



Memorandum

Date June 30, 2007

From Director, Centers for Disease Control and Prevention

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

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

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

1. Whether TAMU meets biosafety standards and requirements appropriate for the select agents and toxins you possess. Specifically, whether your biosafety plan ensures that select agents and toxins are used in a safe manner that is commensurate with the risk of the select agents and toxins (42 CFR § 73.12).
2. Whether TAMU has implemented a security plan that adequately prevents unauthorized persons from gaining access to select agents and toxins (42 CFR § 73.11).
3. Whether TAMU has an occupational health program that provides effective medical surveillance of occupational exposures to select agents and toxins.
4. Whether TAMU has the appropriate administrative control of select agent and toxin activities. Specifically, there is evidence that select agent work (i.e., aerosol studies with *Brucella* species) was performed at TAMU without prior approval by the DSAT. In addition, there is evidence that multiple occupational exposures that occurred at your entity were not properly reported to DSAT as required by 42 CFR § 73.19.
5. Whether the TAMU Responsible Official is familiar with and is ensuring compliance with the requirements of the select agent regulations (42 CFR § 73.9[a]).

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

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

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

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

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

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

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


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