have prepared signed statements indicating our elected medical options. [Subj Specific Info] [Subj Specific Info] elected to consult this clinical group, has visited a clinician and received an appropriate antimicrobial treatment for discretionary use.

To provide a more complete set of information for review, recognize that the statement accompanying the laboratory report for the Q fever IFA states the following:

"A single Q fever IFA titer of greater than or equal to 1:256 is evidence of a prior infection, but it does not confirm that the infection was recent. The most convincing evidence of recent infection is a four-fold rise in antibody titer between an acute serum and a convalescent serum. Reactions to both phase I and phase II antibodies are often seen in test sera. However, in acute Q fever the phase II antibody is usually higher than the phase I titer."



The Texas A&M University System Health Science Center



College of Medicine

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College Station, Texas 77843-1114
979-845-1313 • fax 979-845-3479

Department of Microbial and Molecular
Pathogenesis

In response to your first request:

"1. Follow-up with Scott & White for all lab personnel, including yourself, with elevated titers.

During our conversation, you discussed your SOP for elevated titers and indicated the steps you have taken to ensure the safety of your staff. Please send a complete copy of your lab SOP, including the safety procedures, to my office along with documentation of the steps you have already taken. This information will be reviewed and if changes are needed, you will be notified."

The serological response history of the three individual's that had notifiable titers follows:

Subj Specific Info

10/18/02 1:64 PI
1:64 PII

12/15/03 <1:64 PI
1:64 PII

1/20/05 <1:64 PI
1:64 PII

3/06 <1:64 PI
1:256 PII

Subj Specific Info

1/18/04 <1:64 PI
1:128 PII

5/7/04 <1:64 PI
1:256 PII

3/06 <1:64 PI
1:256 PII

Subj Specific Info

8/25/04 <1:64 PI
1:64 PII

1/20/05 <1:64 PI
<1:64 PII

3/29/05 <1:64 PI
1:128 PII

3/06 1:64 PI
1:1024 PII



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Additional comments for each of these individuals with regard to prior exposure history and interpretations of these data are:

Subj Specific Info presented with clinical symptoms consistent with acute Q fever in 1982 after first working with the agent in graduate school. Prevailing clinical data supports the idea of life-long immunity as a result of a symptomatic disease experience. Individual serological titers vary in many previously sensitized individuals.

Subj Specific Info arrived in my lab and was serologically evaluated prior to working with the agent. Her baseline titer suggests prior exposure, based on the 1:128 titer for phase II. A 2-fold rise in titer does not represent any indication of active infection and she has experienced no clinical signs consistent with acute Q fever.

Subj Specific Info did appear to be serologically negative upon joining the lab. She has developed increasing titers to phase II antigen and recently tittered above baseline for phase I. It is not uncommon for *C. burnetii* BL3 laboratory workers to develop serological cross reaction to *C. burnetii* antigen without developing clinical disease or detectable infection. She has not presented with clinical symptoms consistent with acute Q fever. As noted above, she did visit Scott & White Clinicians and received antimicrobial therapy, which she has elected to use discretionarily after consultation with these clinicians.

A copy of the laboratory SOP and training material associated with our serological monitoring and Occupational Health plan is attached.

"2. The Laboratory should be carefully decontaminated and safety procedures reviewed, including the use of personal protective equipment."

All decontamination and safety procedures including the use of personal protective equipment have been reviewed with the staff in question. The laboratory is routinely decontaminated including weekly general decontamination. In response to your request, the entire BL-3 facility in **public inform** has been decontaminated by surface treatment with bactericidal agent.

Cc Van Wilson, Associate Dean for Research & Graduate Studies
John Quarles, Department Head, Microbial and Molecular Pathogenesis

Whitney, Bruce (NIH/OD) [C]

From: Mattox, Brent S [bsmattox@tamu.edu]
Sent: Friday, July 06, 2007 9:29 AM
To: Samuel, James
Cc: Whitney, Bruce (NIH/OD) [C]
Subject: RE: Request for information

Dr. Samuel:

I have not heard ack from NIH, so I am making an assumption that the questions posed are on the individuals that had elevated titers. Let me have the list of "recombinant organisms" expressing *C. burnetii* antigens and we'll go from there. I need to get this report out today, so let me know. I will stress to NIH that there were no adverse events, no signs of illness, and that elevated titers are not useful as an indicator of exposure by themselves.

Brent

From: Mattox, Brent S
Sent: Tuesday, July 03, 2007 9:37 AM
To: 'Samuel, James'
Cc: 'whitneyb@mail.nih.gov'
Subject: RE: Request for information

I will ask and get back to you with a reply.

Thanks,

Brent

From: Samuel, James [mailto:JSAMUEL@medicine.tamhsc.edu]
Sent: Monday, July 02, 2007 6:18 PM
To: Mattox, Brent S
Subject: Re: Request for information

Brent,

This is actually two questions, one of which is a short answer that I have already replied to you about, and one which I have not been asked.

We do not have recombinant *Coxiella burnetii*.

We do have a variety of *C. burnetii* genes cloned into *E. coli* K12 and express a variety of these antigens. I have a rather long list of cloned genes which we have expressed, either in the past or present. I believe particularly they refer to the research staff. Do they wish to know who the 3 individuals that had elevated titers were and if they were individually expressing a list of antigens. Or do they want a complete accounting of *C. burnetii* genes for which we have expressed protein in *E. coli*.

JImS

8/6/2007

On 7/2/07 5:21 PM, "Mattox, Brent S" <bsmattox@tamu.edu> wrote:

Dr. Samuel:

here is the email from NIH. Help me with the rDNA usage issues, and feel free to add anything you feel as pertinent. I will then generate a report (within 5 days) and have you review it before it goes out.

Thanks,

Brent

From: Whitney, Bruce (NIH/OD) [C] [<mailto:whitneyb@mail.nih.gov>]

Sent: Monday, July 02, 2007 11:49 AM

To: Mattox, Brent S

Subject: Request for information

Dear Mr. Mattox,

Thank you for the information you provided to me in response to my call concerning the incident at Texas A&M University in which research staff were found to have high titers for *Coxiella burnetii*. So that we can better understand what occurred, OBA requests that you provide us with a written report of the incident. Among other facts, we wish to know if the research staff were working, at any time before the high titers were found, with either recombinant *Coxiella burnetii* or with any recombinant organism expressing *Coxiella burnetii* antigen(s). If so, how did such exposure occur? Please respond in 5 working days from receipt of this email.

Thank you for your assistance in this matter.

Bruce Whitney, Ph.D.
Senior Biosafety and Outreach Specialist (contractor)
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985
Tel: (301) 435-2149
Fax: (301) 496-9839

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James E. Samuel, Professor
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College of Medicine
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College Station, TX 77843-1114
PHONE: (979) 862-1684
FAX: (979) 845-3479
e-mail: jsamuel@tamhsc.edu

8/6/2007

Whitney, Bruce (NIH/OD) [C]

From: Mattox, Brent S [bsmattox@tamu.edu]
Sent: Tuesday, July 03, 2007 10:37 AM
To: Samuel, James
Cc: Whitney, Bruce (NIH/OD) [C]
Subject: RE: Request for information

I will ask and get back to you with a reply.

Thanks,

Brent

From: Samuel, James [mailto:JSAMUEL@medicine.tamhsc.edu]
Sent: Monday, July 02, 2007 6:18 PM
To: Mattox, Brent S
Subject: Re: Request for information

Brent,

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JimS

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Thanks,

Brent

From: Whitney, Bruce (NIH/OD) [C] [mailto:whitneyb@mail.nih.gov]
Sent: Monday, July 02, 2007 11:49 AM
To: Mattox, Brent S
Subject: Request for information

Dear Mr. Mattox,

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8/6/2007

incident at Texas A&M University in which research staff were found to have high titers for *Coxiella burnetii*. So that we can better understand what occurred, OBA requests that you provide us with a written report of the incident. Among other facts, we wish to know if the research staff were working, at any time before the high titers were found, with either recombinant *Coxiella burnetii* or with any recombinant organism expressing *Coxiella burnetii* antigen(s). If so, how did such exposure occur? Please respond in 5 working days from receipt of this email.

Thank you for your assistance in this matter.

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Senior Biosafety and Outreach Specialist (contractor)
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James E. Samuel, Professor
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PHONE: (979) 862-1684
FAX: (979) 845-3479
e-mail: jsamuel@tamhsc.edu

Whitney, Bruce (NIH/OD) [C]

From: Mattox, Brent S [bsmattox@tamu.edu]
Sent: Monday, July 02, 2007 6:19 PM
To: Whitney, Bruce (NIH/OD) [C]
Cc: Raines, Angelia
Subject: RE: Request for information

We will be glad to provide you a detailed written report. I need to get back to the researcher for some final specifics, but I will get it to you in the next few days, certainly less than five.

Thanks,

Brent S. Mattox, CIH
Biological Safety Officer

From: Whitney, Bruce (NIH/OD) [C] [mailto:whitneyb@mail.nih.gov]
Sent: Monday, July 02, 2007 11:49 AM
To: Mattox, Brent S
Subject: Request for information

Dear Mr. Mattox,

Thank you for the information you provided to me in response to my call concerning the incident at Texas A&M University in which research staff were found to have high titers for *Coxiella burnetii*. So that we can better understand what occurred, OBA requests that you provide us with a written report of the incident. Among other facts, we wish to know if the research staff were working, at any time before the high titers were found, with either recombinant *Coxiella burnetii* or with any recombinant organism expressing *Coxiella burnetii* antigen(s). If so, how did such exposure occur? Please respond in 5 working days from receipt of this email.

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9/5/2007

Pages 346 through 347 redacted for the following reasons:

Other Agency Record