DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

FY07

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 Building nd 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*, 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 first felt ill on March 25, 2006. On April 12, 2006, informed Principal Investigator (PI) Dr. Tom Ficht that had been diagnosed with brucellosis, with isolation of *Brucella melitensis* on April 16, 2006 by the Texas State Public Health Laboratory. also filed a workman's compensation claim with Texas A& M University turned 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
- Angela Arenas, 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
- 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 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 located in building ice 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 143 since October of 2005.

3. ***An individual or entity required to register under this part may not provide an individual access to a select agent or toxin, and an individual may not access a select agent or toxin, unless the individual is approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General [42 CFR § 73.10(a)].***

   Observation: On February 9, 2006 , who has not received access approval from the DSAT, performed aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. After mpleted the aerosolization experiments with *Brucella melitensis* and *Brucella abortus*, cleaned the aerosolization chamber by wiping down the rear inside of the chamber with disinfectant. This cleaning technique caused ead and arm to enter into the interior of the 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, [redacted] performed aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. According to [redacted] 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 [redacted] 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 ompleted the aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. leaned 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 972, 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 --- that annual verification was performed to ensure that the laboratory meets the design and operational parameters.

   Request for supplemental information: Please provide this documentation.

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

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

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

10. *An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR §73.12]. Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it dispersed away from occupied areas and air intakes [BMBL: D11]*

    Observation: According to documentation provided to the CDC Inspectors, the HEPA systems of the aerosol chamber located in room 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, 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 1 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 occupational exposure.

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

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

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

Observation: On February 9, 2006, [redacted] performed aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. After [redacted] completed the aerosolization experiments with *Brucella melitensis* and *Brucella abortus*, [redacted] cleaned the aerosolization chamber by wiping down the rear inside of the chamber with disinfectant. This cleaning technique caused [redacted] head and arm to enter into the interior of the chamber and most likely resulted in [redacted] occupational exposure to either *Brucella melitensis* or *Brucella abortus*. Based on information provided by [redacted] to the CDC Inspectors, no follow up was conducted by TAMU following [redacted] occupational exposure even though she informed PI Ficht on April 12, 2006 that [redacted] 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 [redacted] 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 [redacted] located of building [redacted] since October of 2005, was completed in laboratory room [redacted] located in building [redacted]

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 [redacted] (building [redacted], to room [redacted] (building [redacted]

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.

Record 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 has been diagnosed with
> brucellosis. pparently contracted the disease during an
> experimental challenge at (CMP) on the ninth of February 2006. At that
> time along with Dr. McMurray were training us in the use of the
> Madison chamber for aerosol inoculations.
>
has been home sick for several weeks being treated by ersonal
> 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 exposure, although we assume
> it may have occurred as a result of cleaning out the Madison chamber after
> an aerosol run. In the future we plan to flush the chamber with
> disinfectant rather than using manual cleaning methods. The chamber will be
> wiped out after running disinfectant through the chamber, but this will
> involve the use of a long-handled applicator or mop. In addition, we will
> not rely on the use of N95 face masks and will instead use positive air
> displacement respirators.
>
> In the initial aerosol trials we relied on the experience of the TB
> researchers for the level of precaution typically employed in such
> experiments. It is suspected
> that a conjunctival route of infection is responsible for
> infection, perhaps as a result of manually cleaning the Madison chamber.
> It is my fault for not recognizing the differences between Brucella and
> Mycobacteria in regard to routes of infection.
>
> An isolation was made from a blood culture by physician and
> sent to TDH for confirmation. It would be helpful if EHSD could requested
> a sample of this isolate for culture confirmation here.
>
>
>
> Thomas A. Ficht, Ph.D.
> Professor
> Veterinary Pathobiology
> Texas A&M University
> 4467 TAMU
> College Station, TX 77843-4467
> 979-845-4118 ph
> 979-862-1089 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
9688 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
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

April 13, 2007

Richard Ewing, Responsible Official
Texas A& M University (Registration #C20060605-0489)
1500 Research Parkway, Suite B150, TAMU 1186
College Station, TX 77843-1186
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.

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(n)]

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 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 in the "Building contains an aerolization chamber used by PI Ficht for work with select agent. There were no SOPs available for review by inspectors to ensure appropriate safety precautions have been established for this procedure. Please provide documentation that this departure has been addressed.

Entity Response: SOP's for the aerolization chamber are now in place. [See Appendix H]

CDC Response: As discussed during the February 22-24 inspection, it was stated that Principal Investigator Ficht would be performing aerosol work with select agents. Please be reminded that 42 CFR 73.7 states that prior to changes in the activities involving any select agents or toxins the certificate of registration must be amended by the entity to include that work. Prior to the work being approved by the Select Agent Program, standard operating procedures regarding the aerosol challenge will need to be submitted to address the following additional issues:

1) Please describe the mechanism used to ensure that after the aerosol procedure, there is no residual select agent remaining on the animal surface.
2) Are there any laboratory air sampling procedures to verify no equipment leaks?
3) How does the laboratorian know the nebulizer is functioning properly and not leaking?
4) Is the HEPA filtration system for aerolizer equipment certified?
5) Is the microisolator cage filtration system certified?
6) Has it been determined how many air changes/hour it takes to remove infected particles after each run?
7) Are the animals anaesthetized prior to transfer back to the microisolator cages? If not, describe the procedure if animals escape. Describe the procedure for animal bites or scratches.
8) Please provide more detail on the cleaning of the chamber to ensure that the worker is not exposed to any agent during the cleaning process.
9) Is there any air sampling of the chamber after cleaning?
10) How has it been determined that dipping the probe in 10% bleach provides adequate contact time for decontamination?

Based upon review of Amendment #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 I-A-05.

If you require additional information or clarification on the comments contained within the attachment, please feel free to contact Angelia Raines, Research Compliance Director, in my office at 979/847-9362 or araines@vprmail.tamu.edu.

We appreciate your continued support and guidance on compliance issues in the CDC Select Agent Program.

Respectfully submitted,

Richard E. Ewing
Responsible Official

Attachment

xc: Dr. Robert M. Gates
President

Dr. David B. Prior
Executive Vice President and Provost

Dr. Fuller W. Bazer
Associate Vice President for Research

Texas A&M University
C20031123-0124
CDC030217
Accession #:
47567
Facility Inspection Report
Response (via mail)

Total # of Pages:
(5

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 11 PM 12:27
CDC SELECT AGENT PROGRAM

RC-004

Attachment #5

CONFIDENTIAL ATTACHMENT 1-A-05

2005 CDC INSPECTION - FIRST RESPONSE

13. Requirement: To apply for a certificate of registration an entity must, in accordance with § 73.21, submit the information requested to the HHS Secretary or the USDA Secretary as specified in the registration application package [CDC Form# 0.1319]. Information submitted will be used to determine whether the applicant would be eligible to conduct activities under this part. Minimum information required includes the location, including building and room and floor plans for each building and room, where each select agent or toxin will be stored or used. [42 CFR 73.7 (b)(2)(iii)]

CDC Observation:	TAMU Comment:
Equipment and structures have been added to rooms . Floor plans on file at the CDC Select Agent Program do not include this added equipment.	Bldgs. are currently utilized for research not involving select agents but are occasionally modified to allow for this type of research to occur. At the time of inspection, no SBAT work was occurring in any of the buildings. When select agents are in use, all buildings housing the select agents are returned to the original design (large animal stalls) as were viewed in and identical to the floor plans on file at CDC. Prior to work with SBATs, AND 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)]

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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Texas A&M
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312 Administration Building
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77843-1112

979.845.8585
FAX 979.845.1855

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 143. In addition, your entity was notified on June 7, 2006 (see Amendment #4) that prior to any changes in the activities involving select agents, the entity's certificate of registration must be amended to include this work with select agents such as aerosolization experiments and that this amendment must be approved by DSAT prior to any work being performed.

Request for supplemental information: Please explain why your entity failed to submit an amendment and receive approval from DSAT prior to the twelve aerosol experiments *with Brucella abortus and Brucella melitensis* that had been performed using the aerosol chamber located in room *143 since October of 2005.*

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 ompleted the aerosolization experiments with *Brucella melitensis* and *Brucella abortus,* she cleaned the aerosolization chamber by wiping down the rear inside of the chamber with disinfectant. This cleaning technique caused head and arm to enter into the interior of the chamber, most likely resulting in occupational exposure to either *Brucella melitensis* or *Brucella abortus.*

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

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

The Institution does not allow unauthorized personnel access to select agents. who was under escort, was exposed to a contaminated surface. did not have access to select agents and did not perform any experiments. 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 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 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*. presence in the laboratory was to assist in the correct operation of the Madison Chamber. should have received training relating to *Brucella melitensis* and *Brucella abortus*.

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

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

Observation: According to laboratory personnel interviewed by the CDC Inspectors, Dr. Ficht had conducted restricted experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture (see 42 C.F.R. § 73.13(b)(1)). Specifically, experiments conducted by Dr. Ficht that involved the introduction of plasrnids containing

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

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

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

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

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

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

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

Observation: On February 9, 2006 , who has not received access approval from the DSAT, performed aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. After completed the aerosolization experiments with *Brucella melitensis* and *Brucella abortus*, 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 have the ability to gain possession of a select agent or toxin." Throughout the entire time was in the laboratory, DOJ approved personnel escorted her. observed and instructed regarding use of the Madison Chamber, but did not perform the experiment.

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

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

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

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

Request for supplemental information: As the CDC Inspectors were not able to confirm that the room had directional airflow, please provide documentation that Room 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 has been tested and it is verified that airflow is directional into the laboratory. An indicator ball used as a visual indicator was stuck and has been repaired. The suite also has an auxiliary fan that is used to increase airflow due to filter loading and it has been engaged to further increase ventilation rates. Documentation provided as **Attachment E**.

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

Observation: The entity did not provide documentation for 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 are included in **Attachment F**. Please note that the most recent verification resulted in an amendment to temporarily move the animals in that BL3 suite. We plan to relocate the animals as soon as the amendment is approved.

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

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

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

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

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

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

10. ***An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR §73.12]. Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it dispersed away from occupied areas and air intakes [BMBL: D11].***

Observation: According to documentation provided to the CDC Inspectors, the HEPA systems of the aerosol chamber located in 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.

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 located in building since October of 2005 was approved by the Institutional Biosafety Committee (IBC) of TAMU. Please provide a copy of any IBC minutes approving the project including a list of the IBC members, date the project was approved, the justification for this approval, and the date(s) of the approval.

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

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

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

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

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

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

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

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

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

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

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

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

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

Observation: On February 9, 2006, ... performed aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. After ompleted the aerosolization experiments with *Brucella melitensis* and *Brucella abortus,* cleaned the aerosolization chamber by wiping down the rear inside of the chamber with disinfectant. This cleaning technique caused nead 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 .... occupational exposure even though .... .nformed PI Ficht on April 12, 2006 that she had been diagnosed with brucellosis.

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

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

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

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

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

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

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

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

Request for supplemental information: Please provide the intra-entity transfer documentation that ensures that a security protocol was in place when these transfers occurred from laboratory room Building to room (Building 972).

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

Mahle, Debbie

From: Meyer, Chris
Sent: Thursday, July 05, 2007 4:51 PM
To: Kelly, Scott
Cc: Clark, Charley
Subject: FW: Re: Lab accident

Scott,

I found the following e-mail which appears to be responsive to the Open Records Request 07-176. I did search my e-mails in response to previous open records requests though I'm not sure that I was tasked to do so. I apparently wasn't thorough enough in my search to find this e-mail. I will continue the search tomorrow for any other records associated with this incident.

Chris

-----Original Message-----
From: Buckley, Michael
Sent: Monday, April 12, 2004 9:00 AM
To: Mattox, Brent S
Cc: Meyer, Chris; Wei Zhao
Subject: Fwd: Re: Lab accident

Brent,

Not sure if you have been informed about this accidental exposure.

I have looked thru the CFRs and can't find anything which requires us report this incident - are you familiar with any requirements? Also, does EHS usually investigate this events and file an internal report on them? I was just curious if we should cross reference the procedure this tech was using with what is described in the protocol as a QA issues to see if there were procedure problems, or just an mistake. If you need any information out of the file here just let me know and we'll have it sent over to you.

What are your thoughts?

Mike

Michael W. Buckley, Ph.D.
Director, Research Compliance
Texas A&M University
MS 1112
Office of the Vice President for Research College Station, Texas 77843-1112

979.847.9362

>>> Michael Buckley 4/12/2004 8:53:17 AM >>>
Betsy,

Thanks for passing this along. I will brief Wei at our meeting this afternoon - not sure what else would be required. I have looked over the federal regulations on SBATs and did not find any reporting requirements for accidental exposures.

Mike

Michael W. Buckley, Ph.D.
Director, Research Compliance
Texas A&M University
MS 1112
Office of the Vice President for Research College Station, Texas 77843-1112
979.847.9362

>>> "Betsy Browder" <ejb@tamu.edu> 4/9/2004 4:59:02 PM >>>
Melanie and Mike,

EHS and HR are informed through the First Report of Injury but I wanted to let you both know about this to avert surprises.
If there is a need for further documentation that either of you might be aware of please let John Quarles know.
Thanks,
bb

>>> John M. Quarles<QUARLES@medicine.tamu.edu> 4/9/2004 4:10:45 PM >>>
Thanks Betsy. We've already done that and the "sharps" report also.

>>> "Betsy Browder" <ejb@tamu.edu> 04/09/04 04:10PM >>>
Hi John,
Nothing specific regarding the animals but the "First Report of Injury"
form needs to get to the Campus Environmental Health and Safety Office.

Their fax number is 5-1348.
bb

>>> John M. Quarles 4/9/2004 10:01:07 AM >>>
Betsy-
One of our graduate students injected hand with Brucella yesterday afternoon. saw a doc at S&W, is on antibiotics, and has a appointment with occupational health. Is there any reporting we need to do to you or ULAC or any thing about animals?
Thanks,
John

Cammack, Pat A

From:
Sent: Wednesday, April 18, 2007 9:01 AM
To: Cammack, Pat A
Subject: misinformation

Importance: High

** High Priority **

Dear Dr. Prior,

I am the researcher involved in The Eagle's headline story today. I am very concerned and unhappy about the misinformation that appears in this article and I am asking your help to issue a retraction. I want it made very clear that I DID NOT CLIMB into the aerosol chamber. I REACHED inside, after the last challenge was completed, to wipe down the chamber AS IS OUR STANDARD PROTOCOL. Furthermore, the (exposure) event did not take place as part of a training session on the use of the Madison Chamber, nor were Drs. McMurray or Ficht present at the time of my exposure. These are serious inconsistences which demand a response.
I am asking you and your office for help with this matter. These inaccuracies MUST be corrected. (It is one thing for these statements to appear on the Sunshine Project's website, which surely is read by precious few. But now, these inaccuracies have made their way to the front page of our newspaper and must be addressed.) I ask for your help in this matter.

Sincerely,

Research Associate
Department of Microbial and Molecular Pathogenesis College of Medicine-MS 1114 Texas A&M Health Science Center College Station, TX 77843-1114
(979)845-3679 (lab)
(979)845-3479 (fax)

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Updated 6:00 AM on Wednesday, April 18, 2007

A&M faces inquiry over brucella infection

University failed to report researcher exposed to bioagent

By HOLLY HUFFMAN
Eagle Staff Writer

Texas A&M University is under review this week by the Centers for Disease Control and Prevention for failing to report that a researcher was accidentally infected with brucella, a bioweapon agent being studied on campus.

The researcher, whose name has not been released, was diagnosed with the infection last April, according to documents obtained by the Sunshine Project, an international organization that aims to uncover biological and chemical weapons research.

Federal law requires institutions working with such dangerous agents to report such an infection within seven days. It was nearly a year before Texas A&M officials filed a report with the CDC, according to the public documents.

CDC officials on Tuesday confirmed the ongoing investigation, but said there did not appear to be any current health threat.

Sunshine Project Director Edward Hammond said□e-mails obtained through the Texas Public Information Act show that university officials discussed the reporting requirement, but then failed to follow through.

"They looked the law in the face and they ignored it," Hammond said Tuesday, calling on investigative agencies to levy a stiff penalty for such a violation. "It's not a lack of training, it's not a lack of knowledge, it wasn't ignorance. It's apparent it was a very deliberate decision."

Brucella is an infectious disease normally passed between animals, according to the CDC. Human symptoms are similar to those experienced with the flu, though severe infections of the central nervous systems or lining of the heart may occur. Chronic symptoms such as recurrent fevers, joint pain and fatigue also can occur.

Texas A&M could be fined up to $500,000, plus up to $250,000 more if the review shows someone knew of the infection and didn't file a report, Hammond said.

Hammond sent a media alert late last week describing his findings. Texas A&M Executive Vice President and Provost David Prior released a statement Monday that didn't refer to Hammond's report, but explained that the event had been confirmed by an internal investigation. He noted the person involved had recovered following treatment.

"We have since strengthened our safety, training and reporting procedures following the human error involved in not reporting this incident," Prior said. He said CDC officials were on campus Monday to conduct an independent review of A&M's policies and procedures.

"We will be fully cooperative, and our goal is to comply with all current biosafety standards."

Prior declined further comment and instructed all university officials to do the same until a final report is issued by CDC.

A&M spokesman Lane Stephenson said Tuesday that he didn't know when the review and ensuing report might be complete.

The infection

The incident happened as several A&M researchers - including professor Thomas Ficht, A&M's lead investigator for the incident - were training on what's called the Madison Aerosol Chamber, Hammond said. The group was being supervised by A&M professor David McMurray, who invented the chamber.

The chamber is in a lab with a biosafety level 3 rating. Such a lab is qualified for infectious agents, such as tuberculosis, that could cause serious or potentially lethal diseases as a result of exposure by inhalation, according to the CDC.

The researcher was infected with brucella after partially climbing into the chamber, which had been used to expose mice to the bioagent, according to Texas A&M documents supplied by the Sunshine Project. was in the process of cleaning and disinfecting the chamber when was infected, Hammond said, noting that A&M officials later determined the bacteria likely entered her body through eyes.

The was home sick for several weeks before formally being diagnosed by her doctor in April 2006. E-mails exchanged among A&M officials last April explain that the infection prompted a change in the method for cleaning the chamber. Rather than manual cleaning, researchers were to flush the unit with disinfectant, the e-mails state.

Hammond said he was not surprised that such an incident had happened. But the Austin-based director said he was surprised to see that A&M officials had talked with each other via e-mail about the reporting requirements, but still didn't report it.

The Sunshine Project obtained e-mails sent between Ficht, the researcher and Environmental Safety Manager Brent Mattox and others. Yet, Hammond said, nothing was reported until this month - six months after he started requesting documents related to a possible infection.

"Nobody learns from mistakes that are covered up," Hammond said, explaining why public accountability is important. "If we're going to conduct this kind of research safely, there needs to be a reporting system so that people know mistakes that have been made in the past and can learn from them."

The National Bio and Agro-Defense Facility

Hammond said he stumbled upon the infection at Texas A&M while reviewing procedures at the dozen or so facilities across the country lobbying to be the home of the new National Bio and Agro-Defense Facility.

The $500 million federal facility, which is being competitively bid by the Department of Homeland Security, will research high-consequence biological threats for humans and animals, as well as foreign animal diseases. Texas A&M is one of the universities trying to land the facility.

In October, Hammond requested a variety of documents, including a copy of all accident reports involving significantly dangerous agents dating back to 2000. In response, he received a sheet of paper with a sparse chart detailing one previous brucella infection that had been treated by antibiotics.

Hammond said he immediately was suspicious. Surely, he speculated, a brucella infection would generate more documentation than the meager chart he had been given.

"It was obvious to me that something more was going on," Hammond said. "That's what triggered me to really go after A&M, to get the goods on what was behind it."

Irked by the possibility that A&M deliberately could be trying to skirt public information laws, Hammond moved forward. It was last week when A&M released the e-mails to Hammond, he said.

Clark, Charley

From: Meyer, Chris
Sent: Thursday, April 12, 2007 3:03 PM
To: Clark, Charley
Subject: FW: Texas A&M Violates Law in Biodefense Lab Infection

Importance: High

-----Original Message-----
From: Mattox, Brent S
Sent: Thursday, April 12, 2007 2:30 PM
To: Meyer, Chris; Salsman, John M
Subject: FW: Texas A&M Violates Law in Biodefense Lab Infection
Importance: High

This just appeared on the listserve.

-----Original Message-----
From: ABSA biosafety forum [mailto:Biosafety@BIOSAFETY.ABSA.ORG] On Behalf Of Edward Hammond
Sent: Thursday, April 12, 2007 1:29 PM
To: Biosafety@BIOSAFETY.ABSA.ORG
Subject: Texas A&M Violates Law in Biodefense Lab Infection

The Sunshine Project
News Release - 12 April 2007
http://www.sunshine-project.org

Texas A&M University Violates Federal
Law in Biodefense Lab Infection

- Student climbs into dirty bioaerosol chamber and contracts brucellosis
- A&M failed to report the incident to federal authorities
- May lose federal funding and owe $750,000 or more in fines.

- Urgent need for mandatory federal accident and near-miss reporting system that publishes institution-level data on mishaps to provide missing lab public accountability.

12 April 2007 - An aerosol chamber mishap at Texas A&M University in February 2006 caused a researcher to be infected with the bioweapons agent brucella. Texas A&M University then violated federal law by not reporting the brucellosis case to the Centers for Disease Control (CDC) and now faces severe penalties. This information has only come to light as a result of persistent Texas Public Information Act requests by the Sunshine Project.

Overdue records obtained by the Sunshine Project in the last two days confirm that A&M officials discussed the fact that the federal Select Agent Rule required reporting the brucella infection; but they chose not to do so. A&M is still holding back additional documentation of crime. The scandal points to the urgent need for a mandatory federal accident and near-miss reporting system that publishes institution-level data on mishaps and creates public accountability for biodefense lab accidents.

For federal violations, Texas A&M may be fined $500,000, plus up to $250,000 for individual(s) that failed to report the incident. In refusing to produce information about the infection, A&M officials also flouted the Texas Public Information Act. The Sunshine Project is filing a complaint with Texas Attorney General Greg Abbott that may result in other fines and/or jail sentences if A&M officials are found guilty of hiding documents.

What Happened: The infection incident occurred on 9 February 2006. Several A&M researchers, including Principal Investigator Thomas Ficht, were in a BSL-3 lab training in the use of the Madison Aerosol Chamber. Supervising was David McMurray, an A&M professor and self-described inventor of the chamber, who has characterized it as "foolproof".

Following a "hot" run that blew aerosolized brucella into the chamber to expose mice, researchers began clean up procedures. Using what Texas A&M now admits were inappropriate protocols, a researcher "cleaned the unit by climbing partially into the chamber to disinfect it." A&M officials later concluded that the brucella bacteria likely entered her body via eyes as a result of this improper procedure. (This is the third instance of lab-acquired infections related to the Madison chamber that the Sunshine Project has uncovered. The others were in Seattle and New York City.)

By April 2006, the researcher had "been home sick for several weeks." Nobody apparently suspected brucellosis, despite the occupational exposure and, presumably, familiarity with its symptoms. Eventually, the researcher's personal physician ordered blood tests and made the diagnosis on about April 10. On 15 April, the infected researcher began a heavy treatment course reflecting the severity of the situation. received a week of intravenous antibiotics followed by a 45-day course of two additional antibiotic drugs. Just over a month later, new blood tests indicated that the infection had passed.

Failure to Report: E-mails that Texas A&M finally released to the Sunshine Project late on Tuesday night reveal that the University broke federal law by not reporting the infection. The Select Agent Rule required A&M to report the infection immediately upon its discovery and for the school to file a formal report, called APHIS/CDC Form 3, within 7 days.

According to A&M records, the sick researcher told Thomas Ficht of the diagnosis on Monday or Tuesday, April 10 or 11, 2006. Based on the records A&M has released, Ficht does not appear to have told A&M administrators until ten days later. On 21 April, a Friday afternoon, Ficht informed other A&M officials, including Angela Raines, the Responsible Official under the Select Agent Rule and Brent Maddox, the A&M biosafety director, in an e-mail titled "Workmen's Compensation".

Texas A&M has also released a partial e-mail sequence involving discussions during the following week between Ficht, the sick researcher, and Maddox (the safety director). On Tuesday April 25, Ficht noted "according to the select agent guidelines [sic] we are required to report any laboratory exposures to the CDC." Yet no report was filed.

Ficht is the Research Standards Officer of Texas A&M University, a member of the NIH bacterial biodefense and bacterial pathogenesis study groups, and is funded to study bioweapons agents by the Department of Homeland Security and National Institutes of Health. Notably, Ficht is one of only a few US researchers who were studying Brucella before the post-9/11 biodefense boom.

A&M has yet to release any of Maddox or Raines' records about the incident, despite having been obligated to do so by Texas law for almost six months. These undoubtedly would shed more light on A&M's violation of the Select Agent Rule.

A Year Too Late: There is no reason to suspect that A&M would have admitted the truth without pressure. It has taken six months for the Sunshine Project to convince A&M to reveal this incident to the limited extent known today. This week, as the Project was closing in on details in a series of tense e-mails with the Texas A&M General Counsel (including a threat to take the matter to law enforcement), A&M officials apparently decided that they could no longer stonewall.

While A&M was refusing to answer Sunshine Project requests, on Tuesday (10 April), A&M e-mailed CDC to inform it of the incident - a full year after the infection should have been reported. Yesterday (11 April), A&M's Angela Raines filed the required APHIS/CDC Form 3 document, 51 weeks after A&M was required to submit it.

Penalties: The Sunshine Project is calling for maximum penalties to be levied. Says Sunshine Project Director Edward Hammond, "The evidence released to us indicates that Texas A&M officials discussed the federal requirement to report the incident, yet they did not do so. They chose to ignore the law, and that irresponsible decision to endanger public health and security should be swiftly and severely punished with maximum fines and

loss of federal research funding."

An Ongoing Problem: For years, watchdogs have pointed to the lack of effective regulation of BSL-3 and BSL-4 labs in the United States, and particularly the need for improved (and transparent) accident reporting. Those calls have grown louder after a series of accidents in recent years that labs tried to hide from the public, including tularemia infections at Boston University, a plague problem in Newark, New Jersey, and a genetically-engineered bird flu incident in Austin, Texas.

The Sunshine Project has gathered data (in press) documenting nearly a score more BSL-3 and BSL-4 accidents, including select agent incidents, almost none of which have been reported to the public. Due to the absence of effective federal regulation, there are, undoubtedly, many more accidents that have been successfully buried, like the Texas A&M brucella incident almost was.

"It is common knowledge in the biodefense business that lab accidents with bioweapons agents are routinely buried in order to avoid negative publicity and endangering funding," says Hammond, "It is only through the power of the Texas Public Information Act that Texas A&M's criminal failures have been revealed."

The Sunshine Project is calling for a mandatory national accident and near-miss reporting system to be established. "When accidents are buried, nobody learns from past mistakes, and communities are kept in the dark about accidents and sloppy labs in their midst." says Hammond, "It's time for biodefense labs to stop talking down to the public with false safety claims and to start being transparent. All BSL-3 and BSL-4 labs should be required to report all significant accidents and near-accidents, and that information should be published by the federal government, with details of every incident, including the name of the lab and the agent involved."

- END -

Note: Look for original A&M documents to be posted online with this news release at the Sunshine Project website.

TEXAS A&M UNIVERSITY
Environmental Health & Safety Department

To: Angelia Raines
Director of the Office of Research Compliance

Institutional Biosafety Committee

From: Brent S. Mattox, CIH
Institutional Biosafety Officer

Date: May 15, 2007, With May 18, 2007 Addendum

Subject: Investigative Report on Elevated Q Fever Titer

The following paragraphs contain the investigative report summarized in an email to your office on May 15, 2007.

On late afternoon of 5/10/2007, Scott and White called to inform Occupational Health that a high titer for Q Fever (Phase II 1:1024) was received on a new addition (baseline titer) to the Occupational Health Surveillance Program. Due to issues with obtaining a copy of the titer results, EHSD did not receive a copy of the titer until Friday, 5/11/07. At that time, (9 AM), the Office of Research Compliance was informed via email that this was a reportable incident. According to the Texas Department of State Health Services, a titer of greater than 1:256 is evidence of a prior infection, but, it DOES NOT confirm that the infection was recent. EHSD spoke with the researcher, Dr. James Samuel, on Friday via cell phone, and was assured that no symptoms of disease had manifested themselves in the individual with the elevated titer, or any other employee. Dr. Samuel was out of town until late Monday, May 14, but responded via email with the hiring date of date he arrived on job, possible past exposures (prior to employment), possible on the job exposures (BL3, BL2 access logs), and any other individuals potentially exposed who were not currently being monitored. According to Dr. Samuel, had been hired 8/18/2005, and had reported for work on 11/07/2005. He had possible exposures while working in a veterinary diagnostic lab in He had been potentially exposed to the agent while at TAMU.

On Tuesday May 15 at 1:45 PM, I met with Dr. Samuel and at their Laboratory in and obtained additional information on the potential exposures. Although had not entered the BL3 laboratory in , he had assisted a Veterinarian on Dr. Samuel's staff with blood drawings of animals at the Building in room on four separate occasions. The individual had been working with antigens of Coxiella. Copies of the entry logs into the BL3 for are attached.

It was determined that , had not had a baseline test until the draw on 4/20/2007. It was also determined that Dr. Samuel's Laboratory Special Practices requires that baselines be collected prior to any exposures.

The following paragraph summarizes the findings.

was CHS approved and had accessed the Facility on four (4) occasions prior to the baseline. Laboratory Special Practices does call for baselines prior to exposure. The Facility Access was for Room NOT the aerosol chamber housed in The individual participated in blood drawing from animals that had been exposed to Coxiella on three of the dates, assisting the DVM. The DVM, who also conducted aerosol studies with Coxiella in the Madison Chamber, has shown elevated titers in the past, but has not been tested this year. According to Dr. Samuel the reason for not having a recent test was due to some individuals being out of town. Dr. Samuel was urged to get the individuals tested as soon as practical. , indicated that he had not been ill, and was not feeling ill at the time. He is scheduled for a follow-up with S&W on June 1, as confirmed by Scott & White. Chen indicated that he had possible previous exposure from a veterinary diagnostic lab in when he was working with cow serum.

The conclusions drawn would suggest possible previous exposure, although lab exposure at TAMU, although remote, cannot be completely ruled out. does work with antigens of Coxiella, which theoretically could cause elevated titers. Although a baseline titer should have been conducted or a serum sample collected prior to access, no unusual incidents or deviations from established protocols were noted. Individual was wearing a PAPR and protective clothing, and followed proper decontamination procedures. will continue to be monitored under the Occupational health Program as outlined above.

Summarizing the findings, the principal investigator failed to follow written protocols requiring baseline blood drawings prior to exposure. Two individuals in the Laboratory have not had 2007 titers drawn. Previous exposure is a possibility, but occupational exposure at TAMU cannot be ruled out.

Addendum, May 18, 2007

A question was raised concerning the access the individual had to the agent, or contaminated surfaces. As a result, I conducted a follow-up phone interview at 12:45 PM on Friday, May 18, 2007, with Kasi Russell-Londrigue, the Veterinarian who was present and escorted on all four visits. Kasi stated that , never came into direct contact or had access to the agent. According to Kasi, did not draw the blood but only observed. At no time during access did he come into direct physical contact with the agent, or the blood drawn. Kasi took the blood and spun it down for serum, placing the serum in a locked refrigerator. In theory, the agent isn't in the serum being only in the cells. The serum was later heat treated in preparation for an ELISA test. This should have completely inactivated any Coxiella that could have been in the serum, although there should not have been any agent present. did have access to the heat treated serum.

FACILITY ACCESS LOG ROOM # ___ BUILDING ___ PI NAME Samuel

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Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)		[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial)
				In / Out				Number		By
8/18/06	Britt Lack	Britt Lack	CMP	8:55	BL					
8/19	Graden Draper		CMP	1023 / 1100						
8/20	Graden Draper		CMP	1020 / 1109						
8.21	Kasi Russell-Lodrigue		MMP	8:55 / 10:00	KR					
8/21	Graden Draper		CMP	221 / 439						
11-6-06	John Delaney		CMP	9:40	JD					
11-6-06	Kasi Russell-Lodrigue		MMP	10:05 / 11:55	KR					
11-6-06			MMP	10:02 / 11:55			R	Arm ID 21600280	KR	KR
11/6										
11/1	Graden Draper		CMP	154 / 301						
11/7/06	Kasi Russell-Lodrigue		MMP	2:15 / 5:35	KR					

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

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Date	Printed Name	Signed Name	Department/ Organization	Time In / Out	Status (Initial One)	Badge Confirmed	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below) Number	Verified/ Escorted By (Initial)	Received Hazard Training (Initial) By
11-14-06	EDWARD SHAW		CSU MMPA	1:45 / 7:30		✓	R	DL 08230644	KR	KR
11/15/06	Kasi Russell-Lodrigue		MMP	8:55 / 10:40	KR					
11/8/06			MMP	8:35 / 10:00			R	UIN 21600686	KR	KR
11/6/06	Gordon Draper		CMP	2:15 / 3:31						
11/6/06	Gordon Draper		CMP	2:50 / 3:50						
11/6/06	Sean Knox		CMP	8:45 / 11:55	SK					
11/17/06	Amy Hanson		CMP	1:20 / 4:35	AH					
11/18/06	Amy Henson		CMP	8:14 / 9:19	AH					
11/19/06	Amy Henson		CMP	8:17 / 9:10	AH					
11/21/06			MMP	9:50 / 11:05			R	UIN 21600686	KR	KR
11/22/06	Kasi Russell-Lodrigue		MMP	9:50 / 11:35	KR					

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG ROOM # ____ BUILDING # ____ PI NAME Samuel

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Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial)
12/1/06	Sean Knox	[signature]	CMP	10:21 / 1:00	SK				
12/4	Gordon Draper	[signature]	CMP	1154 / 102	[illegible]				
12/4	Gordon Draper	[signature]	CMP	846 / 1223	[illegible]				
12/5	Gordon Draper	[signature]	CMP	854 / 1118	[illegible]				
12/6	Amy Henson	[signature]	CMP	9:43 / 12:10	AH				
12/6	[illegible]	[signature]	MMPA	10:00 / 10:40		R	21600 [illegible]	KR	KR
12/6	Kasi Russell	[signature]	MMPA	10:00 / 10:40	KR				
12/6	Kasi Russell-Looijen	[signature]	MMPA	11:11 / [illegible]	KR				
12/7	John D. Delaney	[signature]	CMP	8:54 / 11:07	JD				
12/7	John D Delaney	[signature]	CMP	1:25	JD				
12/8	Amy Henson	[signature]	CMP	2:40 / 5:14	AH				

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

TEXAS DEPARTMENT OF STATE HEALTH SERVICES

DAVID L. LAKEY M.D.
COMMISSIONER

1100 W. 49th Street • Austin, Texas 78756
1-888-963-7111 • http://www.dshs.state.tx.us
TDD: 512-458-7708

Submitter copy to: ** DUPLICATE REPORT ** Date: 5/2/2007

SCOTT AND WHITE CLINIC-02180184
1600 UNIVERSITY DRIVE
attn: Jack Crouch
COLLEGE STATION, TX 77840

Spec #: S07SM001915
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Address:

Date Rcvd: 4/23/2007 Test Reas: DIAGNOSIS
Spec Type: SERUM

Please fax your NPI to 512.458.7533 by May 23, 2007. Delay in sending the NPI risks reimbursement as well as the reimbursement of your health care partners. Federal Regulation (Health Insurance Portability and Accountability Act of 1996 (HIPAA)) outlines you must share your NPI with other providers, health plans, clearinghouses, and any entity that may need it for billing purposes.

Final Results

Specimen Numbers:	S07SM001915
Date Collected:	4/20/2007
BRUCELLA AGGLUTINATION	<1:40

An agglutination titer of <1:40 is considered to be negative.
This test was developed and its performance characteristics determined by the Laboratory Services Section at DSHS. The test has not been approved or cleared by the US Food and Drug Administration (FDA).

Q FEVER IFA	**PHASE I	<1:64
	PHASE II	1:1024

A single Q fever IFA titer of greater than or equal to 1:256 is evidence of a prior infection, but, it does not confirm that the infection was recent. The most convincing evidence of recent infection is a fourfold rise in antibody titer between an acute serum

and [illegible] fluorescent serum. Reactions to both phase I and phase II antibodies often occur. The phase II titer for IgG antibody is usually higher than the phase I titer. In chronic Q fever, phase I titers rise in later specimens while phase II titers fall or remain constant.

DAVID L. LAKEY M.D
COMMISSIONER

(continued)

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
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Submitter copy to: ** DUPLICATE REPORT ** Date: 5/2/2007

SCOTT AND WHITE CLINIC-02180184
1600 UNIVERSITY DRIVE
attn: Jack Crouch
COLLEGE STATION, TX 77840

Spec #: S07SM001915
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Address:

This test was developed and its performance characteristics determined by the Laboratory Services Section at DSHS. The test has not been approved c cleared by the US Food and Drug Administration (FDA).

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

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

URC has been asked to review the University's current event reporting procedures for select agents and toxins. Recommendations are to address modifications, including adequate redundancies, to ensure that appropriate entities receive timely notifications of any reportable event as required by applicable regulations.

this part are accurate, have controlled access, and that their authenticity may be verified.

(c) All records created under this part must be maintained for three years and promptly produced upon request.

§ 73.18 Inspections.

(a) Without prior notification, the HHS Secretary, shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.

(b) Prior to issuing a certificate of registration to an individual or entity, the HHS Secretary may inspect and evaluate the premises and records to ensure compliance with this part.

§ 73.19 Notification of theft, loss, or release.

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

(1) The theft or loss of a select agent or toxin must be reported immediately by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (*e.g.*, strain or other characterization information),

(ii) An estimate of the quantity lost or stolen,

(iii) An estimate of the time during which the theft or loss occurred,

(iv) The location (building, room) from which the theft or loss occurred, and

(v) The list of Federal, State, or local law enforcement agencies to which the individual or entity reported, or intends to report the theft or loss.

(2) A completed APHIS/CDC Form 3 must submitted within seven calendar days.

(b) 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.

(1) The release of a select agent or toxin must be reported by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (*e.g.*, strain or other characterization information),

(ii) An estimate of the quantity released,

(iii) The time and duration of the release,

(iv) The environment into which the release occurred (*e.g.*, in building or outside of building, waste system),

(v) The location (building, room) from which the release occurred,

(vi) The number of individuals potentially exposed at the entity,

(vii) Actions taken to respond to the release, and

(viii) Hazards posed by the release.

(2) A completed APHIS/CDC Form 3 must be submitted within seven calendar days.

§ 73.20 Administrative review.

An individual or entity may appeal a denial, revocation, or suspension of registration under this part. An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 30 calendar days of the decision. Where the denial, revocation, or suspension of registration or the denial, limitation, or revocation of an individual's access approval is based upon an identification by the Attorney General, the request for review will be forwarded to the Attorney General. The HHS Secretary's decision constitutes final agency action.

§ 73.21 Civil money penalties.

(a) The Inspector General of the Department of Health and Human Services is delegated authority to conduct investigations and to impose civil money penalties against any individual or entity in accordance with regulations in 42 CFR part 1003 for violations of the regulations in this part, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188). The delegation of authority includes all powers contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(b) The administrative law judges in, assigned to, or detailed to the Departmental Appeals Board have been delegated authority to conduct hearings and to render decisions in accordance with 42 CFR part 1005 with respect to the imposition of civil money penalties, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188). This delegation includes, but is not limited to, the authority to administer oaths and affirmations, to subpoena witnesses and documents, to examine witnesses, to exclude or receive and give appropriate weight to materials and testimony offered as evidence, to make findings of fact and conclusions of law, and to determine the civil money penalties to be imposed.

(c) The Departmental Appeals Board of the Department of Health and Human Services is delegated authority to make final determinations with respect to the imposition of civil money penalties for violations of the regulations of this part.

42 CFR Chapter V—Office of Inspector General—Health Care, Department of Health and Human Services

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

■ 1. The authority citation for part 1003 continues to read as follows:

Authority: 42 U.S.C. 262a, 1302, 1320–7,1320a–7a, 1320b–10, 1395u(j), 1395u(k), 1395cc(j), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c), and 11137(b)(2).

■ 2. Section 1003.106 is amended by revising introductory paragraph (a)(1) to read as follows:

§ 1003.106 Determinations regarding the amount of the penalty and assessment.

(a) *Amount of penalty.* (1) In determining the amount of any penalty or assessment in accordance with § 1003.102(a), (b)(1), (b)(4), and (b)(9) through (b)(16) of this part, the Department will take into account—

* * * * *

[FR Doc. 05–5216 Filed 3–17–05; 8:45 am]
BILLING CODE 4160–17–P

Callcott, Diane

From: Raines, Angelia
Sent: Thursday, April 12, 2007 2:06 PM
To: James McGee
Cc: Tiffany Agnew
Subject: Form 3

Attachments: Form 3-Ficht (faxed).pdf; Angelia Raines.vcf


Form 3-Ficht (faxed).pdf (253 ...


Angelia Raines.vcf (513 B)

Hi Jim,

Thanks for following up with me regarding the Brucella exposure. I also briefly spoke with Paul Mehta. Attached is an electronic copy of the report that was faxed to you. Per my conversation with Dr. Mehta, I will be prepared to send additional information about changes in our safety plan after we get the official response from your office.

To recap our conversation about the exposure:

- It most likely occurred in February 2006.
- The employee was tested, and treated.
- Other lab personnel were tested and found to be negative for exposure.
- The Lab Director reviewed his Biosafety Plan to determine if changes were needed.
- The Biosafety Plan was modified as a result of the incident.
- Lab personnel were updated and retrained on the changes.
- Form 3 was not submitted at the time of the event, as required; however a process is now in place to ensure immediate notification. We have also submitted the required report.

Thanks for sharing with me that many institutions have been unclear as to whether they needed to report some exposures based on the information contained in the Form-3 instructions. While I fully understand the regulatory requirements, clarity in these instructions could indeed assist the reporting process.

Thanks again for your insight and assistance!

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

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

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

INTRODUCTION

The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules (7 CFR 331, 9 CFR 121, and 42 CFR 73), which implement the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) setting forth the requirements for possession, use, and transfer of select agents and toxins. The select agents and toxins identified in the final rules have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the HHS Secretary and to the Animal and Plant Health Inspection Service (APHIS) by the USDA Secretary. In order to minimize the reporting burden to the public, APHIS and CDC have developed a common reporting form for this data collection.

An entity is required by regulation (7 CFR 331.19, 9 CFR 121.19, and 42 CFR 73.19) to notify APHIS (telephone: 301-734-5960, facsimile: 301-734-3652, e-mail: Agricultural.Select.Agent.Program@aphis.usda.gov) or CDC (telephone: 404-718-2000, facsimile: 404-718-2096, or e-mail: lrsat@cdc.gov) immediately upon discovery of a theft (unauthorized removal of select agent or toxin), loss (failure to account for select agent or toxin), or release (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a select agent and toxin. In addition, clinical or diagnostic laboratories and other entities that possess, use or transfer a select agent or toxin contained in a specimen presented for diagnosis, verification, or proficiency testing must immediately report upon discovery of a theft, loss, or release of select agent or toxin. After the initial reporting, this form (APHIS/CDC Form 3) must be sent to APHIS or CDC within 7 calendar days after the discovery of theft, loss, or release of select agents or toxins.

For theft or loss of select agents or toxins, the entity must notify the appropriate local, state, or federal law enforcement agencies. For release of select agents or toxins, the entity should notify the appropriate local, state, and federal health agencies.

PURPOSE

This form is to be used by the RO or facility director to report the theft, loss, or release of select agents or toxins. A copy of the completed form and attachments must be maintained by the entity for three years.

INSTRUCTIONS

1. Immediately notify APHIS or CDC via telephone, fax, or e-mail and appropriate local, state, or federal law enforcement agencies (theft or loss) or appropriate local, state, and federal health agencies (release).

2. The RO or facility director must complete, sign and date this form. For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration.
   A. For reporting of a theft or loss, complete sections 1 and 2. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified. For reporting a theft or loss that occurred during transfer, complete sections 1, 2, and 3 and include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins."
   B. For reporting a release, complete sections 1, 2, and 4. For reporting a release that occurred during transfer, complete all sections and include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins."

3. The RO or facility director faxes or mails the form to APHIS or CDC **within 7 calendar days** of the theft, loss, or release.

OBTAINING EXTRA COPIES OF THIS FORM

Additional copies of this form are available on APHIS website (http://www.aphis.usda.gov/programs/ag_selectagent/index.html) or CDC website (http://www.cdc.gov/od/sap) or by contacting APHIS at (301) 734-5960 or CDC at (404) 718-2000.

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

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

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

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

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

SECTION 1 – TO BE COMPLETED BY ALL ENTITIES

1. Entity name: Texas A&M University		2. Entity registration number (if applicable): APHIS# CDC# 200606050489		
3. Entity address (NOT a post office address): 1112 TAMU	4. City: College Station		5. State: TX	6. Zip Code: 77843-1112
7. Responsible Official (RO) or facility director First: Richard MI: Last: Ewing	8. Telephone: (979) 847-9362	9. FAX: (979) 862-3176	10. E-mail: araines@vprmail.tamu.edu	
11. RO or facility director address (NOT a post office address): 1112 TAMU	12. City: College Station		13. State: TX	14. Zip Code: 77843-1112
15. Type of incident: ☐ Theft ☐ Loss ☑ Release	16. Immediate notification provided to: ☐ APHIS ☑ CDC	17. Date of immediate notification: 04/10/2007	18. Type of immediate notification: ☑ E-mail ☐ Fax ☐ Telephone	
19. An internal review of laboratory procedures and policies has been initiated to prevent recurrences of loss of select agents and toxins at this entity: ☐ No ☑ Yes (If yes, please provide additional details in an attachment.) (See explanation in Section 2)				

SECTION 2 – TO BE COMPLETED BY ALL ENTITIES

LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED (Please see page 4.)

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

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

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

Several months ago, one of our laboratory employees had an elevated titer (1:160) for Brucella. The lab report stated "...evidence of prior exposure", but "it does not confirm that the exposure was recent." While the exact cause is not known, the exposure could have occurred on 02/09/2006, and would have been the result of improper decontamination procedures. Specifically, the employee may have reached into an aerosol chamber after a run. The chamber was located within the BL3 lab. The laboratory's Bio-safety plan has since been updated and all lab personnel have been retrained. All other lab personnel have also been tested and found to be negative. The incident occurred during the time we were transitioning CDC compliance responsibilities within our organizational structure. This information should have been immediately reported to the CDC, but it was not. We now have a process in place to ensure notification of a loss, theft or release and we are auditing all records to ensure all incidents have been properly reported.

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

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

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

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

SECTION 2 – TO BE COMPLETED BY ALL ENTITIES							
LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED							
	20. Select Agents and Toxins	21. Characterization of Agent	22. Number of Vials	23. Form (powder/liquid/ slant)	24. Vol or Wt per Vial (e.g., ml, mg, ng)	25. Total Quantity	26. Concentration/Vial (e.g., 10^8 pfu/ml)
1	Brucella melitensis						1x10^9 cfu/ml
2							1 x 10
3							1 x 10
4							1 x 10
5							1 x 10
6							1 x 10
7							1 x 10
8							1 x 10
9							1 x 10
10							1 x 10
11							1 x 10
12							1 x 10

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

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

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

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

From: Shannon Davis
To: Bazer, Fuller; Browder, Betsy; bsmattox@tamu.edu; ddavis@cvm.tamu.edu; Ewing, Richard; Ficht, Thomas; gadams@cvm.tamu.edu; mihrig@tamu.edu; Samuel, James; Tesh, Vernon
Date: 4/13/2007 2:01:09 PM
Subject: **Notification of CDC Site Visit 4/16/07**

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

Angelia Raines

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax
(770) 789-3456 Cell

CC: Cornett, Dianne; Raines, Angelia; Wilson, Van

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 [redacted] 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.

incident and report?

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

CDC Emergency Contact Information

Police, Fire, Medical = 9- 911

Dr. L. Garry Adams
(Investigator)
Work (979) 845-5092
Mobile

Dr. Thomas A. Ficht
(Investigator, IBC Co-Chair)
Mobile

Dr. John M. Quarles
(Department Head)
Mobile

Ms. Tiffany Agnew
(Program Coordinator, IBC)
Work (979) 458-3624
Mobile

Dr. Melanie Ihrig
(Director, Comparative Medicine Program)
Work (979) 845-7433
Mobile

Ms. Angelia Raines
(Director, Research Compliance)
Work (979) 847-9362
Mobile

Fuller Bazer
(Assoc. VP for Research)
Work (979) 693-2872
Mobile

Lt. Bert Kretzschmar
(University Police, Crime Prevention Unit)
Work (979) 845-8900
Mobile
UPD (979) 324-0773

Dr. James Samuel
(Investigator)
Work (979) 862-1684
Emergency

Dr. Elizabeth Browder
(Assoc. Director, Comparative Medicine Program Work (979) 845-7433
Mobile

Mr. Brent Mattox
(Alternative Responsible Official)
Work (979) 845-2132
Mobile

Dr. Frank Stein
(Assoc. Director, Comparative Medicine Program)
Work (979) 845-6488
Mobile

Mr. Donald Davis
(Investigator)
Work (979) 845-5174
Mobile

Ms. Ellen Mitchell
()
Work (979) 847-8642
Mobile

Dr. Vernon Tesh
(Investigator)
Work (979) 862-4113
Mobile

Dr. Richard Ewing
(Vice President for Research, Responsible Official)
Work (979) 845-8585
Mobile

Dr. D Partin
USDA
Mobile

Dr. Van Wilson
(IBC Co-Chair)
Work (979) 845-5207

University police.....845-2345
College station police.....764-3600
College station fire.....764-3700
TAMU environmental health and safety.....845-2132
TAMU area maintenance.....845-5542
TAMU maintenance (24 hours).....845-4311
Radiological emergencies 862-1111

THE CHRONICLE OF HIGHER EDUCATION http://chronicle.com/daily/2007/04/2007041306n.htm

Today's News

Friday, April 13, 2007

Texas A&M U.'s Failure to Report Lab Incident That Sickened Researcher Could Cost It $500,000

By KELLY FIELD

Texas A&M University could face a fine of $500,000 or more for failing to report a laboratory incident that infected a researcher with the bacterium that causes brucellosis.

The incident occurred in February 2006, when the researcher, whose name was not disclosed, climbed into a chamber filled with the *Brucella* bacterium, in aerosol form, to disinfect it. She became ill with brucellosis, an illness that can resemble the flu, and notified her superiors of the diagnosis in April 2006.

Under federal law, the university should have reported the incident to the Centers for Disease Control and Prevention within seven days. But the university did not report the infection to the federal government until Tuesday, more than a year after the researcher was exposed. That same day, it released documents detailing the incident to the Sunshine Project, an arms-control group that had requested the records through the Texas Public Information Act.

According to one e-mail message released to the group, the researcher in charge of the project, Thomas A. Ficht, knew that he was required to report the information to the federal government, but did not do so. That lapse could lead to a $500,000 fine, plus up to $250,000 in additional fines for individuals who failed to report the incident, the Sunshine Project said. The Sunshine Project also plans to file a complaint with the Texas attorney general accusing the university of hiding documents.

In an interview on Thursday, Sherylon Carroll, associate vice president for communications at Texas A&M, said, "We are aware of the situation, and we have launched an internal investigation."

Brucellosis is commonly passed among animals and is rare in the United States, where 100 to 200 cases occur in animals each year, according to the CDC. But it can be very common in countries that lack strong programs to control animal diseases.

Clark, Charley

From: Moore, Steve
Sent: Thursday, April 12, 2007 6:06 PM
To: Callcott, Diane; Dr. Alicia Dorsey; Raines, Angelia; Mattox, Brent S; Salsman, John M; McClendon, Rodney P; Meyer, Chris; 'tficht@cvm.TAMU.edu'; 'mcmurray@medicine.tamhsc.edu'; 'gadams@cvm.tamu.edu'; Stephenson, Lane B; Wolf, Cherry Kay; Faber, Jan
Cc: Godfrey, Mike; Lawson, Caroline; Clark, Charley
Subject: RE: Friday meeting, 2pm

I wanted to inform the group that the 2pm meeting mentioned below may indeed occur earlier in the day based on schedules. Charley Clark and Scott Kelly will confirm that time either this evening or early tomorrow.

Steven B. Moore
Chief Marketing Officer & VP Communications Texas A&M University 1180 TAMU College Station, TX 77843-1180
979.458.1729 (office) / 979.204.7185 (cell) steve.moore@tamu.edu

-----Original Message-----
From: Callcott, Diane
Sent: Thursday, April 12, 2007 3:20 PM
To: Dr. Alicia Dorsey; Raines, Angelia; Mattox, Brent S; Salsman, John M; McClendon, Rodney P; Meyer, Chris; tficht@cvm.TAMU.edu; mcmurray@medicine.tamhsc.edu; Moore, Steve; gadams@cvm.tamu.edu; Stephenson, Lane B; Wolf, Cherry Kay; Faber, Jan
Cc: Godfrey, Mike; Lawson, Caroline
Subject: Edward Hammond ABSA News Release
Importance: High

The attached news release was sent to the ABSA (American Biological Safety Association) email listserve today by Edward Hammond of the Sunshine Project. Brent Mattox forwarded it to our office and Scott Kelly has asked me to forward it on to you. We look forward to seeing you at tomorrow's meeting at 2 p.m. in our offices. Please contact Scott (8-6125), his secretary Caroline (8-6129) or me if you have any questions.

Scott also asks that you bring all documents or records related to this matter to tomorrow's meeting.

Diane Callcott
Legal Assistant II / Public Information
Office of General Counsel
The Texas A&M University System
A&M System Bldg. Suite 2079
200 Technology Way
College Station, TX 77845-3424
(979) 458-6149
(979) 458-6150 - facsimilie

Clark, Charley

From: Meyer, Chris
Sent: Thursday, April 12, 2007 3:03 PM
To: Clark, Charley
Subject: FW: Texas A&M Violates Law in Biodefense Lab Infection

Importance: High

-----Original Message-----
From: Mattox, Brent S
Sent: Thursday, April 12, 2007 2:30 PM
To: Meyer, Chris; Salsman, John M
Subject: FW: Texas A&M Violates Law in Biodefense Lab Infection
Importance: High

This just appeared on the listserve.

-----Original Message-----
From: ABSA biosafety forum [mailto:Biosafety@BIOSAFETY.ABSA.ORG] On Behalf Of Edward Hammond
Sent: Thursday, April 12, 2007 1:29 PM
To: Biosafety@BIOSAFETY.ABSA.ORG
Subject: Texas A&M Violates Law in Biodefense Lab Infection

The Sunshine Project
News Release - 12 April 2007
http://www.sunshine-project.org

Texas A&M University Violates Federal
Law in Biodefense Lab Infection

- Student climbs into dirty bioaerosol chamber and contracts brucellosis
- A&M failed to report the incident to federal authorities
- May lose federal funding and owe $750,000 or more in fines.

- Urgent need for mandatory federal accident and near-miss reporting system that publishes institution-level data on mishaps to provide missing lab public accountability.

12 April 2007 - An aerosol chamber mishap at Texas A&M University in February 2006 caused a researcher to be infected with the bioweapons agent brucella. Texas A&M University then violated federal law by not reporting the brucellosis case to the Centers for Disease Control (CDC) and now faces severe penalties. This information has only come to light as a result of persistent Texas Public Information Act requests by the Sunshine Project.

Overdue records obtained by the Sunshine Project in the last two days confirm that A&M officials discussed the fact that the federal Select Agent Rule required reporting the brucella infection; but they chose not to do so. A&M is still holding back additional documentation of crime. The scandal points to the urgent need for a mandatory federal accident and near-miss reporting system that publishes institution-level data on mishaps and creates public accountability for biodefense lab accidents.

For federal violations, Texas A&M may be fined $500,000, plus up to $250,000 for individual(s) that failed to report the incident. In refusing to produce information about the infection, A&M officials also flouted the Texas Public Information Act. The Sunshine Project is filing a complaint with Texas Attorney General Greg Abbott that may result in other fines and/or jail sentences if A&M officials are found guilty of hiding documents.

What Happened: The infection incident occurred on 9 February 2006. Several A&M researchers, including Principal Investigator Thomas Ficht, were in a BSL-3 lab training in the use of the Madison Aerosol Chamber. Supervising was David McMurray, an A&M professor and self-described inventor of the chamber, who has characterized it as "foolproof".

Following a "hot" run that blew aerosolized brucella into the chamber to expose mice, researchers began clean up procedures. Using what Texas A&M now admits were inappropriate protocols, a researcher "cleaned the unit by climbing partially into the chamber to disinfect it." A&M officials later concluded that the brucella bacteria likely entered her body via eyes as a result of this improper procedure. (This is the third instance of lab-acquired infections related to the Madison chamber that the Sunshine Project has uncovered. The others were in Seattle and New York City.)

By April 2006, the researcher had "been home sick for several weeks." Nobody apparently suspected brucellosis, despite the occupational exposure and, presumably, familiarity with its symptoms. Eventually, the researcher's personal physician ordered blood tests and made the diagnosis on about April 10. On 15 April, the infected researcher began a heavy treatment course reflecting the severity of the situation. e received a week of intravenous antibiotics followed by a 45-day course of two additional antibiotic drugs. Just over a month later, new blood tests indicated that the infection had passed.

Failure to Report: E-mails that Texas A&M finally released to the Sunshine Project late on Tuesday night reveal that the University broke federal law by not reporting the infection. The Select Agent Rule required A&M to report the infection immediately upon its discovery and for the school to file a formal report, called APHIS/CDC Form 3, within 7 days.

According to A&M records, the sick researcher told Thomas Ficht of the diagnosis on Monday or Tuesday, April 10 or 11, 2006. Based on the records A&M has released, Ficht does not appear to have told A&M administrators until ten days later. On 21 April, a Friday afternoon, Ficht informed other A&M officials, including Angela Raines, the Responsible Official under the Select Agent Rule and Brent Maddox, the A&M biosafety director, in an e-mail titled "Workmen's Compensation".

Texas A&M has also released a partial e-mail sequence involving discussions during the following week between Ficht, the sick researcher, and Maddox (the safety director). On Tuesday April 25, Ficht noted "according to the select agent guidelines [sic] we are required to report any laboratory exposures to the CDC." Yet no report was filed.

Ficht is the Research Standards Officer of Texas A&M University, a member of the NIH bacterial biodefense and bacterial pathogenesis study groups, and is funded to study bioweapons agents by the Department of Homeland Security and National Institutes of Health. Notably, Ficht is one of only a few US researchers who were studying Brucella before the post-9/11 biodefense boom.

A&M has yet to release any of Maddox or Raines' records about the incident, despite having been obligated to do so by Texas law for almost six months. These undoubtedly would shed more light on A&M's violation of the Select Agent Rule.

A Year Too Late: There is no reason to suspect that A&M would have admitted the truth without pressure. It has taken six months for the Sunshine Project to convince A&M to reveal this incident to the limited extent known today. This week, as the Project was closing in on details in a series of tense e-mails with the Texas A&M General Counsel (including a threat to take the matter to law enforcement), A&M officials apparently decided that they could no longer stonewall.

While A&M was refusing to answer Sunshine Project requests, on Tuesday (10 April), A&M e-mailed CDC to inform it of the incident - a full year after the infection should have been reported. Yesterday (11 April), A&M's Angela Raines filed the required APHIS/CDC Form 3 document, 51 weeks after A&M was required to submit it.

Penalties: The Sunshine Project is calling for maximum penalties to be levied. Says Sunshine Project Director Edward Hammond, "The evidence released to us indicates that Texas A&M officials discussed the federal requirement to report the incident, yet they did not do so. They chose to ignore the law, and that irresponsible decision to endanger public health and security should be swiftly and severely punished with maximum fines and

loss of federal research funding."

An Ongoing Problem: For years, watchdogs have pointed to the lack of effective regulation of BSL-3 and BSL-4 labs in the United States, and particularly the need for improved (and transparent) accident reporting. Those calls have grown louder after a series of accidents in recent years that labs tried to hide from the public, including tularemia infections at Boston University, a plague problem in Newark, New Jersey, and a genetically-engineered bird flu incident in Austin, Texas.

The Sunshine Project has gathered data (in press) documenting nearly a score more BSL-3 and BSL-4 accidents, including select agent incidents, almost none of which have been reported to the public. Due to the absence of effective federal regulation, there are, undoubtedly, many more accidents that have been successfully buried, like the Texas A&M brucella incident almost was.

"It is common knowledge in the biodefense business that lab accidents with bioweapons agents are routinely buried in order to avoid negative publicity and endangering funding," says Hammond, "It is only through the power of the Texas Public Information Act that Texas A&M's criminal failures have been revealed."

The Sunshine Project is calling for a mandatory national accident and near-miss reporting system to be established. "When accidents are buried, nobody learns from past mistakes, and communities are kept in the dark about accidents and sloppy labs in their midst." says Hammond, "It's time for biodefense labs to stop talking down to the public with false safety claims and to start being transparent. All BSL-3 and BSL-4 labs should be required to report all significant accidents and near-accidents, and that information should be published by the federal government, with details of every incident, including the name of the lab and the agent involved."

- END -

Note: Look for original A&M documents to be posted online with this news release at the Sunshine Project website.

From: Shannon Davis
To: Bazer, Fuller; Browder, Betsy; bsmattox@tamu.edu; ddavis@cvm.tamu.edu; Ewing, Richard; Ficht, Thomas; gadams@cvm.tamu.edu; mihrig@tamu.edu; Samuel, James; Tesh, Vernon
Date: 4/13/2007 2:01:09 PM
Subject: Notification of CDC Site Visit 4/16/07

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

Angelia Raines

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax
(770) 789-3456 Cell

CC: Cornett, Dianne; Raines, Angelia; Wilson, Van

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 [redacted] 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.

Incident and report?

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

CDC Emergency Contact Information

Police, Fire, Medical = 9- 911

Dr. L. Garry Adams
(Investigator)
Work (979) 845-5092
Mobile

Dr. Thomas A. Ficht
(Investigator, IBC Co-Chair)
Mobile

Dr. John M. Quarles
(Department Head)
Mobile

Ms. Tiffany Agnew
(Program Coordinator, IBC)
Work (979) 458-3624
Mobile

Dr. Melanie Ihrig
(Director, Comparative Medicine Program)
Work (979) 845-7433
Mobile

Ms. Angelia Raines
(Director, Research Compliance)
Work (979) 847-9362
Mobile

Fuller Bazer
(Assoc. VP for Research)
Work (979) 693-2872
Mobil

Lt. Bert Kretzschmar
(University Police, Crime Prevention Unit)
Work (979) 845-8900
Mobile
UPD (979) 324-0773

Dr. James Samuel
(Investigator)
Work (979) 862-1684
Emergency

Dr. Elizabeth Prowder
(Assoc. Director, Comparative Medicine Program Work (979) 845-7433
Mobile

Mr. Brent Mattox
(Alternative Responsible Official)
Work (979) 845-2132
Mobile

Dr. Frank Stein
(Assoc. Director, Comparative Medicine Program)
Work (979) 845-6488
Mobile

Mr. Donald Davis
(Investigator)
Work (979) 845-5174
Mobile

Ms. Ellen Mitchell
()
Work (979) 847-8642
Mobile

Dr. Vernon Tesh
(Investigator)
Work (979) 862-4113
Mobile

Dr. Richard Ewing
(Vice President for Research, Responsible Official)
Work (979) 845-8585
Mobile (

Dr. D Partin
USDA
Mobile

Dr. Van Wilson
(IBC Co-Chair)
Work (979) 845-5207

University police	**845-2345**
College station police	**764-3600**
College station fire	**764-3700**
TAMU environmental health and safety	**845-2132**
TAMU area maintenance	**845-5542**
TAMU maintenance (24 hours)	**845-4311**
Radiological emergencies	**862-1111**

5-8-07 UT HSC Houston - Bob Emery

D.W. Kinney

Risk given intended use

Bob Emery -

Compliance → balance →

① Support research without grinding to a halt
② Maintain public trust

Faculty →

Biosafety Program

Contracts → human

Biosafety Committee

IBC - protocols
SBAM - protocols

Information flows ARO → RO

- Preventive surveillance
  annual inspections
  more frequently BSL3 -
  outside vendor cabinets ventilation
  detail checklist per lab

- Routine Surveillance -

Communication —

ORC gets inspection from BSO → IBC →
follow up on inspection deficiencies
report back if continuous issues

Security — UPD → Fuller Bazer

BSO { total inspection annual
period – facility issues

IBC – review protocols

IBC does not cross check with IACUC

new initiative – 3 months ago ORC cross check
information IBC + IACUC —
if don't check IACUC protocol not

IACUC – looks only animal issues not SBATS

UCHSC → Look at inspection history
Inspections (last 3) before vote on protocol

BSO → Pre-review → Presentation
Proactive handholding Work with faculty – tell what focus on – bumps in road

Overt Expectation Biosafety

Superimpose SBAT – More stringent reqs
checklist on – frequent reminders

PI → BSO sits down to pick out problems
☆ PI agrees to terms of protocol

What is life span of protocol – 3 yr
Mission creep – same basic – Modify methodology
~~PI agrees~~ Influx of protocols meeting 3 yr threshold
takes a lot of time

not show stopper –
person in lab shouldn't be in lab

ORC acts as monitor

ORC → If go back have not been fixed –
notify IBC – what action to be taken

IACUC – More (cease & desist)

IBC meets once a month

how to address

Surveillence Program → Notify ORC
not if immaterial event.

Brucella
titers done

S&W ~~for~~ Occupational Safety
Health dept – for most part Health Dept does not investigate
Brent →

Each E lab has security procedures
inventory issues

PAYE - ~~Talk~~ ~~to~~ what can do better
Security has been elevated

- ~~Each~~ Each lab has training (PI trains)
Drills - two table tops

Drill Template - table top - did ~~not~~ not go

Larger drill

Larger status report

lots of people doing whack — Communication
~~what is tasks~~ to people above

Creation
of denominator Status ( ) all things need
Creation of denominator to be done

↓

baseline - rules of game - Meet Expectation
Document — verify on ~~web~~

Sub-set list - Monthly list

Protocol specifies expectation + adherence to expectations

Go over Monthly surveys —
catch before get out of hand.

① Minimize Issue
② Periodic Surveillance
③ Expectation Communication up food chain

If not filed — Why!

Man power - 1 FTE SBATS

provisional approval frees up time

Visit + meet with people

leg work up front — reduce debate over single protocol

FRONT END

Amend - Contracts Grants
sit down Contract and identify potential issues

↓

· Cut & Paste - r

Who notifies Sponsor
Protocol to PI - ISC

Who notifies Sponsor Contract or PI

① Create Template

- Comprehensive documentation
- Routine assess - status reports
- Flow information to committees.

Security - Guards - video surveillance

Brent Matters

Come Lunch -
Registrations & Amendment
Communication - more transparent →
changes in personnel.

Is there a place - look at one
★ document that captures all information
Current
amendment - last becomes date of one file
one file with everything

1 suite
3 lab rooms - 1 SBAT

★ Routine Surveillance -
Core Faculty support - what do they
need to do to be compliance.

★ Get sense of status

Biosafety – Generic

Format –

PI does with input BSO (biosafety focus)

Policy Police –

BALANCES
- what regs say
- v police want
- what feasible for labs

Surveillance v Biosafety Risk Assessment

Using BMBL (Using Version 4)

RO

#RO

PI

RC

Strategically wise

level of states – can require feedback

Wallis, Annette

From: Dianne Cornett [dcornett@vprmail.tamu.edu]
Sent: Friday, May 04, 2007 4:07 PM
To: Tom Ficht; Vernon Tesh; Wallis, Annette; Kretzschmar, Bert; Cantrell, Carol; Meyer, Chris; Salsman, John M; Ewing, Richard; Tiffany Agnew; Clark, Charley; Raines, Angelia; Fuller Bazer
Cc: Parker, Cynthia; Mahle, Debbie; Barker, Julie K.; Crawford, Sandy L; Holt, Kathy J.
Subject: MEETING WITH BOB EMERY (UTHSC): TUESDAY, MAY 8

Importance: High

Attachments: UTHSCMtgAgenda_050807.doc; Biosketches for Invited TAMU Biosafety Program Peer Review.doc


UTHSCMtgAgenda_ 050807.doc (29 ...


Biosketches for Invited TAMU B...

** High Priority **

Good afternoon all -

Attached is a draft of the proposed agenda for the meeting with Robert Emery (University of Texas Health Science Center - Houston) on Tuesday, May 8.

Note that the persons listed on agenda have been asked to participate in the 2:30 - 4:00p meeting. Please confirm your attendance to dcornett@vprmail.tamu.edu at your earliest convenience.

For your review, I have also attached the bios for the 3 invited guests from the UTHSC-Houston.

If you have any questions, please let me know.

Thanks,

Dianne Cornett
Texas A&M University
Office of the Vice President for Research
311 Administration Bldg. / 1112 TAMU
College Station, TX 77843-1112
979/845-8585 (Office)
979/845-1855 (Fax)
dcornett@vprmail.tamu.edu

AGENDA

Meeting with Robert J. Emery
University of Texas Health Science Center - Houston
May 8, 2007
10th Floor Rudder

1:30 p.m.	Introductory Meeting Eddie Davis, Bob Emery, Bruce J. Brown (UTHSC), Scott Patlovich (UTHSC)
2:00 p.m.	Meeting with Eddie Davis, Richard Ewing, Bob Emery, Bruce J. Brown, Scott Patlovich
2:30 p.m.	Biosafety Program Peer Review and Discussion UTHSC - Bob Emery, Bruce J. Brown, Scott Patlovich VPR - Richard Ewing, Carol Cantrell, Fuller Bazer EH&S - Charley Clark, Annette Wallis, Chris Meyer, John Salsman UPD - Bert Kretzschmar Research Compliance - Angelia Raines, Tiffany Agnew IBC - Tom Ficht, Vernon Tesh
4:00 p.m.	Exit Meeting Eddie Davis, Bob Emery, Bruce J. Brown (UTHSC), Scott Patlovich (UTHSC)

Created 05/04/07

Biosketches for Invited TAMU Biosafety Program Peer Review

Robert Emery, DrPH, CHP, CIH, CSP, RBP, CHMM, CPP, ARM

Dr. Robert Emery is the Assistant Vice President for Safety, Health, Environment & Risk Management for The University of Texas Health Science Center at Houston and Associate Professor of Occupational Health at the University of Texas School of Public Health. Bob has over 25 years of experience in health & safety and holds masters degrees in health physics and environmental sciences, and a doctorate in occupational health. Bob is unique in that he possesses national board certification and registration in all of the main areas of health & safety;

- health physics [Certified Health Physicist, CHP],
- occupational safety [Certified Safety Professional, CSP],
- industrial hygiene [Certified Industrial Hygienist, CIH],
- biological safety [Registered Biosafety Professional, RBP],
- hazardous materials management [Certified Hazardous Materials Manager, CHMM],
- security [Certified Protection Professional, CPP],
- and risk management [Associate in Risk Management, ARM].

Bob is the author of many peer-reviewed articles on practical health and safety topics and makes frequent presentations on such issues at the local and national level.

Bruce J. Brown, MPH, CBSP, CHMM, ARM

Bruce Brown is the Director of Environmental Health & Safety at The University of Texas Health Science Center at Houston and has over 10 years of experience in the field. Previously, he managed the Chemical, Biological, and Environmental Protection programs at UTHSC-H. He started his career at Silliker Laboratories of Texas. At Silliker Laboratories, he had a wide variety of duties including Microbiologist, Chemical Hygiene/Safety Officer and customer service representative. Bruce graduated from The University of Texas at Austin with a bachelor's degree in Microbiology and completed a Master of Public Health degree in Occupational and Environmental Health at The University of Texas School of Public Health. He is currently pursuing his Doctorate in Public Health. Bruce holds board certifications as a Certified Biological Safety Professional (CBSP), Certified Hazardous Materials Manager (CHMM), and Associate in Risk Management (ARM).

Scott Patlovich MPH, CBSP

Scott Patlovich is the manager of Biological Safety Program at The University of Texas Health Science Center at Houston. Previously, he was a safety specialist within the same program at UTHSC-H, and also worked within the Environmental Health and Safety Department at the University of Northern Colorado. Scott graduated from Colorado State University with a Bachelor of Science degree in Environmental Health and completed a Master of Public Health degree in Occupational and Environmental Health at The University of Texas School of Public Health. He is currently pursuing his Doctorate in Public Health. Scott holds certifications as a Certified Biological Safety Professional (CBSP) from the American Biological Safety Association and a Specialist Microbiologist in Biological Safety Microbiology (SM (NRM)) from the National Registry of Microbiologists.

Wallis, Annette

From: Emery, Robert J [Robert.J.Emery@uth.tmc.edu]
Sent: Wednesday, May 09, 2007 7:25 AM
To: Bazer, Fuller; Brown, Bruce J
Cc: Patlovich, Scott J
Subject: RE: Select agent check list
Attachments: Biosafety Activity Report FY06.xls

Dr. Bazer – in addition to a routine reporting to the biosafety committee on the status of compliance within the select agent lab, the attached spreadsheet is included in each monthly meeting to provide the membership a status report of the overall biosafety program. This may be help as well - Bob

From: Fuller Bazer [mailto:FBazer@cvm.tamu.edu]
Sent: Wednesday, May 09, 2007 6:37 AM
To: Brown, Bruce J
Cc: Emery, Robert J; Patlovich, Scott J
Subject: Re: Select agent check list

Thanks Bruce. We enjoyed our session yesterday and look forward to using inputs to improve our compliance for research. Fuller

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

>>> "Brown, Bruce J" <bruce.j.brown@uth.tmc.edu> 05/08/07 8:37 PM >>>
Dr. Bazer,

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

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

Monthly Activity Summary FY 06

November	December	January	February	March	April	May	June	July	August	Totals
14	14	16	21	12	119	7	8	16	17	426
4	4	4	4	4	4	4	4	4	4	44
0	0	0	0	42	0	0	20	0	0	62
18	18	20	25	58	123	11	32	20	21	532
11	18	14	15	11	33	18	7	9	18	203
2	5	6	2	1	1	4	1	2	4	49
9	7	7	13	9	15	13	6	6	9	119
0	4	1	0	1	17	1	0	0	5	32
0	2	0	0	0	0	0	0	1	0	5
9	13	8	13	10	33	13	7	7	9	152
0	9	2	3	0	22	3	2	0	3	57
9	4	6	10	10	11	10	5	7	6	95
0	0	0	0	0	0	0	0	0	4	4
23	10	15	15	7	12	9	5	17	15	157
0	0	1	0	0	0	0	0	0	0	1
23	10	16	15	7	12	9	5	17	19	162
0	0	0	0	1	2	0	1	0	3	7
0	0	2	2	1	0	2	5	5	6	27
0	0	2	1	3	1	2	2	1	2	19
0	1	3	0	3	2	2	2	0	0	17
0	1	7	3	8	5	6	10	6	11	70
0	0	0	0	1	0	1	1	0	2	6
0	0	0	1	1	1	1	2	1	1	10
0	0	0	3	0	0	1	0	0	0	4
2	0	0	2	0	0	1	4	2	2	15
3	0	5	3	0	2	3	6	1	4	32
4	1	2	6	1	4	1	4	3	1	33
9	1	7	15	3	7	8	17	7	10	100
6	6	7	6	6	5	6	8	9	13	83
4	3	2	2	3	4	2	4	8	10	50
0	4	3	1	2	2	1	1	1	0	17
10	13	12	9	11	11	9	13	18	23	150
28	24	49	27	22	6	31	231	41	312	925
1	5	41	3	14	29	1	23	40	70	356
3	0	7	3	0	0	12	3	3	3	79
2	1	1	29	9	1	1	1	2	1	48
34	30	98	62	45	36	45	258	86	386	1408
18	17	70	16	20	52	9	11	10	11	304

Wallis, Annette

From: Mahle, Debbie on behalf of Clark, Charley
Sent: Wednesday, May 09, 2007 7:46 AM
To: Wallis, Annette
Cc: Clark, Charley
Subject: FW: Select agent check list

Attachments: Select agent check list

Select agent check list

Annette:

This was in Charley's e-mail inbox. I wasn't sure if this needed attention, since you were involved in this meeting

Debbie

Debbie Mahle
Administrative Assistant
University Risk and Compliance
Texas A&M University
1280 TAMU
College Station, TX 77843-1280
979/845-3898 (O)
979/845-6437 (F)
d-mahle@tamu.edu

-----Original Message-----
From: Fuller Bazer [mailto:FBazer@cvm.tamu.edu]
Sent: Wednesday, May 09, 2007 6:43 AM
To: Mattox, Brent S; Ewing, Richard; Clark, Charley; Raines, Angelia; tagnew@vprmail.tamu.edu
Cc: Thomas Ficht; Vernon Tesh; Kretzschmar, Bert
Subject: Fwd: Select agent check list

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

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

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

Date Surveyed:_____ Principal Investigator:_____

Lab location(s):_____ SAT used: _____

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

Biosafety

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

Incident Response

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

Training

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

Transfers

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

COMMENTS

Surveyed by RO / ARO: _____ Date Surveyed: _____

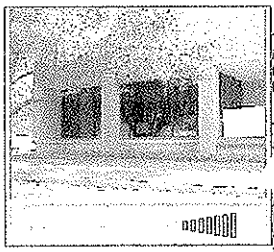
Reviewed by RO: _____ Date Reviewed: _____

CDC Investigation Underway Into A&M Bioweapons Mishap

Posted: 6:47 PM Apr 16, 2007
Last Updated: 12:00 AM Apr 17, 2007

Reporter: Steve Fullhart

Email Address: fullhart@kbtx.com



The Centers for Disease Control and Prevention is investigating Texas A&M after the university apparently failed to report that a researcher had been infected with a bioweapons agent.

The incident happened back in February of last year apparently occurred at the

An arms-control watchdog group called The Sunshine Project and their director, Edward Hammond, were doing a survey of institutions vying for a government facility. He submitted a public information request for accident reports at A&M. All he got back was a sheet of paper simply saying there had been an "occupational exposure" of brucella.

Read all the reports unearthed by The Sunshine Project in the Related Links section at the end of this story.

"It was obvious that an accident that bad would generate more paperwork, so I was puzzled by their first response to me," Hammond said.

E-mails obtained by the Austin-based group show conversations between top A&M research officials about the incident some two months later. That's when researcher was diagnosed. eventually did recover from her illness, which was first discovered in April 2006.

The e-mails indicated the researcher had been infected in February 2006 as : ttempted to clean a chamber where they were conducting experiments on mice.

The bacteria in question is brucella. The CDC reports it is primarily passed through animals like cattle and sheep. Brucellosis symptoms are similar to the flu, but the bacteria can be weaponized.

Those e-mail exchanges included talks that A&M needed to inform the CDC about the incident. By law, a report needed to be filed within seven days of confirmation.

Again according to documents obtained by The Sunshine Project, that notification of the incident did not come until April 10, 14 months after the incident, 12 months after its confirmation.

In documents sent to The Sunshine Project last week, the formal report was included. In a detailed summary, the university says they were transitioning compliance responsibilities at the time of the incident.

However, an e-mail string from April of last year shows officials were aware that a report needed to be sent in by someone.

Hammond is calling for maximum penalties to be levied, which could total in the hundreds of thousands of dollars, if not the millions.

"I think the concern is that because the school apparently didn't follow the law and didn't go through the proper procedures to get this problem reported and corrected, that it raises questions about the integrity of the research oversight at Texas A&M," Hammond said.

Texas A&M released a brief statement Monday afternoon, attributing the failure to report the incident to human error. They added that no further comment would be made until the investigation is complete.

The CDC would only confirm their presence on campus, and would not comment on their investigation.

The following is the statement issued by Texas A&M's Executive Vice President and Provost David B. Prior:

"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."

Related Links:

The Sunshine Project

KBTX.com Top 10

1. Campus Massacre: More Than 30 Killed at Va. Tech
2. Calvert Accident Causes Traffic Delay
3. College Station Traffic Stop Leads to Drug Bust
4. Washington County Wreck Kills One
5. Investigation Launched into A&M Professor's Death
6. CDC Investigation Underway Into A&M Bioweapons Mishap
7. Dancing Into a Healthy Lifestyle
8. Spirit of Aggieland Reunites Aggie with Symbol of Pride
9. Shortage of Prison Guards Leads to Concern
10. Mourners Attend Service for Slain Aggie Coed

First Public Information Act Reply to Sunshine Project

TAMU E-mails Released to Sunshine Project on April 10, 2007

Sunshine Project E-mails to TAMU on April 11, 2007

TAMU Report to CDC on Incident, Released April 11, 2007

Post Your Comments

First Name: Location:

Enter Comments:

E-mail: (optional)

Email will not be displayed on site. For station contact purpose only.

Read Comments

More Stories

Campus Massacre: More Than 30 Killed at Va. Tech	A&M Reacts to Va. Tech Tragedy
Investigation Launched into A&M Professor's Death	Tax Deadline Fast Approaching
Brazos County Officials Gearing Up for Possible Early Primary Election	College Station Traffic Stop Leads to Drug Bust
Calvert Accident Causes Traffic Delay	Washington County Wreck Kills One
Shortage of Prison Guards Leads to Concern	

```
Envelope-to:
Subject: Public Information Request
Date: Tue, 10 Apr 2007 17:04:16 -0500
Thread-Topic: Public Information Request
Thread-Index: Acd7vC5pCFijz2P+ROmxu4OIKeC55g==
From: "Kelly, Scott" <S-Kelly@tamu.edu>
To: "Edward Hammond" <hammond@sunshine-project.org>
Cc: "Yeager, Susan" <s-yeager@tamu.edu>,
        "Raines, Angelia" <araines@vprmail.tamu.edu>,
        "Dr. Alicia Dorsey" <dorsey@tamhsc.edu>,
        "Callcott, Diane" <D-Callcott@tamu.edu>
```

Attached are additional records that our office received today related to the record previously provided to you regarding an incident of occupational exposure to brucella. We have redacted personally identifiable information about the patient as well as information related to the exact location of toxins.

We are also advised by Dr. Alicia Dorsey of the Texas A&M System Health Science Center that the HSC does not have any records responsive to your request.

Mr. Scott A. Kelly
Deputy General Counsel
The Texas A&M University System
Office of General Counsel
A&M System Bldg., Ste. 2079
200 Technology Way
College Station, Texas 77845
(979) 458-6125
(979) 458-6150 - facsimile

```
Content-Type: application/octet-stream;
        name="Hammond Response.pdf"
Content-Description: Hammond Response.pdf
Content-Disposition: attachment;
        filename="Hammond Response.pdf"
```

TEXAS Department of State Health Services

Texas Department of State Health Services

1100 WEST 49TH STREET
AUSTIN, TEXAS 78756-3194
(512) 458-7318

LABORATORY SERVICES SECTION
CLIA #45D0660644

CONFIDENTIAL LABORATORY REPORT

Date: 5/25/2006

Submitter copy to:

SCOTT AND WHITE CLINIC-02180184
1600 UNIVERSITY DRIVE
attn: Jack Crouch
COLLEGE STATION, TX 77840

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

Patient

DOB:

Patient Address:

Date Rcvd: 5/18/2006
Spec Type: SERUM

Test Reas: DIAGNOSIS

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

Final Results

Specimen Numbers:
Date Collected: 5/16/2006

BRUCELLA AGGLUTINATION	**1:160

A single Brucella agglutination titer of greater than or equal to 1:160 is evidence of a prior infection, but, it does not confirm that the infection was recent. The most convincing serologic evidence of recent Brucella infection is a fourfold rise in antibody titer between an acute and a convalescent serum.

cc BRUCELLA AGGLUTINATION is Reportable to Health Dept >>

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

Subject: FW: Workmen's Compensation
Date: Friday, April 21, 2006 1:27 PM
From: Tom Ficht <tficht@cvm.tamu.edu>
To: "Mattox, Brent S" bsmattox@tamu.edu, Angelia Raines ARaines@vprmail.tamu.edu, Tiffany Agnew tmagnew@tamu.edu
Cc: "L. Garry Adams" gadams@cvm.tamu.edu, "David N. McMurray" mcmurray@medicine.tamhsc.edu, njones@medicine.tamhsc.edu, More...
Conversation: Workmen's Compensation

Brent

I wanted to let you know that has been diagnosed with brucellosis. apparently contracted the disease during an experimental challenge at LARR (CMP) on the ninth of February 2006. At that time along with Dr. McMurray were training us in the use of the Madison chamber for aerosol inoculations.

has been home sick for several weeks being treated by 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 exposure, although we assume it may have occurred as a result of cleaning out the Madison chamber after an aerosol run. In the future we plan to flush the chamber with disinfectant rather than using manual cleaning methods. The chamber will be wiped out after running disinfectant through the chamber, but this will involve the use of a long-handled applicator or mop. In addition, we will not rely on the use of N95 face masks and will instead use positive air displacement respirators.

In the initial aerosol trials we relied on the experience of the TB researchers for the level of precaution typically employed in such experiments. It is suspected that a conjunctival route of infection is responsible for infection, perhaps as a result of manually cleaning the Madison chamber. It is my fault for not recognizing the differences between Brucella and Mycobacteria in regard to routes of infection.

An isolation was made from a blood culture by physician and sent to TDH for confirmation. It would be helpful if EHSD could requested a sample of this isolate for culture confirmation here.

Thomas A. Ficht, Ph.D.
Professor
Veterinary Pathobiology
Texas A&M University
4467 TAMU
College Station, TX 77843-4467
979-845-4118 ph
979-862-1088 fax

Subject: Re: <no subject>
Date: Monday, April 24, 2006 4:56 PM
From: Tom Ficht <tficht@cvm.tamu.edu>
To: "Mattox, Brent S" bsmattox@tamu.edu
Cc:
Conversation: <no subject>

Oddly, they asked me to find out about Dr. Ding's number.

I will ask if we can get this info through I was considering asking to take part in our blood testing program which we were going to schedule in May. Unless you think we need it sooner.

On 4/24/06 4:03 PM, "Mattox, Brent S" <bsmattox@tamu.edu> wrote:

> By the way, I heard from Scott & White today: all titers were negative. I do
> need a copy of the Lab results on though. I can go the
> long route or would perfer getting a copy through possible. Did
> you have retested at S&W?
>
> As to the Ding subject, I don't understand why you had to contact Virginia
> Tech instead of our illustrious Office of Compliance. Isn't that their job?
>
> Brent
>
> -----Original Message-----
> From: Tom Ficht [mailto:tficht@cvm.tamu.edu]
> Sent: Monday, April 24, 2006 1:51 PM
> To: Charlotte Waggoner
> Cc: Raines, Angelia; Tiffany Agnew; Mattox, Brent S
> Subject: Re: <no subject>
>
> Thanks. CDC's approval process doesn't seem to be getting any faster. I will
> pass this on to my compliance office.
>
> Taf
>
>
>
>
> On 4/24/06 1:09 PM, "Charlotte Waggoner" <ren@vt.edu> wrote:
>
>> Hi Dr. Ficht....
>>
>> Xicheng's DOJ ID number at Virginia Tech was Hope this helps...
>>

>> At 10:53 AM 4/24/2006, you wrote:
>>> Dear Ms. Waggoner
>>>
>>> We are aware of the need to renew Dr. Ding's CDC approval. We were
>>> asked by our compliance office to obtain his previous number to
>>> expedite this request.
>>>
>>> If you prefer I will ask that the compliance office contact you
>>> directly for this info.
>>>
>>>
>>> Charlotte M. Waggoner, RBP
>>> University Biosafety Officer/Responsible Official Environmental,
>>> Health and Safety Services (MS 0423) Virginia Tech
>>> 459 Tech Center Drive
>>> Blacksburg, Virginia 24061
>>> http://www.ehss.vt.edu/
>>>
>>> ren@vt.edu
>>> (540) 231-5864
>>> (540) 231-3944 FAX
>>>
>>>
>>>
>>>
>>> Sincerely,
>>>
>>> Thomas A. Ficht, Ph.D.
>>> Professor
>>> Veterinary Pathobiology
>>> Texas A&M University
>>> 4467 TAMU
>>> College Station, TX 77843-4467
>>> 979-845-4118 ph
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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

Subject: Re: <no subject>
Date: Tuesday, April 25, 2006 11:46 AM
From: Tom Ficht <tficht@cvm.tamu.edu>
To:
Conversation: <no subject>

I have not heard back from Brent and I think anything will work. But according to the select agent guidelines we are required to report any laboratory exposures to the CDC. So I guess he will need to have some record. I do not know how this impacts on your personal files??? Since this has been done through a personal physician you may be within your rights to deny any of these requests. Having said that I don't know either way how this would impact me or the university, but that should not be your concern.

I guess as PI I can't help but be involved, but it does seem like something that is best handled between you and Brent Mattox (as representative of EHSD).

I am glad to help (as a non-physician), and would like to suggest that you take part in our blood testing so that we can carefully watch your titer. Perhaps you could ask your personal doctor his thoughts?

Another thought is for you to go to Scott and White and get a blood draw immediately (desk E is Occupational Health) . I can meet you there if you like.

tom

On 4/25/06 11:30 AM, wrote:

> Tom,
>
> All I have is a preliminary report on the blood cultures done at St. Joseph's as well as the earlier report from CPL on the first blood culture. Serology was never done on me. Is this what Brent needs to see? I can copy both sheets and campus mail them to you tomorrow as I don't have them here at work.
>
> >>> Tom Ficht <tficht@cvm.tamu.edu> 04/24/06 4:56 PM >>>
> Oddly, they asked me to find out about Dr. Ding's number.
>
> I will ask if we can get this info through I was considering

asking [redacted] to take part in our blood testing program which we were going to schedule in May. Unless you think we need it sooner.

On 4/24/06 4:03 PM, "Mattox, Brent S" <bsmattox@tamu.edu> wrote:

> By the way, I heard from Scott & White today: all titers were negative. I do
> need a copy of the Lab results on [redacted] though. I can go the
> long route or would perfer getting a copy through [redacted] if possible. Did
> you have [redacted] retested at S&W?
>
> As to the Ding subject, I don't understand why you had to contact Virginia
> Tech instead of our illustrious Office of Compliance. Isn't that their job?
>
> Brent
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> From: Tom Ficht [mailto:tficht@cvm.tamu.edu]
> Sent: Monday, April 24, 2006 1:51 PM
> To: Charlotte Waggoner
> Cc: Raines, Angelia; Tiffany Agnew; Mattox, Brent S
> Subject: Re: <no subject>
>
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will
> pass this on to my compliance office.
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>> Hi Dr. Ficht....
>>
>> Xicheng's DOJ ID number at Virginia Tech was [redacted] Hope this
helps...
>>
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>>> Dear Ms. Waggoner
>>>
>>> We are aware of the need to renew Dr. Ding's CDC approval. We were
>>> asked by our compliance office to obtain his previous number to

>>> expedite this request.
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>>> If you prefer I will ask that the compliance office contact you
>>> directly for this info.
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>>> Charlotte M. Waggoner, RBP
>>> University Biosafety Officer/Responsible Official Environmental,
>>> Health and Safety Services (MS 0423) Virginia Tech
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>>> Sincerely,
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>>
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College Station, TX 77843-4467
979-845-4118 ph
979-862-1088 fax

Subject: FW: Prophylaxis for Lab exposure to Brucella
Date: Tuesday, September 19, 2006 10:21 AM
From: Tom Ficht <tficht@cvm.tamu.edu>
To: ZakirShaikh@mhd.com
Conversation: Prophylaxis for Lab exposure to Brucella

Dear Dr. Shaikh

Here are some references containing new approaches that were used in conjunction with oral doxycyclin+rifampin to treat a recent exposure here.

Sincerely,

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

------ Forwarded Message
From:
Date: Tue, 19 Sep 2006 09:23:05 -0500
To: Tom Ficht <TFICHT@cvm.tamu.edu>
Subject: Re: FW: Prophylaxis for Lab exposure to Brucella

Hi Tom,

This is the reference and I both happened to find; ironically, it appeared in print on my first day of treatment. Anyway, he actually deviated from this protocol because I received the gentamicin IV for 7 days, not IM, as this regimen suggests. PLUS I also took a combination of oral rifampin AND doxycycline for a 45 day period. I can't imagine any organisms surviving that!

Take care,

p.s. we've added some dates to our BSL3 calendar for this Fall, but I think we can still easily accommodate your group's needs.

Clin Infect Dis. <javascript:AL_get(this, 'jour', 'Clin Infect Dis.');> 2006 Apr 15;42(8):1075-80. Epub 2006 Mar 13.
Efficacy of gentamicin plus doxycycline versus

streptomycin plus doxycycline in the treatment of brucellosis in humans.

- **Hasanjani Roushan MR** <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Search&itool=pubmed_AbstractPlus&term=%22Hasanjani+Roushan+MR%22%5BAuthor%5D> ,
- **Mohraz M** <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Search&itool=pubmed_AbstractPlus&term=%22Mohraz+M%22%5BAuthor%5D> ,
- **Hajiahmadi M** <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Search&itool=pubmed_AbstractPlus&term=%22Hajiahmadi+M%22%5BAuthor%5D> ,
- **Ramzani A** <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Search&itool=pubmed_AbstractPlus&term=%22Ramzani+A%22%5BAuthor%5D> ,
- **Valayati AA** <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Search&itool=pubmed_AbstractPlus&term=%22Valayati+AA%22%5BAuthor%5D> .

Department of Infectious Diseases, Yahyanejad Hospital, Babol Medical University, Babol, Iran. hagar2q@yahoo.ca

BACKGROUND: In the treatment of human brucellosis, antibiotic regimens containing an aminoglycoside are reportedly associated with fewer relapses. METHODS: This prospective, randomized study employed doxycycline (100 mg administered orally twice daily for 45 days) in combination with either streptomycin (1 g administered intramuscularly daily for 14 days; the DS regimen) or gentamicin (5 mg/kg per day administered intramuscularly for 7 days; the DG regimen). Efficacy of treatment was determined by rates of failure or relapse with a follow-up period of 1 year. RESULTS: Ninety-seven patients with a mean age (+/- standard deviation [SD]) of 33.74+/-15.47 years and 94 patients with the a mean age (+/-SD) of 36.2+/-14.14 years were treated with regimens DG and DS, respectively (P = .277). The clinical manifestations in both groups of patients were similar with the exception of sweating, which was more common in the DG group (P = .04). Three (3.2%) of the patients in the DS group and 3 (3.1%) of patients in the DG group experienced relapse (difference, 0.1%; 95% confidence interval [CI], -4% to 5%; P = 1.0). Overall, 7 (7.4%) of the patients in the DS group and 5 (5.2%) of the patients in the DG group experienced failure of therapy or relapse (difference, 2.2%; 95% CI, -4.5% to 8.9%; P = .563). The actuarial probability for relapse at 12 months after completion of therapy was 4.3% in the DS group and 2.1% in the DG group (difference, 2.2%; 95% CI, -2.8% to 7.2%). CONCLUSIONS: The combination of oral doxycycline for 45 days plus intramuscular gentamicin for 7 days is equally as effective as traditional therapy using doxycycline for 45 days plus streptomycin for 14 days.

PMID: 16575723 [PubMed - indexed for MEDLINE]

>>> Tom Ficht <tficht@cvm.tamu.edu> 09/19/06 8:45 AM >>>

Do you have the reference for the iv gentamycin treatment?

Tom

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

—— Forwarded Message
From: "Shaikh MD, Zakir A" <ZakirShaikh@mhd.com>
Date: Thu, 14 Sep 2006 17:37:55 -0500
To: <Paul.Southern@utsouthwestern.edu>, <Rita.gander@utsouthwestern.edu>, <tficht@cvm.tamu.edu>
Conversation: Prophylaxis for Lab exposure to Brucella
Subject: Prophylaxis for Lab exposure to Brucella

Hi All,
I would like to find out if there are any recent updates in recommendations for prophylaxis of Microbiology personnel with potential exposure to Brucella (as a result of bubbling while performing catalase test from misreading of gram stain as GPC). The exposed personnel has been counseled about lack of data about prophylaxis in this scenario, but has elected for antimicrobial prophylaxis.

I would certainly appreciate any input in this regard.
Zakir

Zakir Shaikh, MD, MPH, CPE, FIDSA

Hospital Epidemiologist

Medical Director, Infection Control

Methodist Health System

Dallas, TX

(214)947-2351

****

------ End of Forwarded Message

------ End of Forwarded Message

OPERATING PROCEDURES FOR THE BIOSAFETY LABORATORY SUITE,

THOMAS A. FICHT, PROFESSOR AND L. GARRY ADAMS, PROFESSOR

VETERINARY PATHOBIOLOGY

February 22, 2007

Table of Contents

Acknowledgements

Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents, and are supervised by competent scientists who are experienced in working with these agents.

Personnel wearing appropriate personal protective clothing and equipment conduct all procedures involving the manipulation of infectious materials. Additionally, all procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices. The laboratory has special engineering and design features.

The following standard and special safety practices, equipment and facilities apply to the Biosafety Level 3 Laboratory Suite. Disinfectants used include ethanol, 1% (w/v) Virkon-S and 10% (v/v) commercial bleach. Virkon-S is safe for use on human skin and is as effective as bleach at reducing *Brucella* viability. Ethanol is used for flame sterilization and may be used to clean surfaces, but is much less effective than either Virkon-S or bleach at inactivating *Brucella*.

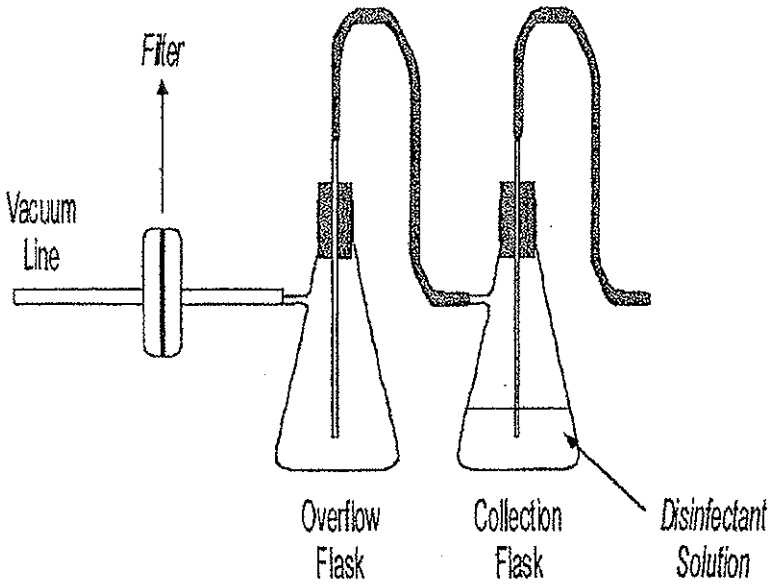


Fig. 1 Safety trap setup for use with in house vacuum line.

3.11 Spill procedures have been posted in

3.12 To use the vacuum lines for aspirating biological fluids, use two large flasks in series with a microbiological filter (0.2 – 0.45 μm).

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

13.1 Remove the outer pair of latex exam gloves before picking up the receiver.

13.2 Decontaminate the receiver immediately after every use.

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

4. Aerosol Challenges

4.1 Intrafacility transfer forms are completed and faxed to EHSD before transfer.

4.2 *Brucella* suspensions used for inoculations are prepared and loaded into

conical tubes in [redacted] the biological safety cabinets.

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

3.1 This packaging requires the "Infectious Substance" label on the outside of the package. This packaging must be certified to meet rigorous performance tests as outlined in the DOT, USPS, PHS, and IATA regulations.

3.2 Such samples are transported through the men's or women's locker rooms at the [redacted] under constant supervision from approved persons.

4.4 At the [redacted], personnel will change from street clothes into appropriate wardrobe

4.1 In the outer locker room, street clothes are removed and scrubs put on.

4.2 In the inner changing room, two pairs of gloves, facemask, tyvek suits and masks (N95 rated 3M 8210 or Tecnol PFR95) are put on before entry into the main hallway.

4.5 At the [redacted], animals will be transported to [redacted] in microisolyzer cages and removed in the biological safety cabinets and loaded into cages for challenges.

4.6 Madison Chamber preparation and use

6.1 Plug cord from control box into the wall socket. Check the light on the control box. Connect the source of compressed air (e.g., building; tank) through the small flow meter to the nebulizer. Make sure that the compressed air regulator reads at least 30 psig. When the main switch is on, the vacuum pump, fans, and timer should be operating.

6.2 Carefully unscrew the glass jar from the nebulizer and place about 10 ml of challenge suspension in the jar. Attach the jar to the nebulizer unit and adjust the vertical stainless steel tube so that the lower (intake) end is about half an inch below the level of fluid in the jar.

6.3 Load the animal basket into the chamber, being careful to center it so that it doesn't touch the fan blades. Close the door and turn on the main switch, activating the vacuum pump, fans, and timer. Reset the timer to zero.

6.4 Check the main (room) air flow meter (the larger meter on the right). The center of the float (ball) should run about "21".

6.5 Turn on the compressed air and simultaneously start the timer. The air flow rate through the compressed air flow meter should read about 5 psig. Check visually to be certain that the challenge inoculum is being nebulized.

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

activity. The timer should continue to run.

6.7 After an additional 600 seconds (10 min) or 900 seconds (15 min) total on the timer, turn off the main switch, stopping the vacuum pump, fans, and timer.

6.8 Open the chamber door and remove the animal basket. Remove the glass nebulizer jar, discard the challenge suspension, wash the jar thoroughly, and reload a fresh 10 ml volume of nebulizer suspension. Return to Step 3 above.

6.9 At the end of the infection procedure, spray the inside of the chamber with disinfectant and wipe down very thoroughly. Leave clean nebulizer jar upside down on paper towels on the sideboard to drain and dry.

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

7.1 After use, culture will be decanted back into 50 ml conical tubes under the cabinet and saved and transported back to building

7.2 The nebulizer jar is filled with bleach to disinfect. The nebulizer "probe" is dipped in 10% bleach, followed by two dips in sterile water.

4.8 Mice are removed from the chamber and placed back into the microisolyzer cages under the biological safety cabinet. Sealed cages are transported back to the room housing the mice.

4.9 After animals are removed, tubes are disinfected under the safety cabinet (Clorox bleach wipes, 10% bleach on paper towels, 1% (w/v) virkon on paper towels) before being brought to the sink for washing.

4.10 The inside of the chamber is cleaned from front to back with 10% bleach or 1% (w/v) virkon to surface decontaminate the chamber.

4.11 The innoculum is returned to / in approved containers

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

4.12 Personnel remove tyvek suits and place in approved containers to be autoclaved by CMP personnel.

12.1 Full-face respirators are surface decontaminated with 70% ethanol.

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

12.3 Hands are thoroughly washed before entering the outer changing room.

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

5. Routine Cleaning and Decontamination Procedures

5.1 Sharp objects

Brucella Exposure

According to the personal physician individual tested positive for Brucella and has been under treatment. Actual exposure occurred on 2/9/06, during the cleaning of an aerosolization chamber. Several individuals were present, but only cleaned the unit by climbing partially into the chamber to disinfect it. Follow-up titer 5/16/06 indicated 1:160, satisfactory.

Dr. Field has corrected the cleaning procedures to prevent individuals from contacting internal surfaces until disinfected.

To:
From: Edward Hammond <hammond@sunshine-project.org>

Subject: Fwd: RE: Public Information Request
Cc:
Bcc:
Attachments:

Date: Wed, 11 Apr 2007 10:20:34 -0700
To: "Kelly, Scott" <S-Kelly@tamu.edu>, tficht@cvm.tamu.edu, bsmaddox@tamu.edu, mcmurray@medicine.tamu.edu
From: Edward Hammond <hammond@sunshine-project.org>
Subject: Fwd: RE: Public Information Request
Cc: "Yeager, Susan" <s-yeager@tamu.edu>, "Raines, Angelia" <araines@vpr-mailsrv1.tamu.edu>, "Dr. Alicia Dorsey" <dorsey@tamhsc.edu>, "Callcott, Diane" <D-Callcott@tamu.edu>
Bcc:
X-Attachments:

Mr Scott Kelly
Legal Counsel

Dr Thomas Ficht
Professor

Mr Brent Maddox
Biosafety/Lab Safety Director
Texas A&M Universty

Dr David McMurray
Professor
Texas A&M University Health Science Center

Gentlemen:

My patience is at its end in this matter. As you are well-aware, the Texas Public Information Act sets forth clear deadlines for public officials to produce and/or seek Attorney General ruling on records requested by the public. I requested accident records involving RG2 or higher agents at Texas A&M in October 2006. You have yet to produce a complete set of responsive records, and you are unquestionably in violation of Texas law.

You initially only acknolweged one occupational exposure to brucella, noted in a curious piece of paper that obviously did not consititute anything close to the complete set of records for that incident. You still acknowledge no other records on other possible or actual occupational exposures to RG2 or higher agents at Texas A&M since 2000, an assertion that I frankly find hard to believe.

Having failed to provide anything resembling the responsive records in the first instance, in reply to my complaint, TAMU at first stalled: Then, when I threatened to go to the Attorney General, lo and behold, you produced some rather shocking records about the brucella incident, apparently only in order to forestall the Attorney General's attention. These records still do not form a complete set of those that should have been handed over last year, ***not even for that single incident.***

For example, you have produced no TAMU accident report(s) or recordkeeping by your environmental health department nor the Vet school nor LARR for the brucella incident or any other. You have produced no APHIS/CDC Form 3 for the brucella incident, a form that Mr. Maddox, who I believe is your select agent RO, was required to submit by federal law.

I also note that TAMUHSC, employer of the owner and inventor of the "foolproof" Madison Aerosol Chamber used when the brucella incident occurred, initially did not reply to my PIA request and now denies having any records regarding the incident, another assertion that I frankly find hard to believe.

Therefore, if I do not recieve a complete set of records from TAMU and TAMUHSC for the brucella incident and any others by the end of this day, I will take action including any or all of teh following:

1) Lodging a formal complaint with the Attorney General of Texas for TAMU and/or TAMUHSC violation of the Public Information Act;

2) Reporting to the Federal Bureau of Investigation apparent violation of the implementing regulations for the Bioterrorism Act of 2002 by officials of TAMU, and possibly TAMUHSC.

3) Reporting to the Centers for Disease Control and/or USDA APHIS apparent violation of the Select Agent Rule by TAMU and possibly TAMUHSC.

4) A news release explaining this situation and drawing public and media attention to a possible illegal coverup of violation of federal law and lab-acquired infection by TAMU.

I insist that you reply fully and completely by 5:00PM.

Sincerely,

Edward Hammond

Date: Tue, 10 Apr 2007 22:08:08 -0700
To: "Kelly, Scott" <S-Kelly@tamu.edu>
From: Edward Hammond <hammond@sunshine-project.org>
Subject: RE: Public Information Request
Cc: "Yeager, Susan" <s-yeager@tamu.edu>, "Raines, Angelia" <araines@vpr-mailsrv1.tamu.edu>, "Dr. Alicia Dorsey" <dorsey@tamhsc.edu>, "Callcott, Diane" <D-Callcott@tamu.edu>
Bcc:
X-Attachments:

Mr Kelly:

The issue is not your clarity, it is TAMU (non)compliance with the Texas Public Information Act and TAMU's failure to produce or seek AG ruling on records responsive to a request filed in October, 2006.

You represent TAMU. Where is the APHIS/CDC Form 3, plus any other responsive documents? It is incumbent upon TAMU to produce them. It was many months ago.

Sincerely,

Edward Hammond

At 11:43 PM -0500 4/10/07, Kelly, Scott wrote:
Mr. Hammond,

I thought my previous email was clear. I have provided you with the documents that have been identified, provided to me and been found responsive to your request. If other documents are identified, provided to me and found to be responsive to your request those documents will also be provided to you.

Scott Kelly

From: Edward Hammond [mailto:hammond@sunshine-project.org]
Sent: Tue 4/10/2007 11:31 PM
To: Kelly, Scott
Cc: Yeager, Susan; Raines, Angelia; Dr. Alicia Dorsey; Callcott, Diane
Subject: RE: Public Information Request

Dear Mr. Kelly:

That is not an acceptable response, nor one that I believe is legal under Texas law. A select agent accident resulting in an infection is far from a trivial event, nor could TAMU possibly be ignorant of the reporting requirements of federal law, particularly after the prosecution of Thomas Butler.

Has TAMU replied completely, or not? Has TAMU replied in accordance with the Texas Public Information Act, or have one or more of its officials failed to produce documents as required by law?

Sincerely,

Edward Hammond

At 11:10 PM -0500 4/10/07, Kelly, Scott wrote:
>Mr. Hammond,
>
>You have all of the documents that have been
>located and found responsive to your request.
>If there are other responsive documents that are

>identified those documents will also be provided
>to you.
>
>Scott Kelly
>
>_____
>
>From: Edward Hammond [mailto:hammond@sunshine-project.org]
>Sent: Tue 4/10/2007 6:24 PM
>To: Kelly, Scott
>Cc: Yeager, Susan; Raines, Angelia; Dr. Alicia Dorsey; Callcott, Diane
>Subject: Re: Public Information Request
>
>
>
>Dear Mr. Kelly:
>
>Thank you for your belated reply, however, it remains incomplete.
>
>TAMU is required by federal regulation to contact
>APHIS or CDC immediately upon discovery of a
>theft, loss, or a release (occupational exposure
>or release of an agent or toxin outside of the
>primary barriers of the biocontainment area) of a
>select agent. After the initial report, APHIS/CDC
>Form 3 must be sent to APHIS or CDC within 7
>calendar days. The RO or facility director must
>complete, sign and date the form.
>
>I have no record of an intial report to CDC or
>APHIS, nor have you provided a completed
>APHIS/CDC Form 3 for the confirmed brucella LAI
>of February 2006.
>
>My request, filed on 24 October 2006, included:
>
>>2. All records on possible or actual occupational exposures and/or
>>laboratory-acquired infections with risk group 2 (RG2) or higher
>>agents at TAMU, from 1 January 2000 through the present. You may omit
>>the name(s) of exposed persons.
>
>The APHIS/CDC Form 3 is clearly responsive, and
>the time allowed under the Texas Public
>Information Act to produce this record is long
>since past.
>
>I insist that you immediately provide this record
>and all other responsive records that you have
>yet to produce.
>
>I am very disturbed by TAMU's response to this request.
>
>Sincerely,
>
>Edward Hammond
>
>
>
>
>
>At 5:04 PM -0500 4/10/07, Kelly, Scott wrote:
>>Attached are additional records that our

>>office received today related to the record
>>previously provided to you regarding an incident
>>of occupational exposure to brucella. We have
>>redacted personally identifiable information
>>about the patient as well as information related
>>to the exact location of toxins.
>>
>>We are also advised by Dr. Alicia Dorsey of
>>the Texas A&M System Health Science Center that
>>the HSC does not have any records responsive to
>>your request.
>>
>>Mr. Scott A. Kelly
>>Deputy General Counsel
>>The Texas A&M University System
>>Office of General Counsel
>>A&M System Bldg., Ste. 2079
>>200 Technology Way
>>College Station, Texas 77845
>>(979) 458-6125
>>(979) 458-6150 ~ facsimile
>>
>>
>>Content-Type: application/octet-stream;
>> name="Hammond Response.pdf"
>>Content-Description: Hammond Response.pdf
>>Content-Disposition: attachment;
>> filename="Hammond Response.pdf"
>>
>>Attachment converted: Red Fish:Hammond Response.pdf (PDF /«IC») (00D24885)

```
Envelope-to: hammond@ud04.underdoghosting.com
Subject: Form 3
Date: Wed, 11 Apr 2007 20:56:37 -0500
Thread-Topic: Form 3
Thread-Index: Acd8pc3RGIEH//NKTqGIsi9jR45Iww==
From: "Kelly, Scott" <S-Kelly@tamu.edu>
To: "Edward Hammond" <hammond@sunshine-project.org>
Cc: "Callcott, Diane" <D-Callcott@tamu.edu>
```

Mr. Hammond,

After our telephone conversation this afternoon, I learned that a Form 3 was filed today. A copy is attached. I am continuing to follow up as we discussed and I will get back to you Friday as we discussed. I was also made aware of the two public information requests you submitted to Texas A&M University and the Health Science Center today. My office has directed that any responsive information be gathered and provided to me. I will work to expidite these requests.

Mr. Scott A. Kelly
Deputy General Counsel
The Texas A&M University System
Office of General Counsel
A&M System Bldg., Ste. 2079
200 Technology Way
College Station, Texas 77845
(979) 458-6125
(979) 458-6150 - facsimile

```
Content-Type: application/octet-stream;
        name="CDC Form 3.pdf"
Content-Description: CDC Form 3.pdf
Content-Disposition: attachment;
        filename="CDC Form 3.pdf"
```

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

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

INTRODUCTION

The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules (7 CFR 331, 9 CFR 121, and 42 CFR 73), which implement the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) setting forth the requirements for possession, use, and transfer of select agents and toxins. The select agents and toxins identified in the final rules have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the HHS Secretary and to the Animal and Plant Health Inspection Service (APHIS) by the USDA Secretary. In order to minimize the reporting burden to the public, APHIS and CDC have developed a common reporting form for this data collection.

An entity is required by regulation (7 CFR 331.19, 9 CFR 121.19, and 42 CFR 73.19) to notify APHIS (telephone: 301-734-5960, facsimile: 301-734-3652, e-mail: Agricultural.Select.Agent.Program@aphis.usda.gov) or CDC (telephone: 404-718-2000, facsimile: 404-718-2096, or e-mail: lrsat@cdc.gov) immediately upon discovery of a theft (unauthorized removal of select agent or toxin), loss (failure to account for select agent or toxin), or release (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a select agent and toxin. In addition, clinical or diagnostic laboratories and other entities that possess, use or transfer a select agent or toxin contained in a specimen presented for diagnosis, verification, or proficiency testing must immediately report upon discovery of a theft, loss, or release of select agent or toxin. After the initial reporting, this form (APHIS/CDC Form 3) must be sent to APHIS or CDC within 7 calendar days after the discovery of theft, loss, or release of select agents or toxins.

For theft or loss of select agents or toxins, the entity must notify the appropriate local, state, or federal law enforcement agencies. For release of select agents or toxins, the entity should notify the appropriate local, state, and federal health agencies.

PURPOSE

This form is to be used by the RO or facility director to report the theft, loss, or release of select agents or toxins. A copy of the completed form and attachments must be maintained by the entity for three years.

INSTRUCTIONS

1. Immediately notify APHIS or CDC via telephone, fax, or e-mail and appropriate local, state, or federal law enforcement agencies (theft or loss) or appropriate local, state, and federal health agencies (release).

2. The RO or facility director must complete, sign and date this form. For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration.
   A. For reporting of a theft or loss, complete sections 1 and 2. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified. For reporting a theft or loss that occurred during transfer, complete sections 1, 2, and 3 and include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins."
   B. For reporting a release, complete sections 1, 2, and 4. For reporting a release that occurred during transfer, complete all sections and include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins."

3. The RO or facility director faxes or mails the form to APHIS or CDC **within 7 calendar days** of the theft, loss, or release.

OBTAINING EXTRA COPIES OF THIS FORM

Additional copies of this form are available on APHIS website (http://www.aphis.usda.gov/programs/ag_selectagent/index.html) or CDC website (http://www.cdc.gov/od/sap) or by contacting APHIS at (301) 734-5960 or CDC at (404) 718-2000.

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

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

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

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

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

SECTION 1 - TO BE COMPLETED BY ALL ENTITIES

1. Entity name: Texas A&M University			2. Entity registration number (if applicable): APHIS# CDC# 200606050489	
3. Entity address (NOT a post office address): 1500 Research Parkway, Suite B150 TAMU 1186	4. City: College Station		5. State: TX	6. Zip Code: 77843-1186
7. Responsible Official (RO) or facility director First: Richard MI: Last: Ewing	8. Telephone: 979 847-9362	9. FAX: 979 862-3176	10. E-mail: araines@vprmail.tamu.ed	
11. RO or facility director address (NOT a post office address): 1500 Research Parkway, Suite B150	12. City: College Station		13. State: TX	14. Zip Code: 77843-1186
15. Type of incident: ☐ Theft ☐ Loss ☑ Release	16. Immediate notification provided to: ☐ APHIS ☑ CDC	17. Date of immediate notification: 04/10/2007	18. Type of immediate notification: ☑ E-mail ☐ Fax ☐ Telephone	

19. An internal review of laboratory procedures and policies has been initiated to prevent recurrences of loss of select agents and toxins at this entity:
☐ No ☑ Yes (If yes, please provide additional details in an attachment.) (See explanation in Section 2)

SECTION 2 - TO BE COMPLETED BY ALL ENTITIES

LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED (Please see page 4)

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

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

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

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

SECTION 3 – IF THE INCIDENT OCCURRED DURING TRANSFER PROVIDE THE FOLLOWING INFORMATION				
38. APHIS authorization number from transfer form:			39. CDC authorization number from transfer form:	
40. Name of carrier:			41. Airway bill number/bill of lading number/tracking number:	
42. Package description (size, shape, description of packaging including number and type of inner packages; attach additional sheets if necessary):				
	SENDER INFORMATION		RECIPIENT INFORMATION	
43. Name of person:	a. First: MI: Last:		b. First: MI: Last:	
44. Name of entity:	a.		b.	
45. APHIS/CDC registration number:	a. APHIS:	b. CDC:	c. APHIS:	d. CDC:
46. PHS/USDA import permit number:	a. PHS:	b. USDA:	c. PHS:	d. USDA:
47. Date shipped:	a.		b.	
48. Telephone:	a.		b.	
49. FAX:	a.		b.	
50. Package with select agents and toxins received by requestor: ☐ No ☐ Yes			51. Package with select agents and toxins appears to have been opened: ☐ No ☐ Yes (If Yes, explain)	
52. Sender was contacted regarding incident: ☐ No ☐ Yes			53. Carrier/courier was contacted regarding incident: ☐ No ☐ Yes	

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

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

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

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

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

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

Wallis, Annette

From: Wallis, Annette
Sent: Monday, July 02, 2007 5:25 PM
To: Kelly, Scott
Subject: FW: Public Information Request 07-176 Amy Rosen/Dallas Morning News
Importance: High
Attachments: Rosen request.176.pdf; Scan001.pdf

Scott,

Do the attached files in the PDF file titled Scan 001 need to be submitted for this information request?

Annette Wallis

From: Clark, Charley
Sent: Monday, July 02, 2007 8:29 AM
To: Wallis, Annette
Subject: FW: Public Information Request 07-176 Amy Rosen/Dallas Morning News
Importance: High

From: Yeager, Susan
Sent: Wednesday, June 27, 2007 4:43 PM
To: Ewing, Richard; Calvin, James; Bazer, Fuller; Raines, Angelia; Clark, Charley; Meyer, Chris; Salsman, John M; Mattox, Brent S; Tom Ficht; jsamuel@medicine.tamhsc.edu; dmcmurray@medicine.tamhsc.edu; Garry Adams
Cc: Kelly, Scott; Callcott, Diane; Lawson, Caroline; Carroll, Sherylon; Dr. Alicia Dorsey; Parker, Terri; McConnell, Bill; Spang Terry; McClendon, Rodney P; Bisor, Robert T
Subject: Public Information Request 07-176 Amy Rosen/Dallas Morning News
Importance: High

Scott Kelly asked that I send the attached Public Information Request to each of you for response. Please see Mr. Kelly's note below:

> *"Although documents responsive to this request were provided in response to an earlier request from Edward Hammond, it is necessary that responsive documents be produced again in response to this new request. Furthermore, this request needs to be considered under the standard for reporting suspected occupational exposures adopted by the university in April 2007. Elevated titers are now regarded by the university as a reportable suspected occupational exposure."*

Thank you for your assistance. Suzy

Suzy Yeager
Director, Open Records
Texas A&M University
1181 TAMU
College Station, TX 77843-1181
979/862-4571 (Phone)
979/862-7778 (Fax)
s-yeager@tamu.edu

Attached information provided by
Annette Wallis 7-09-07

3-2-4-07

John Salmon
Angelia Raines
Annette Walles
renovation

[illegible]

security - [illegible]
Security risk assessment

[illegible]

always
Question — access of personnel + documentation to CDC
Yes agent can be there

Jim McGee
73.10

personnel were not being escorted
security issue personnel accessing to facility

Reg - not facility specific

[illegible] air flow
hand washing

complete renovation - [illegible]
lab inspection

[illegible] triggers E450 inspection.

John Salsman
(ACU)

Occupational Health

4-20-09 Middle of 2004 Ken McGuiness

9-'05 Funding —

Funding for Occupational Health & accidents

Workers Comp [illegible] injuries & accidents

1st focus: ALAC (lab animal uses) accreditation

2nd focus: Leadership program [illegible] high priority
Chem [illegible]
Health Lab safety
Hurricane Response.

Tiffany needs help —

Samuels coxiella — positive titers come back elevated. No expression of disease. If work with [illegible] elevated titers — does this qualify as disease?

(Q [illegible])

Fickt — ask Tiffany — take [illegible] HSC

Records —

4-30-07 Chris Sheppard John Saltman CDC ARO

Discussion topics – Research

- Lack of clarity in communication – Contradictory rather than just confusing
  - February 23, 2006 e-mail sent by Tiffany Agnew stating ORC will begin managing all correspondence related to the CDC Select agent Program. This process is effective Friday, February 24, 2006
    - No knowledge of when Angelia became ARO
    - ORC had access to ARO through Fuller Bazer and RO through Ewing
    - Template for new Incident response Plan presented to PATF with 4-21-06 date presented to PATF on May 4, 2006.
    - May 18 minutes (PI asked about primary contact for changes in CDC registration) Minutes state ORC will be the main contact for any information that requires paperwork being submitted to CDC. Brent will be the main contact for subject matter issues. If PI unsure who to contact, ORC may be contacted
  - Responses to CDC Feburary ~~23-24~~ 22-2, 2006 inspection distributed to PATF May 18, 2006
    - Incident response Plan for BSL3 Suite (rooms ; and BSL# buildings ___ states Dr. Ficht (PI) will report incidents, as required, to the Biosafety Officer, and the RO and ARO. **Where required, the RO will report incidents to CDC.**
    - Entity Crisis Management Plan Appendix J: Annex P (date entered 5-31-05) states EHS will notify the Brazos County Healt Departmen. EHS will also notify CDC and/or USDA as appropriate. A report will be supplies to TAMU administration with copy to University relations, as necessary. Also need to look at Annex (7-5-05)

EHSD - Update Crisis Management Plan (needs to be reviewed each time protocols change.

- Enhanced communication
  - Clarification of roles and responsibilities
    - Documented agreement of scope of responsibilities
    - Clear effective date of any change in roles
    - Review of all documents that could be impacted by change
- ORC - Ownership of Security Plan, Incident Response Plan, and Safety Plan
- Occupational Safety Program
  - Clear documented expectations of roles and responsibilities
    - Notification protocols
    - Communication with CDC
    - PI's role –
      - (who supervises work and approves leave)
      - Changes in protocols
    - Other interfaces – Biosafety committee
    - Follow-up procedures and consultations when there is incident
- Risk Assessment – Do we have check lists and templates for each lab/agent
- Biosafety Plan
- Follow-up procedures (processes flows and changes) when there is any incident, e.g., CMP did not follow-through with procedure changes after mouse incident

Over - continued

Page 1 of 2

4/30/07

Lack of communication

- Elevated Fiber Optic/Ice Sample - Brent gave input on Tuesday - (5-24-06) - Ace was told would get draft of information to be forwarded to CDC - Neither office got correspondence.

- On Friday 5-27-07 - Chris at Meeting with Gary Adams, Angelia and Dave briefly - email from CDC to Angelia not to use Madison Chamber EHSD has not been notified - are about to order more suits for safety CMP, Fiber, Biosafety, Security should know if it is unsafe

- No feedback on protocols/procedures to be developed by CMP on Moose incident

Very important to have good communication flow and have clear understanding of roles & responsibility

May add to Response Incident Sheet.

Better define Occupational Safety Program
Brent looking for federal guidance

Wallis, Annette

From: Tiffany Agnew [tmagnew@tamu.edu]

Sent: Wednesday, January 03, 2007 5:44 PM

To: Karen kerussell@cvm.tamu.edu; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; ~~Meyer, Chris~~; Schneider, Elmer; ~~Gabrielle Kapp~~; ~~Salsman, John M~~; jsamuel@tamu.edu; ~~Kenneth Gillenwater~~; Ihrig, Melanie; Eaker, Nancy L; Betsy Browder

Cc: Raines, Angelia

Subject: Assessment Meeting

Happy New Year!

Based upon recent events involving the incident in Dr. Samuel's lab revolving around a discrepancy in inventory , it is necessary to discuss the current process in effect. On behalf of Dr. Samuel, our office is helping to coordinate a meeting of the minds. The meeting is scheduled to take place on **Friday, January 5, 2007** in the *Reynolds Medical Building* **Room 403,** from **8:45 am - 9:30 am.**

We are looking forward to hearing all of your suggestions and professional insight on how to improve.

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

Thank you in advance!

Best regards,

Tiffany

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

all appropriate authorities Notified
animal considered as Select agent to CDC — use not inventory (SAME PROCESS)
PI to review incidence response plan, Security plan, safety plan and amend as appropriate, train
CMP to enhance count procedures for biohazards
Counts done when transfer to another cage (CMP) PI count when handle mice
Clarify notification process - timelines & PI → EOC → Responsible Official
When notice discrepancy - freeze action to investigate - brief Vault
CDC wants immediate notification even if uncertain if there is/is not discrepancy.
UPD — Bio Terrorism Task Force
PI to get report to Angelia today who will file with CDC today

MOUSE

(1)

1-5-06

In room - only Dr. Samuels has Mice in room
don't count all mice - 17 cages

Betsy Bowden
Melanie
Nancy Walker
Brent Mattox
Bert Fretchman
Casey Russell ← ~~Med School~~ EMS
Dr. Samuels
Elmer Schneider
Angelica Reines
Tiffany Agnew

Noticed 12-20-06
Comparative Medicine 12-21-06

Casey reports
Betsy Bowden - Manuals - ORC notified

look for mouse
look at the Room

Animal considered as select agent to CSC

3rd hand report - ~~Mike~~ investigating site - Samuels didn't know - never found

Inventory -

Mouse has not been located

CDC consider use not inventory

Process is the same whether use or inventory

Incidence response plan -
Near complete - may not be same CMP

~~July~~ June 2006 security plan + incident response plan

CMP - using basically same security plan

Problem

way to account for agent in use

Betsy - is accounting issue if we knew it is missing

Samuels - it probably has gone through autoclave

Cage cards inventory system of sort but does not rise to the level of inventory control

Improving ✓ to monitor animal

Improve

What in place work
Count — change cage
✓ — use animal

Stress accuracy — someone did miscount

What if got out of cage — lab suite, door sweeps — mouse traps } high unlikely

When discovered — only one person there

Resolution: —
extensive search — room

indication — did not expect went missing

however;
checked all mice

Counted 9 white mice

when changed cage — confident had 5 mice

UPD joint terrorism task force wants to be a part of this.

As soon as Mouse discovered missing —
~~did not do~~ Immediately did count
and determined one missing

Casey - counted # cards compared to
log — ("delete" on cage card)

When counts
Are counts done same (consistent)

CMP - count w/end do change out transfers one cage to another
PT - count when weigh

Sequence
Cage change
Sacrifice mice
Weigh - not sure before/after cage change

One Mouse hiding in bedding got
autoclaved out —
If weighed before cage change

Wed 11:00 am
Thurs notification date } interference still
manipulating mice

Cage cards retained - back to central office
to delete from
database

Female Mouse
Check - No available

CULTURES ARE NOT COUNTED

No inventory system —
trying to resolve
did determine one was missing!
cage card not inventory system
inventory - store stock culture

Active culture
system to monitor

mouse vaccinated

How do we freeze everything at the time
did not have a clear understanding
of process

~~why caretaker~~

Caregiver - ~~if started~~ # on log didn't
match - can change - stencil
job: what should be called discrepancy look when

Vol 70 No 52

Record of select agent used

SOP

~~If~~ discrepancy

Samuels – Treat counting of mice more vigoursly
trains in new system every time
something done ~~with~~ when cage manipulation –
clean, weighed   change out + manipulation

Cage card document – count for

Caution against ~~sudden~~ extended stop

~~Notify~~ – Discrepancy } BRIEF
Notify } HALT
~~Investigate~~

Communication – – 24 hr delay contact CPD
Notifies RO
Reporting process to CDC – immediately
[illegible] more details

no negotiation on fine – IMMEDIATELY tell later nothing

① Angelia to report to CDC
tell as much as possible about
final disposition

because we don't know
we will refine process

What time
Changes
occ.

Look at access log -

② Update Plan

Notification
timeline

incident plan
security -
safety -

} Checklist
documentation
of review

Any change - train and document.

Bio-Terrism Task Force

Belay

Cage card Numbering &
may not stay home cage

Select Agent — If discrepancy - Notify
If DI sacrifice - mark off cage card

~~Want Consistency~~
Change — Bio Hazard Not just SBAT

(8)

Bio Safety Officer —
give input to Plan
Keep Brent in process

New

4p-26-07 - Med Angelia Raines after BMF

Attachment sent to CBC —
SBAT tracking Sheet — Add CBC - Risk
to keep in communication loop

Comparative Medicine
- did not follow up on Mouse Procedure
Map who has responsibelities
training is issue

PI responsible for SBATs - even when at LAR
PI - no authority over Lar-
CAR — no authority over PI

Angie's Roles - setup Broad Model -
PI - tailors for specic SBAT
PI should follow when feasible CMP
Procedures as CMP also has
to meet GLP and other standar

Angelia Wants support from this occess -
flow and Procedures
Discussed two options
① IBC - unoffical member
② Projects or requests
Made clear I would be independent from ORC
and information I obtained - CBC informed

May want discuss on IBC - discussed "apparent conflict" -
told Angelia to visit size her people

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 1:33 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: Select Agent Training

Attachments: Houston Map_1.pdf; Select Agent training announcment .pdf; Select Agent Training Agenda.doc


Houston Map_1.pdf (4 MB)


Select Agent :raining announcm..


Select Agent Training Agenda.d...

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

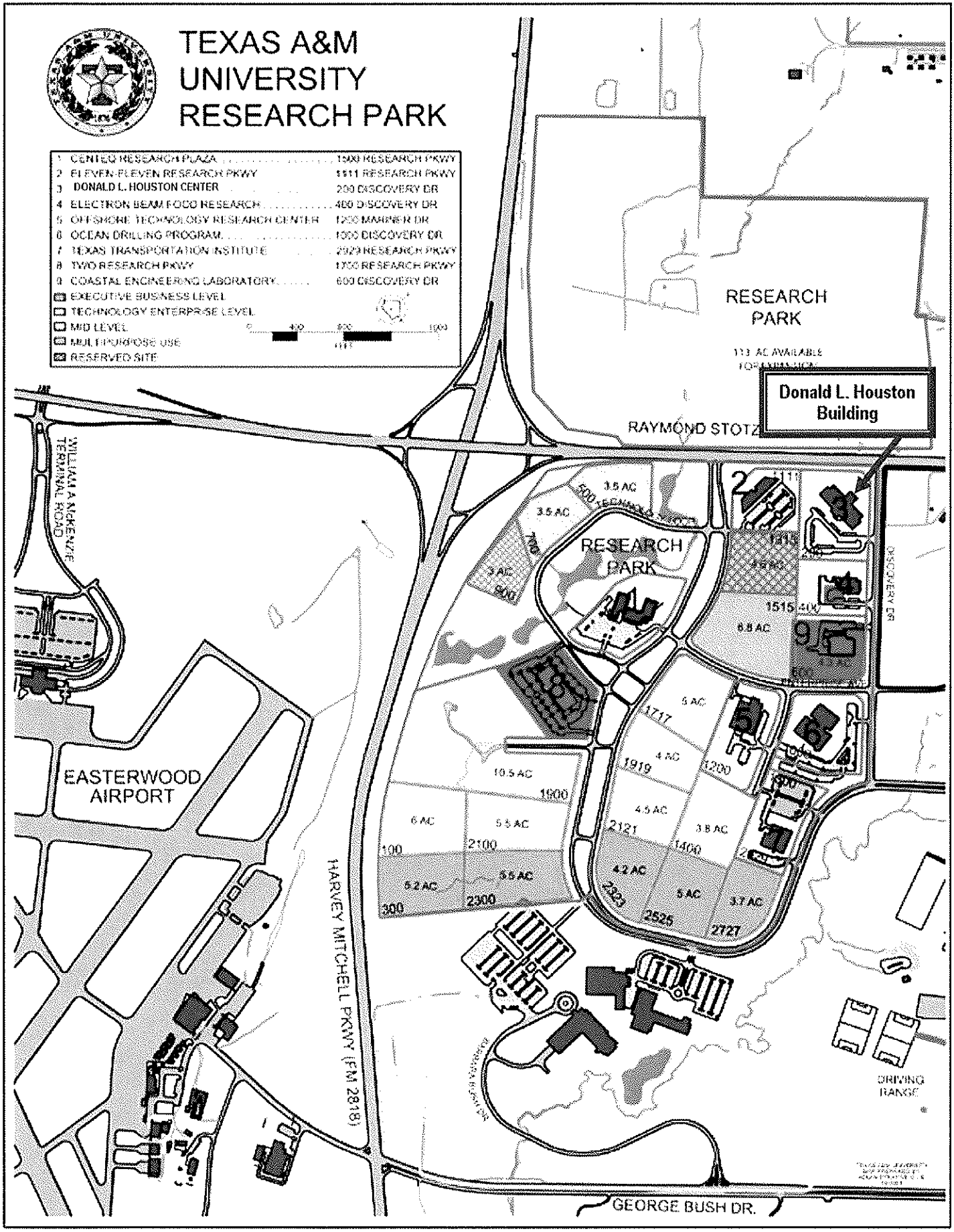
-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Friday, May 25, 2007 3:50 PM
To: ibc@tamu.edu
Cc: Tiffany Agnew
Subject: Select Agent Training

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 1511 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 1000
RESEARCH PARK
113 AC AVAILABLE
Donald L. Houston Building
RAYMOND STOTZ
WILLIAM A McKENZIE TERMINAL ROAD
RESEARCH PARK
DISCOVERY DR
EASTERWOOD AIRPORT
HARVEY MITCHELL PKWY (FM 2818)
DRIVING RANGE
GEORGE BUSH DR.

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

May 25, 2007

Memorandum

Richard E. Ewing
Vice President for Research

Academy for Advanced Telecommunications and Learning Technologies

Center for Information Assurance and Security

Comparative Medicine Program

Institute for Scientific Computation

Integrative Center for Homeland Security

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 979.845.1853

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

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

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 1:59 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: CDC Notification

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

From: Wallis, Annette
Sent: Friday, May 11, 2007 4:35 PM
To: Clark, Charley
Cc: Wallis, Annette
Subject: CDC Notification

Charley,

I talked to Chris, and he did receive an e-mail from Angelia Raines stating she had notified CDC and Dr. Ewing. Also, neither Chris nor I have received a copy of the report that incorporates everyone's responses.

Enjoy your weekend,
Annette

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 2:01 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: CDC Response Documents

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

From: Meyer, Chris
Sent: Friday, May 11, 2007 3:13 PM
To: Raines, Angelia
Cc: Clark, Charley; Wallis, Annette; Salsman, John M; Mattox, Brent S
Subject: FW: CDC Response Documents

Angelia,

When will we meet to review the collective responses before they are submitted to CDC? Speaking for myself, I will bend my schedule as necessary to find a meeting time next week.

Chris

From: Salsman, John M
Sent: Friday, May 11, 2007 10:56 AM
To: Meyer, Chris
Subject: FW: CDC Response Documents

From: Mattox, Brent S
Sent: Friday, May 11, 2007 10:53 AM
To: Raines, Angelia
Cc: Salsman, John M
Subject: CDC Response Documents

Please see the attached. We have submitted scanned copies, but files are available.

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 2:03 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: Elevated Titer for Q Fever
Attachments: DOC023.PDF

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

From: Meyer, Chris
Sent: Friday, May 11, 2007 9:32 AM
To: Clark, Charley
Cc: Wallis, Annette; Kretzschmar, Bert; Schneider, Elmer
Subject: FW: Elevated Titer for Q Fever

Charley, FYI...I wanted to keep you in the loop, however, I think that this is for Dr. Ewing to address with management (university and HSC).

From: Mattox, Brent S
Sent: Friday, May 11, 2007 9:00 AM
To: Raines, Angelia; 'jsamuel@medicine.tamhsc.edu'
Cc: Meyer, Chris; Salsman, John M
Subject: Elevated Titer for Q Fever

Angelia/Dr. Samuel:

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

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

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

TEXAS DEPARTMENT OF STATE HEALTH SERVICES

DAVID L. LAKEY M.D.
COMMISSIONER

1100 W. 49th Street • Austin, Texas 78756
1-888-963-7111 • http://www.dshs.state.tx.us
TDD: 512-458-7708

Submitter copy to: ** DUPLICATE REPORT **
Date: 5/2/2007

SCOTT AND WHITE CLINIC-02180184
1600 UNIVERSITY DRIVE
attn: Jack Crouch
COLLEGE STATION, TX 77840

Spec #: S07SM001915
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Address:

Date Rcvd: 4/23/2007
Spec Type: SERUM

Test Reas: DIAGNOSIS

Please fax your NPI to 512.458.7533 by May 23, 2007. Delay in sending the NPI risks reimbursement as well as the reimbursement of your health care partners. Federal Regulation (Health Insurance Portability and Accountability Act of 1996 (HIPAA)) outlines you must share your NPI with other providers, health plans, clearinghouses, and any entity that may need it for billing purposes.

Final Results

Specimen Numbers:	S07SM001915
Date Collected:	4/20/2007
BRUCELLA AGGLUTINATION	<1:40

An agglutination titer of <1:40 is considered to be negative. This test was developed and its performance characteristics determined by the Laboratory Services Section at DSHS. The test has not been approved or cleared by the US Food and Drug Administration (FDA).

Q FEVER IFA	**PHASE I	<1:64
	PHASE II	1:1024

A single Q fever IFA titer of greater than or equal to 1:256 is evidence of a prior infection, but, it does not confirm that the infection was recent. The most convincing evidence of recent infection is a fourfold rise in antibody titer between an acute serum

and convalescent serum. Reactions to both phase I and phase II antibody are often detected in chronic Q fever. The phase II antibody is usually higher than the phase I titer. In chronic Q fever phase I titers rise in later specimens while phase II titers fall or remain constant.

(continued)

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Submitter copy to: ** DUPLICATE REPORT ** * Page 2 of 2* Date: 5/2/2007

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Patient

Patient Address:

This test was developed and its performance characteristics determined by the Laboratory Services Section at DSHS. The test has not been approved or cleared by the US Food and Drug Administration (FDA).

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

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

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 2:06 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: CDC Doc
Attachments: DOC070.PDF

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

From: Salsman, John M
Sent: Thursday, May 10, 2007 11:51 AM
To: Wallis, Annette
Subject: CDC Doc

TEXAS A&M UNIVERSITY

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

Telephone: (979) 458-1467 **Facsimile: (979) 862-3176**

Date: May 9, 2007

To: EHSD- Attn: John Salsman & Brent Mattox

Facsimile: 5-1348

From: Tiffany M. Agnew

CONFIDENTIAL

Greetings!

In the body of the attached document, we have placed names by those responsible for drafting the response. However, please get input from any and all parties necessary for the most comprehensive response.

Pages Sent (Including Cover Page): 21

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

May 4, 2007

Richard Ewing, Responsible Official
Texas A& M University (Registration #C20060605-0489)
1112 TAMU
College Station, TX 77843-1112
FAX: (979) 845-1855

Subject: Texas A& M University: Report of Site Visit; Request for Additional Information

On April 11, 2007, the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) received the APHIS/CDC Form 3 (Report of Theft, Loss, or Release of Select Agents and Toxins) from Texas A&M University (TAMU) reporting the occupational exposure to *Brucella* on February 9, 2006 that resulted in infection of a laboratory worker.

During the period April 16, 2007 through April 18, 2007, the following representatives from the CDC visited TAMU located at 1112 TAMU, College Station, TX 77843:

Diane Martin, Lead Inspector
Richard Henkel, Biosafety Manager
Melissa Resnick, Epidemic Intelligence Service Officer

Individuals from TAMU present during the site visit included:

Richard Ewing, Vice President (VP) of Research, Responsible Official
Angelia Raines, Dir-Office of Research Compliance, alternate Responsible Official
John Salsman, Director, Environmental Health and Safety Department (EHSD)
Brent Mattox, Biosafety Officer, EHSD, alternate Responsible Official
Chris Meyer, Asst. VP, Safety & Security
Tiffany Agnew, Environmental Biosafety Program Coordinator
Thomas Ficht, Professor, Principal Investigator
L.G. Adams, Associate Dean, Principal Investigator
Angela Arenas, Graduate Student
Christine McFarland, Research Associate
Jianwu Pei, Assistant Research Scientist
Linda Clark, Assistant Executive Director, Scott & White Clinic
Jack Crouch, Occupational Medicine Supervisor, Scott & White Clinic
Melissa Kahl-McDonagh, Postdoctoral Research Fellow

The purpose of the site visit was to (1) review the events surrounding the occupational exposure to *Brucella* that occurred on February 9, 2006 in Room of Building and assess the measures implemented to prevent other such incidents; (2) assess measures implemented by TAMU to protect the staff and public from exposure to pathogenic microorganisms; and (3) and to otherwise evaluate your entity's compliance with the select agent regulations (7 C.F.R. part 331, 9 C.F.R. part 121, 42 C.F.R. part 73).

Overview of the incident:

The incident occurred in 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 , first felt ill on March 25, 2006. On April 12, 2006, 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. ; 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 ocated in building being kept during the time the room was used for work with select agents.

Browder **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.

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.

Raines **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*.

Ficht **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 did not receive training or have any experience in handling *Brucella melitensis, Brucella abortus* or *Brucella suis*.

Ficht

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."

Ficht Samuel Tesh Adams

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*.

Ficht

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

Salsman Mattox

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 , that annual verification was performed to ensure that the laboratory meets the design and operational parameters.

Salsman
Mattox

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.

Ficht
Samuel

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.

Salsman
Mattox

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.

Salsman Mattox

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.*

Ficht Salsman Mattox partial

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.

Salsman Mattox

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.

Ficht → **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.

Ficht Samuel CMP

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]***

Raines Agnew

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 Dr. McFarland's occupational exposure.

Raines

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).

Raines Salsman Mattox

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 Dr. completed the aerosolization experiments with *Brucella melitensis* and *Brucella abortus*, 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 occupational exposure even though she informed PI Ficht on April 12, 2006 that she had been diagnosed with brucellosis.

Salsman
Mattox

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 located of building since October of 2005, was completed in laboratory room located in building

Mattox→ **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.*

Mattox – **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.

Mattox – **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.

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

Ficht – **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.

Ficht – **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:

Agnew
Samuel
Kretzschmar

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)."

Mattox **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.

Samuel **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.

Samuel **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.

Samuel **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.

Samuel **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)].***

Raines **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.

Read 4-17-07

From: Tom Ficht <tficht@cvm.tamu.edu>
To: "Mattox, Brent S" <bsmattox@tamu.edu>, Angelia Raines <ARaines@vprmail.tamu.edu>, Tiffany Agnew <tmagnew@tamu.edu>
Date: 4/21/2006 1:28:18 PM
Subject: FW: Workmen's Compensation

> Brent
>
> I wanted to let you know that has been diagnosed with
> brucellosis. apparently contracted the disease during an
> experimental challenge at (CMP) on the ninth of February 2006. At that
> time along with Dr. McMurray were training us in the use of the
> Madison chamber for aerosol inoculations.
>
has been home sick for several weeks being treated by 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 exposure, although we assume
> it may have occurred as a result of cleaning out the Madison chamber after
> an aerosol run. In the future we plan to flush the chamber with
> disinfectant rather than using manual cleaning methods. The chamber will be
> wiped out after running disinfectant through the chamber, but this will
> involve the use of a long-handled applicator or mop. In addition, we will
> not rely on the use of N95 face masks and will instead use positive air
> displacement respirators.
>
> In the initial aerosol trials we relied on the experience of the TB
> researchers for the level of precaution typically employed in such
> experiments. It is suspected
> that a conjunctival route of infection is responsible for
> infection, perhaps as a result of manually cleaning the Madison chamber.
> It is my fault for not recognizing the differences between Brucella and
> Mycobacteria in regard to routes of infection.
>
> An isolation was made from a blood culture by physician and
> sent to TDH for confirmation. It would be helpful if EHSD could requested
> a sample of this isolate for culture confirmation here.
>
>
>
> Thomas A. Ficht, Ph.D.
> Professor
> Veterinary Pathobiology
> Texas A&M University
> 4467 TAMU
> College Station, TX 77843-4467
> 979-845-4118 ph
> 979-862-1088 fax

Attachment #2

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

April 13, 2007

Richard Ewing, Responsible Official
Texas A& M University (Registration #C20060605-0489)
1500 Research Parkway, Suite B150, TAMU 1186
College Station, TX 77843-1183
Fax: (979) 862-3176

Subject: 42 C.F.R. § 73.19 (Notification of theft, loss, or release)

Dear Dr. Ewing:

This is to acknowledge the receipt of the APHIS/CDC Form 3 (Report of Theft, Loss, or Release of Select Agents and Toxins) from Texas A& M University dated April 11, 2007 that reported an occupational exposure to *Brucella*. Based upon the review of the report, the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) has additional questions:

1. Please provide a copy of the medical surveillance plan and describe how the follow up was conducted as a result of the incident.
2. Please provide all occupational health records pertaining to the exposed individuals and any individuals that have presented with symptoms associated with a possible exposure to *Coxiella, Brucella,* or *Mycobacterium tuberculosis*.
3. Please provide documentation in regards to the risk assessment that was preformed for work with *Brucella*.
4. Please describe the decontamination procedures used for the aerosol chamber and any modifications incorporated to these procedures as a result of this incident.
5. Please provide all standard operating procedures (SOPs) and certification documents as it relates to the aerosol chamber.
6. Please provide a summary of events that occurred with this incident including the follow-up review that your entity conducted to assure that any other similar incidents do not occurred.
7. Since your entity failed to meet the reporting requirements of 42 C.F.R. § 73.19, please provide a plan of how Texas A& M University will achieve compliance with 42 C.F.R. 73. In addition, please explain if your entity failed to meet other required federal and state reporting requirements.
8. Please provide access logs for 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

P. 1

x x x COMMUNICATION RESULT REPORT (APR. 13. 2007 2:33PM) x x x

FAX HEADER 1: SELECT AGENTS PROGRAM 4047182096
FAX HEADER 2:

TRANSMITTED/STORED : APR. 13. 2007 2:32PM

FILE MODE	OPTION	ADDRESS	RESULT	PAGE
9688 MEMORY TX		979 862 3176	OK	2/2

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

April 13, 2007

Richard Ewing, Responsible Official
Texas A& M University (Registration #C20060605-0489)
1500 Research Parkway, Suite B150, TAMU 1186
College Station, TX 77843-1183
Fax: (979) 862-3176

Subject: 42 C.F.R. § 73.19 (Notification of theft, loss, or release)

Dear Dr. Ewing:

This is to acknowledge the receipt of the APHIS/CDC Form 3 (Report of Theft, Loss, or Release of Select Agents and Toxins) from Texas A& M University dated April 11, 2007 that reported an occupational exposure to *Brucella*. Based upon the review of the report, the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) has additional questions:

1. Please provide a copy of the medical surveillance plan and describe how the follow up was conducted as a result of the incident.
2. Please provide all occupational health records pertaining to the exposed individuals and any individuals that have presented with symptoms associated with a possible exposure to *Coxiella*, *Brucella*, or *Mycobacterium tuberculosis*.
3. Please provide documentation in regards to the risk assessment that was preformed for work with *Brucella*.
4. Please describe the decontamination procedures used for the aerosol chamber and any modifications incorporated to these procedures as a result of this incident.
5. Please provide all standard operating procedures (SOPs) and certification documents as it relates to the aerosol chamber.
6. Please provide a summary of events that occurred with this incident including the follow-up review that your entity conducted to assure that any other similar incidents do not occurred.
7. Since your entity failed to meet the reporting requirements of 42 C.F.R. § 73.19, please provide a plan of how Texas A& M University will achieve compliance with 42 C.F.R. 73. In addition, please explain if your entity failed to meet other required federal and state reporting requirements.
8. Please provide access logs for Room and all rooms were work with *Brucella* is performed.
9. Please explain how your incident response plan, security plan, and biosafety plan have been modified as a result of this incident.

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 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 143 in the LARR "Building contains an aerolization chamber used by PI Ficht for work with select agent. There were no SOPs available for review by inspectors to ensure appropriate safety precautions have been established for this procedure. Please provide documentation that this departure has been addressed.

Entity Response: SOP's for the aerolization chamber are now in place. [See Appendix H]

CDC Response: As discussed during the February 22-24 inspection, it was stated that Principal Investigator Ficht would be performing aerosol work with select agents. Please be reminded that 42 CFR 73.7 states that prior to changes in the activities involving any select agents or toxins the certificate of registration must be amended by the entity to include that work. Prior to the work being approved by the Select Agent Program, standard operating procedures regarding the aerosol challenge will need to be submitted to address the following additional issues:

1) Please describe the mechanism used to ensure that after the aerosol procedure, there is no residual select agent remaining on the animal surface.
2) Are there any laboratory air sampling procedures to verify no equipment leaks?
3) How does the laboratorian know the nebulizer is functioning properly and not leaking?
4) Is the HEPA filtration system for aerolizer equipment certified?
5) Is the microisolator cage filtration system certified?
6) Has it been determined how many air changes/hour it takes to remove infected particles after each run?
7) Are the animals anaesthetized prior to transfer back to the microisolator cages? If not, describe the procedure if animals escape. Describe the procedure for animal bites or scratches.
8) Please provide more detail on the cleaning of the chamber to ensure that the worker is not exposed to any agent during the cleaning process.
9) Is there any air sampling of the chamber after cleaning?
10) How has it been determined that dipping the probe in 10% bleach provides adequate contact time for decontamination?

Based upon review of Amendment #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

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@vprmail.tamu.edu.

We appreciate your continued support and guidance on compliance issues in the CDC Select Agent Program.

Respectfully submitted,

Richard E. Ewing
Responsible Official

Attachment

xc: Dr. Robert M. Gates
President

Dr. David B. Prior
Executive Vice President and Provost

Dr. Fuller W. Bazer
Associate Vice President for Research

RECEIVED
2005 APR 11 PM 10:27
CDC SELECT AGENT PROGRAM

FC 004

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

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)]

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 2:07 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: Thursday, May 10, 2007- 11:00 am- B130

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Wednesday, May 09, 2007 3:22 PM
To: gadams@cvm.tamu.edu; Melanie Ihrig; Tom Ficht; James Samuel; David N. McMurray; TESH@medicine.tamhsc.edu; Mattox, Brent S; Meyer, Chris; Faber, Jan; Salsman, John M; Tiffany Agnew; Betsy Browder
Cc: Bazer, Fuller; DSCarlson@tamhsc.edu; Wallis, Annette; Ewing, Richard
Subject: Re: Thursday, May 10, 2007- 11:00 am- B130

Hi Everyone,

The purpose of the meeting tomorrow was to make sure everyone understood the responses that each person is being asked to develop and to answer questions. However, in order to allow more time for you to create and send your responses to our office, we will not meet. Instead, just call me if you need assistance.

Please send your responses as they are completed so we can compile them. I would like to have the first draft ready by Friday morning (9:00 a.m.), if not sooner.

Again, please call (458-1467) if you have questions or need assistance.

Thank you,
Angelia

>>> Tiffany Agnew 5/9/2007 12:42:52 PM >>>
Greetings All!

We are planning to meet tomorrow, Thursday (5/10/07) at 11:00 am in the Centeq Building Conference Room- B130. Please keep in mind that a final draft is needed on Friday (5/11/07), no later than 9:00 am.

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

Thank you in advance for all of your diligence and cooperation!

Regards,

Tiffany

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

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 2:11 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: Adverse Event Report and SBAT Incident Report

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,

Annette Wallis

From: Carlson, David S. [mailto:DSCarlson@tamhsc.edu]
Sent: Tuesday, May 08, 2007 8:44 PM
To: Tiffany Agnew; Tom Ficht; TESH@medicine.tamhsc.edu; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Salsman, John M; Fuller Bazer
Cc: Raines, Angelia
Subject: RE: Adverse Event Report and SBAT Incident Report

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

From Jim Joyce:

My main concern is that there continues to be no notification of the HSC (or other agency or institution as the case may be) in these procedures.

Theoretically, since these are discussed at the IBC, the HSC member at those committees should bring the information back to the HSC. But this could be weeks or months after the event. And if the HSC members aren't at the committee meeting, the HSC may never be notified. There needs to be a step included in each of these processes to contact other institutions, if necessary.

Also, the processes discuss contacting the "Responsible Official". I assume this is Dr. Ewing?? It's

not clear whether the HSC has (or needs) a separate Responsible Official. Perhaps the HSC does for non-College Station activities??

Thanks, Jim

From Victor Pantusa:

Dr. Carlson,

My comments on the two IBC documents:

For Both: Verify that PI's and / or lab directors have copies of and are familiar with these two documents and their contents.

601 Report of Theft, Loss, or Release from SBAT Facilities

- 1.3 – Should include statement about completing First Report of Injury for occupational exposure (this may be required only for employees NOT enrolled in Occupational Health Program)

- Include notification of HSC Administration (ie., VP Research, Chief Safety Officer, Director of Admin, etc.) by the ORC or EHSD

602 Adverse Events involving a Biohazard / Reports of Non-Compliance

- 7. Process Overview – Who e-mails the IBSP staff? Is this notification after the BSO and IBC are notified?

- Same as above, I would like to see a statement that HSC (or other Agency depending on the affected employees) Administration will be notified.

Victor

Victor Pantusa, MS
Chief Safety Officer
Texas A&M Health Science Center

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

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

Greetings All!

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

Thank you in advance for your assistance!

Regards,

Tiffany

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

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 2:11 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: Drafts fo IBC Policy 602 and 601

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

From: Wallis, Annette
Sent: Monday, May 07, 2007 4:40 PM
To: Angelia Raines
Cc: Wallis, Annette
Subject: Drafts fo IBC Policy 602 and 601

Angelia,

I tried to call you a few minutes ago and you were out for the day. I am not finished with the edits. I will e-mail them early tomorrow morning. If you are not able to make the meeting tomorrow afternoon, I will take draft copies with me.

I plan on seeing you tomorrow.

Annette

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 2:12 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: Adverse Event Report and SBAT Incident Report

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

-----Original Message-----
From: Salsman, John M
Sent: Monday, May 07, 2007 2:02 PM
To: Wallis, Annette
Subject: FW: Adverse Event Report and SBAT Incident Report

Annette,

Here are Brent's comments. By the way, Jan Faber is out of the office.
John

-----Original Message-----
From: Mattox, Brent S
Sent: Friday, May 04, 2007 1:31 PM
To: Salsman, John M
Subject: FW: Adverse Event Report and SBAT Incident Report

This makes us (EHSD) or the BSO the responsible person(s) for notifying the ORC. I strongly suggest that the PI/Researcher be also required to notify the ORC up front. Additionally, the BSO should not be named anywhere as the contact, but the EHSD. That way if the BSO is unavailable, the process goes ahead. I do not recommend accepting the two documents as they now read without these corrections.

-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Friday, May 04, 2007 1:07 PM
To: Tom Ficht; TESH@medicine.tamhsc.edu; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Salsman, John M; Tiffany Agnew; Fuller Bazer
Subject: Re: Adverse Event Report and SBAT Incident Report

Hi Everyone,

Please note that the draft policy regarding SBAT incident reporting has just been re-formatted based on our SOP standards. The content is the same as previously distributed. The second policy is new and I am hoping that it will help us define and manage Biosafety adverse events or issues of non-compliance.

Please distribute to those on your teams as you deem necessary. All feedback is welcome!

Thank you,
Angelia

P.S. Tiffany, thank you for sending the drafts.

>>> Tiffany Agnew 5/4/2007 12:51 PM >>>
Greetings All!

Per Angelia, attached you will find two policies we would like to put into effective by May 10, 2007- the Adverse Event Report Policy and the SBAT Incident Report Policy. Please

feel free to provide your input no later than May 8, 2007, as we will attempt to notify the Research Community of the processes they will need to follow .

Thank you in advance for your assistance!

Regards,

Tiffany

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

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 2:20 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: FW: Report of Illness, Revised

Attachments: FW: Report of Illness, Revised

FW: Report of Illness, Revised...

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Monday, April 23, 2007 1:54 PM
To: Wallis, Annette
Subject: Fwd: FW: Report of Illness, Revised

Please add your comments and forward to John so he can update the policy based on his comments(attached).

Thanks for handling!
Angie

Yeager, Susan

From: Salsman, John M
Sent: Monday, April 23, 2007 9:30 AM
To: Raines, Angelia
Cc: Tiffany Agnew; Mattox, Brent S; Meyer, Chris
Subject: FW: Report of Illness, Revised

Angelia,

Below are comments for the policy. Let me know if you have any questions.

Thanks, John

-----Original Message-----
From: Mattox, Brent S
Sent: Monday, April 23, 2007 8:49 AM
To: Salsman, John M
Subject: RE: Report of Illness, Revised

The only problem is the EHSD notifying all individuals immediately. We may not even know who that is. Normally, we do the following:

1. Contact Lab Director or PI to obtain a list of all exposed individuals.
2. PI is instructed to immediately notify all of his/her personnel as soon as practical
3. EHSD will follow up with contacts once list is provided to EHSD by PI/Lab Director.

The problem is, we don't have immediate access to the entry/exit records, SBAT approval, visitors, etc. We only obtain that via request or investigation.

Brent

-----Original Message-----
From: Salsman, John M
Sent: Monday, April 23, 2007 8:42 AM
To: Mattox, Brent S
Subject: FW: Report of Illness, Revised

Brent,

Have you had a chance to review this? I did a quick review and it looks okay. Let's discuss this morning and get comments (if any) back to Angelia today.

Thanks, John

-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Friday, April 20, 2007 6:51 PM
To: Wallis, Annette; Mattox, Brent S; Salsman, John M; Robinson, Kristen E; Tiffany Agnew
Cc: Meyer, Chris; Fuller Bazer
Subject: Re: Report of Illness, Revised

Hi Everyone,

Attached is the draft policy for incident response with additional changes. Please review and issue feedback. Thanks, Angie

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 2:21 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: Review of Reportable Events for Select Agents and Toxins

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

From: Clark, Charley
Sent: Monday, April 23, 2007 12:55 PM
To: Wallis, Annette
Subject: FW: Review of Reportable Events for Select Agents and Toxins

---

From: Clark, Charley
Sent: Wednesday, April 18, 2007 1:59 PM
To: Ewing, Richard
Cc: Prior, David; Wallis, Annette
Subject: Review of Reportable Events for Select Agents and Toxins

Dick,

University Risk and Compliance has been asked to review the University's current procedures regarding notification of reportable events for select agents and toxins. Our review will focus on procedures, including redundancies, to ensure that CDC and other entities receive timely notification of reportable events as required by applicable regulations.

We would like to discuss the project with you. Please e-mail or call me at 845-0977 if you have questions, etc.

Thanks,
Charley

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 2:24 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: Review of Reportable Events for Select Agents and Toxins

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

From: Clark, Charley
Sent: Wednesday, April 18, 2007 1:59 PM
To: Ewing, Richard
Cc: Prior, David; Wallis, Annette
Subject: Review of Reportable Events for Select Agents and Toxins

Dick,

University Risk and Compliance has been asked to review the University's current procedures regarding notification of reportable events for select agents and toxins. Our review will focus on procedures, including redundancies, to ensure that CDC and other entities receive timely notification of reportable events as required by applicable regulations.

We would like to discuss the project with you. Please e-mail or call me at 845-0977 if you have questions, etc.

Thanks,
Charley

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 2:25 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: CDC Visit- No Update

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Monday, April 16, 2007 6:49 AM
To: ddavis@cvm.tamu.edu; gadams@cvm.tamu.edu; tficht@cvm.tamu.edu; TESH@medicine.tamhsc.edu; wilson@medicine.tamhsc.edu; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Meyer, Chris; Clark, Charley; Callcott, Diane; Faber, Jan; Salsman, John M; jsamuel@tamu.edu; Ihrig, Melanie; Ewing, Richard; McClendon, Rodney P; Kelly, Scott; Moore, Steve; Tiffany Agnew; Fuller Bazer; Betsy Browder
Cc: Shannon Davis
Subject: Re: CDC Visit- No Update

Good Morning,

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

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

Thank you,
Angelia

Angelia Raines
Director, VPR Office of Research Compliance TAMU 1186 1500 Research Parkway Suite 150 B (Centeq Building) College Station, Texas 77843-1186 araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax
(770) 789-3456 Cell

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

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

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

Thank you!

Regards,

Tiffany

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

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 2:25 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: CDC Visit- No Update

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,

Annette Wallis

From: Tiffany Agnew [mailto:tmagnew@tamu.edu]
Sent: Sunday, April 15, 2007 7:43 PM
To: ddavis@cvm.tamu.edu; gadams@cvm.tamu.edu; Tom Ficht; TESH@medicine.tamhsc.edu; Van Wilson; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Meyer, Chris; Clark, Charley; Callcott, Diane; Faber, Jan; Salsman, John M; jsamuel@tamu.edu; Ihrig, Melanie; Ewing, Richard; McClendon, Rodney P; Kelly, Scott; Moore, Steve; Fuller Bazer; Betsy Browder
Cc: Shannon Davis; Raines, Angelia
Subject: CDC Visit- No Update

Greetings All!

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

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

Thank you!

Regards,

Tiffany

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 1:46 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: 4/17 CDC Response Draft: For final comments
Attachments: CDC Paragraph 16 sak.doc

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

From: Kelly, Scott
Sent: Thursday, May 17, 2007 2:28 PM
To: Meyer, Chris; Salsman, John M; 'Shannon Davis'; Bazer, Fuller; 'gadams@cvm.tamu.edu'; 'David N. McMurray'; 'Vernon Tesh'; 'James Samuel'; 'DSCarlson@tamhsc.edu'; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Cantrell, Carol; Clark, Charley; Barker, Julie K.; Faber, Jan; Ihrig, Melanie; Clark, Neville; Ewing, Richard; 'Thomas Ficht'; 'Tiffany Agnew'; 'Betsy Browder'
Cc: Raines, Angelia
Subject: RE: 4/17 CDC Response Draft: For final comments

Is this wording of the section of Paragraph 16 referenced in Chris' email more correct.

Scott Kelly

From: Meyer, Chris
Sent: Thursday, May 17, 2007 2:09 PM
To: Kelly, Scott; Salsman, John M; 'Shannon Davis'; Bazer, Fuller; 'gadams@cvm.tamu.edu'; 'David N. McMurray'; 'Vernon Tesh'; 'James Samuel'; 'DSCarlson@tamhsc.edu'; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Cantrell, Carol; Clark, Charley; Barker, Julie K.; Faber, Jan; Ihrig, Melanie; Clark, Neville; Ewing, Richard; 'Thomas Ficht'; 'Tiffany Agnew'; 'Betsy Browder'
Cc: Raines, Angelia
Subject: RE: 4/17 CDC Response Draft: For final comments

The font size used in the last paragraph of the TAMU response to question 16, part 2 does not match that in the rest of the document.

In answer to Scott Kelly's question on question 16, "Does it [the Feb. 06 security plan] reference release?" The answer is that in the paragraph that directly speaks to reporting to the CDC, no, it only refers to theft or loss. Elsewhere in that subsection, there is a list of incidents for which the PI should notify EHS and or UPD that includes "release".

I have no other comments.

Chris Meyer

From: Kelly, Scott
Sent: Thursday, May 17, 2007 1:29 PM
To: Salsman, John M; 'Shannon Davis'; Bazer, Fuller; 'gadams@cvm.tamu.edu'; 'David N. McMurray'; 'Vernon Tesh'; 'James Samuel'; 'DSCarlson@tamhsc.edu'; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Cantrell, Carol; Meyer, Chris; Clark, Charley; Barker, Julie K.; Faber, Jan; Ihrig, Melanie; Clark, Neville; Ewing, Richard; 'Thomas Ficht'; 'Tiffany Agnew'; 'Betsy Browder'
Cc: Raines, Angelia
Subject: RE: 4/17 CDC Response Draft: For final comments

Attachment _____ contains IBC documentation of the [that] animal work that was approved

Is the above the correction suggested in John's email. Add "of the", Delete "that"?

Scott Kelly

-----Original Message-----
From: Salsman, John M
Sent: Thursday, May 17, 2007 1:20 PM
To: 'Shannon Davis'; Bazer, Fuller; gadams@cvm.tamu.edu; David N. McMurray; Vernon Tesh; James Samuel; DSCarlson@tamhsc.edu; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Cantrell, Carol; Meyer, Chris; Clark, Charley; Barker, Julie K.; Faber, Jan; Ihrig, Melanie; Clark, Neville; Ewing, Richard; Kelly, Scott; Thomas Ficht; Tiffany Agnew; Betsy Browder
Cc: Raines, Angelia
Subject: RE: 4/17 CDC Response Draft: For final comments

Shannon,

Per my phone call, the only change I have was in the response to item #15, delete the 2nd "that" in the first sentence.

Thanks, John

-----Original Message-----
From: Shannon Davis [mailto:s.davis@tamu.edu]
Sent: Thursday, May 17, 2007 11:30 AM
To: Bazer, Fuller; gadams@cvm.tamu.edu; David N. McMurray; Vernon Tesh; James Samuel; DSCarlson@tamhsc.edu; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Cantrell, Carol; Meyer, Chris; Clark, Charley; Barker, Julie K.; Faber, Jan; Salsman, John M; Ihrig, Melanie; Clark, Neville; Ewing, Richard; Kelly, Scott; Thomas Ficht; Tiffany Agnew; Betsy Browder
Cc: Raines, Angelia
Subject: 4/17 CDC Response Draft: For final comments
Importance: High

** Confidential **
** High Priority **

Attached is the final draft. Please review and submit any comments/changes immediately. All input must be received by 11:45 pm.

Thank you,
Shannon

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 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).

Deleted: However

Deleted: making that notification

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 1:46 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: 4/17 CDC Response Draft: For final comments

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

From: Meyer, Chris
Sent: Thursday, May 17, 2007 2:09 PM
To: Kelly, Scott; Salsman, John M; 'Shannon Davis'; Bazer, Fuller; 'gadams@cvm.tamu.edu'; 'David N. McMurray'; 'Vernon Tesh'; 'James Samuel'; 'DSCarlson@tamhsc.edu'; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Cantrell, Carol; Clark, Charley; Barker, Julie K.; Faber, Jan; Ihrig, Melanie; Clark, Neville; Ewing, Richard; 'Thomas Ficht'; 'Tiffany Agnew'; 'Betsy Browder'
Cc: Raines, Angelia
Subject: RE: 4/17 CDC Response Draft: For final comments

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In answer to Scott Kelly's question on question 16, "Does it [the Feb. 06 security plan] reference release?" The answer is that in the paragraph that directly speaks to reporting to the CDC, no, it only refers to theft or loss. Elsewhere in that subsection, there is a list of incidents for which the PI should notify EHS and or UPD that includes "release".

I have no other comments.

Chris Meyer

From: Kelly, Scott
Sent: Thursday, May 17, 2007 1:29 PM
To: Salsman, John M; 'Shannon Davis'; Bazer, Fuller; 'gadams@cvm.tamu.edu'; 'David N. McMurray'; 'Vernon Tesh'; 'James Samuel'; 'DSCarlson@tamhsc.edu'; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Cantrell, Carol; Meyer, Chris; Clark, Charley; Barker, Julie K.; Faber, Jan; Ihrig, Melanie; Clark, Neville; Ewing, Richard; 'Thomas Ficht'; 'Tiffany Agnew'; 'Betsy Browder'
Cc: Raines, Angelia
Subject: RE: 4/17 CDC Response Draft: For final comments

Attachment _____ contains IBC documentation of the [that] animal work that was approved

Is the above the correction suggested in John's email. Add "of the", Delete "that"?

Scott Kelly

-----Original Message-----
From: Salsman, John M
Sent: Thursday, May 17, 2007 1:20 PM
To: 'Shannon Davis'; Bazer, Fuller; gadams@cvm.tamu.edu; David N. McMurray; Vernon Tesh; James Samuel; DSCarlson@tamhsc.edu; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Cantrell, Carol; Meyer, Chris; Clark, Charley; Barker, Julie K.; Faber, Jan; Ihrig, Melanie; Clark, Neville; Ewing, Richard; Kelly, Scott; Thomas Ficht; Tiffany Agnew; Betsy Browder
Cc: Raines, Angelia
Subject: RE: 4/17 CDC Response Draft: For final comments

Shannon,

Per my phone call, the only change I have was in the response to item #15, delete the 2nd "that" in the first sentence.

Thanks, John

-----Original Message-----
From: Shannon Davis [mailto:s.davis@tamu.edu]
Sent: Thursday, May 17, 2007 11:30 AM
To: Bazer, Fuller; gadams@cvm.tamu.edu; David N. McMurray; Vernon Tesh; James Samuel; DSCarlson@tamhsc.edu; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Cantrell, Carol; Meyer, Chris; Clark, Charley; Barker, Julie K.; Faber, Jan; Salsman, John M; Ihrig, Melanie; Clark, Neville; Ewing, Richard; Kelly, Scott; Thomas Ficht; Tiffany Agnew; Betsy Browder
Cc: Raines, Angelia
Subject: 4/17 CDC Response Draft: For final comments
Importance: High

** Confidential **
** High Priority **

Attached is the final draft. Please review and submit any comments/changes immediately. All input must be received by 11:45 pm.

Thank you,
Shannon

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 1:47 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: 4/17 CDC Response Draft: For final comments

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

From: Kelly, Scott
Sent: Thursday, May 17, 2007 1:29 PM
To: Salsman, John M; 'Shannon Davis'; Bazer, Fuller; 'gadams@cvm.tamu.edu'; 'David N. McMurray'; 'Vernon Tesh'; 'James Samuel'; 'DSCarlson@tamhsc.edu'; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Cantrell, Carol; Meyer, Chris; Clark, Charley; Barker, Julie K.; Faber, Jan; Ihrig, Melanie; Clark, Neville; Ewing, Richard; 'Thomas Ficht'; 'Tiffany Agnew'; 'Betsy Browder'
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Cc: Raines, Angelia
Subject: 4/17 CDC Response Draft: For final comments
Importance: High

** Confidential **
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Thank you,
Shannon

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 1:48 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: 4/17 CDC Response Draft: For final comments

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

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To: 'Shannon Davis'; Bazer, Fuller; gadams@cvm.tamu.edu; David N. McMurray; Vernon Tesh; James Samuel; DSCarlson@tamhsc.edu; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Cantrell, Carol; Meyer, Chris; Clark, Charley; Barker, Julie K.; Faber, Jan; Ihrig, Melanie; Clark, Neville; Ewing, Richard; Kelly, Scott; Thomas Ficht; Tiffany Agnew; Betsy Browder
Cc: Raines, Angelia
Subject: RE: 4/17 CDC Response Draft: For final comments

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Thanks, John

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Cc: Raines, Angelia
Subject: 4/17 CDC Response Draft: For final comments
Importance: High

** Confidential **
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Thank you,
Shannon

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 1:48 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: 4/17 CDC Response Draft: For final comments

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

-----Original Message-----
From: Clark, Charley
Sent: Thursday, May 17, 2007 1:17 PM
To: Shannon Davis
Cc: Wallis, Annette
Subject: RE: 4/17 CDC Response Draft: For final comments

I agree with Scott Kelly's comments.

-----Original Message-----
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Sent: Thursday, May 17, 2007 11:30 AM
To: Bazer, Fuller; gadams@cvm.tamu.edu; David N. McMurray; Vernon Tesh; James Samuel; DSCarlson@tamhsc.edu; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Cantrell, Carol; Meyer, Chris; Clark, Charley; Barker, Julie K.; Faber, Jan; Salsman, John M; Ihrig, Melanie; Clark, Neville; Ewing, Richard; Kelly, Scott; Thomas Ficht; Tiffany Agnew; Betsy Browder
Cc: Raines, Angelia
Subject: 4/17 CDC Response Draft: For final comments
Importance: High

** Confidential **
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Thank you,
Shannon

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:34 PM
To: Yeager, Susan
Subject: FW: 4/17 CDC Response Draft: For final comments
Attachments: CDC Paragraph 16 sak.doc

From: Kelly, Scott
Sent: Thursday, May 17, 2007 2:28 PM
To: Meyer, Chris; Salsman, John M; 'Shannon Davis'; Bazer, Fuller; 'gadams@cvm.tamu.edu'; 'David N. McMurray'; 'Vernon Tesh'; 'James Samuel'; 'DSCarlson@tamhsc.edu'; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Cantrell, Carol; Clark, Charley; Barker, Julie K.; Faber, Jan; Ihrig, Melanie; Clark, Neville; Ewing, Richard; 'Thomas Ficht'; 'Tiffany Agnew'; 'Betsy Browder'
Cc: Raines, Angelia
Subject: RE: 4/17 CDC Response Draft: For final comments

Is this wording of the section of Paragraph 16 referenced in Chris' email more correct.

Scott Kelly

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To: Kelly, Scott; Salsman, John M; 'Shannon Davis'; Bazer, Fuller; 'gadams@cvm.tamu.edu'; 'David N. McMurray'; 'Vernon Tesh'; 'James Samuel'; 'DSCarlson@tamhsc.edu'; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Cantrell, Carol; Clark, Charley; Barker, Julie K.; Faber, Jan; Ihrig, Melanie; Clark, Neville; Ewing, Richard; 'Thomas Ficht'; 'Tiffany Agnew'; 'Betsy Browder'
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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 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).

Deleted: However

Deleted: making that notification

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:34 PM
To: Yeager, Susan
Subject: FW: 4/17 CDC Response Draft: For final comments

-----Original Message-----
From: Clark, Charley
Sent: Thursday, May 17, 2007 1:17 PM
To: 'Shannon Davis'
Cc: Wallis, Annette
Subject: RE: 4/17 CDC Response Draft: For final comments

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Scott,

The standard provides detail regarding the methodology for how to test a HEPA filter and defines what is acceptable, "passing". It is the same testing standard used to certify that a biological safey cabinet is working properly, so the reference to the standard demonstrates an acceptable approach for ensuring the HEPA filters on the Madison Aerosol Chamber are functioning appropriately.

EHSD does not have the documentation discussed in the Observation. Dr. McMurray may have it.

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From: Mattox, Brent S
Sent: Thursday, May 17, 2007 3:20 PM
To: Kelly, Scott; 'Shannon Davis'; Bazer, Fuller; 'gadams@cvm.tamu.edu'; 'David N. McMurray'; 'Vernon Tesh'; 'James Samuel'; 'DSCarlson@tamhsc.edu'; Wallis, Annette; Kretzschmar, Bert; Cantrell, Carol; Meyer, Chris; Clark, Charley; Barker, Julie K.; Faber, Jan; Salsman, John M; Ihrig, Melanie; Clark, Neville; Ewing, Richard; 'Thomas Ficht'; 'Tiffany Agnew'; 'Betsy Browder'
Cc: Raines, Angelia
Subject: RE: 4/17 CDC Response Draft: For final comments

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"The filters on the unit have been tested and it was verified by an outside vendor that they passed with no detectable aerosol penetration."

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Brent

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Importance: High

** Confidential **
** High Priority **

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Thank you,
Shannon

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 1:36 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: SBAT training

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Wednesday, May 23, 2007 11:23 AM
To: Wallis, Annette
Subject: SBAT training

Hi Annette,

You are going to be copied on an invitation to SBAT training. Because you work so closely with us, I wanted to include you in the training. It is scheduled for June 1st. More information to come...

Angelia

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 1:36 PM
To: Yeager, Susan
Cc: Wallis, Annette
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Sent: Monday, July 02, 2007 1:37 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: 4/17 CDC Response Draft: For final comments

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From: Salsman, John M
Sent: Thursday, May 17, 2007 3:18 PM
To: Kelly, Scott; Mattox, Brent S; 'Shannon Davis'; Bazer, Fuller; 'gadams@cvm.tamu.edu'; 'David N. McMurray'; 'Vernon Tesh'; 'James Samuel'; 'DSCarlson@tamhsc.edu'; Wallis, Annette; Kretzschmar, Bert; Cantrell, Carol; Meyer, Chris; Clark, Charley; Barker, Julie K.; Faber, Jan; Ihrig, Melanie; Clark, Neville; Ewing, Richard; 'Thomas Ficht'; 'Tiffany Agnew'; 'Betsy Browder'
Cc: Raines, Angelia
Subject: RE: 4/17 CDC Response Draft: For final comments

Scott,

The standard provides detail regarding the methodology for how to test a HEPA filter and defines what is acceptable, "passing". It is the same testing standard used to certify that a biological safey cabinet is working properly, so the reference to the standard demonstrates an acceptable approach for ensuring the HEPA filters on the Madison Aerosol Chamber are functioning appropriately.

EHSD does not have the documentation discussed in the Observation. Dr. McMurray may have it.

John

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From: Kelly, Scott
Sent: Thursday, May 17, 2007 2:41 PM
To: Mattox, Brent S; 'Shannon Davis'; Bazer, Fuller; 'gadams@cvm.tamu.edu'; 'David N. McMurray'; 'Vernon Tesh'; 'James Samuel'; 'DSCarlson@tamhsc.edu'; Wallis, Annette; Kretzschmar, Bert; Cantrell, Carol; Meyer, Chris; Clark, Charley; Barker, Julie K.; Faber, Jan; Salsman, John M; Ihrig, Melanie; Clark, Neville; Ewing, Richard; 'Thomas Ficht'; 'Tiffany Agnew'; 'Betsy Browder'
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