



## TEXAS A&M UNIVERSITY

1246 TAMU  
College Station, Texas 77843-1246  
(979) 845-2217 FAX (979) 845-5027  
E-Mail: PRESIDENT@TAMU.EDU

August 17, 2007

Office of the President  
Eddie J. Davis

Mr. John W. O'Brien  
Senior Counsel  
Office of Inspector General  
JFK Federal Building, Room 2225  
15 New Sudbury Street  
Boston, MA 02203

Dear Mr. O'Brien:

This letter responds to your correspondence of July 18, 2007 and your inspection here at Texas A&M University (TAMU) on July 23-24, 2007 as well as the CDC site inspections of April 16-18, 2007 and July 23-27, 2007. While we have received the CDC report from the April 16-18, 2007 visit to which you verbally asked us to respond on your July visit, we have not yet received the CDC report of findings on the July 23-27, 2007 visit. Without the benefit of this much more lengthy inspection report, and in light of the verbal caveat from you to us during your visit that further matters from that report might yet be referred to you for investigation, we are at a disadvantage in being able to respond fully to your opportunity to propose a settlement letter by your deadline of August 18, 2007. However, we do believe that it is in the best interest of both TAMU and the government to pursue settlement, rather than for you to initiate formal administrative proceedings. We hope that this letter will move us toward such a settlement.

This letter includes our responses to the preliminary violations reported to you by CDC and identified in the body of your letter dated July 18, 2007 incorporating the supporting facts and observations in the CDC report dated May 4, 2007. Although we admit to several of the possible violations investigated during your visit, we have included supporting facts and information provided by the interviews as well as other documentation we believe serve to mitigate, reduce or eliminate other possible violations investigated during your visit. Each of the specific regulatory sections which are indicated in your letter is addressed below:

- 42 CFR 73.7(h)(1). Although TAMU provided amendments to the Certificate of Registration during the application process for becoming a registered facility, TAMU admits that it has failed thereafter to consistently provide amendments to the Certificate of Registration when changes were made.

- 42 CFR 73.9(a). TAMU's Responsible Official ("RO") met the requirements of this section for parts (1)-(4), but not part (5), if read narrowly. This section requires that "annual inspections are conducted for each laboratory where select agents or toxins are stored. . . .[and] the results of each inspection must be documented , and any deficiencies identified during an inspection must be corrected."

The regulation does not require self-inspections; nor does it preclude those annual inspections from being performed by CDC. If this regulation is read more broadly than the reading given to it in your preliminary violations, to include those inspections conducted by CDC on an annual basis and documented and reviewed for deficiencies within the scope of the rule, then the RO also complied fully with part (5). CDC inspections of TAMU occurred on an annual basis on these dates: January 21-23, 2004; February 15-18, 2005; February 22-24, 2006; and April 16-18, 2007.

In response to the reports from those inspections, the RO sought to correct deficiencies and reported those to the CDC in multiple follow up letters following each inspection. These acts to correct these deficiencies were undertaken in good faith and were represented to CDC in good faith, regardless of the quality or to the extent that these deficiencies were ultimately found to be corrected.

- 42 CFR 73.10(a). Individuals involved in the *brucella* aerosolization experiment which resulted in the infection of one of the individuals in the room, upon investigation, were found to all have security risk assessments with the exception of the individual who was infected. The individual who was infected and did not have an SRA clearance was not knowingly given, provided or allowed to have access --- incontrovertible facts, gathered by the OIG team during the July 23-24, 2007. The weight of the facts gathered in the interviews conducted on July 23-24, 2007 indicate that at no time did the individual have the opportunity to hold, use or manipulate the select agent.

Only an impermissibly broad reading of the rule would sweep in these facts, also analogous to such activities as, for example, a vial of a select agent being otherwise legally shipped on a truck, which is inadvertently dropped on the road in an accident, breaks, and rescue and recovery workers are given "access" when they become accidentally and inadvertently infected.

- 42 CFR 73.10(c). We admit that specifically, the individual who was infected with the select agent did not have the appropriate training required under this section which states that "[E]ach 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."

However, the individual did have the appropriate education and experience. The appropriate education, a PhD in Microbiology and significant Post-Doctoral experience in working with infectious agents is appropriate education and experience. If the individual had been working with the appropriate PPE and biological safety precautions appropriate for the aerosolization of tuberculosis, in that individual's experience; then that training and experience would be appropriate to work with *brucella*, the subject select agent.

It was not a failure to properly prepare the individual in education and experience for working with the select agent, but rather a serious deficit in her prior education and experience in a similar working environment, none of which is regulated by CDC under this section, which should have provided exactly the right quality and quantity of education and experience for working with *brucella*.

TAMU had no reason to believe from the record that the individual did not have the appropriate education and experience, and while TAMU admits the individual did not receive the "appropriate . . . training. . . to handle or use such agents", this does not constitute a violation of the section because either education, training "and/or" experience is required by the rule. This individual decidedly has both the education and experience, though flawed, but not the quality of appropriate training; but that is all that the rule requires.

- 42 CFR 73.11(d)(1) and (d)(7)(iv). The first part of this preliminary violation description, indicates that security requirements were not met, regarding access of the individual who was involved with the experiment; however, the facts in the above section which addresses preliminary violations of 42 CFR 73.10(a) also disputes that this individual was not following the security plan.

TAMU admits the second part of this preliminary violation of 42 CFR 73.11(d)(7)(iv), failure to report "any release of a select agent". The violation occurred when the appropriate and timely report of the *brucella* infection was not made to CDC after discovering the infection of the individual. However, the report of the *brucella* infection was made fully in accordance with state law through the Texas Department of Health.

These reports of reportable diseases, such as *brucella*, are sent from the state to CDC, and TAMU has no reason to believe that CDC did not receive this report or have knowledge of the *brucella* infection of this specific individual through this reporting mechanism. In fact, it is of some concern that select agent infection reports made to one part of CDC are not shared with another part of CDC as a matter of public health, safety and public policy.

- 42 CFR 73.12(a). The interview of Dr. Ficht indicates that there was a “written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use,” specifically for the aerosolization of *brucella* utilizing the Madison Chamber. The discovery of the infection led to the modification of the biosafety plan by requiring further disinfection of the Madison Chamber and additional PPE. Dr. McMurray, the investigator responsible for the operation of the Madison Chamber, had not required nor recommended these additional disinfection measures or additional PPE as “commensurate with the risk.”

TAMU reasonably relied upon the extensive knowledge and experience of Dr. McMurray and Dr. Ficht in the construction of the biosafety plan. The facts which emerged from the incident, i.e., that the biosafety plan was not properly observed or in fact the best plan, is not a violation of this section which requires that there be a “written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use.”

- 42 CFR 73.12(b). This section requires that “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.)” The investigation and interviews conducted on July 23-24, 2007 nor the facts or recommendations from the CDC preliminary findings, conclude that any of the biosafety and containment mechanism, e.g., the Madison Chamber was defective, leaking or dangerous for use with the specific select agent.

TAMU admits that the operational and procedural safeguards were not sufficient to contain the select agent, evident from the infection of the individual who cleaned the Madison Chamber used to aerosolize *brucella*. However, upon discovering that these operational and procedural safeguards were not sufficient, TAMU took steps to change those procedures including the use of PAPRs, additional respiratory protective measures, and other additional disinfectant materials and procedures were added in compliance with 42 CFR 73.11(f).

- 42 CFR 73.15(a). TAMU admits that the training program required under this section was inadequate or in some cases, absent. TAMU further admits that the individual infected by *brucella* as a visitor to the laboratory, without access, did not receive adequate training in the hazards of visiting and observing a *brucella* aerosolization experiment.
- 42 CFR 73.17(a)(4). This preliminary violation indicates a failure to maintain complete records and “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.” TAMU admits that although there was substantial compliance with the rule evidenced by written logs of information about entries, there were failures to consistently document “all entries”.

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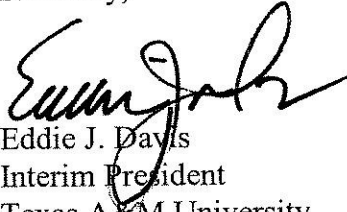
- 42 CFR 73.19(b). TAMU admits that there was failure to immediately report “upon discovery of a release of an agent or toxin causing occupational exposure. . . outside of the primary barriers of the biocontainment area. . .” when, on April 11, 2006, TAMU was notified that an individual involved in a *brucella* aerosolization experiment had been infected and developed symptoms of the disease. TAMU gave immediate attention to the medical care of the individual, and followed her treatment.

TAMU also participated in the reporting of the illness in compliance with state and federal law, through notification to the Texas Department of Public Health, which then made the report to the CDC through the reportable disease regulatory process. These reports of reportable diseases, such as *brucella*, are sent from the state to CDC.

TAMU has no reason to believe that CDC did not receive this report or have knowledge of the *brucella* infection of this specific individual through this reporting mechanism. In fact it is of some concern that select agent infection reports made to one part of CDC are not shared with another part of CDC as a matter of public health, safety and public policy.

Given these admissions, facts and other documentation resulting from the CDC and OIG visits during the week of July 23-27, 2007, TAMU proposes an offer of settlement of \$10,000.00. This represents an unprecedented fine paid by any institution under the CDC select agent program. We hope you will find that this proposal gives both TAMU and the federal government an opportunity to address the consequences of this situation so that we may proceed forward in a cooperative and productive partnership to newly shape our select agent compliance and safety program.

Sincerely,



Eddie J. Davis  
Interim President  
Texas A&M University

cc: Dr. Michael D. McKinney  
Mr. Jay Kimbrough  
Dr. Jerry Strawser  
Dr. Richard E. Ewing  
✓ Mr. Scott A. Kelly