REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS
(APHIS/CDC FORM 3)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2008

Read all instructions carefully before completing the report. Answer all items completely and type or print in ink. The report must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096

SECTION 1 – TO BE COMPLETED BY ALL ENTITIES

1. Entity name: Texas A&M University		2. Entity registration number (if applicable): APHIS# CDC# 200606050489		
3. Entity address (NOT a post office address): 1500 Research Parkway, Suite B150 TAMU 1186	4. City: College Station		5. State: TX	6. Zip Code: 77843-1186
7. Responsible Official (RO) or facility director First: Richard MI: Last: Ewing	8. Telephone: 979 847-9362	9. FAX: 979 862-3176		10. E-mail: araines@vprmail.tamu.ed
11. RO or facility director address (NOT a post office address): 1500 Research Parkway, Suite B150	12. City: College Station		13. State: TX	14. Zip Code: 77843-1186
15. Type of incident: ☐ Theft ☐ Loss ☑ Release	16. Immediate notification provided to: ☐ APHIS ☑ CDC	17. Date of immediate notification: 04/10/2007	18. Type of immediate notification: ☑ E-mail ☐ Fax ☐ Telephone	
19. An internal review of laboratory procedures and policies has been initiated to prevent recurrences of loss of select agents and toxins at this entity: ☐ No ☑ Yes (If yes, please provide additional details in an attachment.) (See explanation in Section 2)				

SECTION 2 – TO BE COMPLETED BY ALL ENTITIES
LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED (Please see page 4.)

27. Date and time of incident: 02/09/2006	28. Date of last inventory: 03/12/2007	29. Name of principal investigator for laboratory with select agents and toxins First: Thomas MI: Last: Ficht	
30. Location of incident (building and room #):	31. Location of incident (within room (e.g., freezer, incubator)): aerosol chamber		32. Biosafety level of laboratory where incident occurred: BSL3
33. Name and telephone number of agencies or local authorities notified: Health Dept. 512 458-7318	34. Symbols or markings on vials (if any):		35. Agent was recovered (theft/loss): ☐ No ☐ Yes

36. Provide a summary of actions taken:
☐ Called ambulance ☐ Called fire department ☐ Closed laboratory doors ☐ Closed building ☐ Consulted MSDS or chemical database
☐ Called police department (case #) ☑ Other (explain): see below

37. Provide a detailed summary of events (attach additional sheets if necessary):

Several months ago, one of our laboratory employees had an elevated titer (1:160) for Brucella. The lab report stated the following ..."evidence of prior exposure" but " it does not confirm that the exposure was recent". While the exact cause is not known, the exposure could have occurred on 2/9/06, and would have been the result of improper decontamination procedures. Specifically, the employee may have climbed into an aerosol chamber after a run. The chamber was located within the BL3 lab. The laboratory's Bio-safety plan has since been updated and all lab personnel have been retrained. All other lab personnel have also been tested and found to be negative. The incident occurred during the time we were transitioning CDC compliance responsibilities within our organizational structure. This information should have been immediately reported to the CDC but was not. We now have a process in place to insure immediate notification of a loss, theft or release and we are auditing all records to ensure all incidents have been properly reported.

SECTION 3 – IF THE INCIDENT OCCURRED DURING TRANSFER PROVIDE THE FOLLOWING INFORMATION	
38. APHIS authorization number from transfer form:	39. CDC authorization number from transfer form:
40. Name of carrier:	41. Airway bill number/bill of lading number/tracking number:
42. Package description (size, shape, description of packaging including number and type of inner packages; attach additional sheets if necessary):	

	SENDER INFORMATION		RECIPIENT INFORMATION	
43. Name of person:	a. First: MI: Last:		b. First: MI: Last:	
44. Name of entity:	a.		b.	
45. APHIS/CDC registration number:	a. APHIS:	b. CDC:	c. APHIS:	d. CDC:
46. PHS/USDA import permit number:	a. PHS:	b. USDA:	c. PHS:	d. USDA:
47. Date shipped:	a.		b.	
48. Telephone:	a.		b.	
49. FAX:	a.		b.	

50. Package with select agents and toxins received by requestor: ☐ No ☐ Yes	51. Package with select agents and toxins appears to have been opened: ☐ No ☐ Yes (If Yes, explain)
52. Sender was contacted regarding incident: ☐ No ☐ Yes	53. Carrier/courier was contacted regarding incident: ☐ No ☐ Yes

SECTION 4 – TO BE COMPLETED ONLY FOR RELEASE OF SELECT AGENTS AND TOXINS
54. Hazards posed by release: ☑ No ☐ Yes (If Yes, explain. Use an attachment if necessary.)
55. Exposures: ☐ No ☑ Yes (If Yes, provide number of persons, animals, and plants exposed. Attach additional sheets if necessary.)
1 employee showed evidence of prior exposure.
56. Area was decontaminated: ☐ No ☑ Yes (If Yes, explain. Use an attachment if necessary.)
The chamber is now flushed with a disinfectant rather than using manual cleaning methods. In addition, personnel are now using positive air displacement respirators instead of the N95 face mask.
57. Medical treatment was provided: ☐ No ☑ Yes (If Yes, explain. Use an attachment if necessary.)
The employee had previously been treated by a private physician and is currently being monitored.

SECTION 2 – TO BE COMPLETED BY ALL ENTITIES							
LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED							
	20. Select Agents and Toxins	21. Characterization of Agent	22. Number of Vials	23. Form (powder/liquid/ slant)	24. Vol or Wt per Vial (e.g., ml, mg, ng)	25. Total Quantity	26. Concentration/Vial (e.g., 10^9 pfu/ml)
1	Brucella abortus						1 x 10
2	Brucella melitensis						1 x 10
3	Brucella suis						1 x 10
4							1 x 10
5							1 x 10
6							1 x 10
7							1 x 10
8							1 x 10
9							1 x 10
10							1 x 10
11							1 x 10
12							1 x 10

I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 42 CFR 73, 9 CFR 121, or 7 CFR 331 may result in civil or criminal penalties, including imprisonment.

Signature of Respondent: _____ Typed or printed name of Respondent: Angelia Raines

Title: ARO, Director of Research Compliance Date: 04/11/2007

Public reporting burden: Public reporting burden of providing this information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).

From: Richard Ewing
To: Raines, Angelia
Date: 1/20/2007 11:38 AM
Subject: Re: Confidential - SBAT Discrepancy Report

CC: Agnew, Tiffany; Bazer, Fuller; bertvk@tamu.edu; Cantrell, Carol; c-m...

Angelia,

Thank you for sending the this report. Given the details in the report, that the discrepancy was accounted for very quickly within the investigator's lab, the fact the Dr. Ficht and his colleagues have reviewed SOP's that will mitigate any further discrepancies, and my reading and interpretation of the CDC rules, I think this report, having been shared with those copied in this e-mail and properly filed for future reference, is sufficient and a formal report to CDC is not necessary at this point. Thank you and all involved for your prompt and effective treatment of this discrepancy and for follow up to ensure that problems causing this discrepancy have been addressed and hopefully mitigated.

Dick

Dr. Richard E. Ewing
Vice President for Research
Texas A&M University
1112 TAMU
College Station, TX 77843-1112
Phone: (979) 845-8585
FAX: (979) 845-1855
E-mail: richard-ewing@tamu.edu

>>> Angelia Raines 01/19/07 5:32 PM >>>
CONFIDENTIAL

Attached is a Select Agent discrepancy report for Dr. Thomas Ficht. A discrepancy occurs when any quantity of a select agent can not be accounted for.

The discreapncy occured on 1/11/07, and was resolved immediately. Please review the attached report and let me know if you have questions or changes.

Thank you,
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

From: Richard Ewing
To: Angelia Raines; f-bazer@tamu.edu
Date: 4/11/2007 6:03 PM
Subject: Re: Select Agent Exposure

CC: Tiffany Agnew

Angie,
Is this case that we talked about today with Garry the same one that we received the open records request from Ed Hammond/Sunshine Project?
Dick

Dr. Richard E. Ewing
Vice President for Research
Texas A&M University
1112 TAMU
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Phone: (979) 845-8585
FAX: (979) 845-1855
E-mail: richard-ewing@tamu.edu

>>> Angelia Raines 4/10/2007 9:20 pm >>>
Several months ago, one of our laboratory employees had a slightly elevated titer, which indicated "evidence of prior exposure" to Brucella. The incident occurred during the time we were transitioning CDC compliance responsibilities from the Environmental Health and Safety Department to the Office of Research Compliance (ORC). It should have been immediately reported to the CDC but was not. All reporting responsibilities are now managed by the ORC and we have a process in place to insure immediate notification of a loss, theft or release/exposure. I have contacted CDC about the oversight and I am in the process of submitting the proper incident report to them.

All other lab personnel have since been tested and found to be negative.

In investigating the incident, we found that the exposure most likely occurred because of improper decontamination procedures. Specifically, the employee climbed into an aerosol chamber which was located in the BL3 lab. Following the incident, the laboratory's operating procedures were updated and all lab personnel were retrained.

Please let me know if you need further information regarding this incident.

Thank you,
Angie

Angelia Raines
Director, VPR Office of Research Compliance
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College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax

From: Richard Ewing
To: Betsy Browder; bsmattox@tamu.edu; ddavis@cvm.tamu.edu; Fuller Bazer; ...
Date: 4/15/2007 7:30 PM
Subject: Re: Notification of CDC Site Visit 4/16/07

CC: Angelia Raines; Dianne Cornett; Van Wilson

All,

I had meetings from when this was sent through close of business on Friday. I have read through what was sent to me on the incident from Angie's staff on Friday, but probably before they received this request. The review team will be here tomorrow, Monday, April 16. I do not have access to the information that they are requesting. I hope that you received this on Friday in time to begin to put this information together. I will cancel any or all of the appointments that I have tomorrow to try to address these concerns. Please let me know if anyone has already put some of this information together for the audit team. Please be reminded that articles in the Chronicle suggest fines up to $500K and reduction of funding overall, so we need to seriously address these problems.

Dick

Dr. Richard E. Ewing
Vice President for Research
Texas A&M University
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College Station, TX 77843-1112
Phone: (979) 845-8585
FAX: (979) 845-1855
E-mail: richard-ewing@tamu.edu

>>> Shannon Davis 4/13/2007 2:01:09 pm >>>

I just got a call from CDC in response to our report of *Brucella* exposure. They are planning on conducting a site visit beginning Monday morning. Further information is attached.

Angelia Raines

Angelia Raines
Director, VPR Office of Research Compliance
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College Station, Texas 77843-1186
araines@vprmail.tamu.edu
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(979) 862-3176 fax

all

From: Richard Ewing
To: Raines, Angelia
Date: 4/16/2007 7:55 AM
Subject: Re: Notification of CDC Site Visit 4/16/07

CC: Agnew, Tiffany; Davis, Shannon

Angelia,
I assume that they will come to your office at (;00 this morning, so I'll be there early.
Dick

Dr. Richard E. Ewing
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E-mail: richard-ewing@tamu.edu

>>> Angelia Raines 04/16/07 7:01 AM >>>
Good Morning,

I just spoke with Diane Martin, one of the inspectors from the CDC. They will arrive this morning at 9:00 a.m. Per Diane, they wish to focus solely on the exposure incident and are not inspecting our entire registration, therefore they do not want to have an entrance briefing.

They want to start the visit by meeting with the two of us. Following that meeting, they will let us know how they wish to proceed. They meeting will take place in Centeq, 130-B.

Diane will call me if any of their plans change and I will call you.

Thank you,
Angelia

Angelia Raines
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>>> Richard Ewing 04/15/07 7:30 PM >>>
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>>> Shannon Davis 4/13/2007 2:01:09 pm >>>
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Angelia Raines

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(979) 862-3176 fax

From: Richard Ewing
To: Agnew, Tiffany; Bazer, Fuller; Raines, Angelia
Date: 4/17/2007 7:48 AM
Subject: Fwd: Texas A&M Brucella Exposure Incident

CC: Calvin, James; Inbody, Tiffany; Richard Ewing; Wolff, Susan

All,
I don't want to defocus anyone from the ongoing CDC visit, but wanted to let everyone know we are also being asked questions by DHS since the experiment was funded by DHS through FAZD.
Dick

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>>> "Clark, Matthew" <Matthew.Clark1@dhs.gov> 04/16/07 1:38 PM >>>
Neville,

As a follow-up to our phone call of Friday night, in which you notified me of a Brucella exposure incident at Texas A&M, DHS needs more information to evaluate (1) the nature of the Brucella exposure incident, (2) the oversight of the Texas A&M select agent program, (3) the personnel changes that were implicated in the failure to report, and (4) any additional measures that have been taken or may be warranted to resolve the issue and ensure future compliance.

Please provide detailed written answers to the following questions:

* When exactly did the incident occur and when was it reported to CDC?
* Who at Texas A&M is now coordinating with CDC in addressing noncompliance issue resulting from the failure to report? What guidance and oversight is CDC now providing on follow-up federal compliance measures that need to be taken? Has the CDC assessed any penalties?
* What personnel and procedural actions is Texas A&M taking to remedy the situation?
* Who was the RO named on the registration at the time of the incident? Was this individual involved in the "personnel changes" that led to the failure to report? Who is the current RO on the University's registration? Please provide copies of the current Certificate of Registration and that held at the time of the incident to DHS for review and record keeping.
* The incident presumably involved one of the Brucella species (abortus, melitensis, or suis) that are listed as a CDC/APHIS overlap select agent.
* Did Texas A&M notify USDA-APHIS of the incident and submit Form 3 -- used to report theft, loss, or release of a select agent -- within 7 days? Note: The occupational exposure at Texas A&M would be considered a "release" based on the broader definition indicated on the form. Have both CDC and APHIS been involved in the noncompliance response?
* Was the laboratory work associated with the incident being conducted under the DHS grant through the COE? Was the work being conducted as it was described in proposals or protocols associated with the award?
* Was the exposure the result of an isolated procedural mishap that was known only to affect the individual involved, or was it linked to protocols, equipment, safety, or bio-containment measures that may present heightened exposure risks for other personnel? Were the protocols for aerosol chamber use/cleaning designed and/or reviewed in

accordance with federal regulations and institutional policies? Were these protocols revised post-incident?

* Who was the PI overseeing the work associated with the incident? Was this PI named in the DHS Center proposal and on the select agent registration for work with both the agent itself and the laboratory involved in the exposure? Please provide verification from the application for select agent registration.
* Which Texas A&M administrators and/or oversight bodies were notified of the exposure? Please provide a clear explanation of the chain of events that caused TAMU to not call CDC or APHIS or submit a Form 3 immediately following the incident.
* What steps have been taken to coordinate with CDC in addressing both the exposure incident and the lapse in oversight that resulted in failure to report? Has a Form 3 been submitted retrospectively? If so, please provide a copy to DHS for review. Has the CDC issued other requirements with respect to the University's registration and/or select agent program? Has CDC conducted any site visits or inspections in response to the incident?

Thank you for your cooperation.

Regards,

Matt

Matthew Clark, Ph.D.

Director, University Programs

Science and Technology Directorate

202-254-6377

From: Richard Ewing
To: c-cantrell@tamu.edu; Julie Barker; Raines, Angelia
Date: 4/18/2007 1:01 PM
Subject: Fwd: RE: misinformation

FYI

Dr. Richard E. Ewing
Vice President for Research
Texas A&M University
1112 TAMU
College Station, TX 77843-1112
Phone: (979) 845-8585
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E-mail: richard-ewing@tamu.edu

>>> "Perry, Bill L" <bperry@tamu.edu> 4/18/07 11:34 AM >>>
All,
I called Rod McCallum of HSC first, so he would know I would be calling have called her and said I would work on this. I have a phone message in to Steve Moore. Charley Clark was here so he knows this.
Will update.
Bill

-----Original Message-----
From: Davis, Eddie J
Sent: Wednesday, April 18, 2007 10:08 AM
To: Perry, Bill L; Clark, Charley; 'Richard Ewing'; Moore, Steve
Subject: FW: misinformation

Suggest one of you get back with Despite her concerns about misinformation, I think we need to get the CDC visit behind us before we begin to debate this issue further in the newspaper. EJD.

-----Original Message-----
From: Prior, David
Sent: Wednesday, April 18, 2007 9:48 AM
To:
Subject: RE: misinformation

thank you for your e-mail. I am presently in Malaysia at an international meeting. You are quite correct that factual information is essential. Please be assured that I will pass this on to those directly involved in my absence.
David Prior

-----Original Message-----
From:
Sent: 4/18/07 8:58:16 AM
To: "dprior@tamu.edu"<dprior@tamu.edu>
Subject: misinformation

** High Priority **

Dear Dr. Prior,

I am the researcher involved in The Eagle's headline story today. I am very concerned and unhappy about the misinformation that appears in this article and I am asking your help to issue a retraction. I want it made very clear that I DID NOT CLIMB into the aerosol chamber. I REACHED

inside, after the last challenge was completed, to wipe down the chamber AS IS OUR STANDARD PROTOCOL. Furthermore, the (exposure) event did not take place as part of a training session on the use of the Madison Chamber, nor were Drs. McMurray or Ficht present at the time of my exposure. These are serious inconsistences which demand a response. I am asking you and your office for help with this matter. These inaccuracies MUST be corrected. (It is one thing for these statements to appear on the Sunshine Project's website, which surely is read by precious few. But now, these inaccuracies have made their way to the front page of our newspaper and must be addressed.) I ask for your help in this matter.

Sincerely,

From: Richard Ewing
To: Raines, Angelia
Date: 4/18/2007 11:04 PM
Subject: Fwd: Select Agent Security Documents

CC: Barker, Julie; c-cantrell@tamu.edu; f-bazer@tamu.edu
FYI

Dr. Richard E. Ewing
Vice President for Research
Texas A&M University
1112 TAMU
College Station, TX 77843-1112
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E-mail: richard-ewing@tamu.edu

>>> "Laboratories Registration/SAT (CDC)" <lrsat@cdc.gov> 4/18/07 11:05 AM >>>
The Centers for Disease Control and Prevention (CDC) and Animal and Plant Health Inspection Service (APHIS) Select Agent Programs are pleased to announce the public release of information to assist entities in complying with the security requirements of the select agent regulations. The documents being released are the result of collaborative work between CDC, APHIS, and many other subject matter experts.

The documents will provide assistance to entities in the development or revision of a written security plan, and in performing a site-specific risk assessment that would assist in addressing incident response requirements, recordkeeping requirements, security requirements, and training requirements. These documents can be viewed at: http://www.selectagents.gov/securitydoc.htm.

If you have questions regarding this correspondence or these documents, please contact your designated CDC representative. If you are unsure who your designated CDC representative is, then please call 404-718-2000.

Thank you.

Robbin Weyant, PhD, CAPT, USPHS
Director, Division of Select Agents and Toxins
Centers for Disease Control and Prevention
1600 Clifton Road N.E., MS A-46
Atlanta, GA 30333
Telephone: 404-718-2000; FAX: 404-718-2096
http://www.cdc.gov/od/sap/

From: Richard Ewing
To: Matthew Clark
Date: 6/14/2007 4:37 PM
Subject: Re: Conditions for Extending the FAZD Grant - Confirmation Requested

CC: Angelia Raines; Neville Clarke; Richard Ewing; Starnes Walker; Steve...

Dr. Clark,

I am in receipt of your e-mail, and we are in the process of preparing a detailed response. You will have it no later than Monday, June 18.

I also look forward to working closely with you in the future. Have a good weekend.

Regards,
Dick Ewing

Dr. Richard E. Ewing
Vice President for Research
Texas A&M University
1112 TAMU
College Station, TX 77843-1112
Phone: (979) 845-8585
FAX: (979) 845-1855
E-mail: richard-ewing@tamu.edu

>>> "Clark, Matthew" <Matthew.Clark1@dhs.gov> 6/11/07 3:55 PM >>>
Dear Dr. Ewing:

This email is to confirm the substance of our phone conversation of last Thursday, June 7, 2007. Please provide a response that confirms your receipt and outlines your agreement in principle with the conditions below.

DHS Science and Technology (S&T) Office of University Programs will provide extension funds for the Center for Foreign Animal and Zoonotic Disease Defense (FAZD) at Texas A&M University (TAMU), subject to the following conditions:

1. DHS University Programs will provide no funding for select agent or other biological laboratory activities at TAMU until the university has been given a clean bill of health by both the CDC and S&T's lead compliance officer. This requires certification for TAMU having the proper policies, procedures, training, and accountability measures in place to handle select agents and other biological materials.

2. TAMU must provide DHS with a new and detailed cost proposal with all biological laboratory work held in abeyance.

3. DHS will recommend that ONR approve a no-cost extension for the existing FAZD grant until December 31, 2007, subject to the same conditions as 1 and 2 above.

4. TAMU will hire personnel and establish mechanisms to ensure full compliance with all regulations, as well as exemplary day-to-day operational management of all FAZD functions. One approach would be for TAMU to establish a full-time position of Chief Operating Officer (COO) or a similar position who will report directly to the Dean of Research at TAMU and have unfettered access, communication and accountability to the DHS Offices of University Programs and Regulatory Compliance. This position would be responsible for all compliance, planning, reporting, budgeting, and accountability issues associated with FAZD, including, for example, that: all proper procedures are in place, all financial and project reports are submitted on time, all projects are on schedule, all projects have transition plans to provide useful results, and all projects are coordinated with other Centers of Excellence and with the S&T Chem-Bio Division, USDA and FDA, as feasible. An example of a potential COO candidate would be someone affiliated with the TAMU business school, as recommended by external reviewers at FAZD's biennial review in September 2006. This position may be funded through the COE grant or with other A&M funds.

We will move forward with the FAZD extension grant as quickly as possible once we have had an opportunity to consider your response to this email, your agreement to these conditions and your plans to implement condition #4.

Thank you for your cooperation, and I look forward to working closely with TAMU in the future.

Regards,

Matt

Matthew Clark, Ph.D.

Director, University Programs

DHS Science and Technology Directorate

From: Richard Ewing
To: Matthew Clark
Date: 6/18/2007 5:20 PM
Subject: Re: Conditions for Extending the FAZD Grant - Confirmation Requested
Attachments: Clark response_061807.pdf; Clark response 061807 _Attachment 1_.pdf

CC: Angelia Raines; f-bazer@tamu.edu; Neville Clarke; Starnes Walker; St...

Dr. Clark,
See attached response. Contact me or Dr. Clarke if further information is needed.

Regards,
Dick

Dr. Richard E. Ewing
Vice President for Research
Texas A&M University
1112 TAMU
College Station, TX 77843-1112
Phone: (979) 845-8585
FAX: (979) 845-1855
E-mail: richard-ewing@tamu.edu

>>> "Clark, Matthew" <Matthew.Clark1@dhs.gov> 6/11/07 3:55 PM >>>
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3. DHS will recommend that ONR approve a no-cost extension for the existing FAZD grant until December 31, 2007, subject to the same conditions as 1 and 2 above.

4. TAMU will hire personnel and establish mechanisms to ensure full compliance with all regulations, as well as exemplary day-to-day operational management of all FAZD functions. One approach would be for

TAMU to establish a full-time position of Chief Operating Officer (COO) or a similar position who will report directly to the Dean of Research at TAMU and have unfettered access, communication and accountability to the DHS Offices of University Programs and Regulatory Compliance. This position would be responsible for all compliance, planning, reporting, budgeting, and accountability issues associated with FAZD, including, for example, that: all proper procedures are in place, all financial and project reports are submitted on time, all projects are on schedule, all projects have transition plans to provide useful results, and all projects are coordinated with other Centers of Excellence and with the S&T Chem-Bio Division, USDA and FDA, as feasible. An example of a potential COO candidate would be someone affiliated with the TAMU business school, as recommended by external reviewers at FAZD's biennial review in September 2006. This position may be funded through the COE grant or with other A&M funds.

We will move forward with the FAZD extension grant as quickly as possible once we have had an opportunity to consider your response to this email, your agreement to these conditions and your plans to implement condition #4.

Thank you for your cooperation, and I look forward to working closely with TAMU in the future.

Regards,

Matt

Matthew Clark, Ph.D.

Director, University Programs

DHS Science and Technology Directorate

Office of the Vice President for Research

Richard E. Ewing
Vice President for
Research

June 18, 2007

Dr. Matthew Clark
Director, Office of University Programs
Science and Technology Directorate
Department of Homeland Security
Washington, DC

Dear Dr. Clark,

I previously acknowledged receipt of your e-mail message of June 11, 2007, describing the conditions for extending the FAZD Center grant. This letter formally responds to your message.

We understand and accept the first three conditions for extending the grant and propose an implementation plan for the fourth condition. Details follow.

1. DHS University Programs will provide no funding for select agent or other biological laboratory activities at TAMU until the university has been given a clean bill of health by both the CDC and S&T's lead compliance officer. This requires certification for TAMU having the proper policies, procedures, training, and accountability measures in place to handle select agents and other biological materials.

   This condition is accepted.

2. TAMU must provide DHS with a new and detailed cost proposal with all biological laboratory work held in abeyance.

   The budget breakdown was provided to your office on June 12, 2007.

3. DHS will recommend that ONR approve a no-cost extension for the existing FAZD grant until December 31, 2007, subject to the same conditions as 1 and 2 above.

   As you know, ONR has restricted biological laboratory research at Texas A&M University involving select agents pending the outcome of the CDC and DHS review of the incident. We presume the continuation of this restriction with the no-cost extension, unless the matter is settled sooner. We have requested that ONR extend the current grant for 12 months to ensure that all funds are properly expended. We have a definitive plan for ensuring that expenditures are kept separate between the current and new grant.

Texas A&M
University

College Station, Texas

4. There are several components to the fourth condition. Below I am providing a summary of the response to the stated conditions for continuation. Attachment 1 includes supplemental information to support this summary.

   Summary of Response to Stated Conditions for Continuation:

   - Texas A&M is reviewing and will revise as needed the current mechanisms and documentation procedures to ensure full and transparent compliance with all regulations, and will establish a focal point for the related compliance and safety aspects of working with select agents and other potentially hazardous materials. This will serve as a point of contact for DHS counterparts to obtain ongoing and timely information on status of projects involving such materials.

   - Texas A&M will recruit an Associate Director of the FAZD Center who will have major responsibility for oversight and management at the Center level of ongoing research projects.

   - Current procedures in the FAZD Center, shown by the expanded management report contained herein are providing timely and accurate reporting both by the Center partners to its headquarters and from the Center headquarters to DHS.

   - The management plan submitted as part of the renewal proposal shows that all projects will have transition plans including relationships to established priorities and identification of and engagement with potential customers as well as identified pathways from discovery to application.

   - The management plan and subsequent and ongoing reports show that the Center is actively engaged with other COEs and that joint projects are both ongoing and emerging.

   - The management plan explicitly shows how the Center is engaging other parts of government, especially the national laboratories, other federal laboratories, and the operating agencies and customers in USDA and HHS.

   - Effective and continuing engagement is being maintained with the Chem Bio Division of the S&T Directorate, the Office of Health Affairs, the Infrastructure Protection Division, and other parts of the DHS. Dr. John Vitko has commended the renewal work plans as being relevant and complimentary to the other parts of the Chem Bio Division's agenda.

   - The Center's Assistant Director for Administration has an undergraduate degree in Communications and a Masters of Business Administration – contributing to the assurance that adequate business expertise in this area is represented in the Center leadership.

- The DHS Office of University Programs has immediate and ongoing access to the Center's leadership, including Director, the assistant and associate directors, and the Science Leaders who have current knowledge about the programs under their theme.

- The FAZD Center leadership will ensure that partner institutions working on select agents and related hazardous materials are engaged with their appropriate biosafety and compliance offices and will be assured that they are in compliance with established procedures.

I believe this provides the response for us to move ahead with the renewal process. Please let me or Neville Clarke know if further information is needed.

Sincerely,

Richard E Ewing

Dr. Richard E. Ewing
Vice President for Research

Attachment

pc: Dr. Neville P. Clarke

Attachment 1
Supplemental Information
Dr. Matthew Clark Message Dated June 11, 2007

Below is supplemental information in response to condition four. The following information is included below:

- Compliance and Safety Related Actions
- Response on Management and Leadership by the FAZD Center
- Current Management and Leadership of FAZD Center

Compliance and Safety Related Actions

An internal review of the compliance functions at Texas A&M University is being conducted as we await the specific guidance from CDC. We will continue to be responsive to the laws, regulations, and policies of the CDC and APHIS. I will take all necessary actions to ensure that Texas A&M is aggressively pursuing a course of action to make it an exemplary institution relative to assuring compliance on a continuing basis. An Associate Vice President for Research in the Office of the Vice President for Research at Texas A&M has been designated to be the specific focal point that brings together all aspects of its compliance functions. This Associate VP for Research will supervise a new Coordinator of Research Compliance to be hired. This person will provide coordination and communication among the Office of Research Compliance, the Office of Environmental Health and Safety and the National Center for Foreign Animal and Zoonotic Disease Defense (FAZD Center) at Texas A&M with respect to animal care and use, biosafety, radiological safey and occupational health and safety issues. The Associate VP for Research will communicate with the Department of Homeland Security full and ongoing information and status about these procedures and information related to any future incidents should they occur. We will also work with the DHS Compliance Office on matters in their area of responsibility such as animal use permits, as needed.

Counterpart compliance offices in the the FAZD Center's partner institutions that do biological research and/or those using select agents as part of the Center's subcontracts will be responsible for assuring full compliance with laws, policies, and procedures governing those experiments at their institutions. As part of the renewal process, the FAZD Center will require that partners confirm that plans of work are developed that meet all compliance requirements and protocols are approved by CDC or APHIS in studies using select agents. The FAZD Center is stating as a condition of the subcontracts with its partner institutions that it will be informed of any incidents, should they occur, requiring reporting to CDC or APHIS at the time they occur. In turn, the FAZD Center and my office are committed to informing DHS of any such incidents as they become known to the Center.

Response on Management and Leadership by the FAZD Center

The leadership of the FAZD Center maintains an active communication with me and my office for planning, progress, and issues requiring attention at the administrative level in the Texas A&M. I continue to be fully supportive of the FAZD Center and its work within Texas A&M and with its partners. I have every confidence in the Director of this Center whose reputation and performance in leadership at this university and elsewhere are recognized as exemplary. I believe that the Center leadership has and continues to communicate with DHS to provide all expected planning, reporting, and other communications called for by the Department. We believe the recommendations of the External Review Committee are fully addressed in the management section of the work plans for renewal previously submitted. There is an active and growing engagement between the FAZD Center and the other DHS

Centers of Excellence. The Center has been able to expand its engagement with its customers very substantially as a result of the reorganization of the DHS Directorate of Science and Technology. The Center is aligned primarily with the Chemical-Biological Division and the Director of that Division. Dr. John Vitko, Director of the Division, has strongly endorsed the renewal plan of work submitted by the Center as being responsive and complimentary to the overall strategy of that division and the expectations related to the reorganization of the Directorate. The Center has active and growing involvement, engagement, and collaboration with other relevant departments of government, including several parts of USDA and the CDC.

Notwithstanding my strong conviction that the Center is functioning very well, the Director and I recognize that the level of engagement needed within and outside DHS, the more dynamic funding strategies, and the growing needs and opportunities for coupling with customers and collaborators place increasing responsibilities for leadership and management at the level of the Center headquarters. I understand that you have recognized this as an important issue and have encouraged the establishment of a new position with responsibilities for the operational aspects of the Center – establishing a team that can more effectively operate in an environment with expanding demands for engagement.

Therefore, my plan is to endorse your and now the Director's proposal that a "number two" associate director be recruited to focus on the operational aspects of the Centers ongoing operations, providing additional time for the current Director to provide leadership at a strategic level with continuing overall responsibilities for the Center. Texas A&M will provide partial support for the salary of this new position, with DHS also providing partial support, as you have suggested. Our intent is to immediately begin to recruit for this position with the goal of filling it as soon as a suitable candidate can be brought aboard. The incumbent for this position must have both the scientific background and management experience to meet the immediate needs described herein for enlightened leadership.

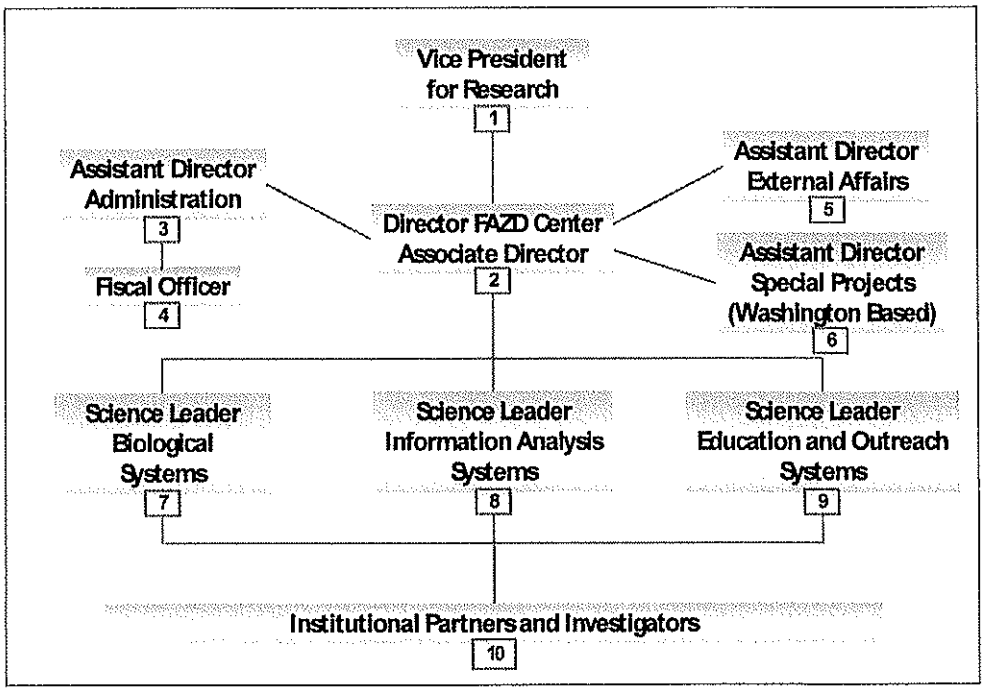
With regard to regulatory compliance related to research using select agents and other issues related to appropriate management of biological research, the incumbent in the new position will also be expected to maintain an ongoing awareness of research and education activities involving the use of select agents both here at Texas A&M in the partner institutions of the Center and be prepared to communicate with DHS on a continuing basis regarding this research.

The Director and Associate Director will continue work with the three Science Leaders that have oversight responsibility for the three major themes of the Center. These individuals have recognized specialized expertise in the areas of research defined in the three themes. They will function as part of the Center leadership team and serve as members of its Executive Committee in ensuring leadership in planning, budgeting, implementing, and evaluating the agenda for the Center. In accordance with your direction, we also have a part time member of the Center located in the Washington area, who functions as the Assistant Director for Special Projects Center that is able to engage our customers and collaborators as well as your office as need arises.

Our intent is to recruit a person for the Associate Director position that will have the ability to provide leadership for the overall ongoing day to day operations of the Center both in terms of scientific expertise and leadership/management experience. Recruiting this person will require at least six months. Meanwhile, I believe that the Center has the resources and organization in place to fully comply with your perceived needs for leadership and management. We are providing an expansion of the management plan previously submitted as part of the renewal process which shows explicitly how the responsibilities for leading and administering the Center are being handled.

Current Management and Leadership of FAZD Center

The renewal proposal contains a substantial section on management of the Center which includes responses to the findings of the External Site Visit of September 2006 as well as the process of planning, engaging investors and customers, and reporting. This document has been slightly updated to reflect changes resulting from inputs from the Office of University Programs and the Chemical and Biological Division of the Science and Technology Directorate. It is resubmitted as a background document. The following document more specifically addresses the leadership functions in the office of the Director and related distributed leadership and management functions across the Center and better defines how these functions address the concerns identified in your message.

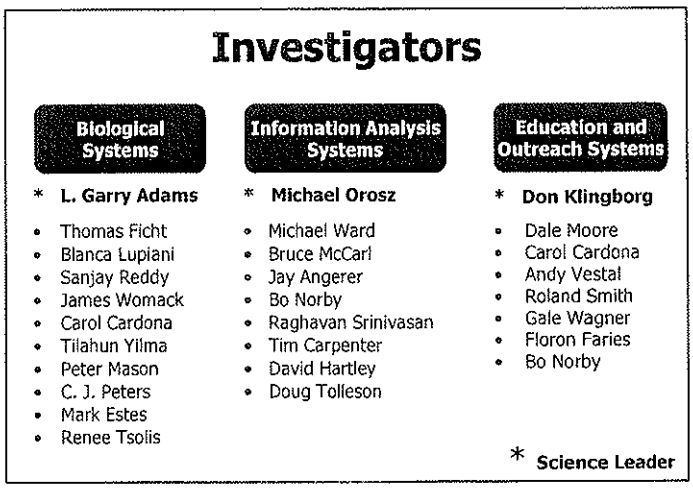


1. The FAZD Center is a component part of the Office of the Vice President for Research, which has administrative oversight for the center.
2. The Director of the FAZD Center has overall leadership responsibility for strategic planning, organizing, executing, advocating, evaluating, and engaging the customers and investors for the Center. The new position of Associate Director will provide day to day management of current programs to compliment the function of the Office of the Director.
3. The Assistant Director for Administration, who has an undergraduate degree in communications and a Masters degree in Business Administration (MBA), is responsible for administrative matters including fiscal and human resources management, engagement with partner institutions on administration of the grant and its subcontracts, organizing and engaging the Internal and External Advisory Committees, oversight of other administrative staff in the Center Headquarters and communication with counterparts in the Office of University Programs and other organizations in DHS. The Assistant Director maintains ongoing engagement with the External and Internal Advisory Committees, providing information, organizing agendas and facilitating meetings.

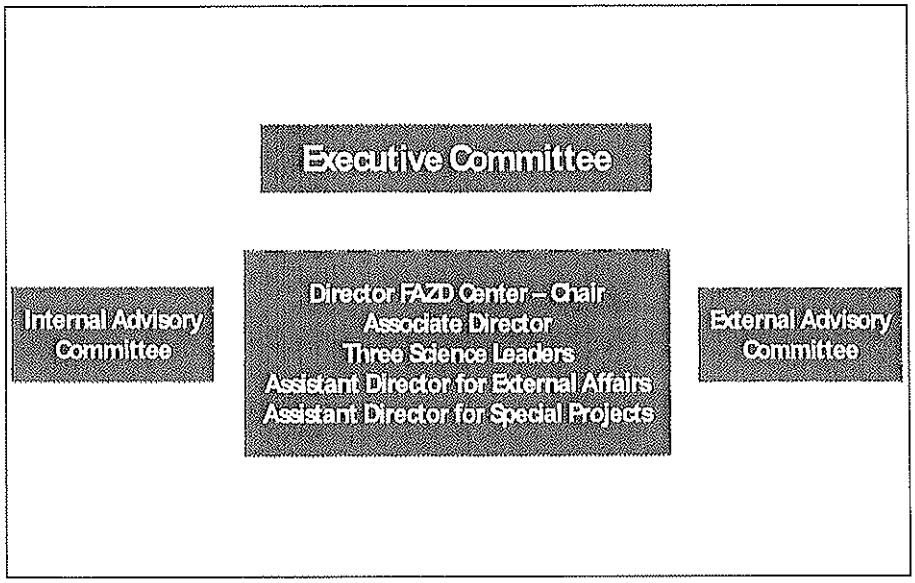
4. The Fiscal Officer for the Center participates in developing financial plans and organizes the budgets for the Center and its subcontractors – working with counterparts in partner universities and with the Grants and Contracting Office at TAES, which has overall responsibility for engagement with the granting agency and with partner institutions on formal contracts. The Fiscal Officer supports the Science Leaders in the development and monthly monitoring of expenditures, provides related reports to Science Leaders and works closely with the Center Director on fiscal affairs. The Fiscal Officer prepares financial reports for the DHS sponsor.
5. The Assistant Director for External Affairs is responsible for developing and maintaining effective engagement with the several granting agencies in DHS and elsewhere and in creating FAZD Center collaborators in responding to and developing proposals for new research to augment core funding of the Center. The Assistant Director facilitates the development of new proposals and engagements between PIs in the Center and sponsors of new research and education.
6. The Assistant Director for Special Projects is responsible for establishing and maintaining the Science and Education Network for Foreign Animal and Zoonotic Disease (SENFAZD) – a consortium of related university and other agency programs that are involved in gap analysis, identification of new projects and maintains an ongoing engagement and represents the Center in ongoing meetings with the Office of University Programs, the Science and Technology Directorate, the Office of Health Affairs, and other elements of the DHS that are investors and customers. The Assistant Director is Washington based and therefore readily available (as you have directed) to represent the center on short notice for such engagements. As a member of the Executive Committee, he is fully informed about the affairs of the Center and can act on its behalf as needed in emergency decisions.

7-10. Science Leaders and Principal Investigators Center leadership involves a distributed system of decision makers with specific levels of authority and responsibility. The Center Director serves as the Chief Operating Officer. The Associate Director shares responsibility with the Director for matters dealing with overall policy and direction.

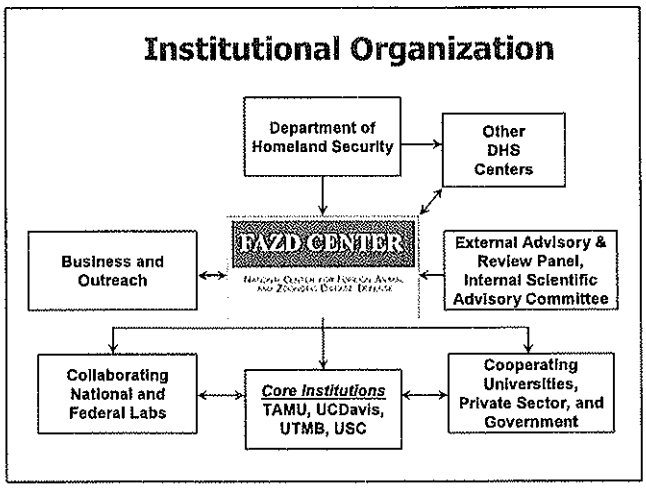
The three main themes of the Center are led by senior scientists with national and international reputations in their field. They have responsibility for leadership of PIs working within and across themes and translate general assessments of priority and need into specific targets for research and education. This includes developing Center investment strategy and translating needs and opportunities into specific goals and objectives. Science leaders monitor ongoing research in their themes, ensure ongoing communication among PIs, provide ongoing programmatic guidance and ensure appropriate use of funds. They ensure that periodic reports from PIs are made and prepare summaries of these reports for sponsors.



Principal investigators propose and defend proposals and are responsible for performance of funded projects. In most cases, the overall design of research and education is interdisciplinary and usually inter-institutional. Communication between PIs and at the Science Leader level is ongoing and critical to maintaining linkages. PIs supervise the activities of research associates, graduate students and post doctoral fellows working on their projects.



The Executive Committee is responsible for consensus based strategic planning, development of overall program goals and objectives, recommendations on assignment of resources, evaluation of progress, and ongoing communication with investors, operational users, and intermediate collaborators and customers. This committee meets at least quarterly and often more frequently and maintains ongoing electronic communication.



This chart shows the broader institutional relationships of the Center, including its other collaborating and cooperating partners. The External Advisory Committee is made up of senior practicing scientists, representatives from the private agricultural sector, government officials involved in foreign animal and zoonotic disease at state and federal levels and representatives from the biologics and pharmaceutical industries. The committee has formal terms of reference that call for their providing advice on priorities and program construction and in evaluating progress on at least a semi-annual basis. The members of the committee provide an important perspective on key issues and concerns in the private sector, approaches and activities in relevant government agencies and offer very valuable advice on linkages, funding, and overall direction. The Committee is being expanded to provide more regional and commodity representation as well as a broader representation of the science base for the Center. The committee will have a more active role in advising on future priorities and in program evaluation.

The Internal Advisory Committee (IAC) is comprised of principal investigators and is organized under the three themes. The IAC usually meets twice each year in two day sessions with both plenary and breakout sessions. The IAC provides a forum of PIs for discussing research strategy and agendas, developing proposals, peer review of progress, and discussion of opportunities for collaboration.

From: Angelia Raines
To: Ewing, Richard
Date: 1/19/2007 5:32 PM
Subject: Confidential - SBAT Discrepancy Report
Attachments: SBAT Discrepancy Report -Ficht-1-19-07.doc; Angelia Raines.vcf

CC: Agnew, Tiffany; Bazer, Fuller; bertvk@tamu.edu; Cantrell, Carol; c-m...
CONFIDENTIAL

Attached is a Select Agent discrepancy report for Dr. Thomas Ficht. A discrepancy occurs when any quantity of a select agent can not be accounted for.

The discreapncy occured on 1/11/07, and was resolved immediately. Please review the attached report and let me know if you have questions or changes.

Thank you,
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

CONFIDENTIAL

Report of SBAT Discrepancy

On January 11, 2007, at approximately 11:45 a.m., Dr. Thomas Ficht reported a discrepancy in the amount Select agent in his lab. There appeared to be one missing vial of working cultures.

Based on the discrepancy, Dr. Ficht immediately activated his incident response process. He contacted UPD (Bert Kretzschmar). I was contacted next and I informed the Responsible Official's designee, Carol Cantrell. Chris Meyer, John Salsman and Brent Mattox were also contacted.

There was no evidence of a security breach, however the lab was locked and work was temporarily halted. Bert Kretzschmar (UPD), Brent Mattox (EH&S) and Thomas Ficht investigated. All employees were interviewed as a group and individually. The area was also searched and the missing vial was located. It had been properly used and disposed.

The discrepancy was resolved at approximately 2:50 p.m.

The discrepancy was documented and will be on file with UPD, the PI and with the Office of Research Compliance.

CDC Select Agent regulations (7 CFR 331.19, 9 CFR 121.19, and 42 CFR 73.19) require that the entity notify them "immediately upon discovery of a **theft** (unauthorized removal of select agent or toxin), **loss** (failure to account for select agent or toxin), or **release** (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a select agent and toxin. "

After initially reporting (via phone and or email) the incident, we are required to complete the APHIS/CDC Form 3 and submit it to CDC within 7 calendar days.

This incident was not reported to the CDC because it was considered to be a discrepancy and because the discrepancy was immediately resolved within the lab.

Following the incident, Dr. Ficht and his staff reviewed their plans and SOPs. They have made the following changes:

1. Label all tubes in the BSL3 lab and record this immediately in laboratory notebook and in a log of cultures incubating in the lab. Always record the number of working stocks created and destroyed in your laboratory notebooks.
2. Encrypt sample identification to prevent personnel from taking or using cultures in error. Label caps and tubes to make certain that nothing has been switched.
3. The PI will evaluate notebooks on a weekly basis and verify that all personnel maintain records of the number of working stocks created and destroyed.

Report submitted by: Angelia Raines
Report submission date: 1/19/07

SBAT Discrepancy Disposition - select one of the following:

X Resolved
___Determined to be a theft and reported to CDC immediately on _____(date)
___Determined to be a loss and reported to CDC immediately on _____(date)
___Determined to be a release and reported to CDC immediately on _____(date)

If reported to CDC:

Reported to: N/A (CDC Representative's name)
Reported by: N/A (The person who reported it to CDC)

Form 3 Completed and submitted to CDC on NA (date)

CONFIDENTIAL

From: "Fuller Bazer" <fbazer@cvm.tamu.edu>
To: <richard-ewing@tamu.edu>
Date: 4/23/2005 9:04 AM
Subject: Re: Fwd: Posting of Select Agent Forms [F20050422A]2

Thanks Dick. Fuller

Fuller W. Bazer, Ph.D., Regents Fellow, Distinguished Professor and O.D. Butler Chair in Animal Science
Associate Vice President for Research
Texas A&M University
Telephone: 979-458-2876
Cell Phone:
Facsimile: 979-845-1855
email: fbazer@cvm.tamu.edu
URL: http://recovery.tamu.edu
URL: http://animalscience.tamu.edu/ansc/index.htm

>>> "Richard Ewing" <richard-ewing@tamu.edu> 04/22/05 3:30 PM >>>
FYI

Dr. Richard E. Ewing
Vice President for Research
Texas A&M University
1112 TAMU
College Station, TX 77843-1112
Phone: (979) 845-8585
FAX: (979) 845-1855
E-mail: richard-ewing@tamu.edu

>>> "Laboratories Registration/SAT" <lrsat@cdc.gov> 4/22/05 11:01:00 AM >>>
Please be advised that the Centers for Disease Control and Prevention (CDC) and Animal and Plant Health Inspection Service (APHIS) Select Agent Programs forms are now available on their respective websites. These new forms supersede all forms previously in use and should be used when submitting new information to the Programs. The HHS final rule and additional information can be viewed at http://www.cdc.gov/od/sap and the USDA final rules and additional information can be viewed at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

Please be reminded that CDC and APHIS adopted a shared numbering system for the identical forms that uses the prefix "APHIS/CDC Form":

* APHIS/CDC Form 1 - Application for Laboratory Registration for Possession, Use, and Transfer of Select Agents and Toxins (CDC Form 0.1319/APHIS Form 2040) * APHIS/CDC Form 2 - Report of Transfer of Select Agents and Toxins (CDC Form EA-101/APHIS 2041)
* APHIS/CDC Form 3 - Report of Theft, Loss, or Release of Select Agents and Toxins (CDC Form 0.1316/APHIS 2043)
* APHIS/CDC Form 4 - Report of Identification of a Select Agents or Toxin in a Clinical or Diagnostic Laboratory (CDC Form 0.1318/APHIS 2044)
* APHIS/CDC Form 5 - Request for Exemption of Select Agents and Toxins for Public Health or Agricultural Emergency or

Investigational/Experimental Product (CDC Form 0.1317/APHIS 2042)

If you have questions regarding this correspondence, please contact your designated CDC representative. If you are unsure who your designated CDC representative is, then please call 404-498-2255.

Charles Brokopp, DrPH
Director, Select Agent Program
Centers for Disease Control and Prevention
1600 Clifton Road N.E., MS E-79
Atlanta, GA 30333
Telephone: 404-498-2255; FAX: 404-498-2265

From: "Fuller Bazer" <FBazer@cvm.tamu.edu>
To: <j-calvin@tamu.edu>, <richard-ewing@tamu.edu>
Date: 2/20/2006 7:31 PM
Subject: Fwd: CDC Communications
Attachments: CDC Communications

Dick and Jim. This is an FYI,but important change so that Angie can provide better oversight of communications with CDC. Fuller

Fuller W. Bazer, Ph.D., Regents Fellow, Distinguished Professor and
O.D. Butler Chair in Animal Science
Associate Vice President for Research
Texas A&M University
Telephone: 979-458-2876
Cell Phone:
Facsimile: 979-845-1855
email: fbazer@cvm.tamu.edu
URL: http://recovery.tamu.edu
URL: http://animalscience.tamu.edu/ansc/index.htm

From: "Fuller Bazer" <FBazer@cvm.tamu.edu>
To: "Richard Ewing" <richard-ewing@tamu.edu>, "Angelia Raines" <ARaines@vprm...
Date: 1/19/2007 5:43 PM
Subject: Re: Confidential - SBAT Discrepancy Report

CC: <bertvk@tamu.edu>, "Brent S Mattox" <bsmattox@tamu.edu>, "Carol Cantrell...

Hi Angie, The following part of the report is not clear to me. I understand that the vial had been properly used, but what is meant by "disposed." Does this mean the sample was returned to secure site, but not in proper location, or disposed of following autoclaving etc?
There was no evidence of a security breach, however the lab was locked and work was temporarily halted. Bert Kretzschmar (UPD), Brent Mattox (EH&S) and Thomas Ficht investigated. All employees were interviewed as a group and individually. The area was also searched and the missing vial was located. It had been properly used and disposed.
Thanks for clarification. I think that this should be added to report.

Thanks and have a good weekend. Fuller

Fuller W. Bazer, Ph.D., Regents Fellow, Distinguished Professor and
O.D. Butler Chair in Animal Science
Associate Vice President for Research
Texas A&M University
Telephone: 979-458-2876
Cell Phone:
Facsimile: 979-845-1855
email: fbazer@cvm.tamu.edu
URL: http://recovery.tamu.edu
URL: http://animalscience.tamu.edu/

>>> "Angelia Raines" <ARaines@vprmail.tamu.edu> 01/19/07 5:32 PM >>>

CONFIDENTIAL

Attached is a Select Agent discrepancy report for Dr. Thomas Ficht. A discrepancy occurs when any quantity of a select agent can not be accounted for.

The discreapncy occured on 1/11/07, and was resolved immediately. Please review the attached report and let me know if you have questions
or changes.

Thank you,
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

From: "Fuller Bazer" <FBazer@cvm.tamu.edu>
To: "Richard Ewing" <richard-ewing@tamu.edu>
Date: 4/21/2007 11:19 AM
Subject: Re: Fwd: Texas A&M Brucella Exposure Incident

CC: <araines@vprmail.tamu.edu>
Thanks Dick. I am sorry that I have not been here for this series of events and now one with Q fever. Angie wished to have reporting of such under ORC because there is too much confusion when one depends on another office and proper reporting is not done. This allows negative aspects of an event to be amplified. I doubt that CDC has provided comments or insights, but hope this issue is resolved soon. I am not sure why HLS is involved with more questions to Neville as they have delegated such to CDC and, in some circumstances, to USDA, e.g. outdoor pens. Fuller

Fuller W. Bazer, Ph.D., Regents Fellow, Distinguished Professor and O.D. Butler Chair in Animal Science
Associate Vice President for Research
Texas A&M University
Telephone: 979-458-2876
Cell Phone
Facsimile: 979-845-1855
email: fbazer@cvm.tamu.edu
URL: http://recovery.tamu.edu
URL: http://animalscience.tamu.edu/

>>> "Richard Ewing" <richard-ewing@tamu.edu> 04/17/07 7:48 AM >>>

All,
I don't want to defocus anyone from the ongoing CDC visit, but wanted to let everyone know we are also being asked questions by DHS since the experiment was funded by DHS through FAZD.
Dick

Dr. Richard E. Ewing
Vice President for Research
Texas A&M University
1112 TAMU
College Station, TX 77843-1112
Phone: (979) 845-8585
FAX: (979) 845-1855
E-mail: richard-ewing@tamu.edu

>>> "Clark, Matthew" <Matthew.Clark1@dhs.gov> 04/16/07 1:38 PM >>>
Neville,

As a follow-up to our phone call of Friday night, in which you notified
me of a Brucella exposure incident at Texas A&M, DHS needs more information to evaluate (1) the nature of the Brucella exposure incident, (2) the oversight of the Texas A&M select agent program, (3) the personnel changes that were implicated in the failure to report, and
(4) any additional measures that have been taken or may be warranted to
resolve the issue and ensure future compliance.

Please provide detailed written answers to the following questions:

* When exactly did the incident occur and when was it reported to CDC?
* Who at Texas A&M is now coordinating with CDC in addressing noncompliance issue resulting from the failure to report? What guidance and oversight is CDC now providing on follow-up federal compliance measures that need to be taken? Has the CDC assessed any penalties?
* What personnel and procedural actions is Texas A&M taking to remedy the situation?
* Who was the RO named on the registration at the time of the incident? Was this individual involved in the "personnel changes" that led to the failure to report? Who is the current RO on the University's registration? Please provide copies of the current Certificate of Registration and that held at the time of the incident to DHS for review and record keeping.
* The incident presumably involved one of the Brucella species (abortus, melitensis, or suis) that are listed as a CDC/APHIS overlap select agent.
* Did Texas A&M notify USDA-APHIS of the incident and submit Form 3 -- used to report theft, loss, or release of a select agent -- within 7 days? Note: The occupational exposure at Texas A&M would be considered a "release" based on the broader definition indicated on the form. Have both CDC and APHIS been involved in the noncompliance response?
* Was the laboratory work associated with the incident being conducted under the DHS grant through the COE? Was the work being conducted as it was described in proposals or protocols associated with the award?
* Was the exposure the result of an isolated procedural mishap that was known only to affect the individual involved, or was it linked to protocols, equipment, safety, or bio-containment measures that may present heightened exposure risks for other personnel? Were the protocols for aerosol chamber use/cleaning designed and/or reviewed in accordance with federal regulations and institutional policies? Were these protocols revised post-incident?
* Who was the PI overseeing the work associated with the incident? Was this PI named in the DHS Center proposal and on the select agent registration for work with both the agent itself and the laboratory involved in the exposure? Please provide verification from the application for select agent registration.
* Which Texas A&M administrators and/or oversight bodies were notified of the exposure? Please provide a clear explanation of the chain of events that caused TAMU to not call CDC or APHIS or submit a Form 3 immediately following the incident.
* What steps have been taken to coordinate with CDC in addressing both the exposure incident and the lapse in oversight that resulted in failure to report? Has a Form 3 been submitted retrospectively? If so, please provide a copy to DHS for review. Has the CDC issued other

requirements with respect to the University's registration and/or select
agent program? Has CDC conducted any site visits or inspections in response to the incident?

Thank you for your cooperation.

Regards,

Matt

Matthew Clark, Ph.D.

Director, University Programs

Science and Technology Directorate

202-254-6377

From: "Fuller Bazer" <FBazer@cvm.tamu.edu>
To: "Richard Ewing" <richard-ewing@tamu.edu>
Date: 4/27/2007 6:54 AM
Subject: Re: Fwd: Lab Incident

Thanks Dick. I appreciate your note. I always appreciate collaborations to get the best job done, but it becomes difficult sometime if two people assume that they are responsible for the same activities. Our relationship with environmental health and safety in terms of coordination of efforts and reporting to you and Provost/President needs to be improved. If you are agreeable, I will talk to Chris Meyers about this next week.

Thanks, Fuller

Fuller W. Bazer, Ph.D., Regents Fellow, Distinguished Professor and O.D. Butler Chair in Animal Science
Associate Vice President for Research
Texas A&M University
Telephone: 979-458-2876
Cell Phone:
Facsimile: 979-845-1855
email: fbazer@cvm.tamu.edu
URL: http://recovery.tamu.edu
URL: http://animalscience.tamu.edu/

>>> "Richard Ewing" <richard-ewing@tamu.edu> 04/27/07 6:04 AM >>>

Fuller,
On the contrary, I think that you and Angie are a great team and are working very well together. I don't want to hurt that relationship. You have effectively worked together on compliance and audit issues, and I appreciate that. I really need your knowledge of the scientific aspect of the research issues that Angie doesn't have and your respect in the academic community.
When we talked yesterday, we discussed that we need to pushto get a better product than Info Ed in plase to help with automated tracking of ourresearch compliande. We also noted that post award support of investigators in general was extremely important for working with selsct agents. Leonarda worked for Carol while developing Epic. If we decide to move this way, Carol can be helpful in working with her. Also, Contracts from all sources will route through Charlene Miller on the front end, and we can work together to put some safeguards in the process at that end.
There is no intention for Angie to Duplicate efforts or to reduce your oversight and support. I just think that a strengthened contract approval and routing process for dealing with select agents will improve our due dilligence process. I'll be happy to discuss this more with you. Thank you for the great work that you do for our team!
Dick

Dr. Richard E. Ewing
Vice President for Research
Texas A&M University
1112 TAMU
College Station, TX 77843-1112
Phone: (979) 845-8585
FAX: (979) 845-1855

E-mail: richard-ewing@tamu.edu

>>> "Fuller Bazer" <FBazer@cvm.tamu.edu> 04/21/07 8:12 AM >>>
Hi Dick, Just asking for a point of clarification as to Carol's role here. Angie and I have been working together on complicance issues and audits such as this one, but it is not clear if a change has been made in that Carol now provides interface with you on these issues. I am not trying to gaurd any territory, but just don't want to have Angie duplicating efforts if that is not necessary. Thanks, Fuller

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O.D. Butler Chair in Animal Science
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email: fbazer@cvm.tamu.edu
URL: http://recovery.tamu.edu
URL: http://animalscience.tamu.edu/

From: "Mattox, Brent S" <bsmattox@tamu.edu>
To: "Raines, Angelia" <araines@vprmail.tamu.edu>
Date: 5/3/2007 9:32 AM
Subject: RE: Incident Report

CC: <f-bazer@tamu.edu>, "Salsman, John M" <jmsalsman@tamu.edu>, <t-ficht@tam...
Angelia:

This is indeed an exempt strain (S19) and is not regulated as a select agent. However, potential exposures to any potentially infectious agents are of concern to the Occupational Health Program. Strain 19 vaccines have caused disease development in laboratory workers through accidental self-inoculation. I would note that the risk of disease development from this particular event is extremely unlikely, if not impossible. Although the individuals will be enrolled in our testing program for titers, I do not consider it likely any positive results will be found.

EHSD will work with the researcher to improve decontamination procedures at the Veterinary Research Park, but no work being performed prior to the incident would have generated an aerosol. Person to Person contact causing illness is extremely rare, with no documented cases from casual contact.

A final report should be available in a few days.

Sincerely,

Brent S. Mattox, CIH

-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Wednesday, May 02, 2007 7:32 PM
To: Mattox, Brent S
Cc: f-bazer@tamu.edu; Salsman, John M; t-ficht@tamu.edu; Tiffany Agnew
Subject: Fwd: Incident Report

Hi Brent,

I believe the attached email is in reference to the incident Tom Ficht contacted you about. I was contacted this afternoon. If I understood the information correctly, the incident involved an exempt vaccine strain of Brucella.

Two people came into contact with a member of the research team who had not yet completed decontamination procedures. They have been asked to undergo medical monitoring. He also indicated that the research team has been re-trained on the safety protocol. I asked him to send an email to you today, detailing everything that happened as well as what steps have been taken to ensure personnel safety. I have also asked him to report this to the IBC. Please let me know immediately, if the strain is not exempt.

By way of this email, I am asking Tiffany to contact you and the IBC Vice Chair to discuss the review/investigation process. She can also discuss the reporting/documentation requirements.

Thank you,
Angelia

From: "Fuller Bazer" <FBazer@cvm.tamu.edu>
To: "Carol Cantrell" <C-Cantrell@tamu.edu>, "Julie Barker" <j-barker@tamu.ed...
Date: 5/3/2007 10:26 AM
Subject: Re: Fwd: FW: Incident Report

Thanks Jim. The good news is that the agent was not a select agent, but we do now have plans for a review process from outside experts that should help. The fact that SOPs were in place and known to PI, but were not adhered to by member of the lab. The reporting issue is under review also by Patriot Act Task Force.

Fuller

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email: fbazer@cvm.tamu.edu
URL: http://recovery.tamu.edu
URL: http://animalscience.tamu.edu/

>>> "James Calvin" <j-calvin@tamu.edu> 05/02/07 10:46 PM >>>

>>> "Carlson, David S." <DSCarlson@tamhsc.edu> 5/2/2007 8:50 pm >>>

From: Carlson, David S.
Sent: Wed 5/2/2007 5:21 PM
To: Dickey, Nancy W.; Alicia Dorsey; Nelson, Barry C.; Joyce, Jim; Van Wilson; Colenda, Christopher; Hanks, Clay D.; Venuti, Douglas; Scholtz, J. Marty
Cc: Bishop, Julie; Raines, Angelia
Subject: Incident Report

Dear All,

Today I received a copy of a memorandum (dated April 30, 2007) regarding a "report of incident" of potential exposure of two HSC employees to a select agent. Upon further investigation and in cooperation with the TAMU Office of Compliance, it was determined that the agent in question is exempt; therefore, the incident does not constitute a reportable event. Because it did constiute a potential safety issue and health-monitoring was involved, however, the PI did notify the Office of Environmental Safety, as required. This incident will be reviewed by the IBC and a report will be provided through the TAMU Office of Compliance to the HSC Office of Environmental Safety and

HSC Office of Research. No additional reporting is indicated at this time.

Although this specific incident apparently does not constitute a problem, it does further indicate the importance of awareness of the policies and procedures for communicastion regarding potential incidents involving research and laboratory safety. This matter will be reviewed by the HSC Office of Research in cooperation with the Office of Facilities and Safety.

David S. Carlson, PhD

Regents Professor

Vice President for Research & Graduate Studies

Texas A&M Health Science Center

From: "Fuller Bazer" <FBazer@cvm.tamu.edu>
To: "David S. Carlson" <DSCarlson@tamhsc.edu>
Date: 5/9/2007 6:29 AM
Subject: RE: Adverse Event Report and SBAT Incident Report

CC: "Richard Ewing" <richard-ewing@tamu.edu>, <araines@vprmail.tamu.edu>
Hi Dave, We are working on new reporting information now and will discuss them with you soon. At present, Angie's office is working on a response to CDC that is extensive and must be completed by the end of next week. Thanks, Fuller

Fuller W. Bazer, Ph.D., Regents Fellow, Distinguished Professor and
O.D. Butler Chair in Animal Science
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URL: http://animalscience.tamu.edu/

>>> "David S. Carlson" <DSCarlson@tamhsc.edu> 05/08/07 8:44 PM >>>

I have some substantive concerns about the document as is. These are summarized in the comments bleow from Jim Joyce and Victor Pantusa. I would like to discuss these issues before anything goes forward.
Thanks,
dsc

From Jim Joyce:
My main concern is that there continues to be no notification of the HSC (or other agency or institution as the case may be) in these procedures. Theoretically, since these are discussed at the IBC, the HSC member at those committees should bring the information back to the HSC. But this could be weeks or months after the event. And if the HSC members aren't at the committee meeting, the HSC may never be notified. There needs to be a step included in each of these processes to contact other institutions, if necessary.Also, the processes discuss contacting the "Responsible Official". I assume this is Dr. Ewing?? It's not clear whether the HSC has (or needs) a separate Responsible Official. Perhaps the HSC does for non-College Station activities??Thanks,
Jim----------
From Victor Pantusa:

Dr. Carlson,
My comments on the two IBC documents: For Both: Verify that PI*s and / or lab directors have copies of and are familiar with these two documents and their contents.601 Report of Theft, Loss, or Release from SBAT Facilities· 1.3 * Should include statement about completing First Report of Injury for occupational exposure (this may be required only for employees NOT enrolled in Occupational Health Program) · Include notification of HSC Administration (ie., VP Research, Chief Safety Officer, Director of

Admin, etc.) by the ORC or EHSD 602 Adverse Events involving a Biohazard / Reports of Non-Compliance · 7. Process Overview * Who e-mails the IBSP staff? Is this notification after the BSO and IBC are notified? · Same as above, I would like to see a statement that HSC (or other Agency depending on the affected employees) Administration will be notified. Victor Victor Pantusa, MSChief Safety OfficerTexas A&M Health Science Center

David S. Carlson, PhD
Vice President for Research & Graduate Studies
Texas A&M Health Science Center

David S. Carlson, PhD
Vice President for Research & Graduate Studies
Texas A&M Health Science Center

From: Tiffany Agnew [mailto:tmagnew@tamu.edu]
Sent: Fri 5/4/2007 12:51 PM
To: Tom Ficht; TESH@medicine.tamhsc.edu; a-wallis@tamu.edu; bertvk@tamu.edu; bsmattox@tamu.edu; jmsalsman@tamu.edu; Fuller Bazer
Cc: Angelia Raines
Subject: Adverse Event Report and SBAT Incident Report

Greetings All!

Per Angelia, attached you will find two policies we would like to put into effective by May 10, 2007- the Adverse Event Report Policy and the SBAT Incident Report Policy. Please feel free to provide your input no later than May 8, 2007, as we will attempt to notify the Research Community of the processes they will need to follow .

Thank you in advance for your assistance!

Regards,

Tiffany

Tiffany M. Agnew
Program Coordinator (Office of Research Compliance)
Texas A&M
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
(979) 458-3624
(979) 862-3176 - fax
tagnew@vprmail.tamu.edu

From: "Fuller Bazer" <FBazer@cvm.tamu.edu>
To: "Brent Mattox" <bsmattox@tamu.edu>, "Richard Ewing" <richard-ewing@tamu....
Date: 5/9/2007 6:43 AM
Subject: Fwd: Select agent check list
Attachments: Select agent check list

CC: "Thomas Ficht" <TFICHT@cvm.tamu.edu>, "Vernon Tesh" <TESH@medicine.tamhs...

Here is information (check list) from Bruce Brown at UTHSC Houston that we met with yesterday. Fuller

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From: "Brown, Bruce J" <bruce.j.brown@uth.tmc.edu>
To: <fbazer@cvm.tamu.edu>
Date: 5/8/2007 8:37 PM
Subject: Select agent check list
Attachments: SAT PROGRAM EVALUATION FORM.doc

CC: "Emery, Robert J" <Robert.J.Emery@uth.tmc.edu>, "Patlovich, Scott J" <sc...

Dr. Bazer,

I have attached our select agent survey form that we discussed at today's meeting. If you would be so kind to please distribute it to the group for use as a template to help create a select agent specific survey for your program, it would be greatly appreciated. Please let us know if we can be of any further assistance. Thanks, Bruce

Bruce J. Brown, MPH, CBSP, CHMM, ARM
Director, Environmental Health & Safety
The University of Texas Health Science Center at Houston
713-500-8100

The University of Texas Health Science Center at Houston
Environmental Health and Safety – Biological Safety Program
Comprehensive Select Agent/Toxin Program Evaluation Form

Date Surveyed:_____ Principal Investigator:_____

Lab location(s):_____ SAT used: _____

Registration / Security Risk Assessment	**YES**	**NO**	**N/A**
CDC/USDA registration current Date:_____	☐	☐	☐
Date of last CDC/USDA inspection _____			
Deficiencies adequately resolved, if any?	☐	☐	☐
Authorized personnel list is current	☐	☐	☐
Any employees leave since last inspection?	☐	☐	☐
If yes, please list name(s): _____			
Any new employees since last inspection?	☐	☐	☐
If yes, please list name(s): _____			
Security			
Visitor logs are in use	☐	☐	☐
Electronic door use log checked	☐	☐	☐
Unapproved guest / personnel are escorted	☐	☐	☐
Card reader properly functioning	☐	☐	☐
Guards are on patrol	☐	☐	☐
All packages are inspected upon arrival	☐	☐	☐
Video surveillance properly functioning	☐	☐	☐
All doors are closed and secured	☐	☐	☐
Equipment is properly secured (refrigerators, incubators, etc.)	☐	☐	☐
Process in place for exiting authorized personnel (badge deactivation, keys returned, passwords changed, etc)	☐	☐	☐
Inventory control records available?	☐	☐	☐
Date of last P.I. review of records _____			
Loss, theft, or compromise of the following:			
Select agent / toxin?	☐	☐	☐
Keys?	☐	☐	☐
Passwords?	☐	☐	☐
Records (i.e. inventory)?	☐	☐	☐

Biosafety

PPE entry requirements posted on lab door(s)	☐	☐	☐
Notice to Employees/Emergency/Spill info posted	☐	☐	☐
Written SOPs approved by IBC	☐	☐	☐
Aerosol producing procedures are contained	☐	☐	☐
Chem. hood verified within past year _____	☐	☐	☐
BSC certified within past year Exp._____	☐	☐	☐
Ventilation is negative to hallway	☐	☐	☐
Check and record HEPA Filter numbers			
Fire extinguisher available	☐	☐	☐
Adequately charged/inspection tag current	☐	☐	☐
Eyewash / shower available	☐	☐	☐
Inspection tag current	☐	☐	☐
Autoclave usage is properly documented (logs, spore strips, etc.)	☐	☐	☐
Personnel have received appropriate vaccinations	☐	☐	☐

Incident Response

Emergency egress plan established and adequate	☐	☐	☐
Spill response/decontamination SOPs established	☐	☐	☐
Emergency medical treatment / first aid available	☐	☐	☐
Reporting mechanism in place for incidents?	☐	☐	☐

Training

Initial select agent specific employee training completed for all individuals?	☐	☐	☐
Annual select agent regulations refresher completed for all employees?	☐	☐	☐
Personnel have attended required training (BLCS, BBP, Shipping ,DOT security, Rad Safety, other)	☐	☐	☐
Drill exercise for biosafety/incident response plan conducted at least annually?	☐	☐	☐

Transfers

Form 2 transfer paperwork reconciled	☐	☐	☐
Any transfer of select agent since last monthly inspection?	☐	☐	☐
DOT/ IATA shipping training received for all applicable employees?	☐	☐	☐

COMMENTS

Surveyed by RO / ARO: _____ **Date Surveyed:** _____

Reviewed by RO: _____ **Date Reviewed:** _____

From: "Fuller Bazer" <FBazer@cvm.tamu.edu>
To: "Brent S Mattox" <bsmattox@tamu.edu>, "Richard Ewing" <richard-ewing@tam...
Date: 5/15/2007 4:45 PM
Subject: Re: Elevated Coxiella Titer, BL3 ventilation Work

CC: "James Samuel" <JSAMUEL@medicine.tamhsc.edu>, "Chris Meyer" <c-m-meyer@t...
Thanks for this informat Brent. Fuller

Fuller W. Bazer, Ph.D., Regents Fellow, Distinguished Professor and
O.D. Butler Chair in Animal Science
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URL: http://animalscience.tamu.edu/

>>> "Brent S Mattox" <bsmattox@tamu.edu> 05/15/07 4:35 PM >>>

To All: EHSD has completed our investigation of the elevated Coxiella titer from Dr. Samuel*s Laboratory. A written report should be available by tomorrow and will be forwarded to the Office of Research Compliance. The following paragraph summarizes the findings. The individual had a baseline titer performed on 4/20/2007.Individual was CJIS approved and had accessed the Facility on four (4) occasions prior to the baseline.Laboratory Special Practices does call for baselines prior to exposure.The Facility Access was for , NOT the aerosol chamber housed The individual participated in blood drawing from animals that had been Coxiella on three of the dates, assisting the DVM.The DVM, who also conducted aerosol studies with Coxiella in the Madison Chamber, does not, and has never had a high titer.Individual has shown no signs or symptoms of illness, and is scheduled for a follow-up with S&W in June.Individual has possible previous exposure from Veterinary Diagnostic Lab work in China, working with cow serum. The conclusions drawn would suggest possible previous exposure, although lab exposure at TAMU, although remote, cannot be completely ruled out. Individual does work with antigens of Coxiella, which theoretically could cause elevated titers. Although a baseline titer should have been conducted or a serum sample collected prior to access, no unusual incidents or deviations from established protocols were noted. Individual was wearing a PAPR and protective clothing, and followed proper decontamination procedures. The DVM present during the blood drawing who ran a greater risk of exposure did not have elevated titers. COXIELLA EXPERIMENTS I have two other points on Coxiella burnetti aerosol research. Individuals (both DVMs) who were present during the Coxiella aerosol experiments have never shown elevated titers. The aerosol experiments are approved by CDC. Although the Brucella experiments are still awaiting amendments, CDC may wish to consider resumption of the aerosol work with Coxiella, as evidence supports its safe usage. Separately, Dr. Samuel indicated that they do indeed annually inspect all 2000 to 3000 vials (question raised in yesterday*s meeting). LAB VENTILATION I met with Physical Plant, Dave

Carlton of CMP, and a contractor today to formulate a plan to modify the ventilation bypass. Basically, we have decided to place caps between the bypass and the main filtration system to permanently seal it off from the air handling system. Upon observation, it was determined that the bypass duct would have to be relocated anyway if ever used, so the permanent *abandon in place* activity will have no effect on future plans. As to the cost/payment, we don*t have an estimate yet, but a work order is being generated by CMP. We will determine the funding source(s) once we have the estimate. Related to this issue, I have a meeting with Dr. Mackey (Occupational health Physician at S&W) tomorrow. If anyone has any questions for Dr. Mackey, let me know, but I will also be discussing the screening I am requiring for the contractor. Right now, that will include baseline titers for Coxiella and Brucella, along with TB testing. This is due to the fact we will be cutting into the unfiltered side of the duct. They will, of course, be wearing respirators and protective clothing. They will not be in the suite itself, but in the Penthouse. If anyone has any questions or concerns, please let me know. Sincerely, Brent S. Mattox, CIHBiological Safety Officer

From: "Fuller Bazer" <FBazer@cvm.tamu.edu>
To: "Bert Kretzschmar" <bertvk@tamu.edu>, "Brent S Mattox" <bsmattox@tamu.ed...
Date: 5/18/2007 4:40 PM
Subject: Re: Elevated Q Fever Titer

Thanks Brent. Fuller

Fuller W. Bazer, Ph.D., Regents Fellow, Distinguished Professor and O.D. Butler Chair in Animal Science
Associate Vice President for Research
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Cell Phone:
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email: fbazer@cvm.tamu.edu
URL: http://recovery.tamu.edu
URL: http://animalscience.tamu.edu/

>>> "Mattox, Brent S" <bsmattox@tamu.edu> 05/18/07 3:06 PM >>>

To All: A question was raised concerning the access had to the select agent, and if unauthorized access had occurred. As a result, I made an additional inquiry to reconfirm that no direct access to the agent had occurred during the periods of escorted entry into he veterinarian present and serving as the escort reconfirmed that no direct access to the agent or the blood samples had occurred. A revised copy of the initial investigation report is attached with an addendum added. The addendum summarizes my conversation with the veterinarian. In summary, there is no evidence that unauthorized access to the agent occurred. However, because a baseline serum titer was not taken prior to entering the facility, I cannot rule out with absolute certainty that incidental exposure a d not occur, even though the chance of exposure was extremely low. Sincerely, Brent S. Mattox, CIHBiological Safety Officer

From: Angelia Raines
To: Ewing, Richard
Date: 4/17/2007 8:20 AM
Subject: Update
Attachments: Angelia Raines.vcf

CC: Agnew, Tiffany; Bazer, Fuller

Yesterday after the CDC meeting, Brent informed me (and gave me some emails) regarding elevated titers for Q fever that occurred at the same time as the Brucella incident. I went back and looked at my previous emails and found that I was notified as well as the Provost and others. As with the other incident, my office thought Brent was handling this at the time and I did not create a record for it. I need to notify CDC immediately and I need to file a report.

Angie

Angelia Raines
Director, VPR Office of Research Compliance
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Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax

From: Angelia Raines
To: Ewing, Richard
Date: 4/17/2007 3:53 AM
Subject: Documents requested
Attachments: Documents Requested by CDC.doc; Angelia Raines.vcf

Attached are documents requested by CDC. In addition, they plan to interview all lab personnel, as well as the PI.

I will keep you updated...

Angie

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College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax

Documents Requested by CDC

4/16/07 – 5:30 pm

Items requested	**Requested from:**	Comments
1. Access records for	Ihrig	Records recd and given to CDC. Did not see records for Spoke with M. Ihrig and informed her that they were needed.
2. Study protocols for Dr. Ficht's Brucella	Ficht	Requested 4/16/07
3. Culture results for aerosol chamber after cleaning	Ficht	Requested 4/16/07
4. Titer results for all Brucella lab workers (April & Oct 2006, April 2007)	Mattox	Recd 4/16/07
5. Dates aerosol chamber used and agent used	Ficht	Recd update from Ficht. See summary sheet all are Brucella experiments with one correction 2 runs on 10/05/05. One with McMurray was blank and one had Brucella with others listed.
6. Titer results for all TB & Coxiella lab workers	Mattox	Recd 4/16/07
7. SOPs for cleaning aerosol chamber	Ficht	Recd 4/16/07
8. Lab notes/protocols	Ficht	
9. Animal health records housed in (sick animal records)	Ihrig/Browder	Recd 4/16/07
10. Occupational Health records for 9 people identified as having entered Room they visited OH)	Mattox	Recd 4/16/07
11. Sick leave records for others in room on 2/9/06	Ficht	Requested 4/16/07
12. Brent's notes/emails regarding Brucella exposure	Brent	Recd 4/16/07
13. Inventory records for select agents	Ficht	Requested 4/16/07
14. Training records – especially safety re: Brucella	Ficht	Requested 4/16/07
15. Protocol for handling Brucella in lab	Ficht	Requested 4/16/07
16. Maintenance records for chamber	McFarland	
17. Incident Response Plan – PI and entity	Ficht/Raines	Recd entity plan from Raines
18. Any post-exposure investigation documentation (including exposure notification of 4 people in room)	Mattox/Ficht	Requested 4/16/07
19. Security plan for PI & entity	Ficht/Raines	Recd entity plan from Raines
20. Dates veloped symptoms, diagnosed and contacted TAMU	Ficht/McFarland	
21. Internal inspections for	Agnew	Recd 4/16/07

Notes:

Per Chris Meyer – CDC questioned whether the was approved for Dr. Ficht's study. I checked the registration information and it appears that he has been approved to conduct aerosol studies since 10/2004. Checked IACUC records and found approval that dated back to 2004 and January 2006. However, there should have been a protocol written for how the room would have been used because it was used for more than one agent.

Many questions about Occupational Health. Asked Brent why Occ. Health did not conduct post incident inspection. Asked for any documentation regarding post exposure investigation. Gave them the emails already been disclosed.

Spoke with employee who was exposed. Wanted to know why it took so long for this to be investigated. Stated that MD indicated that it would be investigated by Health Dept and CDC when the exposure happened. Never heard anything. Was sick for quite some time. Also not comfortable speaking in front of Tom Ficht.

CDC requested a copy of the Texas A&M Crisis Management Plan, which indicates EHSD will notify CDC of release and will notify Health Department.

Dr. Ficht did not have training records for the Employee, which is a regulatory requirement. Indicated that she was trained by his staff prior to experiment. He was not present.

From: Angelia Raines
To: f-bazer@tamu.edu,Ewing@vprmail.tamu.edu,c-m-meyer@tamu.edu,jmsalsman@tam...
Date: 12/22/2006 5:48 PM
Subject: Incident Response

CC: TAgnew@vprmail.tamu.edu

Hello Everyone,

I wanted to let you know that I have submitted a report to the CDC regarding the 'missing mouse.' The information was submitted based on the requirments of APHIS/CDC Form 3 - Report of Theft, Loss, or Release of Select Agents and Toxins.

After the holidays we can discuss any further actions that might be needed, but for now have a wonderful Christmas!

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

From: Angelia Raines
To: ddavis@cvm.tamu.edu,gadams@cvm.tamu.edu,tficht@cvm.tamu.edu,TESH@medic
in...
Date: 4/16/2007 6:49 AM
Subject: Re: CDC Visit- No Update

CC: SDavis@vprmail.tamu.edu
Good Morning,

I just spoke with Diane Martin, one of the inspectors from the CDC. They will arrive this morning at 9:00 a.m. Per Diane, they wish to focus solely on the exposure incident and are not inspecting our entire registration, therefore they DO NOT want to have an entrance briefing. They do want everyone involved to be available but have not yet decided how they are going to approach the inspection. Per Diane, they will most likely want to start off by meeting with Dr. Ewing and myself. Following that meeting, they will let us know how they want to proceed.

My office will contact you as quickly as possible to provide additional updates.

Thank you,
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

>>> Tiffany Agnew 04/15/07 7:43 PM >>>
Greetings All!

Angelia has asked that I inform you all that as of 7:30 pm, our office has not received any new information in regards to the arrival time of the CDC inspection team. The only information that has been confirmed is that the inspection is scheduled to take place on Monday, April 16, 2007. At this time, our office is unable to provide any times or locations; however, we will inform you as soon as information becomes available.

In addition, our office has begun compiling information based upon the questions submitted by the CDC on Friday. Dr. Ficht has been very instrumental in providing extremely detailed answers to all 13 questions.

Thank you!

Regards,

Tiffany

Tiffany M. Agnew
Program Coordinator (Office of Research Compliance)
Texas A&M
1500 Research Parkway
Suite 150 B (Centeq Building)

College Station, Texas 77843-1186
(979) 458-3624
(979) 862-3176 - fax
tagnew@vprmail.tamu.edu

From: Angelia Raines
To: fbazer@cvm.tamu.edu,ddavis@cvm.tamu.edu,gadams@cvm.tamu.edu,jsamuel@me
di...
Date: 4/16/2007 5:12 AM
Subject: Re: Notification of CDC Site Visit 4/16/07
Attachments: BL3 SOP .doc; BL3 SOP (current).doc; CDC Inspection
Respo
nse (taf#26).doc; 06) response.doc

CC: v-wilson@tamu.edu,DCornett@vprmail.tamu.edu,TAgnew@vprmail.tamu.edu

Brent and/or John,

Please review the attached draft response (from Tom Ficht) and let us know if there are any remaining safety questions. I also need a copy of the lab inspection that was performed as a result of the incident as well as any other inspections of the chamber. Our office will resond to question 7 as well as format the response to RO signature after final review/input.

I have not heard from CDC yet so I still do not know when to expect them. I will update you as I learn more. In the mean time, please prepare to see them anytime after 8:00 a.m. should they come come directly to the lab.

Thank you,
Angie

Angelia Raines
Director, VPR Office of Research Compliance
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Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax

>>> Richard Ewing 04/15/07 7:30 PM >>>
All,
I had meetings from when this was sent through close of business on Friday. I have read through what was sent to me on the incident from Angie's staff on Friday, but probably before they received this request. The review team will be here tomorrow, Monday, April 16. I do not have access to the information that they are requesting. I hope that you received this on Friday in time to begin to put this information together. I will cancel any or all of the appointments that I have tomorrow to try to address these concerns. Please let me know if anyone has already put some of this information together for the audit team. Please be reminded that articles in the Chronicle suggest fines up to $500K and reduction of funding overall, so we need to seriously address these problems.

Dick

Dr. Richard E. Ewing
Vice President for Research
Texas A&M University
1112 TAMU
College Station, TX 77843-1112
Phone: (979) 845-8585
FAX: (979) 845-1855

E-mail: richard-ewing@tamu.edu

>>> Shannon Davis 4/13/2007 2:01:09 pm >>>
I just got a call from CDC in response to our report of Brucella exposure. They are planning on conducting a site visit beginning Monday morning. Further information is attached.

Angelia Raines

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

From: Angelia Raines
To: Ewing@vprmail.tamu.edu
Date: 4/16/2007 7:01 AM
Subject: Re: Notification of CDC Site Visit 4/16/07

CC: TAgnew@vprmail.tamu.edu,SDavis@vprmail.tamu.edu

Good Morning,

I just spoke with Diane Martin, one of the inspectors from the CDC. They will arrive this morning at 9:00 a.m. Per Diane, they wish to focus solely on the exposure incident and are not inspecting our entire registration, therefore they do not want to have an entrance briefing.

They want to start the visit by meeting with the two of us. Following that meeting, they will let us know how they wish to proceed. They meeting will take place in Centeq, 130-B.

Diane will call me if any of their plans change and I will call you.

Thank you,
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
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Dick

Dr. Richard E. Ewing
Vice President for Research
Texas A&M University
1112 TAMU
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Phone: (979) 845-8585
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E-mail: richard-ewing@tamu.edu

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Angelia Raines

Angelia Raines
Director, VPR Office of Research Compliance
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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

From: Angelia Raines
To: McGee, James
Date: 4/17/2007 1:32 PM
Subject: Question regarding Registration C20060605-0489
Attachments: Angelia Raines.vcf

CC: Agnew, Tiffany; Bazer, Fuller; Ewing, Richard

Jim,

Last year after the CDC site visit for the renewal of our registration, I contacted your office regarding our registration. I spoke with Brian Satterfield as a follow up to the inspection report, which we received in April 2006,

The report indicated that Jim Samuel was approved to do work in B , but at the exit briefing, the question of the aerosol chamber had been posed to Tom Ficht. After speaking with Brian, he confirmed that PI Ficht's section of the registration had been amended in 2004 to do work in ! and he was the one the one that should respond to question 26 of the response (aerosol questions).

I spoke with Diane Martin today and she stated that the aerosol work was not approved because the 'Objective Section' was never changed to reflect that ! /ould be used for anything other than storage. Please review Section 4-A of our registration, which list . as a laboratory and please let me know what we need to do to rectify this issue.

Thank you,
Angelia

Angelia Raines
Director, VPR Office of Research Compliance
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Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax

From: Angelia Raines
To: Mattox, Brent S
Date: 5/11/2007 10:01 AM
Subject: Re: Elevated Titer for Q Fever

CC: Bazer, Fuller; bertvk@tamu.edu; Carlson, David S.; Ewing, Richard; F...

Brent,

Thank you for letting me know. I have notified the RO as well as CDC and others on our contact list. Please keep me updated as you investigate the incident. We will need the results of the investigation within 5 days. Also, please let me know if the IBC needs to convene a meeting to immediately review this incident.

Finally, please let me know if this incident involves work with rDNA so we can inform NIH.

Thank you,
Angelia

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
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araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax

>>> "Mattox, Brent S" <bsmattox@tamu.edu> 5/11/2007 9:00 AM >>>
Angelia/Dr. Samuel:

Scott and White informed me that a high titer (Phase II 1:1024) was received on a new addition (baseline titer) to the Occupational Health Surveillance Program yesterday afternoon (5/11/07). Due to issues with obtaining a copy of the titer results, our response was delayed until this morning. According to the Texas Department of State Health Services, a titer of greater than 1:256 is evidence of a prior infection, but, it DOES NOT confirm that the infection was recent. EHSD will be conducting an investigation concerning this issue, and will need the date of hire and the work history of the individual, including any possible exposures, since employment at Texas A&M Health Sciences Center. If any other individuals have been potentially exposed, please notify our office. A detailed occupational history of past possible exposures prior to employment is also requested from the employee.

According to recent statements from CDC, it is EHSD's opinion that this constitutes a reportable condition to CDC. It is also our understanding that this reporting is to be done by the Office of Research Compliance. We will provide a summary of our findings to the Office of Research upon completion of the investigation. The employee will continue to be monitored by the Occupational Health Program as directed by the occupational health physician at Scott & White.

If you have any further questions, please let me know. A copy of the titer result is attached.

From: "Diane Gilliland" <d-gilliland@tamu.edu>
To: "Gary Adams" <gadams@cvm.tamu.edu>, "Mark Hussey" <MHussey@tamu.edu>, "N...
Date: 5/15/2007 4:55 PM
Subject: FAZD
Attachments: eev38500.PDF

CC: "Lori Olivarez" <LROlivarez@ag.tamu.edu>, "Jackie A Slovacek" <j-slovace...

ONR was much faster than they indicated they would be. The award modification came in today. I've attached a copy. The last page of the attached is where the critical information is. The restriction to working with select agents applies to this grant only. It only applies to work at TAMU, not our subawardees.

Dr. Clarke,
I have not shared this information with anyone outside this group. Would you notify the researchers who are working with select agents at TAMU?

Angie,
What are our next steps to clearing this up and getting CDC review and authorization to resume the research on this project? Is there someone else I need to get on board?

I appreciate your help and look for your guidance.
Thanks.
Diane

AWARD/ MODIFICATION

3a. ISSUED BY:
Office of Naval Research
875 North Randolph Street
Arlington, VA 22203-1995

1. INSTRUMENT TYPE: Grant
3b. CFDA: 12.300
2. AUTHORITY: 10 USC 2358, 31 USC 6304
3c. DUNS NUMBER:

4. AWARD NO.:	5. MODIFICATION NO.:	6. MODIFICATION TYPE:	7. PR NO.:
N00014-04-1-0660	P00004	Admin Mod	07PR07632-00

8. ACTIVITY/AGENCY PROPOSAL NO.:	9. RECIPIENT PROPOSAL NO.:	10. PROPOSAL DATE:	11. ACTIVITY TYPE:	12. PROGRAM TYPE:
N/A	N/A	Undated	Research	

13. ISSUED TO
13a. ADDRESS:
13b. CAGE: 00JP8
13c. EDI/EFT NUMBER: 5035AA

TEXAS AGRICULTURAL EXPERIMENT STATION THE
TEXAS A AND M UNIVERSITY SYSTEM
ADMINISTRATION BLDG RM 6
COLLEGE STATION, TX 77843-2147

14. REMITTANCE ADDRESS (IF DIFFERENT FROM BLOCK 13):
Same as block #13

13d. BUSINESS OFFICE CONTACT: DIANE M GILLILAND
13e. TELEPHONE NUMBER: (979) 8454761
13f. EMAIL ADDRESS: d-gilliland@tamu.edu

15. RESEARCH TITLE AND/OR DESCRIPTION OF PROJECT AND/OR PROPOSAL TITLE:
National Center for Foreign Animals and Zoonotic Disease Defense

16. FUNDING	ACTIVITY/AGENCY SHARE	RECIPIENT SHARE	TOTAL
PREVIOUSLY OBLIGATED:	$18,000,000.00	$.00	$18,000,000.00
OBLIGATED BY THIS ACTION:	$.00	$.00	$.00
TOTAL OBLIGATED ON AWARD:	$18,000,000.00	$.00	$18,000,000.00
FUTURE FUNDING:	$.00	$.00	$.00
GRANT TOTAL:	$18,000,000.00	$.00	$18,000,000.00

17. CURRENT FUNDING PERIOD
N/A THROUGH N/A

18. PERIOD OF PERFORMANCE
01-JUN-04 THROUGH 30-SEP-07

19. ACCOUNTING AND APPROPRIATION DATA:
See attached Financial Accounting Data Sheet (s)

20a. PRINCIPAL INVESTIGATOR/RECIPIENT TECHNICAL REPRESENTATIVE:
NEVILLE P CLARKE
20b. TELEPHONE NUMBER: (979) 8452855
20c. EMAIL ADDRESS: n-clarke@tamu.edu

21. TECHNICAL REPRESENTATIVE
21a. NAME: LAURA PETONITO
21b. CODE: ONR 0811
21c. ADDRESS:
University Programs
Washington, DC 20528
21d. TELEPHONE NUMBER: (202) 2545840
21e. EMAIL ADDRESS: laura.petonito@hq.navy.mil

22. AWARDING OFFICE CONTACT
22a. NAME: Brian K. Kehoe
22b. CODE: ONR BD252
22c. ADDRESS:
Office of Naval Research
875 North Randolph Street
Arlington, VA 22203-1995
22d. TELEPHONE NUMBER: (703) 588-0610
22e. EMAIL ADDRESS: kehoeb.onr.navy.mil

23a. ADMINISTRATIVE OFFICE:
23b. CODE: N66018
ONR REG SAN DIEGO-N66018
FAX 619 221 5615
140 SYLVESTER ROAD
BLDG 140 ROOM 218
SAN DIEGO, CA 92106-3521
FAX: ()

24. SUBMIT PAYMENT REQUEST TO:
Same as block #23a

25a. PAYING OFFICE:
25b. CODE: N68892
DFAS CHARLESTON-N68892
CHARLESTON, SC 29423-8054

26a. PATENT OFFICE:
26b. CODE: N00014
Office of Naval Research
ATTN: ONR 00CC
One Liberty Center
875 North Randolph Street, Suite 1425
Arlington, VA 22203-1995

AWARD NO. N00014-04-1-0660	**AWARD/MODIFICATION**	MODIFICATION NO. P00004	

27. SPECIAL INSTRUCTIONS:
See "Special Requirements" Attachment

28. DELEGATIONS: The administration duties listed below have been delegated to the administrative office (block 23a). Upon request the awarding office contact (block 22) will make their full text available. Please direct questions to the contacts @: http://www.onr.navy.mil/02/024/offices.asp

Full Delegation

29. TERMS AND CONDITIONS: The following terms and conditions are incorporated herein by reference with the same force and effect as if they were given in full text. Upon request the awarding office contact named in block 22 will make their full text available, or they can be found at the specified URL.

DOCUMENT	URL	CLAUSES
UAAC Acceptance C	http://www.onr.navy.mil/02/terms.htm	
UAWA Award A	http://www.onr.navy.mil/02/terms.htm	
UBB1 FDP IV APR 2005	http://www.onr.navy.mil/02/docs/2005apr_fdp_general_terms_conditions.pdf	
UVV1 ONR FDP Specific OCT 2002	http://www.nsf.gov/pubs/fdp/onr02.pdf	

30. OPTIONS OPTION NO. AMOUNT PERIOD
(1)
(2)
(3)
(4)

31. REPORTS: The following reports must be submitted to the indicated addressees, in the indicated quantities, within 90 days following the expiration or termination of the project. Final Technical Reports must have a SF298, Report Documentation Page, accompanying them. Unless otherwise stated in the award/modification, complete Block 12a of the SF298 as follows: "Approved for Public Release; distribution is Unlimited".

ADDRESSEE	REPORT TYPE	COPIES
See block #21 (Frequency)	Final Technical Report with SF298 Performance/Technical Report (Annually) with SF298	1 1
See block #23a	Report of Inventions and Subcontracts - DD 882 Final Technical Report - Transmittal Letter only Performance/Technical Report (Annually) Final Financial Status Report - SF269A - If advances used	1 1 1 1
Defense Technical Information Center 8725 John J Kingman Road Ste 0944 Fort Belvoir, VA 22060-6218	Final Technical Report with SF298 Performance/Technical Report (Annually) with SF298	1 1
See block #26a	Report of Inventions and Subcontracts - DD 882	1
Naval Research Laboratory ATTN: CODE 5596 4555 Overlook Avenue SW Washington, DC 20375-5320	Final Technical Report Performance/Technical Report (Annually) with SF298	1 1

32. FOR THE RECIPIENT		33. FOR THE UNITED STATES OF AMERICA	
32a. SIGNATURE OF PERSON AUTHORIZED TO SIGN N/A - SIGNATURE NOT REQUIRED ON THIS AWARD		33a. SIGNATURE OF AWARDING OFFICER Brian D. Glance	
32b. NAME AND TITLE OF SIGNER	32c. DATE SIGNED	33b. NAME AND TITLE OF AWARD OFFICER Brian D. Glance	33c. DATE SIGNED 15-MAY-07

FINANCIAL ACCOUNTING DATA SHEET - NAVY

1. CONTRACT NUMBER (CRITICAL)	2. SPIIN (CRITICAL)	3. MOD (CRITICAL)	4. PR NUMBER	
N00014-04-1-0660		P00004	07PR07632-00	

CLIN/SLIN	6. LINE OF ACCOUNTING													7.	
	A. ACRN (CRITICAL)	B. APPROPRIATION (CRITICAL)	C. SUBHEAD (CRITICAL)	D. OBJ CLA	E. PARM	F. RFM	G. SA	H. AAA (CRITICAL)	I. IT	J. PAA	K. COST CODE			AMOUNT (CRITICAL)	NAVY INTERNAL USE ONLY REF DOC/ACRN
											PROJ UNIT	MCC	PDLI & SUF		

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PAGE TOTAL	$.00	
GRAND TOTAL	$.00	

PREPARED/AUTORIZED BY:

DATE:

COMPTROLLER APPROVAL:
FOR FISCAL DATA AND SIGNATURE
BY _____ for COMPTROLLER, ONR CONTRACT REVIEWED
DATE:

ONR AWARD FORM (10/99) - version 1.1

FINANCIAL ACCOUNTING DATA SHEET – NON-NAVY DoD ACTIVITIES

1. CONTRACT NUMBER (CRITICAL)	2. SPIN (CRITICAL)	3. MOD (CRITICAL)	4. PR NUMBER	
N00014-04-1-0660		P00004	07PR07632-00	

5. CLIN/SLIN	6 ACRN (CRITICAL)	7. ACCOUNTING CITATION	8. AMOUNT (CRITICAL)		NAVY INTERNAL USE ONLY REF DOC/ACRN
		This page is intentionally blank			
		PAGE TOTAL	$.00		
		GRAND TOTAL	$.00		

PREPARED/AUTHORIZED BY:

DATE:

COMPTROLLER APPROVAL:
FOR FISCAL DATA AND SIGNATURE
BY_____ for COMPTROLLER, ONR CONTRACT REVIEWED
DATE:

ONR AWARD FORM (10/99) - version 1.1

AWARD NO. N00014-04-1-0660	SPECIAL REQUIREMENTS	MODIFICATION NO. P00004	

Effective as of the date of this modification:

The Texas A&M University shall cease conducting any research funded under this grant involving "Select Agents and Toxins" as defined/listed at 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121 . Activities authorized are limited to the administration of awards to its subrecipients.

After the effective date of the modification, any costs incurred by the Texas A&M University for research involving "Select Agents and Toxins" as defined/listed at 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121 conducted by Texas A&M University shall be considered unallowable.

This restriction may only be altered by written modification to the grant.

From: Angelia Raines
To: Ewing, Richard
Date: 5/18/2007 12:22 PM
Subject: Draft - RE: Investigative Report on Q Fever

CC: Agnew, Tiffany; Bazer, Fuller; Ficht, Thomas; Kelly, Scott; Kretzsch...

Dr. Ewing,

I am trying to draft our report to CDC and need input regarding how the institution is going to handle this issue of non-compliance.

Per the response from Brent below, it appears that an employee who was not approved for access to a select agent was allowed to use it. I am very concerned and think that immediate action is needed in order to prevent future occurrence. We are planning training for all Select Agent personnel and it will be conducted by June 30th, but in the mean time I would like to suggest some type of immediate action be taken.

I have to submit the report to CDC today. With your input on the action required, I will include it in the documentation. I will send a draft of the of the report to you as well as the PI, BSO, IBC and Departmental contacts for review as quickly as possible.

Thanks,
Angie

>>> "Mattox, Brent S" <bsmattox@tamu.edu> 5/18/2007 11:39:33 AM >>>
Below are responses to your three questions concerning the high titer issue. Please note that the employee has not shown signs or symptoms of any illness, so this is an investigation of a high Q fever titer, not an investigation of Q fever.

1. The first visit to s to draw blood from pre-exposed varmints (in other words, no potential exposure to the agent). The remaining three were to draw blood that would have potentially contained the AGENT, not antigen. These three trips would constitute documented risk of exposure due to the proximity of the agent (in rodent and blood). The first exposure is more remote, with the agent not being present in the same room as the employee. Further, I recommend that all work with select agents involve pre-exposure screening, including all visitors. I recommend (for example) that all individuals entering the BL3 suite at e required to have titers drawn for Q fever and Brucella, in addition to TB testing. Obviously, this recommendation needs to go to the IBC.

2. The researcher's own protocols require pre-exposure monitoring and were apparently disregarded. However, we may want to look at the facility plan to require not just TB screening for access, but baseline serum titers for anyone entering the facility (BL3 rooms) regardless of planned exposure. That is what we are doing with the contractor, but his risk is obviously higher (cutting into contaminated ductwork linking all the rooms).

3. The SOP regarding pre-screening was not followed, according to the PI. I do not know if re-training is necessary, but clearly the PIs should be informed that pre-screening is a necessity for their employees, and that they must strictly adhere to their written SOPs.

Hope this helps,

Brent S. Mattox
Biological Safety Officer

-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Friday, May 18, 2007 11:06 AM
To: Mattox, Brent S

Cc: Vernon Tesh; Kretzschmar, Bert; Meyer, Chris; Salsman, John M; Thomas Ficht; Tiffany Agnew; Fuller Bazer
Subject: Re: Investigative Report on Q Fever

Hi Brent,

Thanks for sending the report. I am preparing form-3 to send to CDC and want to make sure I have the correct information. I will send it to you, Jim and Bert to review before I send it. However before completing it, I have a few questions:

1. During the 4 times the employee accessed the Lab, was he exposed to the antigen only?
He was not DSAT approved until 1/07 and the facility access logs were completed prior to that approval. I want to make sure we include the correct information in the report.

2. Do the plans (security, safety, incident or surveillance) need to be changed as a result of this incident? If so, what changes are needed.

3. In reviewing the report, it appears that the SOP that required screening prior to work in the lab was not followed. If this is the case, when will refresher training be conducted? Since your report will be presented to the IBC at the next meeting, we will need to be sure the follow up letter from the committee indicates what type of training documentation is required.

Thanks again for the report.

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" <bsmattox@tamu.edu> 5/17/2007 10:05:52 AM >>>
Angelia:

Please find attached another pdf of the investigative report on the Q fever titer. I inadvertently left off copies of the entry logs for 972.

Thanks,

Brent

From: Angelia Raines
To: ibc@tamu.edu
Date: 5/25/2007 3:50 PM
Subject: Select Agent Training
Attachments: Houston Map_1.pdf; Select Agent training announcment .pdf; Select Agent Training Agenda.doc

CC: Agnew, Tiffany

Attached is an announcement for Select Agent Program training. The training will be held on June 1, 2007, in the auditorium of the Houston Building. Training will begin at 9:00 a.m.

An agenda has also been included as well as directions to the Houston Building.

Thank you,
Angelia Raines

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
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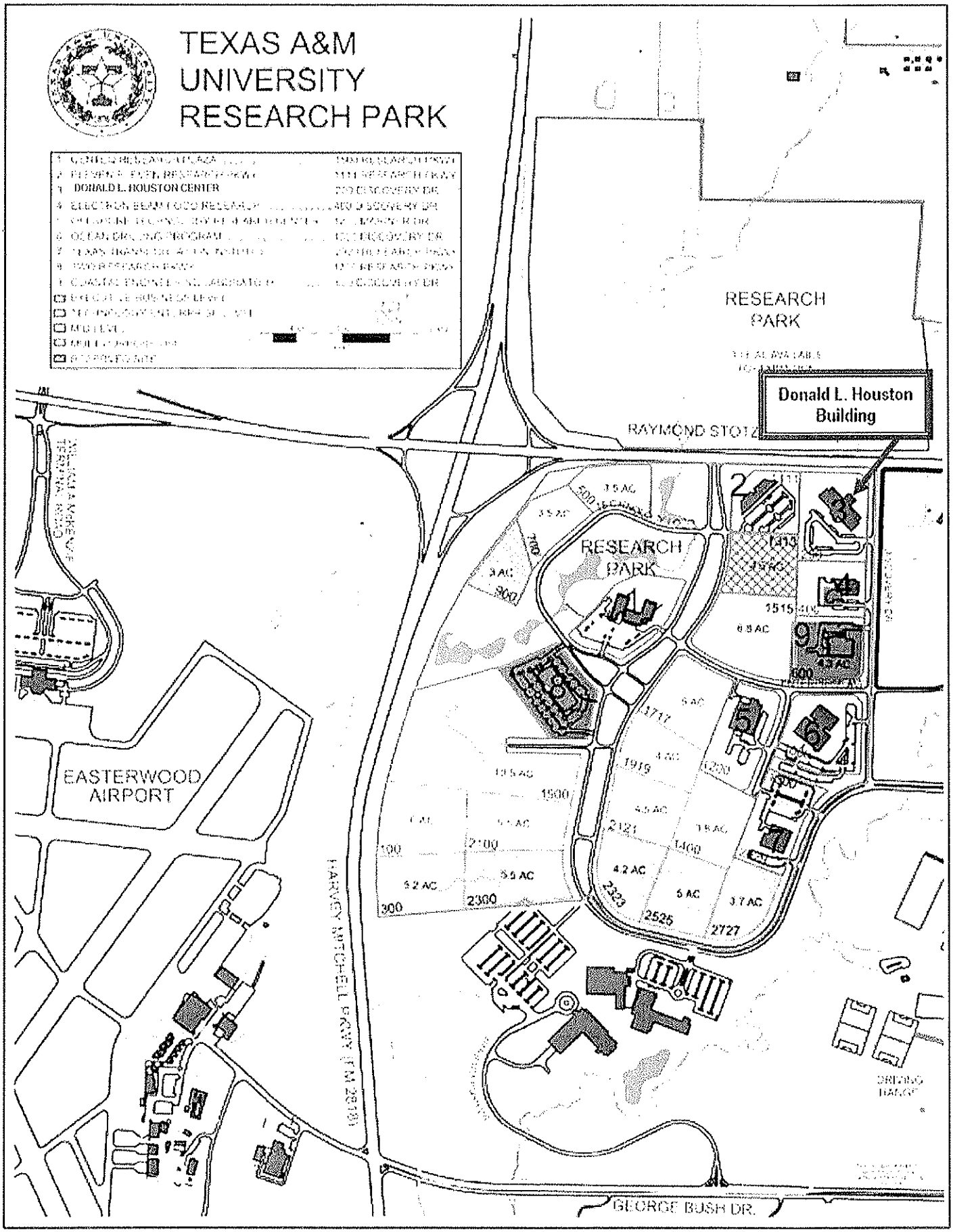
(979) 847-9362 office
(979) 862-3176 fax
(770) 789-3456 Cell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VPR
Office of the Vice President for Research
Texas A&M University

May 25, 2007

Memorandum

Richard E. Ewing
Vice President for Research

Academy for Advanced Telecommunications and Learning Technologies

Center for Information Assurance and Security

Comparative Medicine Program

Institute for Scientific Computation

Integrative Center for Homeland Security

Management and Leadership Center

National Center for Foreign Animal and Zoonotic Disease Defense

Office of Distance Education

Office of Graduate Studies

Office of Proposal Development

Office of Research Compliance

Office of Sponsored Projects

Professional Development Group

Texas A&M University Research Park

Texas A&M University

212 Administration Building
1112 TAMU
College Station, Texas
77843-1112

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From: Dr. Richard E. Ewing Richard E. Ewing

To All employees involved in research using Select Agents

Subject: Mandatory Training

All institutions and individuals that conduct research using select agents and toxins are required to adhere to federal regulations regarding their possession, use, and transfer. Select Agents are those identified on the HHS and USDA Select Agents and Toxins List and are considered to be agents posing a severe threat to human and/or animal health, plant health, or animal and plant products.

The Centers for Disease Control and Prevention (CDC) regulates and oversees the possession, use, and transfer of select agents and toxins that are used here at Texas A&M University. These regulations establish requirements for registration, risk assessments, access, safety plans, security plans, incident response plans, training, transfers, record keeping, inspections, and reporting.

Texas A&M University is committed to the protection of its staff and the public from the risks of exposure to Select Agents. After investigating recent events involving our Select Agent program, we have recognized the crucial need for training across campus.

In order to proceed in a timely manner to ensure that all employees involved in research using select agents are aware of and understand all of the regulatory requirements, mandatory training will be held on June 1, 2007. Training will begin at 9:00 a.m. and end at 1:00 p.m. It is imperative that you receive this training.

Attached is the agenda.

pc: Dr. Eddie J. Davis
Dr. James A. Calvin
Dr. David Carlson
Dr. Fuller W. Bazer
Mr. Chris M. Meyers
Mr. Charley B. Clark
Ms. Angelia M. Raines
Mr. Brent S. Mattox
Dr. Vernon L. Tesh
Dr. Tom A. Ficht
Dr. L. Garry Adams
Dr. James E. Samuel
Ms. Tiffany M. Agnew

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

CONFIDENTIAL

SECURITY PLAN

TEXAS A&M UNIVERSITY
FACILITIES AND RESEARCH LABORATORIES WITH SELECT AGENTS

Dr. James E. Samuel

June 2007

Responsible Official:
Richard E. Ewing, Ph.D.
Vice President for Research

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 security plan. The security plan must be sufficient to safeguard the Select Agent or toxin against unauthorized access, theft, loss, or release. The plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the Select Agent or toxin.

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

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

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

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

Principal investigators and laboratory supervisors responsible for laboratories and other facilities where select agents are used or stored must adopt these procedures and develop a security plan that is

facility-specific. Both safety and security experts should be consulted in the evaluations and development of individual facility-specific recommendations.
This security plan includes the following major components:

a) Physical Security;
b) Information Systems Control;
c) Personnel Security;
d) Access Control;
e) Inventory Control;
f) Shipping, Receiving, & Transferring Select Agents;
g) Incident Reporting & Breaches in Security;
h) Emergency Response Plan;
i) Policies that address Breaches in Security;

Note: Any deviations to the above approved plans must be requested in writing by the Principal Investigator and approved in advance by the Responsible Official or his designated Alternate Responsible Official.

A. Physical Security:

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

- Each BSL-3 laboratory shall post entry requirement procedures. All visitors shall follow the facilities entry requirements.

- A background check and/or security risk assessment (SRA) is required before new employees are assigned to the facility or laboratory area. Guests must be escorted or cleared for entry using the same procedures as for regular workers.

- Before entering the laboratories, check the reading of the room pressure monitor. Do not enter the laboratory if the monitor indicates a red light. If the monitor indicates a red light (negative room pressure), the laboratory director must be contacted immediately. Laboratory personnel must verify that the direction of the airflow is going into the BSL-3 laboratory. Read and follow all entry procedures. Biohazard door signs, entry requirements and procedures must be posted.

- Entry into the facility is restricted to DOJ Authorized Personnel. All persons entering the BSL-3 facility must be advised of the potential biohazards and informed of laboratory procedures.

- Keep facility and laboratory doors closed at all times to prevent unauthorized entry. Establish procedures for securing the laboratory, room, or area when approved individuals (under HHS 42 CFR part 73.8) under are not present (e.g., card access system, key pads, locks, etc.).

- When no one is present, lock facility and laboratory doors.

- DOJ Authorized Persons are always required to swipe their ID card when entering and leaving the suite, even if the door has already been opened by another user. DOJ Authorized Persons are also responsible for making sure that non-authorized persons do not enter the laboratory after an authorized person has opened the door with a card key. **SHARING OF CARD ACCESS AND/OR ENTRY CONTROLS BY ANY INDIVIDUAL IS NOT PERMITTED.**

- Access to BSL 3 labs to those who do not have written authorization to enter the suite is not permitted. Visitors must sign in and out in the lab log book and must be escorted at all times by an authorized individual. DOJ Authorized Persons must maintain visual contact with the visitor(s) at all times. At no point, may a visitor(s) be left unattended while in secured areas or laboratories containing Select Agents. Visitors who are not United States citizens are required to have written authorization before entering labs.

- Proper training of all staff (including students) that uses the BSL3 suite will be provided by **Dr. James E. Samuel.**.

- Laboratories, facilities, and storage equipment (refrigerators, freezers, cabinets, incubators, and other containers) that contain a Select Agent need to be separate from the public areas of the buildings.

- Select Agents and toxins requiring freezers, refrigerators, cabinets, and other containers where they are stored will be secured against unauthorized access (e.g., card access system, lock boxes, etc.).

- Lock all equipment (e.g. freezers, cabinets, incubators, scintillation counters) that contain hazardous materials and are locked in hallways or areas outside of facilities or laboratories.

- Laboratories, storage areas, and equipment (e.g. freezers, refrigerators, cabinets, etc.) will be locked when the Select Agents (stocks of biological agents, hazardous chemicals or radioactive materials) are not in direct view of authorized staff (e.g. when located in unattended storage areas).

- Protocols for changing access numbers or locks following staff changes are included in the **Biosafety Plan**.

- Emergency contact signs will be placed on facility and laboratory doors, including 24-hour contact numbers. Emergency contact signs include the names and contact information such as work telephone and alternate telephone numbers of the Principal Investigator, Biosafety Officer, and the person(s) responsible for the building or facility. Also, included are telephone numbers for the University Police Department and College Station Fire Department. (Emergency contact information is found in the **Incident Response Plan**.)

B. <u>Information Systems Control</u>:

The facility will systematically integrate cyber security into management and work practices at all levels so that missions are accomplished while protecting electronic information and electronic information systems. This is to be accomplished through effective integration of cyber security management into all facets of work planning and execution. The overall management of

cyber security functions and activities will become an integral part of mission accomplishment. If sensitive electronic data are present in the facility or laboratory, information technology specialists should assess the security of hardware and software products in addition to the security of local area networks. Hard copies of security sensitive records (e.g., inventory records, etc.) will be properly secured and accessed only by individuals with authorized access approval (under HHS 42 CFR part 73.8). Information Services will be used as a resource for data security.

C. **Personnel Security:**

Only DOJ Authorized Persons (cleared by the US Department of Justice as indicated in HHS 42 CFR Part 73.8) will have access to Select Agents. These policies are required for compliance with the HHS/CDC and USDA regulations for Select Agents. Standard Operating Procedures establishing the following requirements, at minimum, have been included in the **Biosafety Plan**.

- All visitors shall be escorted in the BSL-3 facility by a DOJ Authorized Person. Visitors must sign in and out in the Facility Access Log. DOJ Authorized Persons must maintain visual contact with the visitor(s) at all times. At no point, may a visitor(s) be left unattended while in secured areas or laboratories containing Select Agents.

- DOJ Authorized Persons will receive laboratory safety and security training when initial DOJ Select Agent access approval is granted; annually thereafter and when new requirements are implemented. Visitors will receive laboratory safety and security training prior to the first entry to a secured area or laboratory containing Select Agents; annually thereafter and when new requirements are implemented. Additionally, as the Principal Investigator, I will mentor and assess scientific/lab skills with persons working within their labs on an ongoing basis. All training should be documented on the Security and Safety Training Certificate.

- All other individuals, including maintenance workers and visitors, understand security requirements will be trained and equipped to follow established procedures.

- Below is a description of the minimum education and experience criteria for DOJ Authorized Persons with access to Select Agents or toxins, physical security, and cyber security. Describe the minimum education and experience criteria here:

  Minimal education and experience criteria are 6 months of laboratory experience in microbiology and training by the PI on work with *Coxiella burnetii*

  - All DOJ Authorized Persons, as well as workers and new employees, will be known to facility and laboratory personnel.

  - All DOJ Authorized Persons approved for access to Select Agents (including students) will wear a visible identification badge that includes, at a minimum, a photograph, the wearer's name, and an expiration date.

  - Visitors should be issued an identification badge including their name and an expiration date.

  - Visitors will be escorted at all times when in an area where Select Agents are present.

- Police, fire, and other emergency responders will be informed as to the types of biological materials that are in use in the laboratory areas.

- Security procedures will be reviewed whenever an incident occurs or a new threat is identified.

    - Procedures for reporting and removing unauthorized persons are described in the **Incident Response Plan**.

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

D. Access Control:

Standard Operating Procedures, establishing the following requirements, at minimum, to control access to areas where hazardous materials are used and stored, or outlined in the **Biosafety Plan**, and the **Incident Response Plan**.

- Provide provisions that allow unescorted access only to DOJ Authorized Persons (HHS 42 CFR Part 73.8) who are performing a specifically authorized function during hours required to perform the defined job.

- It is best to use the "buddy system" when working with hazardous materials in a facility or laboratory. However, if it is necessary to work in the facility or laboratory alone during non-routine hours, let someone know where you will be and how long you expect to be in the facility or laboratory. Arrange for someone to check on you at least hourly.

- Only DOJ Authorized people (workers, students, visiting scientists, etc.) required to perform a job should be allowed in a facility or laboratory and animal housing areas at hours (when laboratory employees are present) required to perform their particular job (including routine cleaning, maintenance, repairs, also delivery to outside shipping agent for transportation in commerce).

- Access during non-routine work hours should be limited to authorized personnel. Allow individuals not approved for access (HHS 42 CFR Part 73.8) from the HHS Secretary or Administrator to conduct routine cleaning, maintenance, repairs, and other activities not related to Select Agents or toxins only when continually escorted and monitored by approved individuals (Part 73.8). Access for routine cleaning, maintenance, and repairs should be limited to hours when DOJ Authorized Persons are present. DOJ Authorized Persons must maintain visual contact with the visitor(s) at all times. At no point, may a visitor(s) be left unattended while in secured areas or laboratories containing Select Agents.

- Maintain a logbook to record entries of all visitors, maintenance workers, repairmen, and others needing one-time or occasional entry into an area where Select Agents are present. The means of identification should include a current valid picture driver's license or state identification card or passport. This information should be documented on the Facility Access Log.

- Provide provisions for the control of access to containers where Select Agents (stocks of biological agents, hazardous chemicals or radioactive materials) are stored by requiring laboratories, storage areas, equipment, freezers, refrigerators, cabinets, and other containers where stocks of Select Agents and toxins are stored to be locked (e.g., card access system, lock boxes) when they are not in the direct view of a DOJ Authorized Person (e.g. when located in unattended storage areas), and by using other monitoring measures as needed. Access control to areas where Select Agents are present could include card access (preferred), combination keypad, use of lock boxes to secure materials, video surveillance cameras, etc. A protocol for periodically changing combination keypad access numbers should be developed.

- Maintain a current list of authorized persons who possess door keys or those who have knowledge regarding the keypad access numbers or the security entry system.

- Each DOJ Authorized Person is prohibited from sharing with any other person their unique means of accessing a Select Agent or toxin (e.g., keycards or passwords).

- Procedures for loss or compromise of keys, passwords, combinations, change of authorization, reassignment of personnel, or staff changes are described below:

Standard Operating Procedures for Reporting and Removing Unauthorized Person

Maintain a current list of authorized persons who possess door keys or those who have knowledge regarding the keypad access numbers or the security entry system.

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

- Any loss or compromise of keys, passwords, combinations, etc.;
- Any suspicious persons or activities;
- Suspicious packages;
- Any loss or theft of Select Agents or toxins;
- Missing chemicals;
- Any release of select Agents or toxins;
- Cyber security breach;
- Non-biological incident such as violence against person;
- Unusual or threatening phone calls;
- Undocumented visitors;
- Severe weather and natural disasters.
- Any sign that inventory and use records of Select Agents or toxins have been altered or otherwise compromised;

Upon discovery of a theft or loss of a Select Agent or toxin, an individual or entity must immediately notify CDC or APHIS and appropriate Federal, State, or local law enforcement agencies. (Emergency 9-911; non-emergency 845-2345)

E. Inventory Control:

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

At minimum, records should include:

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

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

- Dr. James E. Samuel must provide requirements and procedures for the termination of the use of a Select Agent or toxin in this **Security Plan**.

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

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

F. Shipping, Receiving, & Transferring Select Agents:

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

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

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

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

- The Environmental Health & Safety Department (EH&S), with the assistance of the University Police Department (UPD), will inspect all suspicious packages before they are brought into or removed from the area where Select Agents or toxins are used or stored. The recipient or receiving facility should be known to the sender and the sender should make an effort to ensure the materials are shipped to a facility or laboratory equipped to handle those materials safely. Contaminated or possibly contaminated materials should be decontaminated before they leave the facility or laboratory areas. All unexpected or suspicious packages will be inspected by visual or noninvasive techniques before they are brought into, or removed from, the area where Select Agents or toxins are used or stored. Guidelines for recognizing suspicious packages have been provided by the U.S. Postal Service and can be found at: http://www.usps.com/news/2001/press/pr01_1010tips.htm. If unexpected or suspicious Packages are received, then the sender should be contacted to verify that the package is legitimate. If any individual observes suspicious packages being transported out of the laboratory (for example, packages that have an unusual weight or size), then they should immediately notify UPD and wait for an officer to respond.

- All intra-facility transfers or external shipments (send/receive) of Select Agents must be documented and reported to the Responsible Official or designee (contact the Office of Research Compliance, 458-3624, and the Environmental Health and Safety Department, 845-2132). Transfers will remain under the supervision of a DOJ Authorized Person, including chain-of-custody documents and will remain in the possession of the Authorized person in order to safeguard against theft, loss, or release.

- The DOJ authorized person will inspect all packages upon entry to and exit from the area. All packages will be screened (visual and/or x-ray) before being brought into the laboratory area. If a suspicious or unexpected package is delivered to the facility or laboratory, **do not open it.** Contact the University Police Department (emergency 9-911; non-emergency 845-2345).

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

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

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

    - Dr. James E. Samuel will complete Section B- Sender (TRANSFEROR) Information of the **Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2)** upon receipt of form from the Recipient.
    - Dr. James E. Samuel will send the completed form to the ORC to obain the RO/ARO signature.
    - Dr. James E. Samuel will inform EH&S. EH&S and Dr. James E. Samuel will coordinate to arrange the shipment of the package. EH&S will contact the transferring RO and Principal Investigator to verify shipping date and confirm shipping address.
    - Once the signature has been obtained, the ORC will fax the completed form to the CDC for approval.
    - The CDC will fax an approval to the RO of both the Sender and Receiver. The approval will then be forwarded to the ORC.
    - Notification of approval will be sent to the ORC, and the ORC will inform Dr. James E. Samuel and EH&S of the approval.
    - EH&S will assist Dr. James E. Samuel with the shipment and arrange transfer of package to user laboratory.
    - EH&S will complete blocks 38-40 of Section D- Shipping Information of the form, and

return completed form to the ORC.
- A copy of the Dangerous Goods manifest and air bill is maintained by EH&S.
- EHS/Principal Investigator notifies the receiving institution that the package has been shipped.

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

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

G. Incident Reporting and Breaches in Security:

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

- The University Police Department, the Responsible Official or designee, and Environmental Health and Safety will be notified in the event of:
  1) Any loss or compromise of keys, passwords, combinations, etc.;
  2) Any suspicious persons or activities;
  3) Suspicious packages;
  4) Any loss or theft of Select Agents or toxins;
  5) Missing chemicals;
  6) Any release of Select Agents or toxins;
  7) Any sign that inventory and use records of Select Agents or toxins have been altered or otherwise compromised;
  8) Cyber security breach;
  9) Non-biological incident such as violence against person;
  10) Unusual or threatening phone calls;
  11) Undocumented visitors;
  12) Severe weather and natural disasters.

- Upon discovery of a theft or loss of a Select Agent or toxin, an individual or entity must immediately notify CDC or APHIS and appropriate Federal, State, or local law enforcement agencies. Thefts or losses must be reported even if the Select Agent or toxin is subsequently recovered or the responsible parties are identified. (42 CFR 73.19)

- Establish procedures for removing unauthorized or suspicious persons.

H. Incident Response Plan:

The emergency response plan must be coordinated with any entity-wide plans. The plan must address such events as bomb threats, severe weather (hurricanes, floods), earthquakes, power outages, and other natural disasters or emergencies. Reference: http://finance.tamu.edu/ehsd/resources/gensafety/Emergency_Ref.asp.

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

- Police, fire, and other emergency responders should be informed as to the types of biological materials that are in use in the laboratory areas and special access control devices that are in use (e.g. card-key, etc.).

- Police, fire, and other emergency responders should assist in planning their responses to emergencies in the laboratory areas.

- The emergency response plan includes provisions for immediate notification of (and response by) laboratory directors, laboratory workers, safety office personnel, or other knowledgeable individuals when an emergency occurs.

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

PIs must complete the following: In the event that a Select Agent must be relocated,_____will contact _____, who has agreed to offer their assistance in the storage of the agent. In the event of an emergency, with the approval of CDC and assistance from EHS, the agent will be moved using proper transport/shipping requirements.

I. Policies that address Breaches in Security

The Security Plan must contain procedures that require each individual approved under HHS 42 CFR Part 73.8 to report any of the following immediately to the Responsible Official:

1) Any loss or compromise of their key, passwords, combinations, etc:
2) Any suspicious persons or activities;
3) Any loss or theft of select agents and toxins:
4) Any release of select agents or toxins; and

5) Any sign that inventory and used records of selected agents or toxins have been altered or otherwise compromised.

- Report suspicious or unexplained behavior immediately to the University Police Department (emergency 9-911; non-emergency 845-2345) and the Responsible Official.

- If possible, program speed dial of emergency contacts (e.g., 9-911, facility or laboratory director, University Police 845-2345, etc.) on the phones in the facility or laboratory.

CONFIDENTIAL

SECURITY PLAN

TEXAS A&M UNIVERSITY
FACILITIES AND RESEARCH LABORATORIES WITH SELECT AGENTS

Thomas A. Ficht/Garry Adams,
Gary Adams
ouilding (rooms
June 28, 2007

Responsible Official:
Richard E. Ewing, Ph.D.
Vice President for Research

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 security plan. The security plan must be sufficient to safeguard the Select Agent or toxin against unauthorized access, theft, loss, or release. The plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the Select Agent or toxin.

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

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

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

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

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

a) Physical Security;
b) Information Systems Control;
c) Personnel Security;
d) Access Control;
e) Inventory Control;
f) Shipping, Receiving, & Transferring Select Agents;
g) Incident Reporting & Breaches in Security;
h) Emergency Response Plan;
i) Policies that address Breaches in Security;

Note: Any deviations to the above approved plans must be requested in writing by the Principal Investigator and approved in advance by the Responsible Official or his designated Alternate Responsible Official.

A. Physical Security:

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

- Each BSL-3 laboratory shall post entry requirement procedures. All visitors shall follow the facilities entry requirements.

- A background check and/or security risk assessment (SRA) is required before new employees are assigned to the facility or laboratory area. Guests must be escorted or cleared for entry using the same procedures as for regular workers.

- Before entering the laboratories, check the reading of the room pressure monitor. Do not enter the laboratory if the monitor indicates a red light. If the monitor indicates a red light (negative room pressure), the laboratory director must be contacted immediately. Laboratory personnel must verify that the direction of the airflow is going into the BSL-3 laboratory. Read and follow all entry procedures. Biohazard door signs, entry requirements and procedures must be posted.

- Entry into the facility is restricted to DOJ Authorized Personnel. All persons entering the BSL-3 facility must be advised of the potential biohazards and informed of laboratory procedures.

- Keep facility and laboratory doors closed at all times to prevent unauthorized entry. Establish procedures for securing the laboratory, room, or area when approved individuals (under HHS 42 CFR part 73.8) under are not present (e.g., card access system, key pads, locks, etc.).

- When no one is present, lock facility and laboratory doors.

- DOJ Authorized Persons are always required to swipe their ID card when entering and leaving the suite, even if the door has already been opened by another user. DOJ Authorized Persons are also responsible for making sure that non-authorized persons do not enter the laboratory after an authorized person has opened the door with a card key. **SHARING OF CARD ACCESS AND/OR ENTRY CONTROLS BY ANY INDIVIDUAL IS NOT PERMITTED.**

- Access to BSL 3 labs to those who do not have written authorization to enter the suite is not permitted. Visitors must sign in and out in the lab log book and must be escorted at all times by an authorized individual. DOJ Authorized Persons must maintain visual contact with the visitor(s) at all times. At no point, may a visitor(s) be left unattended while in secured areas or laboratories containing Select Agents. Visitors who are not United States citizens are required to have written authorization before entering labs.

- Proper training of all staff (including students) that uses the BSL3 suite will be provided by **Thomas A. Ficht/Garry Adams**.

- Laboratories, facilities, and storage equipment (refrigerators, freezers, cabinets, incubators, and other containers) that contain a Select Agent need to be separate from the public areas of the buildings.

- Select Agents and toxins requiring freezers, refrigerators, cabinets, and other containers where they are stored will be secured against unauthorized access (e.g., card access system, lock boxes, etc.).

- Lock all equipment (e.g. freezers, cabinets, incubators, scintillation counters) that contain hazardous materials and are locked in hallways or areas outside of facilities or laboratories.

- Laboratories, storage areas, and equipment (e.g. freezers, refrigerators, cabinets, etc.) will be locked when the Select Agents (stocks of biological agents, hazardous chemicals or radioactive materials) are not in direct view of authorized staff (e.g. when located in unattended storage areas).

- Protocols for changing access numbers or locks following staff changes are included in the **Biosafety Plan**.

- Emergency contact signs will be placed on facility and laboratory doors, including 24-hour contact numbers. Emergency contact signs include the names and contact information such as work telephone and alternate telephone numbers of the Principal Investigator, Biosafety Officer, and the person(s) responsible for the building or facility. Also, included are telephone numbers for the University Police Department and College Station Fire Department. (Emergency contact information is found in the **Incident Response Plan**.)

Additional steps to be taken during laboratory renovations:

In order to achieve a higher level of security of the one inventory storage room during the continued renovation period, select personnel will conduct periodic visual exterior examinations of the inventory storage room door throughout the construction work day. The person conducting the visual examination of the door will be looking for any type of tampering to the exterior of the door or the locking mechanism. This person will also visually examine the ceiling adjacent to this room for tampering. After the exterior examination, the person will sign a log attesting to the examination. The log (attached) should contain the person's printed name, signature or initials, date, and time of the examination. Any discrepancies shall be immediately reported to UPD and the lab director using the procedure outlined in the **Incident Response Plan**, as well as a notation in the log.

Examinations shall occur, at a minimum, three times daily during construction. One examination before construction crews begin work; once during the work day; and once after construction crews leave for the work day. Additional daily examinations are encouraged.

After construction crews leave for the work day, all exterior doors to the lab suite under renovation should be secured.

B. **Information Systems Control:**

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

C. **Personnel Security:**

Only DOJ Authorized Persons (cleared by the US Department of Justice as indicated in HHS 42 CFR Part 73.8) will have access to Select Agents. These policies are required for compliance with the HHS/CDC and USDA regulations for Select Agents. Standard Operating Procedures establishing the following requirements, at minimum, have been included in the **Biosafety Plan**.

- All visitors shall be escorted in the BSL-3 facility by a DOJ Authorized Person. Visitors must sign in and out in the Facility Access Log. DOJ Authorized Persons must maintain visual contact with the visitor(s) at all times. At no point, may a visitor(s) be left unattended while in secured areas or laboratories containing Select Agents.

- DOJ Authorized Persons will receive laboratory safety and security training when initial DOJ Select Agent access approval is granted; annually thereafter and when new requirements are implemented. Visitors will receive laboratory safety and security training prior to the first entry to a secured area or laboratory containing Select Agents; annually thereafter and when new requirements are implemented. Additionally, as the Principal Investigator, I will mentor

and assess scientific/lab skills with persons working within their labs on an ongoing basis. All training should be documented on the Security and Safety Training Certificate.

- All other individuals, including maintenance workers and visitors, understand security requirements will be trained and equipped to follow established procedures.

- Below is a description of the minimum education and experience criteria for DOJ Authorized Persons with access to Select Agents or toxins, physical security, and cyber security. Describe the minimum education and experience criteria here:

  Personnel having access to the select agent must (at a minimum) have a bachelor's degree in microbiology or a related field and had training in microbiology including sterile technique and the growth and preservation of bacterial agents, and mammalian cell culture. On the job training includes cyber and physical security, as well as BSL3 safety and select agent security.

  - All DOJ Authorized Persons, as well as workers and new employees, will be known to facility and laboratory personnel.

  - All DOJ Authorized Persons approved for access to Select Agents (including students) will wear a visible identification badge that includes, at a minimum, a photograph, the wearer's name, and an expiration date.

  - Visitors should be issued an identification badge including their name and an expiration date.

  - Visitors will be escorted at all times when in an area where Select Agents are present.

  - Police, fire, and other emergency responders will be informed as to the types of biological materials that are in use in the laboratory areas.

  - Security procedures will be reviewed whenever an incident occurs or a new threat is identified.

    - Procedures for reporting and removing unauthorized persons are described in the **Incident Response Plan**.

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

D. Access Control:

Standard Operating Procedures, establishing the following requirements, at minimum, to control access to areas where hazardous materials are used and stored, or outlined in the **Biosafety Plan**, and the **Incident Response Plan**.

- Provide provisions that allow unescorted access only to DOJ Authorized Persons (HHS 42 CFR Part 73.8) who are performing a specifically authorized function during hours required to perform the defined job.

- It is best to use the "buddy system" when working with hazardous materials in a facility or laboratory. However, if it is necessary to work in the facility or laboratory alone during non-routine hours, let someone know where you will be and how long you expect to be in the facility or laboratory. Arrange for someone to check on you at least hourly.

- Only DOJ Authorized people (workers, students, visiting scientists, etc.) required to perform a job should be allowed in a facility or laboratory and animal housing areas at hours (when laboratory employees are present) required to perform their particular job (including routine cleaning, maintenance, repairs, also delivery to outside shipping agent for transportation in commerce).

- Access during non-routine work hours should be limited to authorized personnel. Allow individuals not approved for access (HHS 42 CFR Part 73.8) from the HHS Secretary or Administrator to conduct routine cleaning, maintenance, repairs, and other activities not related to Select Agents or toxins only when continually escorted and monitored by approved individuals (Part 73.8). Access for routine cleaning, maintenance, and repairs should be limited to hours when DOJ Authorized Persons are present. DOJ Authorized Persons must maintain visual contact with the visitor(s) at all times. At no point, may a visitor(s) be left unattended while in secured areas or laboratories containing Select Agents.

- Maintain a logbook to record entries of all visitors, maintenance workers, repairmen, and others needing one-time or occasional entry into an area where Select Agents are present. The means of identification should include a current valid picture driver's license or state identification card or passport. This information should be documented on the Facility Access Log.

- Provide provisions for the control of access to containers where Select Agents (stocks of biological agents, hazardous chemicals or radioactive materials) are stored by requiring laboratories, storage areas, equipment, freezers, refrigerators, cabinets, and other containers where stocks of Select Agents and toxins are stored to be locked (e.g., card access system, lock boxes) when they are not in the direct view of a DOJ Authorized Person (e.g. when located in unattended storage areas), and by using other monitoring measures as needed. Access control to areas where Select Agents are present could include card access (preferred), combination keypad, use of lock boxes to secure materials, video surveillance cameras, etc. A protocol for periodically changing combination keypad access numbers should be developed.

- Maintain a current list of authorized persons who possess door keys or those who have knowledge regarding the keypad access numbers or the security entry system.

- Each DOJ Authorized Person is prohibited from sharing with any other person their unique means of accessing a Select Agent or toxin (e.g., keycards or passwords).

- Procedures for loss or compromise of keys, passwords, combinations, change of authorization, reassignment of personnel, or staff changes are described below:

Loss of keys is reported to Cheryl Quinlan in VTPB and a new key is issued. Since key and passcard activation are required electronic access is monitored for suspicious activity.
Loss of passcard is reported immediately to Belinda Hale in the Deans's office of the CVM. Access of that card is inactivated.
Combinations to individual labs are updated monthly and whenever personnel changes occur.

E. Inventory Control:

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

At minimum, records should include:

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

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

- Thomas A. Ficht/Garry Adams must provide requirements and procedures for the termination of the use of a Select Agent or toxin in this **Security Plan**.

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

generated through recombinant technologies must be added to the repository and inventory database.

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

F. Shipping, Receiving, & Transferring Select Agents:

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

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

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

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

- The Environmental Health & Safety Department (EH&S), with the assistance of the University Police Department (UPD), will inspect all suspicious packages before they are brought into or removed from the area where Select Agents or toxins are used or stored. The recipient or receiving facility should be known to the sender and the sender should make an effort to ensure the materials are shipped to a facility or laboratory equipped to handle those materials safely. Contaminated or possibly contaminated materials should be decontaminated before they leave the facility or laboratory areas. All unexpected or suspicious packages will be inspected by visual or noninvasive techniques before they are brought into, or removed from, the area where Select Agents or toxins are used or stored. Guidelines for recognizing suspicious packages have been provided by the U.S. Postal Service and can be found at: http://www.usps.com/news/2001/press/pr01_1010tips.htm. If unexpected or suspicious Packages are received, then the sender should be contacted to verify that the package is legitimate. If any individual observes suspicious packages being transported out of the laboratory (for example, packages that have an unusual weight or size), then they should immediately notify UPD and wait for an officer to respond.

- All intra-facility transfers or external shipments (send/receive) of Select Agents must be documented and reported to the Responsible Official or designee (contact the Office of Research Compliance, 458-3624, and the Environmental Health and Safety Department, 845-2132). Transfers will remain under the supervision of a DOJ Authorized Person, including chain-of-custody documents and will remain in the possession of the Authorized person in order to safeguard against theft, loss, or release.

- The DOJ authorized person will inspect all packages upon entry to and exit from the area. All packages will be screened (visual and/or x-ray) before being brought into the laboratory area. If a suspicious or unexpected package is delivered to the facility or laboratory, **do not open it.** Contact the University Police Department (emergency 9-911; non-emergency 845-2345).

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

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

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

    - Thomas A. Ficht/Garry Adams will complete Section B- Sender (TRANSFEROR) Information of the **Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2)** upon receipt of form from the Recipient.
    - Thomas A. Ficht/Garry Adams will send the completed form to the ORC to obtain the RO/ARO signature.
    - t will inform EH&S. EH&S and t will coordinate to arrange the shipment of the package. EH&S will contact the transferring RO and Principal Investigator to verify shipping date and confirm shipping address.

- Once the signature has been obtained, the ORC will fax the completed form to the CDC for approval.
- The CDC will fax an approval to the RO of both the Sender and Receiver. The approval will then be forwarded to the ORC.
- Notification of approval will be sent to the ORC, and the ORC will inform t and EH&S of the approval.
- EH&S will assist t with the shipment and arrange transfer of package to user laboratory.
- EH&S will complete blocks 38-40 of Section D- Shipping Information of the form, and return completed form to the ORC.
- A copy of the Dangerous Goods manifest and air bill is maintained by EH&S.
- EHS/Principal Investigator notifies the receiving institution that the package has been shipped.

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

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

G. Incident Reporting and Breaches in Security:

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

- The University Police Department, the Responsible Official or designee, and Environmental Health and Safety will be notified in the event of:
  1) Any loss or compromise of keys, passwords, combinations, etc.;
  2) Any suspicious persons or activities;
  3) Suspicious packages;
  4) Any loss or theft of Select Agents or toxins;
  5) Missing chemicals;
  6) Any release of Select Agents or toxins;
  7) Any sign that inventory and use records of Select Agents or toxins have been altered or otherwise compromised;
  8) Cyber security breach;
  9) Non-biological incident such as violence against person;
  10) Unusual or threatening phone calls;
  11) Undocumented visitors;
  12) Severe weather and natural disasters.

- Upon discovery of a theft or loss of a Select Agent or toxin, an individual or entity must immediately notify CDC or APHIS and appropriate Federal, State, or local law enforcement agencies. Thefts or losses must be reported even if the Select Agent or toxin is subsequently recovered or the responsible parties are identified. (42 CFR 73.19)

- Establish procedures for removing unauthorized or suspicious persons.

H. Incident Response Plan:

The emergency response plan must be coordinated with any entity-wide plans. The plan must address such events as bomb threats, severe weather (hurricanes, floods), earthquakes, power outages, and other natural disasters or emergencies. Reference: http://finance.tamu.edu/ehsd/resources/gensafety/Emergency_Ref.asp.

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

- Police, fire, and other emergency responders should be informed as to the types of biological materials that are in use in the laboratory areas and special access control devices that are in use (e.g. card-key, etc.).

- Police, fire, and other emergency responders should assist in planning their responses to emergencies in the laboratory areas.

- The emergency response plan includes provisions for immediate notification of (and response by) laboratory directors, laboratory workers, safety office personnel, or other knowledgeable individuals when an emergency occurs.

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

PIs must complete the following:

In the event that a Select Agent must be relocated, t will contact James Samuel at The TAMU Health Science Center, who has agreed to offer their assistance in the storage of the agent. In the event of an emergency, with the approval of CDC and assistance from EHS, the agent will be moved using proper transport/shipping requirements.

I. Policies that address Breaches in Security

The Security Plan must contain procedures that require each individual approved under HHS 42 CFR Part 73.8 to report any of the following immediately to the Responsible Official:

1) Any loss or compromise of their key, passwords, combinations, etc:
2) Any suspicious persons or activities;
3) Any loss or theft of select agents and toxins:
4) Any release of select agents or toxins; and
5) Any sign that inventory and used records of selected agents or toxins have been altered or otherwise compromised.

- Report suspicious or unexplained behavior immediately to the University Police Department (emergency 9-911; non-emergency 845-2345) and the Responsible Official.

- If possible, program speed dial of emergency contacts (e.g., 9-911, facility or laboratory director, University Police 845-2345, etc.) on the phones in the facility or laboratory.

Laboratory Security Assessment

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Date:	April 18, 2007
Time:	09:00 hours
Facility: BSL-3 laboratory renovation / construction	
Location:	
Contact:	Dr. Thomas A. Ficht/Garry Adams Professor Veterinary Pathobiology (979) 845-4118

On Wednesday, April 18, 2007, I met with Dr. Ficht/Garry Adams and members of the laboratory facility renovation project in reference to an on-site security assessment pertaining to the construction period. Mr. Tilson Casey (Planner/Estimator/Project Manager-Physical Plant) was also present. The following observations and recommendations are based on our tour of the facilities and the information provided to me at that time. My goal is to address areas of security concerns that I believe need the most attention in order to achieve a higher level of security for the inventory during the renovation period.

Observations

The lab area renovation started in mid-March, 2007 and is scheduled to be completed by July, 2007. During this time period, lab rooms are closed for research. All four rooms are secured with separate door cipher lock systems. There are no viable cultures in rooms The inventory is secured in locked freezers within room Daily, Dr. Ficht/Garry Adams visually checks the exterior doors to the labs for security.

The two outer hallway doors leading into the shower areas are unlocked in the mornings for construction personnel. They are locked and secured during the evening and night hours.

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The cinderblock walls to the autoclave / decontamination room are currently undergoing renovations for the installation of a new autoclave. The new steel exterior door to the autoclave room is in place; however, the door's locking mechanism is not currently installed. To secure this area after-hours, the loading dock doors are secured to prevent entry into the building and hallway. Currently, there is a sheet of ¾ inch treated plywood (3 ½ feet wide x 6 feet tall) covering the hole space where the old autoclave was located. This covered hole space separates the autoclave room and the hallway adjoining the labs.

Considerations and Recommendations:

In order to achieve a higher level of security for the inventory during this temporary renovation period, two alternatives were discussed. The first alternative would involve physically moving the inventory freezers to another site location. If this alternative is adapted, special considerations and questions would have to be considered:

(1) Will moving the freezers in a non-emergency situation jeopardize the overall current security of the inventory?

(2) Will moving the freezers cause the inventory to melt?
(3) Will the alternate site have sufficient space and electricity?
(4) Finding an alternate site for the inventory would involve physically moving the freezers to another building location. The movement itself may not guarantee the level of security that the freezers currently sustain.
(5) Moving the freezers would also cause a delay in the renovation efforts.

Currently, the inventory is behind a secured door within secured freezers (two levels of security). Moving the inventory during a temporary non-emergency renovation period may not be the best solution.

The second alternative would entail having an on-site access approved researcher monitoring and "escorting" the construction personnel during the work day. This duty would be rotated between researchers during the construction day. The on-site access approved researcher can also monitor the secured inventory room while construction crews are in the area. All exterior doors to the lab area will be kept locked 24 hours / 7 days, except for construction crews removing debris or bringing materials into the area. An on-site access approved researcher will monitor the construction crew's movements. After a discussion, this alternative appears to be the better solution. Dr. Ficht/Garry Adams agreed to adopt this alternative with immediate implementation. He will set up a meeting with his researchers. All agreed.

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It was suggested and recommended that before any renovation continues, the locking mechanism to the new exterior door of the autoclave room be installed. Once installed, this door will remain closed and secured (24 hours), except for construction crews removing debris or bringing materials into the room. During the construction day, an on-site access approved researcher will monitor the construction crew's movement in the area as well as the secured inventory room. All agreed.

It was suggested and recommended that the two outer hallway doors leading into the shower areas be closed and secured during the day (24 hours), except for construction crews removing debris or bringing materials into the area. During the construction day, an on-site access approved researcher will monitor the construction crew's movement as well as the secured inventory room. All agreed.

The representative from Alpha Building Corporation will relinquish his set of door keys to Tilson Casey (Physical Plant-Project Manager) and the Key Control office. An on-site access approved researcher will "escort" and allow entry into the lab area during the renovation period.

The magnetic plate to one of the loading dock security doors has been replaced.

I noticed that the 12 inch electromagnetic bar, to which the door's magnetic plate attaches, is loose on one end. I suggest having this electromagnetic bar secured better to the door frame.

Conclusion:

This security assessment and recommendations for the BSL-3 lab located within the was based on the temporary renovation construction period for the lab. Dr. Ficht/Garry Adams and I certainly welcome any other suggestions or discussions.

Bert Kretzschmar
Texas A&M University Police Department

Updated Laboratory Security Assessment

CONFIDENTIAL

Date:	June 15, 2007
Time:	12:00 hours
Facility:	BSL-3 laboratory renovation / construction
Location:	

On Friday, June 15, 2007, I conferred with Angelia Raines (Director-Research Compliance) and Brent Mattox (Environmental Safety Manager) in reference to enhanced security measures of one SBAT storage room at the during continued renovation of the remaining lab suite. Ms. Raines also conferred with Dr. Gary Adams.

Observations

At this facility, only one room is currently registered with the Centers for Disease Control for the purpose of containing SBAT inventory storage. This room is secured with a cipher door lock system. The inventory is contained within locked freezers within this secured room. Construction workers will not have any type of access into this designated room.

The remaining rooms and areas within the lab suite are not currently registered. No SBAT storage or research is being conducted within the renovation area. Consequently, construction workers need not be escorted within the renovation area. The renovation started in mid-March, 2007 and was temporarily halted.

Recommendations:

In order to achieve a higher level of security of the one inventory storage room during the continued renovation period, my recommendation is to conduct periodic visual exterior examinations of the inventory storage room door throughout the construction work day. The person conducting the visual examination of the door will be looking for any type of tampering to the exterior of the door or the locking mechanism. This person will also visually examine the ceiling adjacent to this room for tampering. After the exterior examination, the person will sign a log attesting to the examination. The log should contain the person's printed name, signature or initials, date, and time of the examination. Any discrepancies shall be immediately reported to me and the lab director as well as a notation in the log.

I recommend the examinations occur, at a minimum, three times daily during construction. One examination before construction crews begin work; once during the work day; and once after construction crews leave for the work day. Additional daily examinations are encouraged.

After construction crews leave for the work day, all exterior doors to the lab suite under renovation should be secured.
The Security Plan for this lab suite should be updated.

Bert Kretzschmar
Assistant Chief of Police
Texas A&M University Police Department

Lab Renovations Security Inspection Log

Date	Time	Printed Name	Initials	Note of any discrepancies

Any discrepancies shall be immediately reported to UPD and the lab director using the procedure outlined in the **Incident Response Plan**, as well as a notation in the log.

INCIDENT RESPONSE PLAN

James Samuel

Building

Texas A&M University, College Station, TX 77843

to ensure compliance with

42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

1.1. General. This is the incident response plan for the possession and use of C. Burnetti, R. Prowazekii, B. Abortus, B. Melitensis and B. Suis. at Texas A&M University (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121. This plan covers the use of these select agents when used in building (rooms

1.2. This plan describe the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

2.1. Principal Investigator. The principal investigator, Dr. James Samuel has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to Dr. James Samuel

2.2. Oversight by Responsible Official and Alternate Responsible Official. Oversight of the select agent program is performed by the Responsible Official, the Alternate Responsible Official and the Biosafety Officer. Richard Ewing, Vice President for Research, is the Responsible Official at TAMU. The Alternate Responsible Officials is **Error! Bookmark not defined.**Angelia Raines. The Biosafety Officer is Brent Mattox. Dr. James Samuel will report incidents, as required, to the Biosafety Officer and the Responsible Official or Alternate Responsible Official. Where required, the Responsible Official will report incidents to CDC.

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

2.4. Contact Information. The **Principal Investigator** may be contacted during business hours at (979) 862-1684, at home at and on his mobile phone at His email address is jsamuel@.tamu.edu. The **Responsible Official**, Richard Ewing, may be contacted during normal business hours at (979) 845-8585 and at all other times at His email address is rewing@vprmail.tamu.edu. If the Responsible Official is unavailable, the **Alternate**

Responsible Official Angelia Raines may be contacted during normal business hours at (979) 847-9362 and at all other times at Her email address is araines@vprmail.tamu.edu. The **Biosafety Officer**, Brent Mattox can be reached at (979) 845-2132 during business hours, and after hours at His email address is bsmattox@neo.tamu.edu.

2.5.

3. **Description of Work**

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

Lab	Work description	Unique features	Biological Use Authorization	Biosafety Level

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

4. **Response to theft:**

4.1. Determination of Loss or Theft. Possible loss or theft of the select agent will be reported if any of the following have occurred:

4.1.1. The lock on the Select Agent storage area has been found open or appears to have been tampered with.

4.1.2. Evidence of forced entry into the laboratory or storage areas has been found.

4.1.3. A discrepancy in the Select Agent inventory has been identified.

4.1.4. An employee reports cultures or samples missing.

4.1.5. A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2.

4.1.6. An infected animal is missing from its microisolator cage.

4.2. Investigation of Loss or Theft by the Principal Investigator. Upon receiving a report of possible loss or theft of select agents, the Principal Investigator will immediately contact all personnel authorized for select agent access and call a meeting to determine whether the report of possible loss or theft can be explained by other means. For example, if an employee reports a malfunctioning lock, failure to note destruction of a strain in the inventory, or locates missing samples, the incident will be considered resolved, and no further report will be made.

4.2.1. Loss or Theft has not occurred: If the incident can be explained by means other than loss or theft (i.e. an employee reports having broken a lock or forgetting to record destruction of a culture, or has replaced the culture in the wrong location), the incident will be considered resolved and internal laboratory report will be filed. Procedures will be reviewed with laboratory personnel to prevent re-occurrence of the incident.

4.2.2. Loss or Theft has occurred: If no alternative explanation for the possible loss or theft of select agent can be found, the Principal Investigator will notify the Responsible Official for assistance in filing CDC Form 3, Report of Loss or Theft of select agent.

4.3. Release of a Select Agent or Toxin. Possible release of the agent or toxin will be reported if any of the following has occurred:

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

4.3.2. Simultaneous failure of the biosafety cabinet and negative pressure in the BSL-3 suite during work in the biosafety cabinet with open cultures.

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

4.3.3.1. Personnel should be advised to immediately leave the lab after removing any contaminated clothing and to return in tyvek suits with full face respirators after the air has been scrubbed clean by air handlers (approx one hour).

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

4.4. Exposure of laboratory personnel to cultures. The following incidents may result in unintentional exposure to the Select Agent that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to TAMU Occupational Health, where they will be given the option to initiate post-exposure prophylaxis. The exposure will be reported by the Principal Investigator to the Responsible Official, who will notify CDC of the exposure.

4.4.1. A spill of live culture outside the biosafety cabinet

4.4.2. Failure of the Biosafety Cabinet during work with the Select Agent

4.4.3. Needle stick or cut with sharps contaminated with enter the Select Agent

4.4.4. A bite from an infected animal, if the bite penetrates the double gloves and breaks the skin

4.4.5. A centrifuge accident that results in aerosolization of the Select Agent.

5. Security Breaches. **A security breach will be determined to have occurred if any of the following are observed:**

5.1. The access control system has failed, leaving the BSL-3 suite accessible to unauthorized persons.

5.2. An unauthorized person is observed unaccompanied in the BSL-3 suite
A lost or stolen card was used to access the BSL-3 laboratory

5.3. An unauthorized person has accessed the computer used to control entry to the BSL-3 suite.

5.4. An unexpected or suspicious package arrives in the laboratory.

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the Responsible Official of the security

breach and take steps to correct the problem. Within 24 hours, an inventory will be performed of all samples in the laboratory and in select agent storage. Any missing select agent samples will be reported to CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator and the Responsible Official will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

6. Severe weather or natural disasters. **The most likely occurrences in this area are severe thunderstorms, floods or earthquakes.**

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

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

   6.3. Power to the BSL-3 suite may be affected if the emergency generator is flooded. In this case, all samples should be secured inside the -80°C freezer. If the vivarium is threatened by flooding, animal cages should be fastened shut, put into secondary containers (biohazard bag or large Tupperware) and transported to LARR (CMP) for secure holding until the threat of flooding has passed. If it becomes necessary to evacuate the College Station area, all animal experiments will be terminated before evacuation by euthanizing the animals and storing the carcasses in the secure select agent storage in room.

   6.4. In case of a power outage, if there is no immediate danger to the building, secure all infectious samples inside a -80°C freezer, the +4°C refrigerator, or the incubators. The Biosafety cabinets and air handling system of the BSL-3 suite are on emergency backup power, which will prevent exposure to infectious samples in case of a power outage. Follow standard procedures for leaving the laboratory and return once the power has been restored to resume work.

7. **Fire, Gas leak, Steam leak, Explosion, Bomb threat:**

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

   7.2. Notify the appropriate emergency responders: Fire 4-911 or 911 from mobile phones, the Principal Investigator and the Biosafety Officer. For steam and gas leaks, notify TAMU Operations and Maintenance.

   7.3. In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police should be notified immediately by calling the emergency number, **9-1-1**. Also inform the Principal Investigator and Responsible Official. Always be sure to give the name of the building, room number, your name and telephone extension number.

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

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

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

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

9. **Workplace violence:**

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

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

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

10.1.1. Entry procedure for the BSL-3 laboratory: Don a Tyvek suit, gloves, shoe covers and respiratory protection (N95 mask) before entering laboratories.

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

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

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

10.1.4.1. Autoclaving. Autoclaves are located within the BSL3 suite.

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

11. Incident Response Plan Testing (Drills)

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

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

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

12. Emergency Response Plans (Crisis Management Plan)

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

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

12.3. The Responsible Official and Biosafety Officer should be contacted immediately in the case of any emergency in a select agent lab. The Responsible Official will coordinate access and information issues with campus police, fire, and emergency responders.

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

13. Site security and Control **are described in detail in the Select Agent Security Plan**

13.1. The laboratories are secured by a card reader and key. Sharing of key cards with other personnel is not permitted.

13.2. Individuals not authorized for access to select agents must be accompanied by approved personnel at all times while in the BSL-3 or ABSL-3 suites.

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

13.4. If approved personnel are observed violating security or biosafety procedures, this observation should be reported immediately to the Principal Investigator. The Principal investigator will investigate the allegation and determine whether the violator should have his/her select agent access suspended or revoked. Suspension of select agent access will be reported to the Responsible Official and the individual's key card access will be terminated within 24 hours.

14. **Inventory Discrepancies:**

14.1. Inventory discrepancies will be documented on the agent access form. The

14.2. All discrepancies will be immediately reported to the PI.

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

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

15. **References**

15.1. 42 CFR Part 73

15.2. 7 CFR Part 331

15.3. 9 CFR Part 121

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

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

Emergency Telephone Numbers

James Samuel	Office: 979 862-1684 Home: Mobile: (enter PI's mobile number)
Emergency	9-911
University Police	(979) 845-2345
College Station Police	(979) 764-3600
College Station Fire	(979) 764-3700
Environmental Health & Safety	(979) 845-2132
TAMU Area Maintenance (HVAC failure, steam leak, gas leak)	(979) 845-5542
TAMU Maintenance (24 hours)	(979) 845-4311
Radiological Emergencies	(979) 862-1111
Responsible University Officials:	
RO-Richard Ewing	Work: (979) 845-8585 Mobile:
ARO-Angelia Raines	Work: (979) 847-9362 Mobile:
Biosafety Officer/ARO -Brent Mattox	Work: (979) 845-2132 Mobile:
Building Manager	
George Martin	Work: 979-845-7902 Home:
James Samuel Lab-	(enter phone number of laboratory)
Neighboring labs to notify in case of simultaneous containment breach and spill outside BSC:	
Lab (enter additional locations)	(enter additional laboratory phone number)
Lab (enter additional locations)	(enter additional laboratory phone number)
Lab (enter additional locations)	(enter additional laboratory phone number)

Decontamination Procedures for Spills of Cultures

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

<u>Contents of spill kit located in BL-3 labs:</u>

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

29517

Office of the Vice President for Research
Texas A&M University

June 30, 2007

Richard E. Ewing
Vice President for
Research

Academic
Telecommunication
and Learning
Technologies

Center for Information
Assurance and Security

Comparative Medicine Program

Institute for
Scientific Computation

Integrative Center for
Homeland Security

Microscopy and Imaging Center

National Center
for Foreign Animal and
Zoonotic Disease Defense

Office of Distance Education

Office of Graduate Studies

Office of Proposal Development

Office of Research Compliance

Office of Sponsored Projects

Professional Development Group

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979.845.8585
FAX 979.845.1855

MEMORANDUM

FROM: Dr. Richard E. Ewing

TO: All employees involved in research with Select Biological Agents and Toxins

SUBJECT: **Cease and Desist Order from Violations of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 262a)**

As of today, June 30, 2007, **CDC's Division** of Select Agents and Toxins (DSAT) has expanded the cease and desist order, originally issued April 20, 2007, to include all work with select agents and toxins at Texas A&M University. Effective immediately, all select agent and toxin work must stop and all select agents and toxins must be securely stored until further notice.

As you are aware, the original cease and desist order issued by the Division of Select Agents and Toxins of the Centers for Disease Control and Prevention (CDC) covered the following:

1. The use of [redacted] Texas A&M University, for any and all manipulations and storage of Brucella abortus, Brucella melitensis, and Brucella suis until such time as a request for the amendment to the Texas A&M University's certificate of registration has been properly submitted by the Texas A&M University and approved by the Division of Select Agents and Toxins (DSAT), Centers for Disease Control and Prevention (CDC) in accordance with 42 C.F.R. part 73.

2. The experimental aerosolization of any select agent or toxin performed at the Texas A&M University.

3. Allowing access to select agents and toxins by any individual who has not been approved for such access by DSAT following a security risk assessment by the Attorney General of the United States.

While the order has now been expanded to cover work with all select agents on the campus of Texas A&M, effective immediately, all select agent and toxin work must stop and all select agents and toxins must be securely stored until further notice.

cc: Dr. Michael D. McKinney
Dr. Eddie J. Davis
Dr. Jerry R. Strawser
Dr. David S. Carlson
Dr. James A. Calvin
Dr. Fuller W. Bazer
Mr. Chris M. Meyers
Mr. Charley B. Clark
Mr. John M. Salsman
Ms. Angelia M. Raines
Mr. Brent S. Mattox
Dr. Vernon L. Tesh
Dr. Thomas A. Ficht
Dr. L. Garry Adams
Dr. James E. Samuel
Ms. Tiffany M. Agnew
IBC

VPR
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Texas A&M University

Fuller W. Bazer
Associate Vice President
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Office of Organizational
Development and Diversity

Professional Development Group

Technology Commercialization
Center

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June 12, 2007

MEMORANDUM

To: Mr. G. Dan Parker, Associate Executive Vice President

Through: Dr. Richard E. Ewing, Vice President for Research

From: Dr. Fuller W. Bazer, Associate Vice President for Research

Subject: Research Compliance for Biological Agents

In order to strengthen compliance for research with biological agents, particularly select agents as identified by the Center for Disease Control, the Office of the Vice President for Research requests the addition of funding to hire a person with a strong background in work with biological agents. This person will provide day-to-day oversight on research compliance issues for all faculties engaged in work with biological agents to ensure full compliance with CDC guidelines. The expectation is for a salary of $80,000 to $100,000 for a person with the desired credentials.

Thank you for your consideration of this request. Please let either of us know if additional information is required.

pc: Dr. James A. Calvin

CDC FY 07 29393

VPR
Office of the Vice President for Research
Texas A&M University

Richard E. Ewing
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May 17, 2007

Robbin Weyant, PhD, CAPT, USPHS
Director
Division of Select Agents and Toxins
Coordinating Office of Terrorism Preparedness and
Emergency Response
Department of Health and Human Services
Centers for Disease Control and Prevention
1600 Clifton Rd. MS A-46
Atlanta, GA 30333

RE: Response to Letter Received on May 4, 2007, Texas A&M University: Report of Site Visit; Request for Additional Information

Dr. Weyant:

The following report provides answers to the questions posed by the Centers for Disease Control and Prevention (CDC) in your letter regarding the site visit request for additional information.

The site visit was in response to a report submitted by Texas A&M University concerning an employee's exposure to Brucella on February 9, 2006.

At the time of the incident, the responsibility for managing CDC correspondence and communication was transitioning from one Alternate Responsible Official (ARO) to another and the report was inadvertently not submitted. Texas A&M University has never purposefully withheld reporting this occupational health exposure.

First, let us state that the exposure to was the result of an inadequate SOP with regard to the cleaning of the Madison Chamber. As you know, this research is proprietary, as is the SOP for cleaning the chamber. Our protocol was consistent with our prior experience using the Madison Chamber in experiments involving other select agents. However, it is now clear that the SOP must be amended to provide for more personal protection. We have enhanced the SOP to reflect this discovery.

Second, while was clearly not on the list to be involved with Brucella experimentation, her exposure was not related to carrying, using, manipulating, or gaining possession of the select agent. Rather, we believe she contacted the select agent as she cleaned the chamber. Therefore, to be clear, was not assisting in conducting the experiment, but did reach into the chamber when attempting to clean it. Again, a new SOP will be in place at Texas A&M to limit access to the labs and to broadly communicate all changes in the rules and procedures.

Texas A&M University is committed to the protection of its staff and the public from the risks of exposure to pathogenic microorganisms. We recognize the crucial need for new and improved practices and communication procedures across campus and have already begun implementing changes to assist in this effort. We are also undergoing an outside review from a peer institution and anticipate implementing many changes in response to the suggestions of the review team.

Observations noted on April 16, 2007, through April 18, 2007, at Texas A&M University (Page numbers from the BMBL or 42 CFR Part 73 specifying each requirement are given in parentheses).

Observations:

1. ***An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: Information about all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), and date and time of entry [42 CFR § 73.17(a)(4)].***

   Observation: At the time of the inspection, there was no record of access to room ated in being kept during the time the room was used for work with select agents.

   Request for supplemental information: Please provide an explanation as to why entries into were not being recorded as required under §73.17 (Records) and how your entity will comply with all the requirements of §73.17.

   Texas A&M Response: There are multiple rooms approved for select agent use within the biohazard facility in Access logs to the biohazard suite recorded facility entry listing a specific animal room housing animals infected with select agents. The animals were moved within the biohazard suite to or short periods of time to perform specific procedures, then returned to their original housing room. A separate log for was not maintained.

   After input from CDC during the last site visit, we have added a separate entry log used specifically for We have attached the log as well as the standard operating procedure for the use o (**Attachment A**).

2. ***A certificate of registration may be amended to reflect changes in circumstances (e.g., changes in the activities involving any select agents or toxins, or the***

addition or removal of select agents or toxins)(1) Prior to any change, the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application. [42 CFR § 73.7(h)(1].

Observation: Documentation provided to the CDC Inspectors indicated twelve aerosol experiments with *Brucella abortus* and *Brucella melitensis* had been performed using the aerosol chamber located in [redacted] located in [redacted] since October of 2005. To date, DSAT has not received or approved an amendment to update your certificate of registration to include these activities for [redacted]. In addition, your entity was notified on June 7, 2006 (see Amendment #4) that prior to any changes in the activities involving select agents, the entity's certificate of registration must be amended to include this work with select agents such as aerosolization experiments and that this amendment must be approved by DSAT prior to any work being performed.

Request for supplemental information: Please explain why your entity failed to submit an amendment and receive approval from DSAT prior to the twelve aerosol experiments *with Brucella abortus and Brucella melitensis* that had been performed using the aerosol chamber located in [redacted] *since October of 2005.*

Texas A&M Response: An amendment request for authorization to use *Brucella abortus* and *Brucella melitensis* was not submitted because the Institution did not recognize that use of the chamber with Brucella was not approved by CDC.

In 2004, use of the chamber for Coxiella was halted by the Institution to await CDC approval. This clear indication of the Institution's desire to comply with the regulations remains our highest priority. However, the Institution should have had knowledge that Dr. Ficht was not approved for use of the chamber with Brucella. Regrettably, the need for an amendment was not recognized. Even after the CDC inspection report of April 2006, which requested SOP's for Dr. Ficht's use of the chamber with Brucella (which were provided to CDC in May 2006), the Institution did not recognize that the use of the chamber with those agents was not authorized.

In response, the Institution has implemented a reorganization of duties for its SBAT program to prevent a reoccurrence of this type of error. Procedures, tracking systems, and training have been developed and additional personnel resources have been dedicated to this program.

3. ***An individual or entity required to register under this part may not provide an individual access to a select agent or toxin, and an individual may not access a select agent or toxin, unless the individual is approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General [42 CFR § 73. 10(a)].***

Observation: On February 9, 2006, , who has not received access approval from the DSAT, performed aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. After completed the aerosolization experiments with *Brucella melitensis* and *Brucella abortus*, she cleaned the aerosolization chamber by wiping down the rear inside of the chamber with disinfectant. This cleaning technique caused head and arm to enter into the interior of the chamber, most likely resulting in occupational exposure to either *Brucella melitensis* or *Brucella abortus*.

Request for supplemental information: Please provide an explanation regarding this apparent allowance of unauthorized access to select agents including: (1) Has your entity allowed other unauthorized access to select agents to other individuals and who are the individuals who had unauthorized access to select agents, along with dates, times, and select agents associated with other incidents of unauthorized access; (2) If your entity has been allowing unauthorized access to select agents besides this incident, what immediate actions have you taken to ensure that these individuals no longer have access; (3) What is your entity's plan of action to assure prevention of similar events from occurring; and, (4) During the unauthorized access, how was the select agent safeguarded against theft, loss, or release *(see* 42 *C.F. R.* § 73,11(a)) during this allowance of unauthorized access to select agents.

Texas A&M Response: did not perform aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. Our understanding of 42 CFR § 73.10 has been that a person is considered to have access to the agent if they have the *ability to carry, use, or manipulate it, or if they have the ability to gain possession of a select agent or toxin.*

The Institution does not allow unauthorized personnel access to select agents. who was under escort, was exposed to a contaminated surface. She did not have access to select agents and she did not perform any experiments. She should not have been allowed to clean the chamber.

To prevent future occurrences, additional training will be required of all approved personnel concerning prevention of escorted visitors having contact with potential contaminated surfaces.

4. ***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 [42 CFR 73,10(c)]. An individual or entity required to register under this part must provide information and training on biosafety and security to each individual with access approval from the HHS Secretary or Administrator before he/she has such access. In addition, an individual or entity must provide information and training on biosafety and security to each individual not approved for access from the HHS Secretary or Administrator before he/she works in or visits areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers,***

animal rooms, greenhouses, storage areas, etc). The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. (42 CFR 73.15 (a)].

Observation: On February 9, 2006, performed aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. According to , she did not receive training or have any experience in handling *Brucella melitensis*, *Brucella abortus* or *Brucella suis*.

Request for supplemental information: Please provide an explanation why did not receive the appropriate training prior to her work with select agents. Based on this incident, please describe your entity's plan of action to assure that all individuals who work or visit areas where select agents or toxins are handled or stored will be provided appropriate training.

Texas A&M Response: did not perform aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. Her presence in the laboratory was to assist in the correct operation of the Madison Chamber. She should have received training relating to *Brucella melitensis* and *Brucella abortus*.

As a result of this incident, no one will be allowed access to the chamber without documented proof of proper training. In addition, all personnel utilizing the BL3 chamber will be required to wear PAPRs. All Select Agent personnel will receive updated training with regard to the necessity of strict adherence to the regulatory requirements and standard operating procedures.

5. ***An individual or entity may not conduct a restricted experiment with a HHS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary. In addition, an individual or entity may not conduct a restricted experiment with an overlap select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary, after consultation with Administrator. Restricted experiments: Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents 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 [42 CFR §73.13 (a),(b)(1)].***

Observation: According to laboratory personnel interviewed by the CDC Inspectors, Dr. Ficht had conducted restricted experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents 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 (see 42 C.F.R. § 73.13(b)(1)). Specifically, experiments conducted by Dr. Ficht that involved the introduction of plasrnids containing

kanamycin and chloramphenicol resistance cassettes used as selectable markers in *Brucella melitensis, Brucella abortus* and *Brucella suis*. Please note that during the February 2005 inspection of your entity, the inspectors identified that PI Tsolis's standard operating procedures indicated restricted experiments being conducted and that this work was not reflected on the PI's statement of work for your entity's certification of registration. On April 11, 2005, you responded that "PI Tsolis' recombinant antibiotic resistance work has ceased and is not currently planned. If this type of work is considered in the future, an amendment to update the current registration for PI Tsolis will be submitted to the CDC."

Request for supplemental information: Please provide a detailed description of all select agent work being conducted by PIs at your entity; describe why any restricted experiments have been performed at TAMU without approval from DSAT, and what steps the entity will take to prevent reoccurrence of a restricted experiment being conducted without approval from the DSAT. Also, please provide a list of all select agent strains currently possessed by TAMU in which antibiotic resistance markers have been introduced using recombinant DNA techniques. In addition, please include a copy of any Institutional Biosafety Committee (IBC) minutes for all projects that involve select agents and toxins including a list of the IBC members, date the project was approved, and the justification for this approval.

Texas A&M Response: **Attachment B** contains details of the work with select agents for each principal investigator. The Institution is not conducting any restricted experiments. By the definition of a restricted experiment found in 42 CFR § 73.13 (b)(1); Experiments utilizing recombinant DNA that involve the deliberate transfer of the drug resistance trait to select agents 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—we do not conduct restricted experiments. Prior to conducting any restricted experiments, Texas A&M University will gain approval from DSAT.

The experiments using kanamycin and chloramphenicol are not restricted under the definition because either they are known to acquire the train naturally or they are not used to control brucellosis in humans, veterinary medicine, or agriculture. Details of PI Ficht's work, found in **Attachment B** contains further information regarding these experiments as well as references.

Attachment C contains the IBC documentation (application containing the risk assessment) for select agent research. This work was reviewed in 2003 and 2004 before IBC guidelines for documentation were clear. All select agent work is being re-reviewed this year. Documentation of those studies that have already been re-reviewed is included in this package. IBC minutes from the 2003-2004 period do not reflect specific project discussion or approval. These minutes do not specifically reference select agents. **Attachment D** contains a list of the IBC

members, and 2007 minutes including review and approval of select agent projects.

6. ***An individual or entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security: Allow access only to individuals with access approval from HHS Secretary or Administrator [42 CFR § 73.11(d) (1)].***

Observation: On February 9, 2006, } who has not received access approval from the DSAT, performed aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. After completed the aerosolization experiments with *Brucella melitensis* and *Brucella abortus*, she cleaned the aerosolization chamber by wiping down the rear inside of the chamber with disinfectant. This cleaning technique caused head and arm to enter into the interior of the chamber, most likely resulting in . occupational exposure to either *Brucella melitensis* or *Brucella abortus*.

Request for supplemental information: As your entity's security plan states *in section* C (Personnel Security) that "only DOJ authorized persons will have access to select agents," please provide an explanation regarding this apparent allowance of unauthorized access to select agents even though this practice deviates from the current policy outlined in your security plan.

Texas A&M Response: did not perform aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. Based on the definition of access found in 42 CFR § 73.10, never had the "ability to carry, use, or manipulate the agent, nor did she have the ability to gain possession of a select agent or toxin." Throughout the entire time she was in the laboratory, DOJ approved personnel escorted her. observed and instructed regarding use of the Madison Chamber, but did not perform the experiment.

As a result of the incident, however, all laboratory personnel are being retrained on the regulatory requirements in order to ensure that no unauthorized person will have access to select agents.

7. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, give its intended use. [42 CFR § 73.12].Ventilation should be provided in accordance with criteria from the Guide for Care and Use of Laboratory Animals. A ducted exhaust air ventilation system is provided. This system creates directional airflow which draws air into the laboratory from "clean" areas toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air may not be required, but should be considered based on site requirements, and specific agent manipulations and use conditions. The exhaust must be***

dispersed away from occupied areas and air intakes, or the exhaust anent be HEPA-filtered. Personnel must verify that the direction of the airflow (into the animal areas) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the animal room entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the animal spaces. Audible alarms should be considered to notify personnel of HVAC system failure [Biosafety in Microbiological and Biomedical Laboratories (BMBL): D8].

Observation: For room located in building the CDC Inspectors were unable to verify that the room had proper directional airflow at the time of the inspection because the visual monitoring system used to confirm directional airflow for the room was not functioning properly.

Request for supplemental information: As the CDC Inspectors were not able to confirm that the room had directional airflow, please provide documentation that Room 143 has a functional visual monitoring device and that the directional airflow is from "clean" area toward "contaminated" area.

Texas A&M Response: Room n Building has been tested and it is verified that airflow is directional into the laboratory. An indicator ball used as a visual indicator was stuck and has been repaired. The suite also has an auxiliary fan that is used to increase airflow due to filter loading and it has been engaged to further increase ventilation rates. Documentation provided as **Attachment E**.

8. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use [42 CFR §73.12]. The completed Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be reverified at least annually against these procedures as modified by operational experience [BMBL: D14].***

Observation: The entity did not provide documentation for located in buildin that annual verification was performed to ensure that the laboratory meets the design and operational parameters.

Request for supplemental information: Please provide this documentation.

Texas A&M Response: Copies of the annual verification for ' are included in **Attachment F**. Please note that the most recent verification resulted in an amendment to temporarily move the animals in that BL3 suite. We plan to relocate the animals as soon as the amendment is approved.

9. ***An individual or entity required to register under this part must develop and***

implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR §73.12]. Equipment and work surfaces in the room are routinely decontaminated with an effective disinfectant after work with the infectious agent, and especially after overt spills, splashes, or other contamination by infectious materials [BMBL: A7].

Observation: During the inspection of the aerosol chamber, the CDC Inspectors noted that the interior and exterior of the chamber contained a significant amount of animal hair.

Request for supplemental information: Please verify standard operating procedures that provide documentation that the chamber is routinely decontaminated with an effective disinfectant after work with the infectious agent to ensure removal of all contaminated materials, including hair and animal waste and explain if there was a deviation in standard protocols, what steps you will take to ensure that standard protocols are followed.

Texas A&M Response: Guinea pig hair was present in the chamber, but it is not considered to pose a risk to safe operation of the chamber. The procedure to disinfect and clean the chamber begins after the animals are removed. A chemical disinfectant is sprayed into the chamber completely coating all surfaces within the chamber. Following a period of several minutes to allow the disinfectant to have its effects, the interior surfaces of the chamber are wiped down manually using absorbent paper towels. This process removes all urine and fecal pellets and most animal hair from the interior of the chamber. However, when white hair from the guinea pigs is wet with disinfectant, it is particularly hard to see against the silver interior of the chamber, which is not well illuminated by room lights. Some hair tends to stick to the sides of the chamber despite thorough cleaning. These hairs pose no risk since they have been disinfected and do not preclude safe operation of the chamber.

The standard operating procedures for the chamber including decontamination are included in **Attachment G**.

10. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR §73.12]. 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 dispersed away from occupied areas and air intakes [BMBL: D11].***

Observation: According to documentation provided to the CDC Inspectors, the HEPA systems of the aerosol chamber located in are not routinely

verified or tested to ensure that the HEPA filters provide adequate protection. Dr. David McMurray provided documentation to the CDC Inspectors that the routine maintenance of the Madison Aerosol Chamber indicated that testing of the HEPA system is not necessary.

Request for supplemental information: Please provide documentation from the manufacturer regarding HEPA system maintenance to support this statement.

Texas A& M Response: The filters on the unit have been tested by an outside vendor and met the requirements of NSF/ANSI Standard 49-2004. Documentation provided in **Attachment H**. To our knowledge, and confirmed by Dr. McMurray, the only relevant documentation provided to CDC by Dr. McMurray was a copy of the May 2004 Operating Procedures for Aerosol Chamber. This documentation does not address testing or maintenance of the chamber. We do not have documentation from the manufacturer regarding HEPA system maintenance. EHSD will add the HEPA filtration on the aerosol chamber to the testing schedule for biological safety cabinets.

11. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR § 73.12]. All manipulations of infectious materials, 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 [BMBL: C5].***

Observation: The CDC Inspectors noted that the design of the chamber is such that after the aerosol challenge, the nebulization unit containing infectious material must be disassembled in the laboratory and not in the biosafety cabinet.

Request for supplemental information: Please provide documentation that safety procedures are established and followed to minimize the risk for laboratorians disassembling the nebulization unit containing infectious material.

Texas A&M Response: The attached standard operating procedures contain the safety procedures established to minimize the risk for laboratory personnel disassembling the nebulization unit containing infectious material (**Attachment I**).

12. ***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 (42 CFR § 73.12(b)]).***

Observation: Documentation provided to the CDC Inspectors indicated twelve aerosol experiments with *Brucella abortus* and *Brucella melitensis* had been performed using the aerosol chamber located in roor cated in since October of 2005. The CDC inspectors were informed that the established

biosafety protocols for work with *Mycobacterium* were used for the aerosol experiments with *Brucella melitensis* and *Brucella abortus*.

Request for supplemental information: Please provide documentation of (1) the dated risk assessment that was performed that indicated the biosafety procedures for work with *Mycobacterium* was sufficient to be used for the aerosol experiments with *Brucella melitensis and Brucella abortus;* (2) risk assessments for all select agent work being conducted by PIs at your entity to ensure that the biosafety and containment procedures are sufficient to contain the select agent or toxin, and (3) the procedures of how risk assessments are conducted to ensure that the biosafety and containment procedures are sufficient to contain the select agent or toxin.

Texas A&M Response: **Attachment C** contains the individual risk assessments for work with *Mycobacterium, Brucella melitensis and Brucella abortus,* as well as all other select agents currently used at Texas A&M University. EHSD reviews risk assessments submitted by the researcher for procedures involving work with select and infectious agents, along with the Institutional Biosafety Committee (IBC). EHSD works with the principal investigators/laboratory directors through the IBC to correct deficiencies noted in the risk assessments. As a result of new information on risk assessment published in the recent 5th edition of the BMBL, the Institution has developed an SOP for risk assessment. This procedure specifically addresses the content of risk assessments and defines the roles and responsibilities for the PI, BSO, and IBC. **Attachment J** contains the Risk Assessment SOP, which now requires signature from the Investigator, BSO and the IBC Chair.

13. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR §73.12]. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g. respirators, face shields) and physical containment devices are used [BMBL: C5].***

Observation: On February 9, 2006, aerosolization experiments were performed with *Brucella melitensis* and *Brucella abortus*. According to interviews with the laboratorians present during these experiments, the CDC Inspectors were told that the personal protective equipment being used consisted of an N-95 respirator, safety glasses with splash guards, tyvek suits and gloves. Based on the CDC Inspectors questions to the laboratorians about quantitative or qualitative fit testing for the N-95 respirators, the CDC Inspectors determined that none of these individuals had been fit tested with the N-95 respirators. In addition, the CDC Inspectors received documentation that annual respirator fit testing is not performed for all laboratory workers that use N-95 respirators.

Request for supplemental information: Please provide an explanation why laboratory workers are not tested to ensure that the N-95 respirator being used provides adequate respiratory protection.

Texas A&M Response: All laboratory workers wearing any respiratory protection are required to be fit-tested and trained prior to wearing respiratory protection. The use of PAPRs is now required in There was an inconsistency between the facility protocol and the researcher protocols and some researchers wore N-95 respirators. IBC will reinforce to all select agent participants that respiratory training and fitting are required prerequisites to wearing respiratory protection and that written protocols on personal protective equipment for joint-use facilities such as Buil nust be strictly adhered to and enforced. Individual protocols for select agent users in have been rewritten to require PAPRs. EHSD will provide the necessary training and fit-testing for personnel. A copy of the Respiratory Protection Plan utilized by EHSD is attached (**Attachment K**).

Observation: The "Operating Procedures for the Biosafety Laboratory Suite, document dated 2/22/07 that was provided to the CDC Inspectors states that N-95 respirators are used for aerosol studies. This contradicts the undated risk assessment document that was provided to the CDC Inspectors which states that powered air purifying respirators should be used.

Request for supplemental information: Please explain this discrepancy.

Texas A&M Response: The document dated 2/22/07 that included the use of N95 masks was in place prior to the incident; however, because of the way the document was set to "track changes," the date changed each time the document was used. The undated risk assessment document was completed after the incident. **Attachment I** contains the most current SOP.

14. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use [42 CFR § 73.12]. Laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures [BMBL: B7].***

Observation: The entity did not provide documentation that individuals operating the aerosol chamber had received training to ensure safety procedures were followed during operation of the chamber for the twelve aerosol experiments *with Brucella abortus and Brucella melitensis* that had been performed using the aerosol chamber located i.. . located in since October of 2005. The entity did not provide documentation that individuals operating the aerosol

chamber had received training to ensure safety procedures were followed during operation of the chamber.

Request for supplemental information: Please provide documentation that training was conducted including the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

Texas A&M Response: Attached are the most recent training documents (**Attachment L**), which includes a statement that the employees were trained to use the chamber in 2005. To ensure safety, security, incident response and regulatory compliance, all select agent personnel will be required to be retrained by June 1, 2007.

15. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR § 73.12]. Aside from the standard policies, procedures, and protocols for emergency situations established by the facility director, appropriate special policies and procedures should be developed as needed and approved by the Institutional Animal Care and Use Committee (IACUC) and the Institutional Biosafety Committee (IBC) [BMBL: A1].***

Request for supplemental information: Please provide documentation that the animal work that had been performed using the aerosol chamber located in room located in building since October of 2005 was approved by the Institutional Biosafety Committee (IBC) of TAMU. Please provide a copy of any IBC minutes approving the project including a list of the IBC members, date the project was approved, the justification for this approval, and the date(s) of the approval.

Texas A&M Response: **Attachment C** contains IBC documentation that animal work was approved. The work was reviewed before IBC guidelines for documentation were clearly established. All select agent work is being re-reviewed this year.

16. ***Upon discovery of a release of an agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area, an individual or entity must immediately notify CDC or APHIS [42 CFR § 73.19 (b]. An Individual or entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security: Require that individuals with access approval from the HHS Secretary or Administrator immediately report any of the following to the Responsible Official, any release of a select agent or toxin [42 CFR § 73.11 (d)(7)(iv)].***

Observation: Based on documentation provided to the CDC Inspectors, PI Ficht sent an email on April 21, 2006 to alternate Responsible Official Brent Mattox and alternate Responsible Official Angelia Raines that notified them of Dr. McFarland's occupational exposure.

Request for supplemental information: Please explain why the alternate Responsible Officials failed to immediately report the occupational exposure to the DSAT as required by 42 CFR §73.19 (b).

Texas A&M Response: The initial incident notification should have occurred during the time Texas A&M was preparing the initial response to the CDC 2006 inspection. The process for handling CDC incident reporting was undergoing organizational transition within the Institution, and as a result, both AROs believed that the other had the responsibility to report to the RO and to the CDC. In addition, there was some question on the part of one ARO as to whether an occupational exposure inside biocontainment constituted a "release". The BSO did work with the Investigator to investigate the incident and did work with the occupational health program to ensure health agency reporting. Nevertheless, the lack of reporting would not have occurred had better communication processes been in place.

In June 2006, the reporting requirements for incident response were clearly established and since then the Office of Research Compliance has been responsible for processing this information with input from the BSO and Principal Investigator, on behalf of the Responsible Official (RO). After discovering in April 2007, that this incident was not reported properly, we have reviewed our entire program and have clarified the incident reporting procedure that was established in June 2006.

Request for supplemental information: Please provide a summary of events that occurred when this email was received by the alternate Responsible Official who was acting on behalf of the Responsible Official including the follow up review that was conducted as a result of this email report. Please also explain why the alternate Responsible Official who was acting on behalf of the Responsible Official did not follow the security protocols outlined in the "TAMU Facilities and Research Laboratories with Select Agents" security plan.

Texas A&M Response: When the email was received by the Biosafety Officer/ARO, he reviewed the incident with the PI. He then worked with the institutional Occupational Health provider to evaluate all other employees who could have been exposed. Because of the way the event occurred, it was determined early on, that the exposure was a result of the employee reaching into the chamber to clean it after the select agent experiments had been completed. She was accustomed to using the chamber for non-select agent work and attempted to clean it as would have been the normal process. After reviewing

the incident, the PI and BSO determined that staff should be retrained to ensure that such an event would not occur again.

This was the first incident that occurred since Texas A&M had registered for the Select Agent program. The process for handling CDC incident reporting was undergoing organizational transition within the Institution and as a result, both AROs believed that the other had the responsibility to report to the RO and to the CDC. In addition, there was some question on the part of one ARO as to whether an occupational exposure inside biocontainment constituted a "release". The "TAMU Facilities and Research Laboratories with Select Agents" security plan, dated February 2006, stated on page 9 that CDC should be notified in the case of theft or loss of a select agent or toxin. It did not however, address notification of CDC in the event of a release. Furthermore, it did not specify who at the institution was responsible for notifying CDC in the event of a loss or a theft. This lack of specificity was a contributing factor to the confusion between AROs as to who had responsibility for reporting. Currently, the Institution reports all occupational exposures, including elevated titers, to CDC and it has been established that reporting requirements are the responsibility of the Office of Research Compliance (ORC).

In June 2006, ORC met with the Investigators and clarified the incident notification and reporting process. In December 2006, the process established in June 2006 was followed as a result of an incident that occurred. All required institutional representatives were informed, beginning with the RO, the BSO and the University Police. CDC was contacted and a report followed. The BSO and University Police immediately investigated with input from the Principal Investigator and laboratory staff. All plans (safety, security and incident reporting) were then reviewed by the Investigator, and changes were recommended and implemented. Staff received training regarding the process for counting animals.

We believe that after establishing the process and clarifying it with the Investigators in December 2006, we handled the incident based on CDC standards and requirements

17. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR § 73.12].An appropriate medical surveillance program is in place. All personnel receive appropriate immunizations or tests for the agents handled or potentially present When appropriate, a serum surveillance system should be implemented In general, persons who may be at increased risk of acquiring infection, or for whom infection might have serious consequences, are not allowed in the animal facility unless special procedures can eliminate the extra risk Assessment should be made by the Occupational Health Physician [BMBL: A3].***

Observation: On February 9, 2006, performed aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. After completed the aerosolization experiments with *Brucella melitensis* and *Brucella abortus*, she cleaned the aerosolization chamber by wiping down the rear inside of the chamber with disinfectant. This cleaning technique caused ead and arm to enter into the interior of the front of the chamber and most likely resulted in occupational exposure to either *Brucella melitensis* or *Brucella abortus*. Based on information provided by to the CDC Inspectors, no follow-up was conducted by TAMU following her occupational exposure even though she informed PI Ficht on April 12, 2006 that she had been diagnosed with brucellosis.

Request for supplemental information: Please describe the medical surveillance system in place at your entity including the post-exposure protocols and explain why your entity failed to follow up regarding occupational exposure.

Texas A&M Response: did not perform aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. A copy of the medical surveillance plan is provided in **Attachment M**. The employee is now regularly monitored in the surveillance program conducted through the Institution's Occupational Health and Safety program and is currently being monitored for Brucellosis serology every six months. Further, Scott & White Occupational Health Clinic, the Institution's occupational health provider since 2002, provides medical support and consultation to the Institution for all individuals enrolled in the medical surveillance program.

Based upon our assessment of the internal follow up, we recognize and acknowledge the opportunity to improve our current processes. While the Investigator contacted the Biological Safety Officer (BSO), and took steps to identify the problem, a more thorough post-exposure investigation should have occurred. In the future, the BSO will lead the post-exposure investigation, which will include immediate steps to isolate the problem, prevent other exposures and work in concert with the Investigator to reassess the risk associated with the laboratory. The PI will then determine the necessity for modifications to the Biosafety Plan, Incident Response Plan, and/or Security Plan and submit any changes to the IBC for review and approval. After IBC approval, the RO or designee will determine if a CDC amendment is required.

Additionally, if an incident occurs, after final disposition, the Office of Research Compliance (ORC) will convene a meeting of all Select Agent Investigators and the Institution's Select Agent Program personnel. The purpose of the meeting will be to provide this research community the opportunity to share information related to best practices in lab safety, security, incident planning and regulatory

compliance. Furthermore, we will pursue peer review by outside researchers familiar with select agent research and operating procedures.

CDC's statement that "no follow up was conducted by TAMU following her occupational exposure..." is incorrect. On April 21, 2006 a positive diagnosis was reported to Dr. Ficht and was immediately referred by Dr. Ficht with concurrence of the BSO, to Scott and White Occupational Health Clinic and remains to this day under Texas A&M's medical surveillance program.

18. ***Establish a protocol for intra-entity transfers under the supervision of an individual with access approval from the HHS Secretary or Administrator, including chain-of-custody documents and provisions for safeguarding against theft, loss, or release [42CFR § 73.9(a)].***

Observation: Based on documentation provided to the CDC Inspectors, the preparation of test samples for the twelve aerosol experiments with *Brucella abortus* and *Brucella melitensis* that had been performed using the aerosol chamber located in room located of building since October of 2005, was completed in laboratory room located in building

Request for supplemental information: Please provide the intra-entity transfer documentation that ensures that a security protocol was in place when these transfers occurred from laboratory room to room Building

Texas A&M Response: While the SOP indicates the process for intra-entity transfers, the Institution utilizes a form to document the chain of custody when a select agent is transferred between authorized users. This was a transfer of location only, not a transfer to another authorized individual. Dr. Ficht was authorized to possess the agent in both locations and the agent never left the possession of the Investigator. Therefore, intra-entity transfer documentation was not required. However, in accordance with the latest CDC Security Plan Template (March 2007), we will modify our institutional procedures to include movement from one location to another.

19. ***Upon discovery of a release of an agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area, an individual or entity must immediately notify CDC or APHIS [42 CFR § 73.19 (b)].***

Observation: Upon review of clinic records, there were laboratorians identified with elevated titers to *Coxiella burnetii,* the causative agent of Q-fever. On April 24, 2007, Angelia Raines submitted APHIS/CDC Form 3 to report the possible occupational exposure to *Coxiella burnetii.*

Request for supplemental information: Please provide occupational health records including the baseline titers pertaining to the exposed individuals that are related to this incident. In addition, please provide the records for John Park, Gordon Draper, Laura Quinlivan, Wilhelmina Boehout, Joshua Hill, Katia Mertens, Kasi Russel-Lodrigue, Jared Barker and James Samuel.

Texas A&M Response: Occupational Health Records, supplied by Scott & White Clinic, are included in **Attachment N**.

Request for supplemental information: Please provide a copy of the medical surveillance plan and describe the follow up that was conducted based on the plan as a result of the incident.

Texas A&M Response: As part of an Occupational Health Plan, workers with access to *Coxiella burnetii* will participate in a periodic serologic analysis for response to *Coxiella burnetii*. A serologic sample will be taken prior to work with virulent *Coxiella 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 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 suites have demonstrated proficiency in standard microbiological practices and techniques as well as practices specific to the suite.

In April 2007, the institution redefined occupational exposures to include elevated titers is now reporting all such incidents to CDC.

Request for supplemental information: Please describe corrective measures that have been implemented in order to prevent future incidents.

Texas A& M Response: The laboratory was completely decontaminated as a precaution; however, since a common source of exposure was not identified, other corrective actions were limited to those described above.

Request for supplemental information: Please describe any training that has been conducted as a result of this incident. Please provide documentation that training was conducted including the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

Texas A& M Response: No additional training has been required at this time.

Request for supplemental information: Please explain how your incident response and biosafety plans have been modified as a result of this incident.

Texas A& M Response: Review of the situation indicated that all components of the SOP for work with the agent are appropriate and ensuring minimal exposure to agent. . The incident response and biosafety plans have been reviewed and found appropriate.

20. ***Upon discovery of a theft or loss of a select agent or toxin, an individual or entity must immediately notify CDC or APHIS [42 CFR § 73.19 (a)].***

Observation: On January 29, 2006, Angelia Raines, the alternate Responsible Official reported a mouse that was infected with *Coxiella burnetii* was discovered missing on 12/21/06. Based on the response from Ms. Raines on 1/18/07, the DSAT has the following additional questions:

Request for supplemental information: Please explain how "Scot Holster" is listed on the "Facility Access Log" for Room when he is not listed as on the "Personnel who are have approved access to Laboratory (1/19/07)."

Texas A& M Response: CDC was contacted by Angelia Raines on December 21, 2006 and the required form was filed on December 22, 2006. Scot Holster should have been included on the list of "Personnel who have approved access to Laboratory (1/19/07)." Although Scot Holster has been approved by DSAT since 2004, our paperwork does not properly reflect the facility in which he is working. We are currently working with Jim McGee, of the CDC to update all of our information in order to ensure accuracy.

Request for supplemental information: Please provide a detailed description of the follow up conducted by your entity that explains your determination that your investigation had been "closed" because "the missing mouse was most likely included in the autoclaved bedding material and disposed." Please provide any logs or documentations that will support your determination. Since you reported the incident to local authorities (case #12-06-5068), please provide results of their investigation.

Texas A& M Response: **Attachment O** contains the case report for the incident, which includes details of the follow up.

Request for supplemental information: Please explain how the inventory records are reconciled as indicated on Section 5B of your approved application. Please provide a detailed description and supporting documents of how the inventories were verified during the report of the loss to ensure select agents were safeguarded against theft, loss, or release.

Texas A& M Response: Inventoried items, those that are stored (-80 C), are reconciled annually, with all individual vials inspected for accuracy. Infected animals are not considered stored, inventoried items. They are considered active and temporary cultures. Records of these cultures are maintained in research notebooks and these documents are used to reconcile their number.

Request for supplemental information: Please explain what security measures are in place at your entity to ensure select agents were safeguarded against theft, loss, or release.

Texas A& M Response: Our entity (. is secured by an approved personnel access system and finger print specific entry only.

Request for supplemental information: Please describe how your security and incident response plans have been reviewed and revised (if needed) as a result of your investigation to this report of loss.

Texas A&M Response: The security and incident response plans were reviewed and training performed to ensure that personnel are knowledgeable and compliant with plans.

Request for supplemental information: Please provide documentation regarding the training that was conducted in follow up to this incident including the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

Texas A&M Response: Documentation of training can be found in **Attachment P**.

21. ***An individual or entity required to register under this part must designate an individual to be the Responsible Official. The Responsible Official must: (1) Be approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General, (2) Be familiar with the requirements of this part, (3) Have authority and responsibility to act on behalf of the entity, (4) Ensure compliance with the requirements of this part [42 CFR § 73.9(a)]).***

Request for supplemental information: Based on the above observations noted during the inspection, please provide documentation that the Responsible Official is familiar and ensures compliance with the requirements of the select agent regulations including documentation of the most recent annual inspection conducted for each laboratory and assurances that no select agent or toxin work is being performed without the proper oversight.

Texas A& M Response: **Attachment F** contains information related to the most recent inspections.

As the RO for Texas A&M University, I am committed to ensuring that the best possible practices are in place to ensure laboratory safety and security as well as to maintain public trust. To that end, I have been approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General to act as the RO. I am familiar with the requirements of 42 CFR 73. I have authority and responsibility to act on behalf of the Texas A&M University, and I have put an organization in place to ensure compliance with the requirements of 42 CFR 73.

In an effort to improve our program, we recently had an external peer review conducted by the University of Texas Health Sciences Center at Houston and we are awaiting a written report. The review was led by UTHSC's Responsible Official and Institutional Biosafety Officer, Dr. Robert Emery. Most notably, based on their preliminary input, I have directed our organization to establish bi-monthly safety, security and compliance inspections so that I can take steps to immediately address any issues that compromise the success of our select agent research program. Other measures to improve our program are also being evaluated and will be implemented as they are developed, including outside peer researcher review.

While we are still establishing and increasing vigor in our procedures and training, I believe that we are building a program of best practices for select agent research.

Sincerely,

Richard E. Ewing

Dr. Richard E. Ewing

Enclosures (19)

pc: Micheal D. McKinney, Chancellor
Eddie J. Davis, Interim President
David B. Prior, Executive Vice President and Provost
Jerry R. Strawser, Interim Executive Vice President and Provost
Fuller W. Bazer, Associate Vice President for Research
Charley B.Clark, Associate VP for Risk, Compliance & Advisory Services
John M. Salsman, Director Environmental Health & Safety
Christopher M. Meyer, Assistant VP for Environmental Health & Safety
Brent S. Mattox, Manager Environmental Health & Safety
Angelia M. Raines, Director, Office of Research Compliance
Scott A. Kelly, Deputy General Counsel

CDC F/07

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April 20, 2007

APR 20 2007

Robbin Weyant, PhD, CAPT, USPHS
Director
Division of Select Agents and Toxins
Coordinating Office of Terrorism Preparedness and
Emergency Response
Department of Health and Human Services
Centers for Disease Control and Prevention
1600 Clifton Rd. MS A-46
Atlanta, GA 30333

RE: Cease and Desist Order from Violations of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 262a)

Dr. Weyant,

Per your letter dated April 20, 2007, Texas A&M University has taken measures to cease and desist from:

1. The use of , Texas A&M University, for any and all manipulations and storage of Brucella abortus, Brucella melitensis, and Brucella suis until such time as a request for the amendment to the Texas A&M University's certificate of registration has been properly submitted by the Texas A&M University and approved by the Division of Select Agents and Toxins (DSAT), Centers for Disease Control and Prevention (CDC) in accordance with 42 C.F.R. part 73.

2. The experimental aerosolization of any select agent or toxin performed at the Texas A&M University.

3. Allowing access to select agents and toxins by any individual who has not been approved for such access by DSAT following a security risk assessment by the Attorney General of the United States.

In addition, we will be providing enhanced training to all personnel involved with the Select Agent Program at Texas A&M, to ensure a program of increased safety and security.

Sincerely,

Richard E Ewing

Richard R. Ewing

VPR
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Texas A&M University

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April 20, 2007

Robbin Weyant, PhD, CAPT, USPHS
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3. Allowing access to select agents and toxins by any individual who has not been approved for such access by DSAT following a security risk assessment by the Attorney General of the United States.

In addition, we will be providing enhanced training to all personnel involved with the Select Agent Program at Texas A&M, to ensure a program of increased safety and security.

Sincerely,

Richard R. Ewing

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention (CDC)
Atlanta, GA 30333

April 20, 2007

Dr. Richard Ewing, Responsible Official
Texas A& M University (Registration #C20060605-0489)
1500 Research Parkway, Suite B150, TAMU 1186
College Station, TX 77843-1183
Fax: (979) 862-3176

SUBJECT: Cease and Desist Order from Violations of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 262a)

Texas A& M University is ordered to immediately cease and desist from:

1. The use of Texas A&M University, for any and all manipulations and storage of *Brucella abortus, Brucella melitensis,* and *Brucella suis* until such time as a request for the amendment of the Texas A&M University's certificate of registration has been properly submitted by the Texas A&M University and approved by the Division of Select Agents and Toxins (DSAT), Centers for Disease Control and Prevention (CDC) in accordance with 42 C.F.R. part 73.
2. The experimental aerosolization of any select agent or toxin performed at the Texas A&M University.
3. Allowing access to select agents and toxins by any individual who has not been approved for such access by the DSAT following a security risk assessment by the Attorney General of the United States.

Failure to immediately cease and desist from violating the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 could result in the immediate revocation of the Texas A&M University's certificate of registration for the possession, use, and transfer of select agents and toxins (42 C.F.R. §73.8); the imposition of civil penalties; and/or criminal prosecution of those individuals and institutions in willful violation. Should it become necessary to revoke the Texas A&M University's certificate of registration, Texas A&M University would be required to (1) immediately stop all use of each select agent or toxin covered by the revocation order; (2) immediately safeguard and secure each select agent or toxin covered by the revocation order from theft, loss, or release; and (3) comply with all DSAT disposition instructions for those select agents or toxins in the possession and control of Texas A&M University. (42 C.F.R. §73.8(b)).

As you know, during the period April 16 through April 18, 2007, CDC inspectors conducted a review of some of the Texas A&M University's facilities associated with the use and storage of select agents and toxins. During the course of that inspection, the inspectors noted numerous serious deficiencies in biosafety and security standards and requirements. You will receive a full

report of their findings under a separate cover.

Our immediate concern is the lack of proper biosafety and security practices used in aerosol experiments conducted under the direction of Dr. Thomas Ficht, in which a laboratorian had an occupational exposure to *Brucella* in February, 2006. While federal regulations (42 C.F.R. §73.19) require immediate notification to DSAT of such an occupational exposure, followed by a written report to DSAT within seven (7) days, DSAT received no notice of the occupational exposure until April, 2007. Additionally, I note that work involving *Brucella abortus, Brucella melitensis,* and *Brucella suis* is not currently approved by DSAT for Room 143 in Building 972.

Please be reminded that a certificate of registration must be amended to reflect changes in circumstances (i.e. changes in the activities involving any select agents or toxins) prior to any change; and that the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application (*See* 42 C.F.R. §73.7(h)).

If you have any questions, please contact Lori Bane, DSAT Compliance Officer at 404-718-2006 or at the address listed below.

Robbin Weyant, PhD, CAPT, USPHS
Director
Division of Select Agents and Toxins
Coordinating Office of Terrorism Preparedness and
Emergency Response

CDC FY 07

Office of the Vice President for Research
Texas A&M University

Richard E. Ewing
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April 20, 2007

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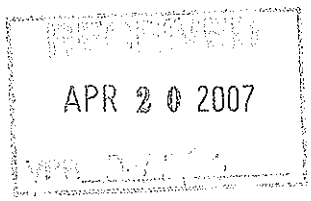

RE: Cease and Desist Order from Violations of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 262a)

Dr. Weyant,

Per your letter dated April 20, 2007, Texas A&M University has taken measures to cease and desist from:

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3. Allowing access to select agents and toxins by any individual who has not been approved for such access by DSAT following a security risk assessment by the Attorney General of the United States.

In addition, we will be providing enhanced training to all personnel involved with the Select Agent Program at Texas A&M, to ensure a program of increased safety and security.

Sincerely,

Richard R. Ewing

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention (CDC)
Atlanta, GA 30333

April 20, 2007

Dr. Richard Ewing, Responsible Official
Texas A& M University (Registration #C20060605-0489)
1500 Research Parkway, Suite B150, TAMU 1186
College Station, TX 77843-1183
Fax: (979) 862-3176

SUBJECT: Cease and Desist Order from Violations of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 262a)

Texas A& M University is ordered to immediately cease and desist from:

1. The use of [redacted] Texas A&M University, for any and all manipulations and storage of *Brucella abortus, Brucella melitensis,* and *Brucella suis* until such time as a request for the amendment of the Texas A&M University's certificate of registration has been properly submitted by the Texas A&M University and approved by the Division of Select Agents and Toxins (DSAT), Centers for Disease Control and Prevention (CDC) in accordance with 42 C.F.R. part 73.
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Our immediate concern is the lack of proper biosafety and security practices used in aerosol experiments conducted under the direction of Dr. Thomas Ficht, in which a laboratorian had an occupational exposure to *Brucella* in February, 2006. While federal regulations (42 C.F.R. §73.19) require immediate notification to DSAT of such an occupational exposure, followed by a written report to DSAT within seven (7) days, DSAT received no notice of the occupational exposure until April, 2007. Additionally, I note that work involving *Brucella abortus, Brucella melitensis,* and *Brucella suis* is not currently approved by DSAT for Room 143 in Building 972.

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If you have any questions, please contact Lori Bane, DSAT Compliance Officer at 404-718-2006 or at the address listed below.

Robbin Weyant, PhD, CAPT, USPHS
Director
Division of Select Agents and Toxins
Coordinating Office of Terrorism Preparedness and
Emergency Response

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

F-107

May 4, 2007

Richard Ewing, Responsible Official
Texas A& M University (Registration #C20060605-0489)
1112 TAMU
College Station, TX 77843-1112
FAX: (979) 845-1855

Subject: Texas A& M University: Report of Site Visit; Request for Additional Information

On April 11, 2007, the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) received the APHIS/CDC Form 3 (Report of Theft, Loss, or Release of Select Agents and Toxins) from Texas A&M University (TAMU) reporting the occupational exposure to *Brucella* on February 9, 2006 that resulted in infection of a laboratory worker.

During the period April 16, 2007 through April 18, 2007, the following representatives from the CDC visited TAMU located at 1112 TAMU, College Station, TX 77843:

Diane Martin, Lead Inspector
Richard Henkel, Biosafety Manager
Melissa Resnick, Epidemic Intelligence Service Officer

Individuals from TAMU present during the site visit included:

Richard Ewing, Vice President (VP) of Research, Responsible Official
Angelia Raines, Dir-Office of Research Compliance, alternate Responsible Official
John Salsman, Director, Environmental Health and Safety Department (EHSD)
Brent Mattox, Biosafety Officer, EHSD, alternate Responsible Official
Chris Meyer, Asst. VP, Safety & Security
Tiffany Agnew, Environmental Biosafety Program Coordinator
Thomas Ficht, Professor, Principal Investigator
L.G. Adams, Associate Dean, Principal Investigator
Angela Arenas, Graduate Student
Christine McFarland, Research Associate
Jianwu Pei, Assistant Research Scientist
Linda Clark, Assistant Executive Director, Scott & White Clinic
Jack Crouch, Occupational Medicine Supervisor, Scott & White Clinic
Melissa Kahl-McDonagh, Postdoctoral Research Fellow

The purpose of the site visit was to (1) review the events surrounding the occupational exposure to *Brucella* that occurred on February 9, 2006 in and assess the measures implemented to prevent other such incidents; (2) assess measures implemented by TAMU to protect the staff and public from exposure to pathogenic microorganisms; and (3) and to otherwise evaluate your entity's compliance with the select agent regulations (7 C.F.R. part 331, 9 C.F.R. part 121, 42 C.F.R. part 73).

Overview of the incident:

The incident occurred in n the TAMU main campus. A free-standing aerosolization chamber is located in this room. At the time of the incident, the room was shared by three research groups, involving work with *Mycobacterium, Coxiella burnetii, Brucella melitensis, Brucella suis,* and *Brucella abortus*. The room is not currently authorized by DSAT for the performance of aerosolization experiments with *Brucella melitensis, Brucella suis,* and *Brucella abortus*. Based on conversations with the laboratory workers present during the February 9, 2006 occupational exposure, id, a researcher from the *Mycobacterium* group who frequently uses the chamber, was asked to assist Melissa Kahl-McDonagh and her fellow *Brucella* researchers with loading and operation of the chamber. has not received select agent access approval from the DSAT lid not receive training to perform aerosolization experiments with *Brucella melitensis, Brucella suis,* and *Brucella abortus*. After completed the aerosolization experiments with *Brucella melitensis* and *Brucella abortus*, she cleaned the aerosolization chamber with disinfectant. This cleaning technique caused head and arm to enter into the interior of the chamber most likely resulted in occupational exposure to either *Brucella melitensis* or *Brucella abortus*. According to laboratorians present during the experiments, the aerosol chamber was not disinfected between the aerosolization experiments with *Brucella melitensis* and *Brucella abortus*.

According to a log kept by l, she first felt ill on March 25, 2006. On April 12, 2006, she informed Principal Investigator (PI) Dr. Tom Ficht that she had been diagnosed with brucellosis, with isolation of *Brucella melitensis* on April 16, 2006 by the Texas State Public Health Laboratory. She also filed a workman's compensation claim with Texas A& M University eturned to work on April 24, 2006. On April 21, 2006, PI Ficht sent an e-mail (see Attachment #2) to alternate Responsible Official Brent Mattox and alternative Responsible Official Angelia Raines, and the IBSP Coordinator, Tiffany Agnew, to notify them of the occupational exposure that resulted in being diagnosed with brucellosis.

Site visit:

On the morning of April 16, 2007, CDC representatives met with the Responsible Official, Dr. Richard Ewing and alternate Responsible Official Angelia Raines. The CDC representatives requested the following:

- All documents requested by DSAT in a fax sent to TAMU on April 13, 2007 (see Attachment #3).
- All records related to the reported occupational exposure including any updates to training, security plan, incident response plan, and the biosafety plan as a result of the incident, incident/corrective action report, access logs to the area and animal health records.
- Access to individuals involved with the reported February 9, 2006 occupational exposure to conduct interviews.
- Access to inspect where the reported occupational exposure had occurred.

The CDC representatives interviewed the following individuals:

- Richard Ewing, Vice President of Research, Responsible Official
- Angelia Raines, Dir-Office of Research Compliance, alternate Responsible Official
- Brent Mattox, Biological Safety Officer, Environmental Health and Safety (EHS)
- John Salsman, Director, EHS
- Thomas Ficht, Principal Investigator
-
- Jianwu Pei, Assistant Research Scientist
- Linda Clark, Assistant Executive Director, Scott & White Clinic
- Jack Crouch, Occupational Medicine Supervisor, Scott & White Clinic
- Melissa Kahl-McDonagh, Postdoctoral Research
- Christine McFarland, Research Associate

Enclosed as attachment 1 to this letter please find a list of observations and accompanying requests for supplemental information concerning the occupational exposure to *Brucella* that occurred on February 9, 2006 in [redacted] at TAMU. The DSAT should receive the supplemental information **by close of business May 18, 2007.**

The DSAT inspects each registered facility to ensure that it meets the appropriate safety and security standards, as well as record-keeping requirements, found in 42 CFR Part 73 ("Possession, Use and Transfer of Select Agents and Toxins; Final Rule"). Please be advised that the HHS Secretary may revoke a certificate of registration if the entity fails to comply with the provisions of 42 CFR Part 73 (*See* 42 C.F.R. § 73.8). On April 20, 2007, the DSAT faxed TAMU the "Cease and Desist Order" to immediately cease and desist from:

- The use of [redacted] Texas A&M University, for any and all manipulations and storage of *Brucella abortus, Brucella melitensis,* and *Brucella suis* until such time as a request for the amendment of the Texas A&M University's certificate of registration has been properly submitted by the Texas A&M University and approved by the Division of Select Agents and Toxins (DSAT), Centers for Disease Control and Prevention (CDC) in accordance with 42 C.F.R. part 73.
- The experimental aerosolization of any select agent or toxin performed at the Texas A&M University.
- Allowing access to select agents and toxins by any individual who has not been approved for such access by the DSAT following a security risk assessment by the Attorney General of the United States.

The DSAT will notify TAMU of any changes to this "cease and desist order" status.

Should you have further questions concerning this correspondence or the requirements of 42 CFR 73, please refer to our web site at http://www.cdc.gov/od/sap/ or contact Diane Martin, Lead Inspector with this office by mail at: Division of Select Agents and Toxins, 1600 Clifton Road, MS A-46, Atlanta, GA 30333, or by phone at (404) 718-2031, or fax at (404) 718-2096.

Sincerely,

Robbin Weyant, PhD, CAPT, USPHS
Director
Division of Select Agents and Toxins
Coordinating Office of Terrorism Preparedness and
Emergency Response

Observations noted on April 16, 2007 through April 18, 2007 at TAMU (Page numbers from the BMBL or 42 CFR Part 73 specifying each requirement are given in parentheses).

Observations:

1. ***An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: Information about all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), and date and time of entry [42 CFR § 73.17(a)(4)].***

   Observation: At the time of the inspection, there was no record of access to room [redacted] ng kept during the time the room was used for work with select agents.

   Request for supplemental information: Please provide an explanation as to why entries into room 143 were not being recorded as required under §73.17 (Records) and how your entity will comply with all the requirements of §73.17.

2. ***A certificate of registration may be amended to reflect changes in circumstances (e.g., changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins)(1) Prior to any change, the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application. [42 CFR § 73.7(h)(1)].***

   Observation: Documentation provided to the CDC Inspectors indicated twelve aerosol experiments with *Brucella abortus* and *Brucella melitensis* had been performed using the aerosol chamber located in [redacted] since October of 2005. To date, DSAT has not received or approved an amendment to update your certificate of registration to include these activities for room 143. In addition, your entity was notified on June 7, 2006 (see Amendment #4) that prior to any changes in the activities involving select agents, the entity's certificate of registration must be amended to include this work with select agents such as aerosolization experiments and that this amendment must be approved by DSAT prior to any work being performed.

   Request for supplemental information: Please explain why your entity failed to submit an amendment and receive approval from DSAT prior to the twelve aerosol experiments with *Brucella abortus* and *Brucella melitensis* that had been performed using the aerosol chamber located in room 143 since October of 2005.

3. ***An individual or entity required to register under this part may not provide an individual access to a select agent or toxin, and an individual may not access a select agent or toxin, unless the individual is approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General [42 CFR § 73.10(a)].***

   Observation: On February 9, 2006, [redacted], who has not received access approval from the DSAT, performed aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. After [redacted] completed the aerosolization experiments with *Brucella melitensis* and *Brucella abortus*, she cleaned the aerosolization chamber by wiping down the rear inside of the chamber with disinfectant. This cleaning technique caused [redacted]'s head and arm to enter into the interior of the chamber, most likely resulting in [redacted] occupational exposure to either *Brucella melitensis* or *Brucella abortus*.

   Request for supplemental information: Please provide an explanation regarding this apparent allowance of unauthorized access to select agents including: (1) Has your entity allowed other

unauthorized access to select agents to other individuals and who are the individuals who had unauthorized access to select agents, along with dates, times, and select agents associated with other incidents of unauthorized access; (2) If your entity has been allowing unauthorized access to select agents besides this incident, what immediate actions have you taken to ensure that these individuals no longer have access; (3) What is your entity's plan of action to assure prevention of similar events from occurring; and, (4) During the unauthorized access, how was the select agent safeguarded against theft, loss, or release (*see* 42 C.F. R. § 73.11(a)) during this allowance of unauthorized access to select agents.

4. ***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 [42 CFR § 73.10(c)]. An individual or entity required to register under this part must provide information and training on biosafety and security to each individual with access approval from the HHS Secretary or Administrator before he/she has such access. In addition, an individual or entity must provide information and training on biosafety and security to each individual not approved for access from the HHS Secretary or Administrator before he/she works in or visits areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, etc.). The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. [42 CFR 73.15(a)]***

Observation: On February 9, 2006, , performed aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. According to , she did not receive training or have any experience in handling *Brucella melitensis, Brucella abortus* or *Brucella suis*.

Request for supplemental information: Please provide an explanation why did not receive the appropriate training prior to her work with select agents. Based on this incident, please describe your entity's plan of action to assure that all individuals who work or visit areas where select agents or toxins are handled or stored will be provided appropriate training.

5. ***An individual or entity may not conduct a restricted experiment with a HHS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary. In addition, an individual or entity may not conduct a restricted experiment with an overlap select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary, after consultation with Administrator. Restricted experiments: Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents 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 [42 CFR §73.13 (a),(b)(1)].***

Observation: According to laboratory personnel interviewed by the CDC Inspectors, Dr. Ficht had conducted restricted experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents 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 (*see* 42 C.F.R. § 73.13(b)(1)). Specifically, experiments conducted by Dr. Ficht that involved the introduction of plasmids containing kanamycin and chloramphenicol resistance cassettes used as selectable markers in *Brucella melitensis, Brucella abortus* and *Brucella suis*. Please note that during the February 2005 inspection of your entity, the inspectors identified that PI Tsolis's standard operating procedures indicated restricted experiments being conducted and that this work was not reflected on the PI's statement of work for your entity's certification of registration. On April 11, 2005, you responded that "PI Tsolis' recombinant antibiotic resistance work has ceased and is not currently planned (see Attachment #5). If this type of work is considered in the future, an amendment to update the current registration for PI Tsolis will be submitted to the

CDC."

Request for supplemental information: Please provide a detailed description of all select agent work being conducted by PIs at your entity; describe why any restricted experiments have been performed at TAMU without approval from DSAT, and what steps the entity will take to prevent reoccurrence of a restricted experiment being conducted without approval from the DSAT. Also, please provide a list of all select agent strains currently possessed by TAMU in which antibiotic resistance markers have been introduced using recombinant DNA techniques. In addition, please include a copy of any Institutional Biosafety Committee (IBC) minutes for all projects that involve select agents and toxins including a list of the IBC members, date the project was approved, and the justification for this approval.

6. ***An individual or entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security: Allow access only to individuals with access approval from the HHS Secretary or Administrator [42 CFR §73.11(d)(1)].***

Observation: On February 9, 2006 , who has not received access approval from the DSAT, performed aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. After completed the aerosolization experiments with *Brucella melitensis* and *Brucella abortus*, she cleaned the aerosolization chamber by wiping down the rear inside of the chamber with disinfectant. This cleaning technique caused 's head and arm to enter into the interior of the chamber, most likely resulting in 's occupational exposure to either *Brucella melitensis* or *Brucella abortus*.

Request for supplemental information: As your entity's security plan states in section C (Personnel Security) that "only DOJ authorized persons will have access to select agents," please provide an explanation regarding this apparent allowance of unauthorized access to select agents even though this practice deviates from the current policy outlined in your security plan.

7. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR §73.12]. Ventilation should be provided in accordance with criteria from the Guide for Care and Use of Laboratory Animals. A ducted exhaust air ventilation system is provided. This system creates directional airflow which draws air into the laboratory from "clean" areas toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air may not be required, but should be considered based on site requirements, and specific agent manipulations and use conditions. The exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Personnel must verify that the direction of the airflow (into the animal areas) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the animal room entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the animal spaces. Audible alarms should be considered to notify personnel of HVAC system failure [Biosafety in Microbiological and Biomedical Laboratories (BMBL): D8].***

Observation: For located in the CDC Inspectors were unable to verify that the room had proper directional airflow at the time of the inspection because the visual monitoring system used to confirm directional airflow for the room was not functioning properly.

Request for supplemental information: As the CDC Inspectors were not able to confirm that the room had directional airflow, please provide documentation that roor as a functional visual monitoring device and that the directional airflow is from "clean" area toward "contaminated" area.

8. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR §73.12]. The completed Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be reverified at least annually against these procedures as modified by operational experience [BMBL: D14].***

   Observation: The entity did not provide documentation for that annual verification was performed to ensure that the laboratory meets the design and operational parameters.

   Request for supplemental information: Please provide this documentation.

9. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR §73.12]. Equipment and work surfaces in the room are routinely decontaminated with an effective disinfectant after work with the infectious agent, and especially after overt spills, splashes, or other contamination by infectious materials [BMBL: A7].***

   Observation: During the inspection of the aerosol chamber, the CDC Inspectors noted that the interior and exterior of the chamber contained a significant amount of animal hair.

   Request for supplemental information: Please verify standard operating procedures that provide documentation that the chamber is routinely decontaminated with an effective disinfectant after work with the infectious agent to ensure removal of all contaminated materials, including hair and animal waste and explain if there was a deviation in standard protocols, what steps you will take to ensure that standard protocols are followed.

10. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR §73.12]. 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 dispersed away from occupied areas and air intakes [BMBL: D11]***

    Observation: According to documentation provided to the CDC Inspectors, the HEPA systems of the aerosol chamber located in room 143 are not routinely verified or tested to ensure that the HEPA filters provide adequate protection. Dr. David McMurray provided documentation to the CDC Inspectors that the routine maintenance of the Madison Aerosol Chamber indicated that testing of the HEPA system is not necessary.

    Request for supplemental information: Please provide documentation from the manufacturer regarding HEPA system maintenance to support this statement.

11. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR §73.12]. All manipulations of infectious materials, 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 [BMBL: C5]***

    Observation: The CDC Inspectors noted that the design of the chamber is such that after the aerosol challenge, the nebulization unit containing infectious material must be disassembled in the laboratory

and not in the biosafety cabinet.

Request for supplemental information: Please provide documentation that safety procedures are established and followed to minimize the risk for laboratorians disassembling the nebulization unit containing infectious material.

12. ***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 [42 CFR § 73.12(b)]).***

Observation: Documentation provided to the CDC Inspectors indicated twelve aerosol experiments with *Brucella abortus* and *Brucella melitensis* had been performed using the aerosol chamber located in r since October of 2005. The CDC Inspectors were informed that the established biosafety protocols for work with *Mycobacterium* were used for the aerosol experiments with *Brucella melitensis and Brucella abortus.*

Request for supplemental information: Please provide documentation of (1) the dated risk assessment that was performed that indicated the biosafety procedures for work with *Mycobacterium* was sufficient to be used for the aerosol experiments with *Brucella melitensis and Brucella abortus;* (2) risk assessments for all select agent work being conducted by PIs at your entity to ensure that the biosafety and containment procedures are sufficient to contain the select agent or toxin, and (3) the procedures of how risk assessments are conducted to ensure that the biosafety and containment procedures are sufficient to contain the select agent or toxin.

13. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR §73.12]. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g. respirators, face shields) and physical containment devices are used [BMBL: C5]***

Observation: On February 9, 2006, aerosolization experiments were performed with *Brucella melitensis* and *Brucella abortus*. According to interviews with the laboratorians present during these experiments, the CDC Inspectors were told that the personal protective equipment being used consisted of an N-95 respirator, safety glasses with splash guards, tyvek suits and gloves. Based on the CDC Inspectors questions to the laboratorians about quantitative or qualitative fit testing for the N-95 respirators, the CDC Inspectors determined that none of these individuals had been fit tested with the N-95 respirators. In addition, the CDC Inspectors received documentation that annual respirator fit testing is not performed for all laboratory workers that use N-95 respirators.

Request for supplemental information: Please provide an explanation why laboratory workers are not tested to ensure that the N-95 respirator being used provides adequate respiratory protection.

Observation: The "Operating Procedures for the Biosafety Laboratory Suite,
' document dated 2/22/07 that was provided to the CDC Inspectors states that N-95 respirators are used for aerosol studies. This contradicts the undated risk assessment document that was provided to the CDC Inspectors which states that powered air purifying respirators should be used.

Request for supplemental information: Please explain this discrepancy.

14. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42***

CFR §73.12]. Laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures [BMBL: B7]

Observation: The entity did not provide documentation that individuals operating the aerosol chamber had received training to ensure safety procedures were followed during operation of the chamber for the twelve aerosol experiments with *Brucella abortus* and *Brucella melitensis* that had been performed using the aerosol chamber located in since October of 2005. The entity did not provide documentation that individuals operating the aerosol chamber had received training to ensure safety procedures were followed during operation of the chamber.

Request for supplemental information: Please provide documentation that training was conducted including the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

15. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR §73.12]. Aside from the standard policies, procedures, and protocols for emergency situations established by the facility director, appropriate special policies and procedures should be developed as needed and approved by the Institutional Animal Care and Use Committee (IACUC) and the Institutional Biosafety Committee (IBC) [BMBL: A1]***

Request for supplemental information: Please provide documentation that the animal work that had been performed using the aerosol chamber located in since October of 2005 was approved by the Institutional Biosafety Committee (IBC) of TAMU. Please provide a copy of any IBC minutes approving the project including a list of the IBC members, date the project was approved, the justification for this approval, and the date(s) of the approval.

16. ***Upon discovery of a release of an agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area, an individual or entity must immediately notify CDC or APHIS [42 CFR §73.19 (b)]. An Individual or entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security: Require that individuals with access approval from the HHS Secretary or Administrator immediately report any of the following to the Responsible Official, any release of a select agent or toxin [42 CFR §73.11 (d)(7)(iv)].***

Observation: Based on documentation provided to the CDC Inspectors, PI Ficht sent an e-mail on April 21, 2006 to alternate Responsible Official Brent Mattox and alternate Responsible Official Angelia Raines that notified them of occupational exposure.

Request for supplemental information: Please explain why the alternate Responsible Officials failed to immediately report the occupational exposure to the DSAT as required by 42 CFR §73.19 (b).

Request for supplemental information: Please provide a summary of events that occurred when this email was received by the alternate Responsible Official who was acting on behalf of the Responsible Official including the follow up review that was conducted as a result of this e-mail report. Please also explain why the alternate Responsible Official who was acting on behalf of the Responsible Official did not follow the security protocols outlined in the "TAMU Facilities and Research Laboratories with Select Agents" security plan.

17. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR §73.12].An appropriate medical surveillance program is in place. All personnel receive appropriate immunizations or tests for the agents handled or potentially present. When appropriate, a serum surveillance system should be implemented. In general, persons who may be at increased risk of acquiring infection, or for whom infection might have serious consequences, are not allowed in the animal facility unless special procedures can eliminate the extra risk. Assessment should be made by the Occupational Health Physician [BMBL: A3].***

Observation: On February 9, 2006, performed aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. After completed the aerosolization experiments with *Brucella melitensis* and *Brucella abortus*, she cleaned the aerosolization chamber by wiping down the rear inside of the chamber with disinfectant. This cleaning technique caused head and arm to enter into the interior of the chamber and most likely resulted in occupational exposure to either *Brucella melitensis* or *Brucella abortus*. Based on information provided by to the CDC Inspectors, no follow up was conducted by TAMU following her occupational exposure even though she informed PI Ficht on April 12, 2006 that she had been diagnosed with brucellosis.

Request for supplemental information: Please describe the medical surveillance system in place at your entity including the post-exposure protocols and explain why your entity failed to follow up regarding occupational exposure.

18. ***Establish a protocol for intra-entity transfers under the supervision of an individual with access approval from the HHS Secretary or Administrator, including chain-of-custody documents and provisions for safeguarding against theft, loss, or release [42CFR § 73.9(a)].***

Observation: Based on documentation provided to the CDC Inspectors, the preparation of test samples for the twelve aerosol experiments with *Brucella abortus* and *Brucella melitensis* that had been performed using the aerosol chamber located in located of since October of 2005, was completed in laboratory room 129 located in

Request for supplemental information: Please provide the intra-entity transfer documentation that ensures that a security protocol was in place when these transfers occurred from laboratory room 120

19. ***Upon discovery of a release of an agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area, an individual or entity must immediately notify CDC or APHIS [42 CFR §73.19 (b)].***

Observation: Upon review of clinic records, there were laboratorians identified with elevated titers to *Coxiella burnetii*, the causative agent of Q-fever. On April 24, 2007, Angelia Raines submitted APHIS/CDC Form 3 to report the possible occupational exposure to *Coxiella burnetii*.

Request for supplemental information: Please provide occupational health records including the baseline titers pertaining to the exposed individuals that are related to this incident. In addition, please provide the records for John Park, Gordon Draper, Laura Quinlivan, Wilhelmina Boehout, Joshua Hill, Katia Mertens, Kasi Russel-Lodrigue, Jared Barker and James Samuel.

Request for supplemental information: Please provide a copy of the medical surveillance plan and describe the follow up that was conducted based on the plan as a result of the incident.

Request for supplemental information: Please describe corrective measures that have been implemented in order to prevent future incidents.

Request for supplemental information: Please describe any training that has been conducted as a result of this incident. Please provide documentation that training was conducted including the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

Request for supplemental information: Please explain how your incident response and biosafety plans have been modified as a result of this incident.

20. ***Upon discovery of a theft or loss of a select agent or toxin, an individual or entity must immediately notify CDC or APHIS [42 CFR §73.19 (a)].***

Observation: On January 29, 2006, Angelia Raines, the alternate Responsible Official reported a mouse that was infected with *Coxiella burnetii* was discovered missing on 12/21/06. Based on the response from Ms. Raines on 1/18/07, the DSAT has the following additional questions:

Request for supplemental information: Please explain how "Scot Holster" is listed on the "Facility Access Log" for when he is not listed as on the "Personnel who are have approved access to Lab (1/19/07)."

Request for supplemental information: Please provide a detailed description of the follow up conducted by your entity that explains your determination that your investigation had been "closed" because "the missing mouse was most likely included in the autoclaved bedding material and disposed." Please provide any logs or documentations that will support your determination. Since you reported the incident to local authorities (case #12-06-5068), please provide results of their investigation.

Request for supplemental information: Please explain how the inventory records are reconciled as indicated on Section 5B of your approved application. Please provide a detailed description and supporting documents of how the inventories were verified during the report of the loss to ensure select agents were safeguarded against theft, loss, or release.

Request for supplemental information: Please explain what security measures are in place at your entity to ensure select agents were safeguarded against theft, loss, or release.

Request for supplemental information: Please describe how your security and incident response plans have been reviewed and revised (if needed) as a result of your investigation to this report of loss.

Request for supplemental information: Please provide documentation regarding the training that was conducted in follow up to this incident including the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

21. ***An individual or entity required to register under this part must designate an individual to be the Responsible Official. The Responsible Official must: (1) Be approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General, (2) Be familiar with the requirements of this part, (3) Have authority and responsibility to act on behalf of the entity, (4) Ensure compliance with the requirements of this part [42 CFR § 73.9(a)].***

Request for supplemental information: Based on the above observations noted during the inspection,

please provide documentation that the Responsible Official is familiar and ensures compliance with the requirements of the select agent regulations including documentation of the most recent annual inspection conducted for each laboratory and assurances that no select agent or toxin work is being performed without the proper oversight.

Recd 4-17-07

From: Tom Ficht <tficht@cvm.tamu.edu>
To: "Mattox, Brent S" <bsmattox@tamu.edu>, Angela Raines <ARaines@vpmail.tamu.edu>, Tiffany Agnew <tmagnew@tamu.edu>
Date: 4/21/2006 1:28:18 PM
Subject: FW: Workmen's Compensation

> Brent
>
> I wanted to let you know that has been diagnosed with
> brucellosis. apparently contracted the disease during an
> experimental challenge at (CMP) on the ninth of February 2006. At that
> time along with Dr. McMurray were training us in the use of the
> Madison chamber for aerosol inoculations.
>
> as been home sick for several weeks being treated by her personal
> physician and was only recently diagnosed. I heard about this last week
> (Mon or Tues) and instructed other personnel present at that challenge to
> have an an immediate blood draw for testing. The results should be
> available in another week or two.
>
> We do not know the exact cause exposure, although we assume
> it may have occurred as a result of cleaning out the Madison chamber after
> an aerosol run. In the future we plan to flush the chamber with
> disinfectant rather than using manual cleaning methods. The chamber will be
> wiped out after running disinfectant through the chamber, but this will
> involve the use of a long-handled applicator or mop. In addition, we will
> not rely on the use of N95 face masks and will instead use positive air
> displacement respirators.
>
> In the initial aerosol trials we relied on the experience of the TB
> researchers for the level of precaution typically employed in such
> experiments. It is suspected
> that a conjunctival route of infection is responsible for
> infection, perhaps as a result of manually cleaning the Madison chamber.
> It is my fault for not recognizing the differences between Brucella and
> Mycobacteria in regard to routes of infection.
>
> An isolation was made from a blood culture by physician and
> sent to TDH for confirmation. It would be helpful if EHSD could requested
> a sample of this isolate for culture confirmation here.
>
>
>
> Thomas A. Ficht, Ph.D.
> Professor
> Veterinary Pathobiology
> Texas A&M University
> 4467 TAMU
> College Station, TX 77843-4467
> 979-845-4118 ph
> 979-862-1088 fax

Attachment #2

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

April 13, 2007

Richard Ewing, Responsible Official
Texas A& M University (Registration #C20060605-0489)
1500 Research Parkway, Suite B150, TAMU 1186
College Station, TX 77843-1183
Fax: (979) 862-3176

Subject: 42 C.F.R. § 73.19 (Notification of theft, loss, or release)

Dear Dr. Ewing:

This is to acknowledge the receipt of the APHIS/CDC Form 3 (Report of Theft, Loss, or Release of Select Agents and Toxins) from Texas A& M University dated April 11, 2007 that reported an occupational exposure to *Brucella*. Based upon the review of the report, the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) has additional questions:

1. Please provide a copy of the medical surveillance plan and describe how the follow up was conducted as a result of the incident.
2. Please provide all occupational health records pertaining to the exposed individuals and any individuals that have presented with symptoms associated with a possible exposure to *Coxiella*, *Brucella*, or *Mycobacterium tuberculosis*.
3. Please provide documentation in regards to the risk assessment that was preformed for work with *Brucella*.
4. Please describe the decontamination procedures used for the aerosol chamber and any modifications incorporated to these procedures as a result of this incident.
5. Please provide all standard operating procedures (SOPs) and certification documents as it relates to the aerosol chamber.
6. Please provide a summary of events that occurred with this incident including the follow-up review that your entity conducted to assure that any other similar incidents do not occurred.
7. Since your entity failed to meet the reporting requirements of 42 C.F.R. § 73.19, please provide a plan of how Texas A& M University will achieve compliance with 42 C.F.R. 73. In addition, please explain if your entity failed to meet other required federal and state reporting requirements.
8. Please provide access logs for ! and all rooms were work with *Brucella* is performed.
9. Please explain how your incident response plan, security plan, and biosafety plan have been modified as a result of this incident.

Attachment #3

10. Please provide any personal protective equipment or entry requirements that may be needed prior to entry into your laboratories.
11. Please provide any documents regarding unexpected animal illness.
12. Please provide an assessment of the risks of continuing to utilize the aerosol chamber.
13. Please provide a detail description of the measures implemented to protect the employees from exposures while decontaminating the aerosol chamber including any enhanced personal protective equipment (PPE) utilized and the medical surveillance activities implemented. The long term follow-up of employees should be included in this response.

The DSAT will be conducting an inspection of your entity on April 16, 2007 to assess the measures implemented by Texas A& M University to protect the staff and public from exposure to pathogenic microorganism, the measures implemented to prevent further incidents and to evaluate your entity's compliance with the select agent regulations. Please make available all staff members involved in the incident described in your report dated April 11, 2007 to be interviewed by the inspection team.

On April 16, 2007, the following representatives from the CDC will be visiting Texas A& M University:

Diane Martin, Lead Inspector
Richard Henkel, Biosafety Officer
Melissa Resnick, EIS Officer

Please have the response and any supporting documentation available for the inspectors upon their arrival to your entity on April 16, 2007.

Please contact Lori Bane, Compliance Officer with the DSAT at 404-718-2006 or at the address listed below if you have questions.

Robbin Weyant, PhD, CAPT, USPHS
Director
Division of Select Agents and Toxins
Coordinating Office of Terrorism Preparedness and
Emergency Response

* * * COMMUNICATION RESULT REPORT (APR. 13. 2007 2:33PM) * * *

FAX HEADER 1: SELECT AGENTS PROGRAM 4047182096
FAX HEADER 2:

TRANSMITTED/STORED : APR. 13. 2007 2:32PM FILE MODE OPTION	ADDRESS	RESULT	PAGE
9608 MEMORY TX	979 862 3176	OK	2/2

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) NO ANSWER
E-3) BUSY
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

April 13, 2007

Richard Ewing, Responsible Official
Texas A& M University (Registration #C20060605-0489)
1500 Research Parkway, Suite B150, TAMU 1186
College Station, TX 77843-1183
Fax: (979) 862-3176

Subject: 42 C.F.R. § 73.19 (Notification of theft, loss, or release)

Dear Dr. Ewing:

This is to acknowledge the receipt of the APHIS/CDC Form 3 (Report of Theft, Loss, or Release of Select Agents and Toxins) from Texas A& M University dated April 11, 2007 that reported an occupational exposure to *Brucella*. Based upon the review of the report, the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) has additional questions:

1. Please provide a copy of the medical surveillance plan and describe how the follow up was conducted as a result of the incident.
2. Please provide all occupational health records pertaining to the exposed individuals and any individuals that have presented with symptoms associated with a possible exposure to *Coxiella*, *Brucella*, or *Mycobacterium tuberculosis*.
3. Please provide documentation in regards to the risk assessment that was preformed for work with *Brucella*.
4. Please describe the decontamination procedures used for the aerosol chamber and any modifications incorporated to these procedures as a result of this incident.
5. Please provide all standard operating procedures (SOPs) and certification documents as it relates to the aerosol chamber.
6. Please provide a summary of events that occurred with this incident including the follow-up review that your entity conducted to assure that any other similar incidents do not occurred.
7. Since your entity failed to meet the reporting requirements of 42 C.F.R. § 73.19, please provide a plan of how Texas A& M University will achieve compliance with 42 C.F.R. 73. In addition, please explain if your entity failed to meet other required federal and state reporting requirements.
8. Please provide access logs for Room and all rooms were work with *Brucella* is performed.
9. Please explain how your incident response plan, security plan, and biosafety plan have been modified as a result of this incident.

Yeager, Susan

From: Callcott, Diane
Sent: Monday, July 16, 2007 3:21 PM
To: Yeager, Susan
Subject: Emily Ramshaw address

Suzy ---The mailing address is:

Emily Ramshaw
Dallas Morning News, Austin Bureau
1005 Congress Avenue
Suite 903
Austin, TX 78701

Phone Number is 512-370-3810

I told her that we had redacted select agent location information and names of persons who had been exposed or had elevated titers. Also told her that we are waiting to hear from University Police to see if they have anything responsive and that if so, we will send it separately or give any additional records to her when she comes to campus on Thursday. I imagine that if UPD does have responsive records, they can be easily emailed.

I asked her to email us that she has received and accepts the information in redacted form after she has reviewed it so that we can withdraw our request to the A.G. for a ruling.

She asked me to send her my contact information as well and, not thinking that you will actually be sending it out from campus, I told her I'd put my card in the package. So why don't you just put a copy of this email in with the CD and she will have my information?. Let me know if you need any help getting it out today. ---Diane

Diane Callcott
Legal Assistant II / Public Information
Office of General Counsel
The Texas A&M University System
A&M System Bldg. Suite 2079
200 Technology Way
College Station, TX 77845-3424
d-callcott@tamu.edu
(979) 458-6149
(979) 458-6150 - facsimile

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

To: Richard E. Ewing, Responsible Official (R. O.)
Vice President for Research
Texas A&M University
1112 TAMU
College Station, TX 77843-1112
FAX: (979)845-1855

From: Centers for Disease Control and Prevention, Division of Select Agents and Toxins

Date: June 7, 2006

Re: Facility Inspection Report Response: Texas A&M University

Thank you for your inspection report responses dated May 4, 2006 and May 15, 2006 to the deficiencies listed in the report from the February 22-24, 2006 inspection of your facility. Please submit additional information with supporting documentation, as noted below, by June 15, 2006:

Observation 5

Requirement: An individual or entity required to register under this part must develop and implement a written biosafety plan 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. [42 CFR 73.12(a)]

Observation: PI Samuel's and Tesh's biosafety plans did not contain sufficient site specific information and documentation to describe the biosafety and containment procedures for work with select agents in laboratory suite Please provide documentation that addresses this requirement.

Entity Response: Tesh-No experiments utilizing the select agent E. coli DH5alpha(pCKS-112) are carried out in the BL3 suite. Room is used to store the agent and the registration has been amended to reflect this. All work on the agent is carried out in Room PI Samuel's plan has bee updated and included in Appendix D.

CDC Response: Please provide updated documentation that PI Samuel's biosafety plan includes, either by inclusion or reference, all of the standard BSL-3 microbiological practices as outlined in "Biosafety in Microbiological and Biomedical Laboratories" 4th ed., p. 27-28.

Observation 12

Requirement: The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. [42 CFR 73.14 (d)]

Observation: The entity incident response plan provided to inspectors was not dated. Although the plan documentation indicates that it will be reviewed and revised annually, there was no signature page or other method to document review. The plan stated that biannual exercises to train response personnel and evaluate the adequacy of the plan would be conducted but there was no evidence of an exercise being completed. The incident response plan template used by the principal investigators did not include a provision for drills or exercises to be conducted at least annually. Please provide documentation to address these requirements.

Entity Response: The entity response plan (crisis management plan) reviewed by the inspection team was a copy of information contained by our website. A signed and dated copy is attached. [See Appendix] The new incident

response plan template, to be used by all principal investigators, now includes a provision for drills or exercises to be conducted at least annually, and is attached. (See Appendix E)

CDC Response: The entity crisis management plan (CMP) states that the CMP shall be reviewed annually and modified as necessary. It also states that biannual exercises shall be held to train response personnel and evaluate the adequacy of the CMP. The entity crisis management plan submitted to CDC on May 15, 2006 is signed and dated in March 2003. The CMP packet does contain a "record of changes" log noting updates to the plan from 2004 and 2005 but it is not clear that this is a review or that these changes have been approved by management. Please provide documentation that this plan has been reviewed annually as stated. Please also provide an example of a report of a biannual exercise completed to evaluate the adequacy of the CMP and train response personnel.

Observation 26

Requirement: Biological safety cabinets and other physical containment devices are used whenever conducting procedures with a potential for creating aerosols. These include necropsy of infected animals, harvesting of tissues or fluids from infected animals or eggs, or intranasal inoculation of animals. At BSL-3 all work should be done in a primary barrier, otherwise respirators should be worn by personnel in the room. [BMBL, p. 66, C(4)]

Observation: Laboratory Building contains an aerolization chamber used by PI Ficht for work with select agent. There were no SOPs available for review by inspectors to ensure appropriate safety precautions have been established for this procedure. Please provide documentation that this departure has been addressed.

Entity Response: SOP's for the aerolization chamber are now in place. [See Appendix H]

CDC Response: As discussed during the February 22-24 inspection, it was stated that Principal Investigator Ficht would be performing aerosol work with select agents. Please be reminded that 42 CFR 73.7 states that prior to changes in the activities involving any select agents or toxins the certificate of registration must be amended by the entity to include that work. Prior to the work being approved by the Select Agent Program, standard operating procedures regarding the aerosol challenge will need to be submitted to address the following additional issues:

1) Please describe the mechanism used to ensure that after the aerosol procedure, there is no residual select agent remaining on the animal surface.
2) Are there any laboratory air sampling procedures to verify no equipment leaks?
3) How does the laboratorian know the nebulizer is functioning properly and not leaking?
4) Is the HEPA filtration system for aerolizer equipment certified?
5) Is the microisolator cage filtration system certified?
6) Has it been determined how many air changes/hour it takes to remove infected particles after each run?
7) Are the animals anaesthetized prior to transfer back to the microisolator cages? If not, describe the procedure if animals escape. Describe the procedure for animal bites or scratches.
8) Please provide more detail on the cleaning of the chamber to ensure that the worker is not exposed to any agent during the cleaning process.
9) Is there any air sampling of the chamber after cleaning?
10) How has it been determined that dipping the probe in 10% bleach provides adequate contact time for decontamination?

Based upon review of Amendment #39968, it is the Select Agent Program's understanding that Principal Investigator Samuel is currently approved to perform aerosolization work with *Coxiella burnetii*. Please provide clarification of the current status of this work including how the aerosol procedure is being conducted.

Observation 38

Requirement: HEPA filtered exhaust air from a Class II biosafety cabinet can be recirculated into the animal room if the cabinet is tested and certified at least annually. When exhaust air from Class II 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. When Class III biological safety cabinets are used, they should be directly connected to the exhaust system. If Class III cabinets are connected to the

VPR
Office of the Vice President for Research

April 11, 2005

Richard E. Ewing
Vice President for Research

VIA FACSIMILE @ 404/498-2265
(Original to follow via U.S. Mail)

Diane P. Martin, Lead Inspector
Select Agent Program
Department of Health and Human Services
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road N.E., MS E-79
Atlanta, Georgia 30333

RE: FACILITY INSPECTION REPORT – TEXAS A & M UNIVERSITY

Dear Mrs. Martin:

We are in receipt of your letter, dated March 25, 2005, detailing the observations made during the February 15 – 18, 2005 CDC Facility Inspection for Texas A & M University. The University has carefully reviewed the observations and offers its comments within Attachment 1-A-05.

If you require additional information or clarification on the comments contained within the attachment, please feel free to contact Angelia Raines, Research Compliance Director, in my office at 979/847-9362 or araines@vprmail.tamu.edu.

We appreciate your continued support and guidance on compliance issues in the CDC Select Agent Program.

Respectfully submitted,

Richard E. Ewing
Responsible Official

Attachment

xc: Dr. Robert M. Gates
President

Dr. David B. Prior
Executive Vice President and Provost

Dr. Fuller W. Bazer
Associate Vice President for Research

Texas A&M University
C20031123-0124
CDC030217
Accession #:
47567
Facility Inspection Report
Response (via mail)

Total # of Pages:
15

Received/Generated:
4/15/2005 at 10:27 AM
Input Date:
5/13/2005
Accessioned by
Paul Johnson
FOR OFFICIAL USE ONLY

RECEIVED
2005 APR 14 PM 12:27
CDC SELECT AGENT PROGRAM

RC-004

Attachment #5

CONFIDENTIAL ATTACHMENT 1-A-05

2005 CDC INSPECTION - FIRST RESPONSE

13. Requirement: To apply for a certificate of registration an entity must, in accordance with § 73.21, submit the information requested to the HHS Secretary or the USDA Secretary as specified in the registration application package [CDC Form 0.1319]. Information submitted will be used to determine whether the applicant would be eligible to conduct activities under this part. Minimum information required includes the location, including building and room and floor plans for each building and room, where each select agent or toxin will be stored or used. [42 CFR 73.7 (b)(2)(iii)]

CDC Observation:	TAMU Comment:
Equipment and structures have been added to rooms ____, ____. Floor plans on file at the CDC Select Agent Program do not include this added equipment.	Bldgs ____ are currently utilized for research not involving select agents but are occasionally modified to allow for this type of research to occur. At the time of inspection, no SBAT work was occurring in any of the ____ buildings. When select agents are in use, all buildings housing the select agents are returned to the original design (large animal stalls) as were viewed in ____ and identical to the floor plans on file at CDC. Prior to work with SBATs, ____ will be returned to the original design as shown on the floor plans submitted to CDC.

14. Requirement: A certificate of registration will be valid only for the specific select agents and toxins, and the specified activities and locations that are consistent with the information provided by the entity upon which the certificate of registration or amendment was granted. The Responsible Official must promptly notify the HHS Secretary in writing in accordance with § 73.21, if a change occurs in any information submitted to the HHS Secretary in the application for the certificate of registration or amendments. This includes modifications to the list of individuals approved under § 73.8, changes in area of work, or changes in protocols or objectives of studies. To apply for an amendment to a certificate or registration to add select agents or toxins or to change specified activities or locations, an entity must obtain the relevant portion of the registration application package and submit the information requested in the package to the agency that issued the certificate of registration. The package must be submitted to the appropriate address specified in the package. [42 CFR 73.7 (d)]

CDC Observation:	TAMU Comment:
Standard operating procedures for PI Tsolis identified recombinant antibiotic resistance work with a select agent. The PI's statement of work from the registration did not include this information.	PI Tsolis' recombinant antibiotic resistance work has ceased and is not currently planned. If this type of work is considered in the future, an amendment to update the current registration for PI Tsolis will be submitted to the CDC.

15. Requirement: Personnel wash their hands after handling cultures and animals, after removing gloves, and before leaving the animal facility. [BMBL, p.64, A(10)]

Compliance FYI

Office of the Vice President for Research
Texas A&M University

MAY 25 2007
VPR 29398

May 25, 2007

Memorandum

From: Dr. Richard E. Ewing

To All employees involved in research using Select Agents

Subject: Mandatory Training

All institutions and individuals that conduct research using select agents and toxins are required to adhere to federal regulations regarding their possession, use, and transfer. Select Agents are those identified on the HHS and USDA Select Agents and Toxins List and are considered to be agents posing a severe threat to human and/or animal health, plant health, or animal and plant products.

The Centers for Disease Control and Prevention (CDC) regulates and oversees the possession, use, and transfer of select agents and toxins that are used here at Texas A&M University. These regulations establish requirements for registration, risk assessments, access, safety plans, security plans, incident response plans, training, transfers, record keeping, inspections, and reporting.

Texas A&M University is committed to the protection of its staff and the public from the risks of exposure to Select Agents. After investigating recent events involving our Select Agent program, we have recognized the crucial need for training across campus.

In order to proceed in a timely manner to ensure that all employees involved in research using select agents are aware of and understand all of the regulatory requirements, mandatory training will be held on June 1, 2007. Training will begin at 9:00 a.m. and end at 1:00 p.m. It is imperative that you receive this training.

Attached is the agenda.

pc: Dr. Eddie J. Davis
Dr. James A. Calvin
Dr. David Carlson
Dr. Fuller W. Bazer
Mr. Chris M. Meyers
Mr. Charley B. Clark
Ms. Angelia M. Raines
Mr. Brent S. Mattox
Dr. Vernon L. Tesh
Dr. Tom A. Ficht
Dr. L. Garry Adams
Dr. James E. Samuel
Ms. Tiffany M. Agnew

Richard E. Ewing
Vice President for Research

Agricultural Experiment Station
Agricultural Research and Extension Center
Agricultural Technologies
Center for Information Assurance and Security
Comparative Medicine Program
Institute for Science Communication
Integrative Center for Homeland Security
Microscopy and Imaging Center
National Center for Foreign Animal and Zoonotic Disease Defense
Office of Distance Education
Office of Graduate Studies
Office of Proposal Development
Office of Research Compliance
Office of Sponsored Projects
Professional Development Group
Texas A&M University Research Park

Texas A&M University
312 Administration Building
1112 TAMU
College Station, Texas
77843-1112

979.845.8585
FAX 979.845.6855

www.vpr.tamu.edu

Texas A&M University
Select Biological Agent and Toxins Program Training

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 and Brent
12 :50 -12:55	Bi-monthly monitoring	Angelia Raines
12:50 p.m.	Closing Remarks	Fuller Bazer

From: Angelia Raines
To: Holt, Kathy
Date: 5/25/2007 1:33 pm
Subject: Fwd: Re: Training Announcement

CC: Calvin, James; Cornett, Dianne; Ewing, Richard

Hi Kathy,

The attached email contains a training announcement that needs to be printed onto VPR letterhead and have Dr. Ewing's signature. You can scan it and send it back to me so we can email it to the training attendees (about 120 people).

Please let me know if you have any questions or need more information from me. Thank you! Angie

From: "Fuller Bazer" <FBazer@cvm.tamu.edu>
To: "Angelia Raines" <araines@vprmail.tamu.edu>
Date: 5/25/2007 7:09 am
Subject: Re: Training Announcement

CC: "Jim Calvin" <j-calvin@tamu.edu>, "Richard Ewin...
Hi Angie, I have made a few changes and can sign memo for Dick before you send it out if that is necessary. I think it is important to cc those who need to know about this training.

Thanks, Fuller

Fuller W. Bazer, Ph.D., Regents Fellow, Distinguished Professor and O.D. Butler Chair in Animal Science
Associate Vice President for Research
Texas A&M University
Telephone: 979-458-2876
Cell Phone: 979-324-7364
Facsimile: 979-845-1855
email: fbazer@cvm.tamu.edu
URL: http://recovery.tamu.edu
URL: http://animalscience.tamu.edu/

>>> "Angelia Raines" <araines@vprmail.tamu.edu> 05/24/07 4:23 PM >>>

Attached is a draft of the training announcement as well as the agenda.

Once you have review it, please make any changes you deem fit and send it back to me. Once you have approved the information, we can send it to all SBAT personnel (about 120 people).

I will send you the input for my performance evaluation tonight as soon as I complete the remaining Select Agent SOPS. Thanks for your patience.

Angie

FYI

VPR Office of the Vice President for Research
Texas A&M University

Richard E. Ewing
Vice President for Research

Academy for Advanced Telecommunications and Learning Technologies

Center for Information Assurance and Security

Comparative Medicine Program

Institute for Scientific Computation

Integrative Center for Homeland Security

Microscopy and Imaging Center

National Center for Foreign Animal and Zoonotic Disease Defense

Office of Distance Education

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312 Administration Building
1112 TAMU
College Station, Texas
77843-1112

979.845.8585
FAX 979.845.[illegible]855

May 25, 2007

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Dr. Tom A. Ficht
Dr. L. Garry Adams
Dr. James E. Samuel
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Texas A&M University
Select Biological Agent and Toxins Program Training

June 1, 2007
9:00 a.m. – 1:00 p.m.

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CC: Calvin, James; Cornett, Dianne; Ewing, Richard

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CC: "Jim Calvin" <j-calvin@tamu.edu>, "Richard Ewin...
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Fuller W. Bazer, Ph.D., Regents Fellow, Distinguished Professor and O.D. Butler Chair in Animal Science
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Cell Phone: 979-324-7364
Facsimile: 979-845-1855
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URL: http://recovery.tamu.edu
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>>> "Angelia Raines" <araines@vprmail.tamu.edu> 05/24/07 4:23 PM >>>

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Angie

Research Compliance 1/07
29517

Office of the Vice President for Research
Texas A&M University

June 30, 2007

Richard E. Ewing
Vice President for
Research

Agricultural
Research
Technology Commercialization
and Economic
Development

Center for Information
Assurance and Security

Comparative Medicine Program

Institute for
Neuroscience

Integrative Center for
Homeland Security

Microscopy and Imaging Center

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Professional Development Group

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University

312 Administration Building
1112 TAMU
College Station, Texas
77843-1112

979.845.8585
FAX 979.845.8555

MEMORANDUM

FROM: Dr. Richard E. Ewing Richard E Ewing

TO: All employees involved in research with Select Biological Agents and Toxins

SUBJECT: **Cease and Desist Order from Violations of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 262a)**

As of today, June 30, 2007, **CDC's Division** of Select Agents and Toxins (DSAT) has expanded the cease and desist order, originally issued April 20, 2007, to include all work with select agents and toxins at Texas A&M University. Effective immediately, all select agent and toxin work must stop and all select agents and toxins must be securely stored until further notice.

As you are aware, the original cease and desist order issued by the Division of Select Agents and Toxins of the Centers for Disease Control and Prevention (CDC) covered the following:

1. The use of , Texas A&M University, for any and all manipulations and storage of Brucella abortus, Brucella melitensis, and Brucella suis until such time as a request for the amendment to the Texas A&M University's certificate of registration has been properly submitted by the Texas A&M University and approved by the Division of Select Agents and Toxins (DSAT), Centers for Disease Control and Prevention (CDC) in accordance with 42 C.F.R. part 73.

2. The experimental aerosolization of any select agent or toxin performed at the Texas A&M University.

3. Allowing access to select agents and toxins by any individual who has not been approved for such access by DSAT following a security risk assessment by the Attorney General of the United States.

While the order has now been expanded to cover work with all select agents on the campus of Texas A&M, effective immediately, all select agent and toxin work must stop and all select agents and toxins must be securely stored until further notice.

cc: Dr. Michael D. McKinney
Dr. Eddie J. Davis
Dr. Jerry R. Strawser
Dr. David S. Carlson
Dr. James A. Calvin
Dr. Fuller W. Bazer
Mr. Chris M. Meyers
Mr. Charley B. Clark
Mr. John M. Salsman
Ms. Angelia M. Raines
Mr. Brent S. Mattox
Dr. Vernon L. Tesh
Dr. Thomas A. Ficht
Dr. L. Garry Adams
Dr. James E. Samuel
Ms. Tiffany M. Agnew
IBC