DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention (CDC)
Atlanta GA 30341-3724

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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

Dear Dr. Ewing:

On June 30, 2007, the Director of Centers for Disease Control and Prevention (CDC) notified Texas A&M University (TAMU) that in order to protect public health and safety, the April 20, 2007 cease and desist order from CDC to TAMU was being expanded to include all work with select agents and toxins at TAMU. This notification also informed TAMU that a comprehensive review of all select agent and toxin activities at TAMU was to be conducted.

During the period July 23, 2007 through July 27, 2007, the following representatives performed a comprehensive site review of TAMU, located at 1112 TAMU, College Station, TX 77843, to evaluate TAMU's compliance with the select agent regulations (42 CFR Part 73):

Robbin Weyant, Director, Division of Select Agents and Toxins (DSAT), CDC
Richard Henkel, Biosafety Manager, DSAT, CDC
Diane Martin, Senior Inspector, DSAT, CDC
Lori Bane, Compliance Officer, DSAT, CDC
James Blaine, Senior Inspector, DSAT, CDC
Marsha Ray, Senior Inspector, DSAT, CDC
Tracy Hewitt, Senior Inspector, DSAT, CDC
Yoon Miller, Senior Inspector, DSAT, CDC
Thomas Miller, Security Specialist, DSAT, CDC
Jeffery Sheppard, Senior Inspector, DSAT, CDC
Rob Marrero, Inspector, DSAT, CDC
Vondgurous McCloe, Inspector, DSAT, CDC
Roger Farmer, Senior Inspector, DSAT, CDC
Dwayne Lasky, Biosafety Officer, Office of Health & Safety, CDC
Mallory Tate, Attending Veterinarian, Division of Scientific Resources, CDC
Nate Powell, Chief of Animal Resources, Division of Scientific Resources, CDC
Eli Warnock, Medical Director, Occupational Health Clinics, CDC
James Holt, Senior Attorney, Office of General Counsel, HHS

Individuals from TAMU present during the introductory meeting held on July 23, 2007 included:

Eddie J. Davis, Interim President
Mike McKinney, Chancellor
Richard Ewing, Vice President (VP) of Research, Responsible Official
Angelia Raines, Director, Office of Research Compliance, Alternate Responsible Official

Fuller Bazer, Associate Vice President for Research, Alternate Responsible Official
Scott Kelly, Deputy General Counsel
Annette Wallis, Director of University Compliance
Vickie Sutton, Professor of Law for Texas Tech University
Chris Meyer, Asst. VP, Safety & Security
Brent Mattox, Biosafety Officer, Alternate Responsible Official
Charley Clark, Asst. Vice President
Vernon Tesh, Associate Professor, Principal Investigator
Thomas Ficht, Professor, Principal Investigator
John Saleman, Director, Environmental Health and Safety Department
Frank Stein, Director of the Veterinary Medical Park
Ellen Mitchell, Chief Security Analyst
Vincent Gresham, Facility Coordinator
Jim Joyce, Asst. VP for Research Administration and Graduate Studies
L.G. Adams, Associate Dean, Principal Investigator
David Carlson, VP for Research Administration and Graduate Studies
Jim Samuel, Professor of Microbial & Molecular Pathogenesis, Principal Investigator
Melanie Burig, Director, Comparative Medicine Program
Elizabeth Browder, Associate Director, Comparative Medicine Program
Elmer Schnieder, Jr., Chief of Police
Bert Kretzschmar, Assistant Chief of Police

Based on the comprehensive review of select agent and toxin activities at TAMU, the CDC has determined that the suspension of select agent and toxin work will remain in effect until the attached programmatic issues that were identified in the CDC review have been addressed. The summarized observations for the entity and the Principal Investigators are in Attachments 1 and 2.

DSAT acknowledges the efforts already undertaken by TAMU leadership to begin to remediate these deficiencies and will continue to provide technical assistance. Please provide written notification to this office after DSAT's concerns have been addressed. A DSAT inspector team will then be scheduled to conduct a verification site visit.

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, Senior 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 for Terrorism Preparedness and
Emergency Response

cc: Julie Gerberding, Director, CDC
Richard Besser, Director, Coordinating Office for Terrorism Preparedness and Emergency Response, CDC

Attachment 1: Below are summarized observations group by category that relate to entity-wide issues identified at TAMU. We have included the appropriate references from 42 CFR Part 73 and CDC/National Institutes of Health (NIH), *Biosafety in Microbiological and Biomedical Laboratories Manual* (BMBL) specifying each requirement.

Responsible Official (42 CFR § 73.9)

1. **Requirement:** *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: Information was provided to inspectors that the Responsible Official had failed to submit amendments and receive prior approval from DSAT for work being performed by TAMU Principal Investigators. In addition to the unapproved *Brucella* work cited in previous correspondence, Inspectors were informed that a researcher was performing restricted experiments with *Coxiella burnetii*. Specifically, Kasi Russell-Lodrigue indicated that aerosolization experiments with *Coxiella burnetii* had been performed on 5/28/03, 7/25/03, 8/4/03, 10/27/03, 11/10/03, 11/18/03, 1/5/04, 1/14/04, and 6/2/05, prior to the approval of this work by the DSAT on 10/2005. In addition, TAMU's approved certificate of registration includes a Principal Investigator (Tsolis) who is no longer employed by TAMU.

   Corrective action: The entity must keep accurate and current records and these records must accurately reflect what is on file with DSAT. In addition, TAMU must not perform select agent work that has not been approved by DSAT until TAMU submits an application to amend your certificate of registration for these additional activities has been approved by DSAT.

2. **Requirement:** ...*The Responsible Official must be familiar with the requirements and ensure compliance. [42 CFR § 73.9(a)]*

   Observation: The safety, security, and incident response plans reviewed by the Inspectors were draft documents. The plans did not contain a provision that they be reviewed annually and revised as necessary. Drills or exercises had not been conducted at least annually to test and evaluate the effectiveness of the plans as required by 42 CFR § 73.11(f), § 73.12(d), and § 73.14(d).

   Corrective action: The Responsible Official must ensure the development of safety, security, and incident response plans that meet the requirements outlined under 42 CFR § 73.11, § 73.12, and § 73.14. Specifically, the plans should contain a provision that at least annually the plans are reviewed and tested to evaluate the effectiveness of the plans. After the plans are developed, the plans should be tested to evaluate the effectiveness of the plans and training should be performed on the revised plans. DSAT will review these plans during the verification site visit.

3. **Requirement:** *The Responsible Official must ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used in order to determine compliance with the requirements of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected [42 CFR § 73.9(a)(5)].*

   Observation: There was no documentation that deficiencies identified during annual inspections conducted by the Institutional Biosafety Committee (IBC) were corrected. The IBC inspection reports

provided by the alternate Responsible Official for inspection conducted in 2007 indicated deficiencies, but no corrective actions to these deficiencies were provided. Inspectors noted that biosafety observations were not noted by the IBC such as the biosafety cabinet in Room which had a large crack in the front sash. This apparent biosafety concern was not noted on the IBC inspection report for this room provided by the alternate Responsible Official. Inspectors also noted that observations cited on previous inspections reported to be resolved by TAMU had not been resolved. For example, workers wore front-buttoned laboratory coats into suite , Building , contrary to the description in the laboratory's biosafety manual that "protective clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls must be worn." Prior to the 2007 IBC inspection dates, the laboratorians interviewed could not recall regular visits, or acknowledged "very rare visits" by the Responsible Official to the BSL-3 facility (Building room over the last year; and the majority of the interviewees could not recall the Responsible Official's or the Alternate Responsible Officials' names.

Corrective action: The Responsible Official must ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used in order to determine compliance with the requirements of the select agent regulations. The results of each inspection must be documented, any deficiencies identified during an inspection must be corrected, and these corrective actions should be documented.

4. **Requirement:** *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 [42 CFR § 73.13(a)].*

   Observation: During an interview by the Inspectors, Principal Investigator Samuel indicated that he was trying to establish recombinant DNA mutants of *Coxiella burnetii* using chloramphenicol, kanamycin, ampicillin, and rifampin antibiotic resistance markers. To date, these restricted experiments have not been approved by DSAT. TAMU must not perform restricted experiments that have not been approved by DSAT until TAMU receives approval from DSAT to perform restricted experiments.

   Corrective action: TAMU must not perform select agent work that has not been approved by the DSAT until TAMU submits an application to amend your certificate of registration for these additional activities has been approved by DSAT.

Biosafety (42 CFR § 73.12)

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: The biosafety manuals for Principal Investigators reviewed by Inspectors contained inadequate site-specific, agent-specific information. The plans did not consider the risk of the select agent or toxin or the research being performed on these agents.

   Corrective action: Develop and implement a biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use and meets all the required elements outline in 42 CFR § 73.12

6. **Requirement:** *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)]*

Observations: Upon review of medical records and access logs that were given to Inspectors, it was determined that individuals were granted access to the laboratories and the animal rooms without the proper medical entry requirements. It was also noted that there was no policy or procedure in place as recommended by the BMBL that states *"...only persons who have been advised of the potential biohazard, who meet any specific entry requirements (e.g., immunization), and who comply with all entry and exit procedures, enter the laboratory or animal rooms" [BMBL: B3, p.29].* In addition, most of the workers assigned to support the high containment labs were unaware of the potential hazards present in their work environment, methods for mitigating these hazards and available resources for protecting and monitoring their health. During the inspection, Inspectors were informed that a member of the support staff had entered the BSL3 laboratory wearing "some type of mask". The Inspectors were told that no fit testing or training had been provided to this employee. Based upon the description provided to the Inspectors, it was determined that the employee, who had a full beard, was wearing an N-95 respirator which is inconsistent with Occupational Safety and Health Administration's safety standards. Since an N-95 respirator would not have provided adequate protection for this worker, the employee should have been provided with the proper type of respiratory protection before entering a potential hazardous area and been appropriately trained to use the assigned respiratory protection.

During the inspection, there was no evidence of baseline serum being collected for all laboratory and other at-risk personnel as described in the medical surveillance plan and as recommended by the BMBL that states *"baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel" [BMBL: B6, p.29].* For example, the APHIS/CDC Form 3 which was faxed to DSAT on May 18, 2007 reported the elevated titer for Q-fever (1:1024) for an employee, but no baseline serum had been collected to determine when the titer developed. According to the Form 3, the Principal Investigator failed to follow his written protocol regarding baseline serum collection.

Based on interviews of laboratory staff, there was no effective medical surveillance program that was appropriate for work with select agents and toxins as recommended by the BMBL that states *"an appropriate medical surveillance program is in place" [BMBL: A3, p.62].* The Inspectors determined through interviews and provided documents that elevated serological titers for Q fever were reported for approximately 17% of personnel who had worked in laboratories or had been in laboratories where research with *Coxiella burnetii* had been conducted. For example, the *Coxiella burnetii* reportable titers for (1:64 phase I antigen and 1:1024 phase II antigen on 3/05), (< 1:64 phase I antigen and 1:1024 phase II antigen, 5/18/07) (<1:64 phase I antigen and 1:256 phase II antigen, 3/06), and (<1:64, phase I antigen and 1:512 phase II antigen, 6/16/05) were not investigated to determine if an occupational exposure had occurred. There was no evidence that a coordinated response or biosafety assessment was performed as a result of these elevated titers. In addition, there is no procedure in place to provide laboratory staff instructions on how to determine whether they should seek an evaluation by the Occupational Health provider or how they should obtain the evaluation. Inspectors noted inconsistencies in how Principal Investigators and laboratory workers were notified and responded to situations where the worker's titer was elevated.

The Madison Aerosol Chamber used for animal studies in Building opened directly into the research laboratory without any primary containment barriers. The BMBL states *"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" [BMBL: D11, p.35].*

Administrative controls in place to prevent workers from being exposed to biohazards were not adequate. Standard operating procedures were not available to address animal handling or maintenance procedures for laboratory workers using the Madison Aerosol Chamber. In addition, laboratory workers

did not know how to determine that the unit was functioning properly or what routine maintenance was required. The BMBL recommends that "*laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures*" *[BMBL. B8, p.30]*.

During the inspection of the large animal isolation buildings, the inspectors were told that the rooms were fumigated but the standard operating procedure was not provided for review. The Inspectors noted considerable dirt and debris in many of the buildings after fumigation. There was no documentation to support the use of quality controls during this process. DSAT inspectors were informed by support staff that they were unaware of the health hazards associated with formaldehyde, which is a common fumigant used by TAMU. According to TAMU support staff, the Principal Investigators conducting the experiments are responsible for decontamination of the suites. However, the animal care staff and the Building operator were not familiar with the process and no independent verification system is in place. The BMBL recommends that "*laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures*" *[BMBL: B8, p.30]*.

Inspectors had concerns about waste handling procedures at the Veterinary Medical Park. After euthanasia, large animals are sectioned, double bagged in plastic, sprayed with a disinfectant, and passed through a thirty inch square opening for transport by truck or front end loader to the incinerator located approximately one mile away at the College of Veterinary Medicine. The BMBL recommends that "*all wastes from the animal room must be autoclaved prior to incineration or other appropriate terminal treatment [BMBL: B3, p.65]*. In addition, there was no standard operating procedure available that specifies appropriate contact time for the disinfectant sprayed on the outside of the bagged waste prior to opening the outside door of the containment area and no procedures were in place to address potential spills that could occur during transport of waste. The BMBL recommends that "*all wastes from the animal room (including animal tissues, carcasses, contaminated bedding, unused feed, sharps, and other refuse animal tissues) are transported from the animal room in leak-proof, covered containers for appropriate disposal in compliance with applicable institutional or local requirements. Incineration is recommended. The outer surface of the containers is disinfected prior to moving the material*" *[BMBL: A6, p. 63]*.

Inspectors had concerns about the overall condition and age of the animal facilities at TAMU such as the physical facility conditions at Veterinary Medical Park and the limitations of decreased operational efficiency in Building The approximately twenty year old mechanical cage washer in Building currently supports four separate facilities. The increased requirement for clean cages and limited throughput capacity of the cage washer negatively impacts the animal care and use program. The cage washer also does not consistently reach the required 180° Fahrenheit temperature in the final rinse cycle as recommended by the BMBL, which states "*the mechanical cage washer has a final rinse temperature of at least 180F*" *[BMBL: D10, p. 68]*.

Inspectors have concerns regarding the difficulty in maintaining relative air pressures in the containment suite in Building In order to maintain negative air pressures in animal and laboratory areas and not over-ride the automatic door closure and latching mechanisms, the air balance required frequent adjustment and support from the physical facility staff. The BMBL recommends "a ducted exhaust air ventilation system is provided; this system creates directional airflow which draws air into the laboratory from 'clean' areas and toward 'contaminated' areas; and the exhaust air is not recirculated to any other area of the building" *[BMBL: D9, p.34]*.

Corrective action: Develop and implement operational and procedural safeguards sufficient to contain the select agent or toxin as required by 42 CFR § 73.12(b) by developing policies and procedures as recommended by the BMBL.

Security (42 CFR § 73.11)

7. **Requirement:** *The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use [42 CFR § 73.11 (b)].*

   Observation: There was no documentation that the security plan had been designed according to a site-specific security risk assessment. In addition, security plans did not adequately address procedures for moving select agents and toxins from one building to another. For example, a security risk assessment should be conducted and appropriate procedures developed and implemented for the transportation of select agents between laboratories in Building through the the .

   Corrective action: Develop and implement a security plan according to site-specific risk assessment and risk of the select agent and toxin, given its intended use.

8. **Requirement:** *... allow access only to individuals with access approval from the HHS Secretary or Administrator [42 CFR § 73.11(d)(1)].*

   Observation: At the time of the inspection, Inspectors confirmed at least 7 times where unauthorized access to select agents was allowed by TAMU. Specifically, Chen Chen told Inspectors that he had entered the BSL3 specifically room on three occasions to filter or centrifuge sera from animals infected with *Coxiella burnetii*. Using access records, the Inspectors confirmed that Chen had entered on 11/15/06, 11/22/06, 12/13/06, and 6/07. Chen was not approved to have access to select agents until 1/11/07. On 7/26/07, Inspectors reviewed the notebook of Kasi Russell-Lodrigue and determined that she had conducted aerosolization experiments with *Coxiella burnetii* on 5/28/03, 7/25/03, 8/4/03, and subsequent dates. She was not approved to have access to selects agents until 10/2/03. The electronic access logs reviewed by Inspectors noted individuals who have not received access approval had entered into registered rooms. The TAMU security plan also does not contain adequate procedures for the control of access to select agents and toxins. For example, laboratory workers informed Inspectors that they use keys to access laboratories; however, the security plan does not contain provisions for the management of laboratory keys to ensure only authorized access to select agents and toxins. In addition, TAMU does not appear to have an administrative plan in place to review access logs on an ongoing basis for errors or unauthorized entry.

   Corrective action: The entity must not allow unauthorized access to select agents. In addition, the security plan must be sufficient to safeguard the select agent against unauthorized access and meets all the requirements as outlined in 42 CFR § 73.11.

Training (42 CFR § 73.15)

9. **Requirement:** *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. Refresher training must be provided annually. A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training [42 CFR § 73.15].

Observation: Training records were not provided to inspectors for individuals approved to perform select agent activities supervised by Principal Investigators. In addition, there was no documentation provided that a formal training program had been established for all personnel that work in laboratories supervised by Principal Investigators. Based on interviews, new personnel are expected to read the required plans and standard operating procedures before working in laboratories supervised by the Principal Investigators and are expected to observe a procedure conducted by a more experienced individual prior to performing the procedure under their guidance. The provided training also did not address the particular needs of the individual, the work they will do, and the risks posed by select agents and toxins. For example, inspectors observed safety lapses indicative of an ineffective training program. Laboratory workers were observed entering the laboratories wearing inappropriate personal protective equipment (PPE) and wearing lab coats outside the laboratories, contrary to the description in the site-specific biosafety manual and recommended guidelines described in the BMBL. It was also determined that annual refresher training was not being performed annually.

Corrective action: Provide training as required by 42 CFR § 73.15 that addresses the particular needs of the individual, the work they will do, and the risk posed by the select agents and toxins. The training must be provided to all individuals that are approved to perform select agent activities in the laboratories supervised by the Principal Investigators and those individuals who visit or work in these laboratories. A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training. This training must occur on an annual basis.

Records (42 CFR § 73.17)

10. **Requirement:** ... *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 registered laboratory rooms such as '

    Corrective action: Records must be kept for all entries into areas containing select agents and toxins.

11. **Requirement:** ... *A current list of all individuals that have been granted access approval from the HHS Secretary or Administrator [42 CFR § 73.17(a)(3)].*

    Observation: The TAMU's approved certificate of registration did not match the list of individuals provided by the Principal Investigators.

    Corrective action: The entity must keep accurate and current records and these records must accurately reflect what is on file with DSAT.

12. **Requirement:** *The individual or entity must implement a system to ensure that all records and data bases created under this part are accurate, have controlled access, and that their authenticity may be verified [42 CFR § 73.17(b)].*

Observation: The Inspectors noted that the institutional inventory oversight for select agent materials was inadequate. Inventory discrepancies were noted between the inventory records and actual inventory. Inspectors noted that three vials containing a select agent for one Principal Investigator were missing and additional vials not accounted for in the inventory records of another Principal Investigator. Three of the four Principal Investigators had poorly organized inventory records that made inventory reconciliation difficult and cumbersome.

Corrective action: The entity must keep accurate and current records and these records must accurately reflect what is on file with DSAT. In addition, the entity must implement a system to ensure that all records and data bases are accurate, have controlled access, and that their authenticity has been verified.

Attachment 2: Below are summarized observations group by category that relate to Principal Investigators at TAMU. We have included the appropriate references from 42 CFR Part 73 and CDC/ NIH, *Biosafety in Microbiological and Biomedical Laboratories Manual* (BMBL) specifying each requirement.

A. Dr. Garry Adams

Biosafety (42 CFR § 73.12)

1. **Requirement:** *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)]*

   Observations: Upon review of medical records and access logs that were given to Inspectors, it was determined that individuals were granted access to the laboratories and the animal rooms without the proper medical entry requirements. In addition, it was noted that there was no policy or procedure in place as recommended by the BMBL that states "*...only persons who have been advised of the potential biohazard, who meet any specific entry requirements (e.g., immunization), and who comply with all entry and exit procedures, enter the laboratory or animal rooms" [BMBL: B3, p.29].*

   There was no documentation that personnel who worked with *Brucella abortus, Brucella melitensis, and Brucella suis* received the appropriate serological testing as described in the medical surveillance plan and as recommended by the BMBL that states *"laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled" [BMBL: B5, p.29].*

   During the inspection, there was no evidence of baseline serum being collected for all laboratory and other at-risk personnel as described in the medical surveillance plan and as recommended by the BMBL that states *"baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel" [BMBL: B6, p.29].*

   Based on interviews of laboratory staff, there was no effective medical surveillance program that was appropriate for animal work with *Brucella abortus, Brucella melitensis, and Brucella suis* as recommended by the BMBL that states *"An appropriate medical surveillance program is in place" [BMBL: A3, p.62].*

   Corrective action: Develop and implement operational and procedural safeguards sufficient to contain the select agent or toxin as required by 42 CFR § 73.12(b) by developing policies and procedures as recommended by the BMBL that include only persons who have been advised of the potential biohazard, who meet any specific entry requirements (e.g., immunization), and who comply with all entry and exit procedures, enter the laboratory or animal rooms. These specific entry requirements may include immunizations, baseline serum collection, and periodic testing of serum samples. In addition, these policies and procedures should include an appropriate medical surveillance program that is in place and the assessment of the program should be made by the Occupational Health Physician.

Security (42 CFR § 73.11)

2. **Requirements:** ... *allow access only to individuals with access approval from the HHS Secretary or Administrator [42 CFR § 73.11(d)(1)]. 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 § 73.11(f)].*

   Observations: The electronic access logs reviewed by Inspectors for Building noted individuals who have not received access approval had entered into registered laboratory rooms.

   Based on the review of the security plan dated July 23, 2007, the Inspectors noted that the plan did not indicate an annual review must be performed. In addition, it was determined that no drills or exercises had been conducted to evaluate the effectiveness of the plans for 2005, 2006, and 2007.

   Corrective action: Develop and implement a security plan that meets the requirements outlined under 42 CFR § 73.11. Specifically, the plan is sufficient to safeguard the select agent against unauthorized access and contains a provision that at least annually the plan is reviewed and tested to evaluate the effectiveness of the plan. After the plan is developed, the plan should be tested to evaluate the effectiveness of the plan.

Incident Response (42 CFR § 73.14)

3. **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: Based on the review of the incident response plan, the Inspectors noted that the plan did not indicate an annual review must be performed. In addition, it was determined that no drills or exercises had been conducted to evaluate the effectiveness of the plans for 2005, 2006, and 2007.

   Corrective action: Develop and implement an incident response plan that meets the requirements outlined under 42 CFR § 73.14. Specifically, ensure the plan contains a provision that it is to be reviewed at least annually and tested to evaluate its effectiveness. After the plan is developed, the plan should be tested and evaluated for effectiveness.

Training (42 CFR § 73.15)

4. **Requirement:** *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. Refresher training must be provided annually. A record of the training provided to each individual must be maintained. The record must include the name of the*

individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training [42 CFR § 73.15].

Observations: The Principal Investigator could not provide documentation that each individual approved to perform select agent activities in Dr. Garry Adams' laboratory had received training as required by 42 CFR § 73.15.

The Inspectors were informed that a surgical mask, N-95, or Powered Air Purifying Respirator (PAPR) was used as respiratory protection while conducting animal experiments. However, the Principal Investigator could not provide documentation of fit testing for N-95 respirators or documentation of training for the proper use of a PAPR.

The training that was provided did not address the particular needs of the individual, the work they will do, and the risks posed by *Brucella abortus, Brucella melitensis, and Brucella suis.*

The Principal Investigator could not provide documentation that any training had occurred in 2006.

Corrective action: Provide training as required by 42 CFR § 73.15 that addresses the particular needs of the individual, the work they will do, and the risk posed by *Brucella abortus, Brucella melitensis, and Brucella suis*. The training must be provided to all individuals that are approved to perform select agent activities in Dr. Adams' laboratory and those individuals who visit or work in Dr. Adams' laboratory. A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training. This training must occur on an annual basis.

Records (42 CFR § 73.17)

5. **Requirement:** ... *Accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials) [42 CFR § 73.17(a)(1)].*

   Observation: The documents presented consisted of an inventory check log, a log containing an inventory maintained by individual staff employees, and a log maintained by a graduate student. All logs were poorly kept and organized. The inventory check log consisted simply of a date and initials with no instructions or statements as to what should have been done, or what had been done, in terms of validating the inventory. The Inspectors spent a considerable amount of time to determine the tracking and accounting of selected *Brucella* isolates. While the appropriate information was present for the inventory tracking and disposition of the agents, it is not organized well.

   Corrective action: Records must be maintained that meet the requirements outlined in 42 CFR § 73.17(a)(1). Consideration should be given towards consolidation of the inventory into one log book under the control of Principal Investigator.

6. **Requirement:** ... *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 rooms and located in Building

Corrective action: Records must be kept for all entries into areas containing select agents and toxins.

7. **Requirement:** ... *A current list of all individuals that have been granted access approval from the HHS Secretary or Administrator [42 CFR § 73.17(a)(3)].*

Observation: The TAMU's approved certificate of registration listed individuals that were no longer employed by TAMU such as Josely Figueiredo, Paul Patrancila, Carlos Rossetti, and Forest Thompson.

Corrective action: The entity must keep accurate and current records and these records must accurately reflect what is on file with DSAT.

B. Dr. James Samuel

* *The indicated observations were also cited in the DSAT inspection report of February 2006.*

Security (42 CFR § 73.11)

1. **Requirements:** ... *allow access only to individuals with access approval from the HHS Secretary or Administrator [42 CFR § 73.11(d)(1)].* ... *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 §73.11(d)(5)].*

Observations: At the time of the inspection, Inspectors confirmed at least 7 times where unauthorized access to select agents was allowed by TAMU. Specifically, Chen Chen told Inspectors during an interview conducted on 7/24/07 that he had entered the BSL3 suite specifically room Building , on three occasions to filter or centrifuge sera from animals infected with *Coxiella burnetii*. Using access records, the Inspectors confirmed that Chen had entered suite on 11/15/06, 11/22/06, 12/13/06, and 6/07. Chen was not approved to have access to select agents until 1/11/07. On 7/26/07, the Inspectors reviewed the notebook of Kari Russell-Lodrigue and determined that she had conducted aerosolization experiments with *Coxiella burnetii* on 5/28/03, 7/25/03, 8/4/03, and subsequent dates. She was not approved to have access to selects agents until 10/2/03.

At the time of the inspection, there was no documentation of an intra-entity transfer that occurred between Principal Investigator Samuel and Principal Investigator Tsolis for *Brucella abortus, B. melitensis*, and *B. suis* strains. Inspectors were shown an e-mail trail (dated from 7/13/05 to 7/24/07) indicating that Principal Investigator Samuel had taken possession of Principal Investigator Tsolis' select agents. The security plan for Principal Investigator Samuel included procedures and a template for intra-facility transfers, but the procedures had not been followed, and the template had not been used. In addition, there were no intra-agency transfer documents located for this intra-entity transfer as required in Records Section (42 CFR 73.17 (a)(1)(vii)).

Corrective action: The entity must not allow unauthorized access to select agents, and develop a security plan that must be sufficient to safeguard the select agent against unauthorized access and meets all the requirements outline in 42 CFR § 73.11 including following established protocols for intra-entity transfers.

Biosafety (42 CFR § 73.12)

2. **Requirements:** *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)]. 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)]*

Observations: At the time of the inspection, the biosafety manual presented to Inspectors for Principal Investigator Samuel contained inadequate site-specific, agent-specific information for *Coxiella burnetii* work at BSL3; there was no agent specific information for the other registered select agents: *Brucella abortus, B. melitensis, B. suis, and Rickettsia prowazekii.* The standard microbiological practices, as outlined in BMBL were included in the training booklet, but these practices were neither included nor referenced in the biosafety plan.

Based upon a review of the safety practices as described by the laboratory workers, the Inspectors noted that the biosafety procedures used in suite / Building are not sufficient to contain the select agents. Specifically, information derived from laboratorian interviews revealed that the procedures employed during *Coxiella* aerosolization experiments in the animal facility did not employ primary containment barriers. Although present practices designate the use of PPE, past history has demonstrated that the risk of exposure is still sufficiently high to warrant the use of primary containment barriers during the aerosolization experiments in question, and also during subsequent decontamination of all equipment employed in said experiments.

Inspectors noted inconsistencies in the posting of spill procedures in BSL3 suite as recommended by the BMBL and those described in the biosafety manual. Interviews with laboratory workers determined that there were considerable differences in their descriptions of how to clean up spills.

There was no hands-free sink located in laboratory rooms and , Building as recommended by the BMBL that states "*the sink is hands-free or automatically operated and is located near the room exit door*" *[BMBL: D2, p. 33]*. Subsequently, hand-washing was performed in the adjacent BSL-2 lab in room which contradicts the recommendation provided by the BMBL that states "*persons wash their hands after handling infectious materials, after removing gloves, and when they leave the laboratory*" *[BMBL:A2, p. 27]*.

During the inspection, there was no evidence of baseline serum being collected for all laboratory and other at-risk personnel as described in the medical surveillance plan and as recommended by the BMBL that states "*baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel*" *[BMBL: B6, p.29]*. At the time of the inspection, Sections 8.5 and 8.6 of the biosafety plan for Principal Investigator Samuel contained a description of his Occupational Health Plan. The plan stated that "a serologic sample will be taken prior to work with virulent *C. burnetii* as a baseline sample," yet Chen Chen had worked in on three occasions (11/15/06, 11/22/06, and 12/13/06) before a "baseline serum sample" was drawn on 5/18/07. The plan stated that "personnel will be advised of the opportunity to consult with Scott and White clinicians about the relationship between serological titer, clinical disease, and treatment options." There were signed statements to indicate that this policy had been adhered to for K. Mertens, J. Samuel, and D. Rattanasavanh, but there was no documentation of follow-up for and who also had reportable titers. Per interview with Principal Investigator Samuel and his staff, oversight of the Occupational Health Plan was the

responsibility of the Principal Investigator, and there was a lack of any additional oversight by the entity. In addition, Inspectors did not see any evidence of an entity-wide Occupational Health Plan.

*At the time of the inspection, workers were front-buttoned laboratory coats into suite / Building , contrary to the description in the biosafety manual that "protective clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls must be worn in" and the recommendation outlined in the BMBL which states *"Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls are worn by workers when in the laboratory" [BMBL: CI, p.32]*. In addition, Principal Investigator Samuel and Eunhee Lee at the time of the inspection removed their PPE in (anteroom) and returned to / (lab room) and Inspectors were told that workers don their PPE in the anteroom, but the laboratory coats were located in room which contradicts the Corrective action by the BMBL which states *"Protective clothing is not worn outside the laboratory" [BMBL: CI, p.32]*.

Centrifuge safety cups were used in room / but during the interviews conducted, the Inspectors were informed by two laboratory workers that they did not load and unload select agents for centrifugation under a biosafety cabinet. The biosafety manual also did not detail the proper procedures for centrifuge use. In addition, there was a centrifuge in room that did not appear to have any aerosol-retardant equipment. The BMBL recommends that *"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 (e.g., centrifuge safety cups or sealed rotors) are used" [BMBL: C5, p.33]*.

Corrective action: Develop and implement operational and procedural safeguards sufficient to contain the select agent or toxin as required by 42 CFR § 73.12(b) by developing policies and procedures as recommended by the BMBL. The plan should include provisions that only persons who have been advised of the potential biohazard, who meet any specific entry requirements (e.g., immunization), and who comply with all entry and exit procedures, enter the laboratory or animal rooms. These specific entry requirements may be immunizations, baseline serum, and periodic testing of serum samples. In additional, these policies and procedures should include an appropriate medical surveillance program that is in place and the assessment of the program should be made by the Occupational Health Physician.

Records (42 CFR § 73.17)

3. **Requirement:** *... Accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials) [42 CFR § 73.17(a)(1)].*

Observations: At the time of the inspection of the select agent inventory maintained in room located in Building it was discovered that three (3) vials of select agent strains of *Brucella abortus*, attributed to the strain collection of a former TAMU researcher, Renee Tsolis, were missing. The vials were documented as stored in box "2F", and were subsequently identified by Principal Investigator Samuel as having the following descriptors: "WT+ II0681/FT", "Mut+ FC/A0598 11/12/04" and "8 combination 5/13/05". On July 31, 2007, TAMU faxed DSAT a Form 3 that reported 3 vials of *Brucella abortus* were unaccounted for during an inventory check at the time of the inspection.

Upon review of the Tsolis' inventory, the Inspectors noted the inventory records did not meet all requirements with respect to the Records Section (42 CFR § 73.17).

Corrective action: Records must be maintained that meet the requirements outlined in 42 CFR § 73.17.

4. **Requirement:** ... *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 rooms .

Corrective action: Records must be kept for all entries into areas containing select agents and toxins.

5. **Requirement:** ... *Accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials) [42 CFR § 73.17(a)(1)].*

***Observation:** The select agent inventory record keeping procedure was found to be cumbersome to use; requiring the use of a hand-written "Agent Access Log" in conjunction with a computer-generated inventory spreadsheet, periodically updated to reflect the activity recorded on the Agent Access Log. The spreadsheet inventory – intended to be a "snapshot" of the state of the inventory since the last date of reconciliation with the Agent Access Log – did not contain sufficient information to definitively determine sources, quantities initially acquired, and current volumes of select agent strains in storage. Further, the hard copies of the inventory sheets and respective access logs must be maintained together, in order to update and verify the running inventory information. There was no easily discernible cross referencing information contained on either of the related documents; thus making it difficult, if not impossible, to identify and cross reference the inventory information, should the sheets become separated.

During the last inspection conducted February, 2007, it was noted that "there was improper use of the agent access log; entries were not complete and there were many inconsistencies." The Inspectors noted that there were still differences amongst the staff in how the inventory was tracked. One of employees indicated that she only entered information on the inventory tracking sheets when the vial was depleted, not "when moved from storage and by whom and when returned to storage and by whom" as required by 42 CFR § 73.17 (a)(1)(iv).

Corrective action: Records must be maintained that meet the requirements outlined in 42 CFR § 73.17.

Training (42 CFR § 73.15)

6. **Requirement:** *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. Refresher training must be provided annually. A record of*

the training provided to each individual must be maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training [42 CFR § 73.15].

Observations: Interviews of the staff under Principal Investigator Samuel and review of training records indicated the following: (1) There were inconsistencies in how employees described how to clean up spills inside and outside the biosafety cabinet. (2) There were inconsistencies in how staff exited the BSL3 suite. (3) There were inconsistencies in how staff loaded and unloaded the centrifuge. (4) There were inconsistencies in how staff tracked inventory. (5) Staff generally did not know who the Responsible Official (RO) and Alternate Responsible Officials were, let alone the reporting requirements to the RO under § 73.11. In fact, the training conducted on 6/1/07 by the university did not instruct employees to notify the RO during a theft, loss, or release. (6) Staff was trained on the hazards of *Coxiella burnetii*, and to a lesser extent on those of *Rickettsia prowazekii*. There was no evidence of any training on the hazards of *Brucella abortus, B. melitensis, and B. suis*. (7) Visitor training covered the hazards of *Coxiella burnetii, Brucella abortus, B. melitensis, and B. suis*, but not those for *Rickettsia prowazekii*. (8) Training on the use of the aerosolization chamber was minimal, and included a one-time "show and tell" exercise. In sum, the training was provided, but it did not sufficiently address the particular needs of the individual, the work they will do, and all of the risks posed by the select agents.

The biosafety manual described the use of a "mask," but Inspectors were told that workers wore an N-95 respirator. Fit testing had recently been conducted for the laboratory staff which work under Principal Investigator Samuel, but three individuals had failed the test (L. Hendris, N. Unsworth, and E. Lee). Principal Investigator Samuel failed to follow-up with retesting these individuals or other documented corrective actions. In addition, the Principal Investigator could not provide documentation of training for the proper use of a PAPR.

Provide training as required by 42 CFR § 73.15 that addresses the particular needs of the individual, the work they will do, and the risk posed by the select agents. The training must be provided to all individuals that are approved to perform select agent activities in Dr. Samuel's laboratory and those individuals who visit or work in Dr. Samuel's laboratory. A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training. This training must occur on an annual basis.

Corrective action: Provide training as required by 42 CFR § 73.15 that addresses the particular needs of the individual, the work they will do, and the risk posed by the select agents. The training must be provided to all individuals that are approved to perform select agent activities in Dr. Samuel's laboratory and those individuals who visit or work in Dr. Samuel's laboratory. A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training. This training must occur on an annual basis.

Incident Response (42 CFR § 73.14)

7. **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 incident response plan presented to Inspectors was a draft document.

Corrective action: Develop and implement an incident response plan that meets the requirements outlined under 42 CFR § 73.14. Specifically, ensure the plan contains a provision that states it is to be reviewed at least annually and tested to evaluate its effectiveness. After the plan is developed, the plan should be tested to evaluate its effectiveness.

C. Dr. Vernon Tesh

Biosafety (42 CFR § 73.12)

1. **Requirement:** *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)]*

Observations: At the time of inspection, the Inspectors observed a large crack in the sash of the biological safety cabinet in Room . Since it was not determined when this crack had occurred and whether the biological safety cabinet was verified with this crack during the cabinet's last certification on January, 19, 2007, the Inspectors determined that this biological safety cabinet is not being properly maintained as recommended by the BMBL.

At the time of inspection, laboratory personnel were observed walking in and out of laboratory rooms and while not wearing laboratory coats. Wearing laboratory coats is listed as an entry requirement to these laboratory rooms and is recommended by the BMBL which states "*protective laboratory coats, gowns, smocks, or uniforms designated for lab use are worn while in the laboratory.*"

At the time of inspection, no documentation was provided that autoclaves handling select agents and toxins were maintained on a regular bi-weekly basis as described in the laboratory's standard operating procedure. The BMBL recommends that *all cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving [BMBL. A8, p. 21; appendix G].*

Corrective action: Develop and implement operational and procedural safeguards sufficient to contain the select agent or toxin as required by 42 CFR § 73.12(b) by developing policies and procedures as recommended by the BMBL.

Training (42 CFR § 73.15)

2. **Requirement:** ... *Refresher training must be provided annually. A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training [42 CFR § 73.15].*

Observation: There was no documentation for all authorized individuals working in the laboratories supervised by Principal Investigator Tesh that annual refresher training was being performed.

Corrective action: Provide training as required by 42 CFR § 73.15 including a record of the training provided to each individual must be maintained. The record must include the name of the individual, the

date of the training, a description of the training provided, and the means used to verify that the employee understood the training. This training must occur on an annual basis.

Records (42 CFR § 73.17)

3. **Requirement:** *... Accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials) [42 CFR § 73.17(a)(1)].*

Observation: Inventory records for Principal Investigator Tesh did not include all the elements required in 42 CFR § 73.17. Specifically, the records did not include the initial quantity acquired, the date of acquisition, storage location and freezer number. In addition, there was no provision regarding inventory records are to be maintained for a minimum of three years.

Corrective action: Records must be maintained that meet the requirements outlined in 42 CFR § 73.17.

D. Dr. Thomas Ficht

Biosafety (42 CFR § 73.12)

1. **Requirement:** *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)]*

Observations: According to Dr. Ficht, extracted DNA is not moved from the BSL-3 area to the BSL-2 laboratory until it is checked for sterility. However, there was no protocol provided that describes this process. The "NIH Guidelines for Research Involving Recombinant DNA Molecules" states that *if experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiringBSL-3 level physical containment, they shall be conducted in accordance with all BSL-3 level laboratory practices [NIH: G-II: C-1-h].*

Upon review of medical records and access logs that were given to Inspectors, it was determined that individuals were granted access to the laboratories and the animal rooms without the proper medical entry requirements. In addition, it was noted that there was no policy or procedure in place as recommended by the BMBL that states *"...only persons who have been advised of the potential biohazard, who meet any specific entry requirements (e.g., immunization), and who comply with all entry and exit procedures, enter the laboratory or animal rooms" [BMBL: B3, p.29].*

There was no documentation that personnel that worked with *Brucella abortus, Brucella melitensis, and Brucella suis* received the appropriate serological testing as described in the medical surveillance plan and as recommended by the BMBL that states *"laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled" [BMBL: B5, p.29].*

During the inspection, there was no evidence of baseline serum being collected for all laboratory and other at-risk personnel as described in the medical surveillance plan and as recommended by the BMBL

that states *"baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel" [BMBL: B6, p.29].*

Based on interviews of laboratory staff, there was no effective medical surveillance program that was appropriate for work with *Brucella abortus, Brucella melitensis, and Brucella suis* as recommended by the BMBL that states *"An appropriate medical surveillance program is in place" [BMBL: A3, p.62].*

Corrective action: Develop and implement operational and procedural safeguards sufficient to contain the select agent or toxin as required by 42 CFR § 73.12(b) by developing policies and procedures as recommended by the BMBL that include only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures, enter the laboratory or animal rooms. These specific entry requirements may be immunizations, baseline serum collection, and periodic testing of serum samples. In additional, these policies and procedures should include an appropriate medical surveillance program that is in place and the assessment of the program should be made by the Occupational Health Physician.

Incident Response (42 CFR § 73.14)

2. **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: There was no documentation provided to Inspectors that incident response drill or exercise had been conducted at least annually to test and evaluate the effectiveness of the plan.

   Corrective action: Develop and implement an incident response plan that meets the requirements outlined under 42 CFR § 73.14. Specifically, the plan contains a provision that it is reviewed at least annually and reviewed and tested to evaluate its effectiveness. After the plan is developed, it should be tested to evaluate its effectiveness.

Training (42 CFR § 73.15)

3. **Requirement:** *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. Refresher training must be provided annually. A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training [42 CFR § 73.15].*

   Observation: There was no documentation provided that a formal training program had been established for all personnel that work in laboratories supervised by Dr. Ficht. Specifically, new personnel are expected to read the safety plan and standard operating procedures before working in laboratories supervised by Dr. Ficht and are expected to observe a procedure conducted by a more

experienced individual prior to performing the procedure under their guidance. This process is not documented and records are not kept of this training.

Corrective action: Provide training as required by 42 CFR § 73.15 that addresses the particular needs of the individual, the work they will do, and the risk posed by the select agents. The training must be provided to all individuals that are approved to perform select agent activities in Dr. Ficht's laboratory and those individuals who visit or work in Dr. Ficht's laboratory. A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training. This training must occur on an annual basis.

Records (42 CFR § 73.17)

4. **Requirement:** ... *Accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials) [42 CFR § 73.17(a)(1)].*

   Observation: Inventory records for Principal Investigator Ficht did not include all the elements required in 42 CFR § 73.17. Specifically, the records did not include the initial quantity acquired, the date of acquisition, source, select agent used, and the purpose of the use. In addition, there was no provision regarding inventory records are to be maintained for a minimum of three years.

   Corrective action: Records must be maintained that meet the requirements outlined in 42 CFR § 73.17.

5. **Requirement:** ... *A current list of all individuals that have been granted access approval from the HHS Secretary or Administrator [42 CFR § 73.17(a)(3)].*

   Observation: The TAMU's approved certificate of registration did not match the list of individuals provided by Dr. Ficht.

   Corrective action: The entity must keep accurate and current records and these records must accurately reflect what is on file with DSAT.