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, Epicdemic 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 Mattos, 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 Arencas, Graduate Student
Christine McFarland, Research Associate
Jianwu Pei, Assistant Research Scientist
Linda Clark, Assistant Executive Director, Scott & White Clinic
Jack Crouch, Occupational Medicine Supervisor, Scott & White Clinic
Melissa Kahl-McDonagh, Postdoctoral Research Fellow

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

The incident occurred in 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. Did not receive training to perform aerosolization experiments with Brucella melitensis, Brucella suis, and Brucella abortus. After completing 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 laboratory 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 i, she first fell ill on March 25, 2006. On April 12, 2006, she informed Principal Investigator (PI) Dr. Tom Ficht that she had been diagnosed with brucellosis, with isolation of Brucella melitensis on April 16, 2006, by the Texas State Public Health Laboratory. She also filed a workman’s compensation claim with Texas A&M University and returned to work on April 24, 2006. On April 21, 2006, PI Ficht sent an email (see Attachment #2) to alternate Responsible Official Brent Mattix and alternative Responsible Official Angelia Raines, and the ISBP Coordinator, Tiffany Agnew, to notify them of the occupational exposure that resulted in being diagnosed with brucellosis.

Site visit:

On the morning of April 16, 2007, CDC representatives met with the Responsible Official, Dr. Richard Ewing and alternate Responsible Official Angelia Raines. The CDC representatives requested the following:
- All documents requested by DSAT in a fax sent to TAMU on April 13, 2007 (see Attachment #3).
- All records related to the reported occupational exposure including any updates to training, security plan, incident response plan, and the biosafety plan as a result of the incident, incident/corrective action report, access logs to the area and animal health records.
- Access to individuals involved with the reported February 9, 2006 occupational exposure to conduct interviews.
- Access to inspect where the reported occupational exposure had occurred.

The CDC representatives interviewed the following individuals:
- Richard Ewing, Vice President of Research, Responsible Official
- Angelia Raines, Dir- Office of Research Compliance, alternate Responsible Official
- Brent Mattix, Biological Safety Officer, Environmental Health and Safety (EHS)
- John Salsman, Director, EHS
- Thomas Ficht, Principal Investigator
- Jianwu Pei, Assistant Research Scientist
- Linda Clark, Assistant Executive Director, Scott & White Clinic
- Jack Crouch, Occupational Medicine Supervisor, Scott & White Clinic
- Melissa Kahl-McDonagh, Postdoctoral Research
- Christine McFarland, Research Associate
Enclosed as attachment 1 to this letter please find a list of observations and accompanying requests for supplemental information concerning the occupational exposure to *Brucella* that occurred on February 9, 2006 in 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 *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/](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,

[Signature]

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 143 kept during the time the room was used for work with select agents.

   Request for supplemental information: Please provide an explanation as to why entries into room 143 were not being recorded as required under §73.17 (Records) and how your entity will comply with all the requirements of §73.17.

2. A certificate of registration may be amended to reflect changes in circumstances (e.g., changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins)(1) Prior to any change, the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application [42 CFR § 73.7(h)(1)].

   Observation: Documentation provided to the CDC Inspectors indicated twelve aerosol experiments with *Brucella abortus* and *Brucella melitensis* had been performed using the aerosol chamber located in room 143 since October of 2005. To date, DSAT has not received or approved an amendment to update your certificate of registration to include these activities for room 143. In addition, your entity was notified on June 7, 2006 (see Amendment #4) that prior to any changes in the activities involving select agents, the entity’s certificate of registration must be amended to include this work with select agents such as aerosolization experiments and that this amendment must be approved by DSAT prior to any work being performed.

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

3. An individual or entity required to register under this part may not provide an individual access to a select agent or toxin, and an individual may not access a select agent or toxin, unless the individual is approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General [42 CFR § 73.19(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 wining down the rear inside of the chamber with disinfectant. This cleaning technique caused dissection of head and arm to enter into the interior of the chamber, most likely resulting in occupational exposure to either *Brucella melitensis* or *Brucella abortus*.

   Request for supplemental information: Please provide an explanation regarding this apparent allowance of unauthorized access to select agents including: (1) Has your entity allowed other
Unauthorized access to select agents to other individuals and who are the individuals who had unauthorized access to select agents, along with dates, times, and select agents associated with other incidents of unauthorized access; (2) If your entity has been allowing unauthorized access to select agents besides this incident, what immediate actions have you taken to ensure that these individuals no longer have access; (3) What is your entity’s plan of action to assure prevention of similar events from occurring; and, (4) During the unauthorized access, how was the select agent safeguarded against theft, loss, or release (see 42 C.F.R. § 73.11(a)) during this allowance of unauthorized access to select agents.

4. Each individual with access to select agents or toxins must have the appropriate education, training, and/or experience to handle or use such agents or toxins [42 CFR § 73.10(c)]. An individual or entity required to register under this part must provide information and training on biosafety and security to each individual with access approval from the HHS Secretary or Administrator before he/she has such access. In addition, an individual or entity must provide information and training on biosafety and security to each individual not approved for access from the HHS Secretary or Administrator before he/she works in or visits areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, etc.). The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. [42 CFR §73.15(a)]

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

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

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

Observation: According to laboratory personnel interviewed by the CDC Inspectors, Dr. Ficht had conducted restricted experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture (see 42 C.F.R. § 73.13(b)(1)). Specifically, experiments conducted by Dr. Ficht that involved the introduction of plasmids containing kanamycin and chloramphenicol resistance cassettes used as selectable markers in Brucella melitensis, Brucella abortus and Brucella suis. Please note that during the February 2005 inspection of your entity, the inspectors identified that Dr. Tsoolis’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 “Dr. Tsoolis’ 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 Dr. Tsoolis 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 recurrences 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, the individual, who has not received access approval from the DSAT, performed aerosolization experiments with Brucella melitensis and Brucella abortus. After completing the aerosolization experiments with Brucella melitensis and Brucella abortus, she cleaned the aerosolization chamber by wiping down the rear inside of the chamber with disinfectant. This cleaning technique caused her head and arm to enter into the interior of the chamber, most likely resulting in her 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 an area located in the CDC Inspectors were unable to verify that the room had proper directional airflow at the time of the inspection because the visual monitoring system used to confirm directional airflow for the room was not functioning properly.

Request for supplemental information: As the CDC Inspectors were not able to confirm that the room had directional airflow, please provide documentation that room as a functional visual monitoring device and that the directional airflow is from “clean” area toward “contaminated” area.
8. An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR §73.12]. The completed Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be reverified at least annually against these procedures as modified by operational experience [BMBL: D14].

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

Request for supplemental information: Please provide this documentation.

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

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

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

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

Observation: According to documentation provided to the CDC Inspectors, the HEPA systems of the aerosol chamber located in room 143 are not routinely verified or tested to ensure that the HEPA filters provide adequate protection. Dr. David McMurray provided documentation to the CDC Inspectors that the routine maintenance of the Madison Aerosol Chamber indicated that testing of the HEPA system is not necessary.

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

11. An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR §73.12]. All manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, etc. are conducted in a Class II or Class III biological safety cabinet [BMBL: C5].

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

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

12. The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards [42 CFR § 73.12(b)])

**Observation:** Documentation provided to the CDC Inspectors indicated twelve aerosol experiments with *Brucella abortus* and *Brucella melitensis* had been performed using the aerosol chamber located in r since October of 2005. The CDC Inspectors were informed that the established biosafety protocols for work with *Mycobacterium* were used for the aerosol experiments with *Brucella melitensis* and *Brucella abortus*.

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

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

**Observation:** On February 9, 2006, aerosolization experiments were performed with *Brucella melitensis* and *Brucella abortus*. According to interviews with the laboratorians present during those 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: E7].

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

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

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

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

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

Observation: Based on documentation provided to the CDC Inspectors, PI Ficht sent an e-mail on April 21, 2006 to alternate Responsible Official Brent Mattox and alternate Responsible Official Angela Raines that notified them of occupational exposure.

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

Request for supplemental information: Please provide a summary of events that occurred when this email was received by the alternate Responsible Official who was acting on behalf of the Responsible Official including the follow up review that was conducted as a result of this e-mail report. Please also explain why the alternate Responsible Official who was acting on behalf of the Responsible Official did not follow the security protocols outlined in the “TAMU Facilities and Research Laboratories with Select Agents” security plan.
17. An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. [42 CFR §73.12]. An appropriate medical surveillance program is in place. All personnel receive appropriate immunizations or tests for the agents handled or potentially present. When appropriate, a serum surveillance system should be implemented. In general, persons who may be at increased risk of acquiring infection, or for whom infection might have serious consequences, are not allowed in the animal facility unless special procedures can eliminate the extra risk. Assessment should be made by the Occupational Health Physician [BMBL: A3].

Observation: On February 9, 2006, performed aerosolization experiments with *Brucella melitensis* and *Brucella abortus*. After completed the aerosolization experiments with *Brucella melitensis* and *Brucella abortus*, she cleaned the aerosolization chamber by wiping down the rear inside of the chamber with disinfectant. This cleaning technique caused hazardous exposure to either *Brucella melitensis* or *Brucella abortus*. Based on information provided by TAMU following her occupational exposure even though she informed PI Ficht on April 12, 2006 that she had been diagnosed with brucellosis.

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

18. Establish a protocol for intra-entity transfers under the supervision of an individual with access approval from the HHS Secretary or Administrator, including chain-of-custody documents and provisions for safeguarding against theft, loss, or release [42 CFR § 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 laboratory 1 located at located of located of since October of 2005, was completed in laboratory room 129 located in 1.

Request for supplemental information: Please provide the intra-entity transfer documentation that ensures that a security protocol was in place when these transfers occurred from laboratory room 120.

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

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

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