From: James Calvin
To: Calvin, James
Date: 7/5/2007 2:59 PM
Subject: Fwd: Administrative Leave

>>> James Calvin 6/27/2007 11:32 AM >>>
Jerry:

As a follow up to your concerns about the impact of administrative leave, I think the following issues are ones that play a role in what decisions need to be made. They are clearly not the whole story, but are items that deserve consideration:

1) The CDC order places a cease and desist order on aerosolization research, but not on any specific PI who may be engaged in research outside this area. Thus, without the leave, a PI could still be active in the lab if grants existed to support non-restricted research.

2) Administrative leave, if too long, can put the PI in jeopardy of losing grant funding, either through direct non-performance or through an inability to obtain grant renewals.

3) The leave also impacts any students who are supported and/or advised by the PI. If students leave the lab then, again, the completion of research becomes more difficult. If they do not then their graduation timetable is put at risk. This also assumes that labs exist that can and will take on new students.

4) There is also the potential for reputational risk if the leave appears to have no end or it is not clear how it will be resolved.

In the end, I think the issue really revolves around how quickly any investigation can be completed. Please let me know if I can provide you with any additional information.

Jim

From: James Calvin
To: Calvin, James
Date: 7/5/2007 2:59 PM
Subject: Fwd: FW: CONFIDENTIAL CLIENT COUNSEL COMMUNICATION

>>> "Strawser, Jerry R" <jstrawser@tamu.edu> 6/27/2007 11:59 AM >>>
As I read this, I have a few questions that I would appreciate you responding to:

1. When did the investigation that Karan refers to in the first paragraph begin?

2. Are there bases for concern regarding ongoing practices in the lab (question [2])?

3. Who are the "other administrators" referred to in her question (3)?

4. Is Karan's statement about the one error correct?

Jerry

Jerry Strawser | Interim Executive Vice President and Provost

Texas A&M University | 979.845.4016 | jstrawser@tamu.edu
<BLOCKED::mailto:jstrawser@tamu.edu>

From: Watson, Karan
Sent: Wednesday, June 27, 2007 9:16 AM
To: Kelly, Scott; Adams, Richard; Gerald Bratton; Davis, Eddie J; Strawser, Jerry R
Cc: Raines, Angelia
Subject: RE: CONFIDENTIAL CLIENT COUNSEL COMMUNICATION

Based on what I have been told, I do not approve the extension of Ficht's administrative leave.

I was led to believe there was an investigation in progress in May, and that imminent discussions with lab personnel warranted placing the faculty member on leave for this phase of the process. I was not then, or now, informed of a basis for concern of ongoing practices in this lab, but instead led to believe that our need to get uninhibited communications from the personnel would be valuable to all, including the faculty member. Now I learn that the investigation was not even initiated yet.

1. Please let me know the basis for placing someone on leave while we negotiate a contract.

2. I have not been informed of our concerns about ongoing practices by this faculty member or imminent safety concerns, please let me know what information we have to substantiate this type of concern.

3. What I have been told is that other administrators, who arguably but by the information posted in our procedures, had responsibilities to report mishaps to the CDC, did not do their job. Have any of these people been placed on administrative leave?

The sense I am left with based on the information you have given me thus far, is that Dr. Ficht appears to be singled out in a manner that others have not been for a potential investigation. I understand that his lab was where the accident occured which ultimatley led to our current investigation by the CDC, but I was told that the lab followed appropriate procedures upon the occurance of the accident. The information I was given was that the one error, other than the actual procedure in cleaning equipment with a particular agent in it, was how the incident was reported to the CDC. Now it appears that this information may not be the case, so I am seeking clarity to understand if I have been misinformed about the lab and the procedures they followed.

Karan

From: Kelly, Scott
Sent: Tue 6/26/2007 3:13 PM
To: Watson, Karan; Adams, Richard; Gerald Bratton; Davis, Eddie J; Strawser, Jerry R
Cc: Raines, Angelia
Subject: RE: Memo from Dean Adams

The outside counsel contract with Vickie Sutton is being completed. We sent her all of the annual CDC reviews for her review. I have asked though Angie Raines for copies of Dr. Ficht's lab books, but I have not received those yet.

Scott Kelly

From: Watson, Karan
Sent: Tuesday, June 26, 2007 3:10 PM

To: Adams, Richard; Gerald Bratton; Davis, Eddie J; Strawser, Jerry R; Kelly, Scott
Subject: RE: Memo from Dean Adams

Please inform me what is being done and by whom. As of last week it was reported to me that after 3 weeks into the administrative leave, Dr. Ficht had not been approached by anyone on the investigation. Extending this leave has serious impact on his currently funded experiment. Please tell me what is the basis and finding for keeping this leave, and who else involved in the alleged missteps have been put on leave during the investigation. Karan

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From: Richard Adams [mailto:RAdams@cvm.tamu.edu]
Sent: Tue 6/26/2007 2:27 PM
To: Gerald Bratton; Davis, Eddie J; Strawser, Jerry R; Kelly, Scott; Watson, Karan
Subject: Fwd: Memo from Dean Adams

>>> Martha Huebner 6/26/2007 2:15 PM >>>
Dear Dr. Ficht,

Please see attached memo from Dean Adams. The original is being sent to you.

Thank you,

Martha

From: James Calvin
To: Calvin, James
Date: 7/5/2007 2:59 PM
Subject: Fwd: Re: FW: CONFIDENTIAL CLIENT COUNSEL COMMUNICATION

>>> James Calvin 6/27/2007 1:16 PM >>>
Jerry:

I am getting exact dates for you for tomorrow's meeting, but here is probably what you are looking for.

1) There have been two outside reviews. The first involved a group from UT-Houston HSC. We have received some preliminary findings on improvements in oversight that are being implemented. One result of this review is the hiring of a new biosafety officer who will report jointly to OVPR and EH&S. I believe that the second review is the one Karan is referring to. The Chancellor identified Dr. Vickie Sutton, from TTU, as someone who should lead a review. Dr. Sutton came down for a visit in May, but the process of engaging her has been delayed due to an issue in initiating her contract. During the visit, she request some material, which has all been provided to Scott Kelly. The request for lab books is more recent and, I believe that it is still being worked on.

2) I do not believe that concerns exist about ongoing practices other than ensuring that Dr. Ficht receives approval for his revised protocols. The focus of the review is on past actions. As a result of established expectations with CDC, we have initiated and completed a new training process for all researchers using select agents. Nearly all users attend one of the course times. I believe that approximately 23 people did not. They have now been excluded from access to the affected labs until they have completed
the training.

3) I believe that Karan is referring to individuals within EH&S.

4) The CDC report had 21 observations, but in relation to Dr. Ficht's actions they basically get boiled down to two issues. The first is that someone was exposed in his lab. The second is that the amended protocol to use aerosolization had not been approved by CDC.

Jim

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Thank you,

Martha

From: James Calvin
To: Calvin, James
Date: 7/5/2007 2:59 PM
Subject: Fwd: Confidential Draft - for review and input
Attachments: Confidential Draft - discussion outline.doc

>>> "Angelia Raines" <araines@vpr-mailsrv1.tamu.edu> 6/28/2007 6:32 AM >>>
Confidential Draft - Please review and igive input.

Thanks! Angie

Draft – Discussion Outline

General Background - Roles

Responsible Official (RO)/Institutional Official (IO) - is Richard Ewing.

- designated by Texas A&M to have management and oversight of the Select Agent Program. The RO must have authority and control to ensure compliance with the regulations.

Environmental Health and Safety

- Reports to Risk Management
- Responsible for environmental, occupational and radiation safety programs.
- The Biosafety Officer, who resides in EHSD, is responsible for ensuring lab practices are safe and followed correctly; that regulatory requirements are followed; that safety assessments are in compliance with requirements set forth in CDC's Bio... (BMBL). The BSO is a member of the IBC, and reviews all Select Agent Applications and has oversight for all select agent transfers. The BSO is one of 4 Alternate Responsible Officials (ARO), designated by the RO to assume some of the management responsibilities of the Select Agent program.

Office of Research Compliance (ORC)–

- Reports to the Vice President for Research through the Associate VP for Research.
- Provides operational/administrative management for select Agent programs.
- Provides administrative support to the IBC, who is responsible for reviewing and approving Select Agent applications and changes to applications.
- Works with Environmental Health and Safety and the BSO to ensure regulatory compliance of the Select Agent program. The ORC director is one of 4 Alternate Responsible Officials (ARO), designated by the RO to assume some of the management responsibilities of the Select Agent program. The Director communicates directly to the RO or through the Associate VP on select Agent matters.

Comparative Medicine (CMP) –

- Reports to the Vice President for Research through the Executive Associate VP for Research.
- Provides animal care and animal housing for Select Agent Investigators.
- Provides veterinary expertise to the IBC, who is responsible for reviewing and approving Select Agent applications and changes to applications.
- Works with Environmental Health and Safety and the BSO to ensure labs are safe and meet the regulatory requirements for Select Agents.

Institutional Biosafety Committee (IBC) –

- Review, approve, and oversee all teaching, testing, and research projects involving recombinant DNA, infectious agents, and toxins.
- Responsible for the review and approval of Select Agent applications or changes in applications.

CDC Reporting and investigation process:

Reporting Process: Texas A&M is responsible for reporting all registration changes, or incidents (loss, theft or release, including occupational exposures). Incident reports must occur immediately.

Investigation process involved:

- Request for information (4/11/07)
- Site visit (4/16/07-4/19/07)
- Cease and desist of all aerosol studies using select agents
- Additional request for information noting multiple observations and included three distinct issues –
    - 4/3/06 release (occupational exposure – reported 4/17/07
        - Incident involved elevated Q-fever titers in 3 Select Agent Personnel – PI Samuel's Coxiella Lab. Elevated titers were noted in April 2006, when Texas A&M did not consider titers without clinical symptoms to be a release. Reviewed the policy in April 07 and decided to include all elevated titers. Reported previous titers to CDC.
    - 4/20/06 incident Reported to CDC 4/10/07
        - Incident involved a lab visitor who was exposed to a select agent in PI Ficht Brucella study in the Aerosol lab. CDC asked about Aerosol incident with specific questions related to protocol review and monitoring, occupational safety, training and reporting.
    - 12/22/06 loss– Reported to CDC 12/22/06
        - Incident involved a missing mouse in the PI Samuel's Coxiella Lab.

Next Steps:

- Notification of deficiencies
- Penalty

Possible Penalties:

- Restriction of aerosol studies at Texas A&M until deficiencies are resolved.
- Restriction/suspension of all select agent research until deficiencies are resolved (registration suspension).
- Civil penalties:
    - Up to $250,000 for an individual for each violation
    - Up to $500,000 for an organization for each violation
- Criminal penalties, which are very unlikely:
    - Imprisonment for up to 5 years, a fine, or both for:
    - Transfer of a select agent to an unregistered person
    - Possession of a select agent by an unregistered person
    - Knowingly making a false statement

Actions taken or to be taken to satisfy CDC and ensure compliance:

- Training - 3 sessions held in June – with the exception of 7 individuals, all Select Agent personnel have been trained.
- UT HSC visit
    - New Biosafety Officer proposed as a result of their input
- TTU contract

Response to Media
Current press is a related to 4/3/06 elevated Q-fever titers. Information was released as part of the initiating event (aerosol incident) open records request

From: James Calvin
To: Calvin, James
Date: 7/5/2007 3:00 PM
Subject: Fwd: Re: Confidential Draft - for review and input
Attachments: Confidential Draft - discussion outline 062807.doc

>>> "Fuller Bazer" <FBazer@cvm.tamu.edu> 6/28/2007 7:12 AM >>>
Thanks Angie. This looks good. I have made a few edits for consideration by you and Jim. I will be happy to have a look at subsequent drafts. 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> 06/28/07 6:32 AM >>>

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Thanks! Angie

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- Responsible Official status also includes animal care and use, human subjects research and all aspects of institutional biosafety

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Response to Media

- Current press is a related to 4/3/06 elevated Q-fever titers. Information was released as part of the initiating event (aerosol incident) open records request
- Office of Vice President for Research has Communications Section that interfaces with ORC to provide input to Texas A&M officials to inform and allow factual information to be shared with media

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From: James Calvin
To: Calvin, James
Date: 7/5/2007 3:00 PM
Subject: Please review Fwd: RE: CONFIDENTIAL CLIENT COUNSEL COMMUNICATION
Attachments: RE: CONFIDENTIAL CLIENT COUNSEL COMMUNICATION

>>> "Angelia Raines" <araines@vpr-mailsrv1.tamu.edu> 6/28/2007 7:48 AM >>>
Confidential - for review and input

From: "Richard Adams" <RAdams@cvm.tamu.edu>
To: "Gerald Bratton" <GBRATTON@cvm.tamu.edu>, "Eddie J Davis" <edavis@tamu.e...
Date: 6/27/2007 11:48 AM
Subject: RE: CONFIDENTIAL CLIENT COUNSEL COMMUNICATION

CC: "Angelia Raines" <araines@vprmail.tamu.edu>

Dr. Watson:

It is my understanding that when the outside investigation began, there was a request for the outside investigator to receive all lab information dealing with the lab's work associated with the incident. It is also my understanding that the related lab notebooks have only now been made available to the investigator. At the time of the first leave letter, it was assumed that 30 days would have been adequate to conclude the investigation. But, until the notebooks were available, the investigation could not be concluded. It seemed practical to have the leave time undefined in the second letter while the university awaited the results of the outside investigation so that repeat letters would be unnecessary.

I too have heard the same information about failure of a campus office to report the incident to federal authorities, and that our faculty did indeed file the appropriate report of the incident with that campus office in a timely manner. However, because I have no responsibility for any university staff outside the CVM, I have no authority to deliver a message of leave with pay to any one outside the CVM.

I expect the outside investigation to surely determine exactly the question you raise. That is, did CVM faculty follow all reporting procedures as federal law requires. And, was the fault instead because a campus office neglected to inform federal authorities of the incident report. That is a critical distinction that must be answered by the outside investigation. If it is not being addressed, then the outside investigator did not receive the full charge necessary to conclude the investigation in a fair and open manner.

Moreover, it is my understand that the involved faculty has yet to be interviewed by the outside investigator. I can not understand how an outside investigation could reach a confident conclusion without an interview of the involved faculty.

I will be the first to offer my regrets to the involved faculty if the incident was caused not by him, but instead only because a campus and/or System office failed to forward the report of the incident to federal authorities, believe me. In the mean time, I believe I am following the appropriate procedures that stand before us relative to federal law and university/System policy. If I am incorrectly discharging my responsibility as dean, then I certainly request correction from my supervisors.

I have avoided any investigative action myself, because as dean I may be called upon to participate in my faculty's appeal of the leave that was issued to him. The appeal process should allow us to resolve any misunderstandings and incompletions that may surround this incident.

Please let me know if additional information would be helpful.

Richard

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Thank you,

Martha

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To: Calvin, James
Date: 7/5/2007 2:53 PM
Subject: Fwd: Re: Texas A&M Brucella Exposure Incident
Attachments: Incident at TAMU

>>> Richard Ewing 4/16/2007 5:39 PM >>>
This is the response that Neville Clarke sent to DHS about the incident and included David's announcement.
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

>>> "Neville Clarke" <n-clarke@tamu.edu> 4/16/2007 5:27 pm >>>
Matt,

This will acknowledge receipt of your message. I am forwarding it to appropriate authorities in the University at their instruction to all who are asked to provide information. CDC is on site at this time and reviewing the incident and pursuing most if not all the questions you pose. We expect we will have their findings in a few days. I am not privy to all the information you have requested and will not see it myself until the CDC report is received and the university responds. I believe I should have their report before responding to you. In fact, it seems to me their report is what you need. If this is not agreeable, I can either discuss options by phone with you or come to your office We would like to comply with your direction but also want to comply with our own university guidance. I am attaching the statement made by the university this morning and sent to you earlier in the day.

I realize that your office wants to be able to respond if this situation gains high visibility. Unless you think otherwise, I advise that if necessary, you respond in the interim as we are doing by saying that you are waiting for the CDC Report I can confirm that the incident is related to a project funded in part in the Center on which progress has been very good. Please advise.

Neville

From: James Calvin
To: Calvin, James
Date: 7/5/2007 3:00 PM
Subject: Fwd: CDC Cease and Desist Order
Attachments: DSAT Expansion of Order to Cease & Desist.doc

>>> Richard Ewing 7/1/2007 5:39 PM >>>
As you can see in the attached memorandum, the Department 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 TAMU. Effective immediately, all select agent and toxin work must stop and all select agents and toxins must be securely stored until further notice.

Richard Ewing
Responsible Officer

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

June 30, 2007

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, the Department 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 TAMU. 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 Department of Select Agents of the Centers for Disease Control and Prevention (CDC) covered the following:

1. The use of Room Building 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 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

From: James Calvin
To: Calvin, James
Date: 7/5/2007 3:00 PM
Subject: Fwd: Centers for Disease Control and Prevention (CDC) Review

>>> "President" <s-carroll@tamu.edu> 7/2/2007 4:06 PM >>>
2 July 2007

MEMORANDUM

TO: Texas A&M Faculty & Staff

SUBJECT: Centers for Disease Control and Prevention (CDC) Review

As you may already be aware, the Centers for Disease Control and Prevention (CDC) notified us over the weekend that we must suspend our homeland security-related research with selected agents and toxins pending the outcome of another site visit by CDC representatives. That next visit is scheduled later this month--in the July 9-23 timeframe.

The CDC notification stems from safety and reporting considerations. First, let me make the point that the cited incidents at Texas A&M University did not pose a continuing threat to anyone on or off our campus. The first incident, an exposure to Brucella, was the University's error in not reporting the exposure in a timely manner. The more recently reported exposure was simply due to the fact that we have initiated more stringent testing and reporting criteria than in prior periods and than is the norm at other similar research facilities. In fact, none of the individuals with the latest reported elevated blood tests (a reading known as a titer) became ill from that exposure. This is generally the standard at other select agent research facilities used in determining whether to report an exposure to the CDC. In our case, we are exceeding that standard. Safety is always of paramount importance when anyone on campus--be they faculty, staff or students-- who handles or otherwise deals with materials that are hazardous or even potentially hazardous. Nothing--absolutely nothing--is more important than safeguarding the health of our personnel.

We are unequivocally committed to taking all appropriate steps to ensure we are in full compliance with all CDC and any other relevant policies and regulations. In fact, we have already strengthened our safety, training and reporting procedures. In addition, we are retaining the services of an independent expert and the environmental health and safety group from the UT Health Science Center in Houston to provide their views on how we can most expeditiously redeploy a fully compliant select agent research program. This action, in coordination with further discussion with CDC, will form the basis for our action plan going forward.

In summary, we plan to cooperate fully with the CDC and look forward to resolving this matter in an appropriate manner as quickly as possible so that we can move forward in our work supporting the nation's homeland security initiatives. Texas A&M is among the world's leading research institutions with a long history of producing solid results that help mankind in many different ways. This is apparent day in and

day out in disciplines all across this campus and state. Our goal is to ensure that our select agent research continues to be recognized at that same high standard.

Eddie J. Davis
Interim President

From: "Neville Clarke" <n-clarke@tamu.edu>
To: "Neil <CTR> Franz" <Neil.Franz@associates.dhs.gov>, "Matthew Clark" <Mat...
Date: 4/16/2007 11:57 AM
Subject: Incident at TAMU

CC: "Thomas Powdrill" <TFPowdrill@ag.tamu.edu>, "Rusty Cawley" <RCawley@vprm...

The following is a statement issued by Texas A&M*s Executive Vice President and Provost David B. Prior on April 16, 2007:

"An internal investigation has confirmed that an occupational exposure to the bacterium that causes brucellosis occurred on our campus and that the individual was successfully treated. We have since strengthened our safety, training and reporting procedures following the human error involved in not reporting this incident.

An independent review of our processes and procedures will be conducted by representatives of the Center for Disease Control (CDC), who are on campus today (Monday, April 16). We will be fully cooperative and our goal is to comply with all current biosafety standards.

No university officials will make further comments regarding this incident until our final internal report is issued following the CDC review.*

From: James Calvin
To: Calvin, James
Date: 7/5/2007 2:54 PM
Subject: Fwd: Texas A&M Brucella Exposure Incident

>>> Richard Ewing 4/17/2007 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: James Calvin
To: Calvin, James
Date: 7/5/2007 2:53 PM
Subject: Fwd: Incident at TAMU

>>> Richard Ewing 4/16/2007 5:36 PM >>>
FYI Again, the response is from the Provost, not the VPR.
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

>>> "Neville Clarke" <n-clarke@tamu.edu> 4/16/2007 11:57 am >>>
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No university officials will make further comments regarding this incident until our final internal report is issued following the CDC review.*

From: James Calvin
To: Calvin, James
Date: 7/5/2007 2:54 PM
Subject: Fwd: FW: Incident Report

>>> "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: "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: James Calvin
To: Calvin, James
Date: 7/5/2007 2:55 PM
Subject: Re: Fwd: FW: Incident Report

>>> "Fuller Bazer" <FBazer@cvm.tamu.edu> 5/3/2007 10:25 AM >>>
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

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/

>>> "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

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David S. Carlson, PhD

Regents Professor

Vice President for Research & Graduate Studies

Texas A&M Health Science Center

From: James Calvin
To: Calvin, James
Date: 7/5/2007 2:55 PM
Subject: Fwd: Re: IBC

>>> "Fuller Bazer" <FBazer@cvm.tamu.edu> 5/23/2007 9:50 AM >>>
Hi Angie, This is a good plan. I agree that all need to attend. I will be happy to write a letter over Ewing's signature and sign for him to indicate that this training is mandatory for all who are working in an SBAT facility.

I will be here on June 1st to participate as you indicated. 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> 05/23/07 8:46 AM >>>

I was out sick Monday afternoon and yesterday so I am trying to catch up. I am trying to pull together all of the SBAT personnel for a June 1st training event. The following is a list of agenda items:

Approval process prior to accessing select agents -
Approval process prior to accessing an SBAT facility -
Incident Response process -
Intra-facility transfers -
Inter-facility transfers -
Process for New submissions, amendments and annual reviews (including risk assessment process and medical surveillance process)
Requirement Personal Protection Equipment (PPE)
Review of Security Plan, Safety Plan and Incident Response Plan
Quality assurance reviews (bi-monthly inspections)

I would like you to give opening and closing remarks regarding the importance of following all SBAT requirements.

Because I am trying to pull this together so quickly, I am anticipating that some employees will not be able to attend. I will schedule two follow up sessions, however, I believe that all employees must be required to complete the training by mid June. I also want to require the same training for all new employees before they are allowed to work in an SBAT lab.

Please let me know if there are other items that you believe need to be covered. I am planning to communicate the plan with the SBAT PIs today so let me know if there are changes you would like to see.

Thanks!
Angie

>>> "Fuller Bazer" <FBazer@cvm.tamu.edu> 5/23/2007 7:46 AM >>>
Angie, I met with Chris Meyer yesterday to let him know that I was going to make a short address to IBC today regarding: 1) PI responsibilities to follow SOPs; 2) increasing commitment to compliance by all parties; 3) need for increased communication between PI, ORC and EHS; and 4) need for PI, in the event of an incident, to fully engage EHS and give full information to facilitate the investigation, determine the facts and report to ORC so that responses and decisions on reporting are based on solid evidence.

Next, we need to meet with those PI working with select agents to discuss these issues. One of them being bimonthly inspections and another being related to responses to peer-review team recommendations. We need to have this meeting later this week or early 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: 979-324-7364
Facsimile: 979-845-1855
email: fbazer@cvm.tamu.edu
URL: http://recovery.tamu.edu
URL: http://animalscience.tamu.edu/

From: James Calvin
To: Calvin, James
Date: 7/5/2007 2:56 PM
Subject: Fwd: Subject: Mandatory Training, To: All employees involved in research using Select Agents
Attachments: letter+attachment.pdf

>>> Kelly Marcum 5/25/2007 3:30 PM >>>
All,

Attached is the Memorandum to all employees involved in research using Select Agents and Agenda, from Dr. Ewing.

Thank you,

Kelly Marcum

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

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

Academy for Advanced 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

Texas A&M University Research Park

Texas A&M University

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

979.845.8585
FAX 979.845.1855

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

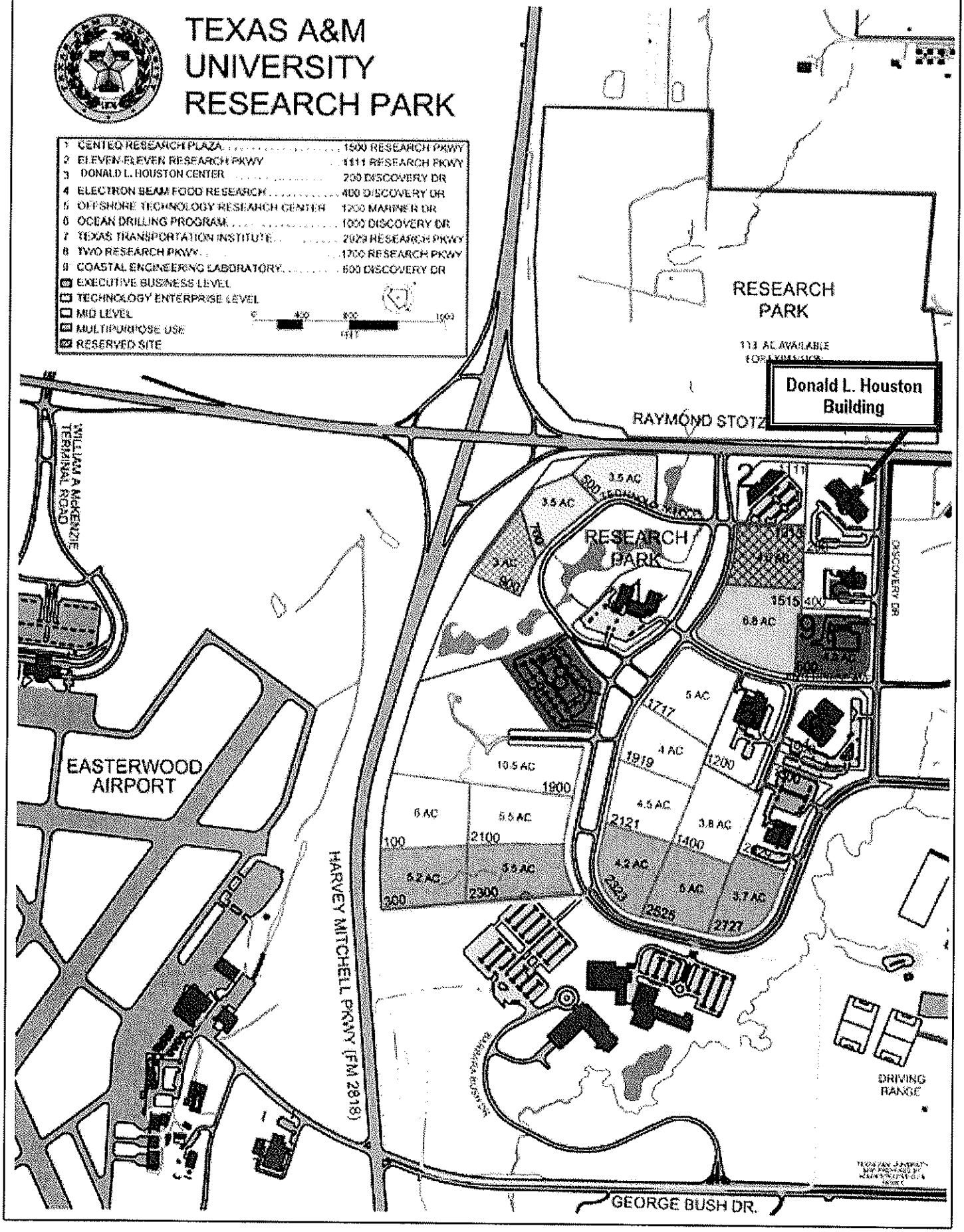
From: James Calvin
To: Calvin, James
Date: 7/5/2007 2:56 PM
Subject: Fwd: Select Agent Training
Attachments: Houston Map_1.pdf; Select Agent training announcment .pdf; Select Agent Training Agenda.doc

>>> Angelia Raines 5/25/2007 3:50 PM >>>
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)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax
(770) 789-3456 Cell


TEXAS A&M UNIVERSITY RESEARCH PARK
1 CENTEQ RESEARCH PLAZA ..... 1500 RESEARCH PKWY
2 ELEVEN-ELEVEN RESEARCH PKWY ..... 1111 RESEARCH PKWY
3 DONALD L. HOUSTON CENTER ..... 200 DISCOVERY DR
4 ELECTRON BEAM FOOD RESEARCH ..... 400 DISCOVERY DR
5 OFFSHORE TECHNOLOGY RESEARCH CENTER ..... 1200 MARINER DR
6 OCEAN DRILLING PROGRAM ..... 1000 DISCOVERY DR
7 TEXAS TRANSPORTATION INSTITUTE ..... 2929 RESEARCH PKWY
8 TWO RESEARCH PKWY ..... 1700 RESEARCH PKWY
9 COASTAL ENGINEERING LABORATORY ..... 600 DISCOVERY DR
EXECUTIVE BUSINESS LEVEL
TECHNOLOGY ENTERPRISE LEVEL
MID LEVEL
MULTIPURPOSE USE
RESERVED SITE
0 400 800 1600
FEET
RESEARCH PARK
113 AC AVAILABLE
Donald L. Houston Building
RAYMOND STOTZ
WILLIAM A McKENZIE TERMINAL ROAD
EASTERWOOD AIRPORT
HARVEY MITCHELL PKWY (FM 2818)
GEORGE BUSH DR.
DISCOVERY DR
DRIVING RANGE
RESEARCH PARK
3.5 AC
3.5 AC
3 AC
800
1515
6.8 AC
5 AC
1717
4 AC
1919
1200
10.5 AC
1900
6 AC
5.5 AC
100
2100
4.5 AC
2121
3.8 AC
1300
5.2 AC
5.5 AC
200
2300
4.2 AC
2323
6 AC
2525
3.7 AC
2727

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

May 25, 2007

Memorandum

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Subject: Mandatory Training

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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

From: James Calvin
To: Calvin, James
Date: 7/5/2007 2:57 PM
Subject: Fwd: Research Compliance Request

>>> "Richard Ewing" <richard-ewing@tamu.edu> 6/14/2007 9:24 PM >>>
Dan,

I'm writing to follow up to the recent request from my office for additional funding to support a new hire with strong experience with biological agents to help strengthen the university's research compliance program. Charley Clark and I met on Wednesday and agreed that we should move immediately to hire such a person that would report jointly to John Salsman in Charley's shop and to my office. We agreed that this dual reporting would help facilitate effective communication between the two offices, and the establishment of this new position would be a positive and immediate action in response to the CDC findings. Additionally, it would address some of the recent requests we have received from DHS regarding our select agent research activities. We appreciate your quick feedback regarding this request so that our offices can move immediately toward establishing, posting and searching for a qualified candidate.

Best regards,
Dick

Dr. Richard E. Ewing
Vice President for Research
Texas A&M University
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College Station, TX 77843-1112
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date June 30, 2007

From Director, Centers for Disease Control and Prevention

Subject Suspension of Select Agent Work: Texas A&M University

To Dr. Richard Ewing, Responsible Official
Texas A&M University (Registration # C20060605-0489)

The Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins (DSAT) has received and reviewed your responses to the observations in the DSAT report from the April 16-18, 2007, site visit inspection of your facility. Based on the inspection and the information provided in your responses dated May 17, 2007, the DSAT has the following concerns regarding the select agent work being performed at Texas A&M University (TAMU):

1. Whether TAMU meets biosafety standards and requirements appropriate for the select agents and toxins you possess. Specifically, whether your biosafety plan ensures that select agents and toxins are used in a safe manner that is commensurate with the risk of the select agents and toxins (42 CFR § 73.12).

2. Whether TAMU has implemented a security plan that adequately prevents unauthorized persons from gaining access to select agents and toxins (42 CFR § 73.11).

3. Whether TAMU has an occupational health program that provides effective medical surveillance of occupational exposures to select agents and toxins.

4. Whether TAMU has the appropriate administrative control of select agent and toxin activities. Specifically, there is evidence that select agent work (i.e., aerosol studies with *Brucella* species) was performed at TAMU without prior approval by the DSAT. In addition, there is evidence that multiple occupational exposures that occurred at your entity were not properly reported to DSAT as required by 42 CFR § 73.19.

5. Whether the TAMU Responsible Official is familiar with and is ensuring compliance with the requirements of the select agent regulations (42 CFR § 73.9[a]).

Due to the serious nature of these deficiencies, I have determined that in order to protect public health and safety, the cease and desist order from CDC to TAMU of April 20, 2007, shall be expanded to include all work with select agents and toxins at TAMU. Effective immediately, all select agent and toxin work must stop and all select agents and toxins must be securely stored until further notice. The DSAT intends to conduct a comprehensive review of all select agent and toxin activities at TAMU to determine what steps will be required to ensure compliance with 42

CFR Part 73. This review will include a site visit to your facility at a date to be determined between July 9 and July 23, 2007. If it is determined that TAMU cannot or will not comply with all provisions of the select agent regulations, the DSAT may recommend that TAMU's certificate of registration should be revoked (*See* 42 CFR § 73.8). The revocation of your certificate of registration would require the cessation of all work with select agents and toxins and either the destruction or transfer of these materials to other registered facilities.

To facilitate a comprehensive review of the select agent and toxin activities at TAMU, please have the following documentation immediately available for the inspectors upon their arrival for a comprehensive site visit of your entity:

- All correspondence including e-mails related to all occupational exposures with select agents and toxins that have occurred at your entity;
- All occupational health records for individuals conducting aerosol work with select agents or working in buildings where aerosol work was being conducted;
- All laboratory records and notebooks for work with select agents and toxins;
- All training records for individuals working with select agents and toxins;
- All records pertaining to the maintenance and repair of laboratory facilities involved with select agent and toxin work; and,
- All records related to internal and external audits, reviews, safety inspections, and incident reports pertaining to work with select agents.

In addition, please ensure that key personnel will be available for interviews including, but not limited to:

- The Responsible Official
- All Alternate Responsible Officials
- The Occupational Health Director
- The Biosafety Officer
- Principal Investigators working with select agents and toxins
- Institutional Biosafety Committee Members
- Director of Environmental Health and Safety

Please contact Dr. Robbin Weyant, Director, DSAT, at (404) 718-2000 if you have questions regarding this correspondence.

Julie Louise Gerberding, M.D., M.P.H.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

July 5, 2007

Richard Ewing, Ph.D.
Vice President for Research
Texas A & M University
312 Jack K. Williams Administration Building
1112 TAMU
College Station, Texas 77843-1112

JUL 0 6 2007

Re: Suspension of Select Agent Work – NIH-Supported Projects

Dear Dr. Ewing:

On June 30th, Dr. Julie Lousie Gerberding, Director of the Centers for Disease Control, directed Texas A&M University (TAMU) to stop all select agent and toxin work and to securely store all select agents and toxins effective immediately until further notice. By this letter, and in response to CDC's action, the National Institutes of Health (NIH) is requiring that all work on NIH-supported projects involving select agents at TAMU cease immediately and until further notice. Due to the CDC action, NIH believes that TAMU is unable to materially comply with the terms and conditions of the awards that require the use of select agents or toxins. Accordingly, no funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving select agents at TAMU until this situation is resolved. Only activities that are clearly severable and independent of activities involving select agents may be conducted at this time.

In addition, TAMU must provide NIH with a listing of grants, cooperative agreements, and contracts involved in select agent research either as a direct recipient or as the sub-recipient funded through subcontract/consortium agreements. The listing should include the NIH grant, cooperative agreement, or contract number, the Principal Investigator, and the amount of funding in each project allocated for select agent research. This information must be provided to the NIH at the following below no later than July 16, 2007:

Diane Dean
Director, Division of Grants Compliance and Oversight
Office of Policy for Extramural Research Administration, OER
National Institutes of Health
6705 Rockledge Drive, Suite 350/MSC 7974
Bethesda, MD 20892 (for express mail use 20817)

Thank you for your cooperation. If you have any questions, please feel free to contact me at 301-435-0935.

Sincerely,

Joseph Ellis,
Director, Office of Policy for Extramural
Research Administration
Office of Extramural Research
Office of the Director
National Institutes of Health, DHHS

cc:
Dr. Robbin Weyant, Director, DSAT, CDC
Dr. Norka Ruiz Bravo, NIH
Dr. Lana Skirboll, NIH
Diane J. Frasier, NIH

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 Room Building 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

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

Richard E. Ewing
Vice President for
Research

Academy for
Advanced
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

Technology Commercialization
Center

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Research Park

Texas A&M
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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, exposure was not related to carrying, using, manipulating, or gaining possession of the select agent. Rather, we believe 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 located in building 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 room 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 Building including Room 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 Room for short periods of time to perform specific procedures, then returned to their original housing room. A separate log for Room was not maintained.

   After input from CDC during the last site visit, we have added a separate entry log used specifically for Room We have attached the log as well as the standard operating procedure for the use of Room (**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 room located in building 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 . 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 *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 her 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 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. 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 ocated 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 has a functional visual monitoring device and that the directional airflow is from "clean" area toward "contaminated" area.

Texas A&M Response: Room in Building nas 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 room located in building 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 Room re 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 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.

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 room located in building 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 Room in Building 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 Building must be strictly adhered to and enforced. Individual protocols for select agent users in Building 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, Veterinary Research Building" 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 in room located in building 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 ɔcated 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 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.

How could this have happened if she was escorted at All times?

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 head 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 ocated of building since October of 2005, was completed in laboratory room ocated 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 Building 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 (Building 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 (Building Rooms , 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

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 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

Texas A&M University Research Park

Texas A&M University

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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

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

MAY 04 2007

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 Room f Building d 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 Building Room on 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, , 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. did 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 , 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 returned 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 room in building 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
- Graduate Student
- 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 Room of Building 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 Room Building 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 located in building , 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 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 room ocated in building 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 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 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, , 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.

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 he 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 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.

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 room ocated 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 has 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 room located in building .hat 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 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 room · located in building 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, Veterinary Research Building" 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 room located in building 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 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.

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 ccupational 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 room ocated of building since October of 2005, was completed in laboratory room ocated 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 (building) to room building

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 Room Building , 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.

Received 4-17-07

From: Tom Ficht <tficht@cvm.tamu.edu>
To: "Mattox, Brent S" <bsmattox@tamu.edu>, Angelia 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 [redacted] has been diagnosed with
> brucellosis. [redacted] apparently contracted the disease during an
> experimental challenge at [redacted] (CMP) on the ninth of February 2006. At that
> time [redacted] along with Dr. McMurray were training us in the use of the
> Madison chamber for aerosol inoculations.
>
> [redacted] has 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 of [redacted] 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 [redacted] 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 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.

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-3) NO ANSWER
E-2) BUSY
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 #C20060005-0489)
1300 Research Parkway, Suite B150, TAMU 1186
College Station, TX 77843-1183
Fax: (979) 862-3176

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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.

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 420. 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

Attachment #4

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 room the ; "Building contains an aerolization chamber used by PI Fight 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 Fight 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 #29968, 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

Richard E. Ewing
Vice President for Research

April 11, 2005

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@vpmail.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 4:27
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)]