Department of Health and Human Services
Centers for Disease Control and Prevention
Division of Select Agents and Toxins
Atlanta, Georgia

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Agriculture Select Agent Services
Riverdale, Maryland

June 05, 2015

[redacted]
Life Science Test Facility
[redacted]

RE: Entity Inspection Report: Life Science Test Facility (LSTF)

Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the United States Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) have established regulatory requirements for the possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to public health and safety, animal and plant health, and animal and plant products. These requirements can be found at 42 CFR Part 73 (HHS), 7 CFR Part 331 (USDA-PPQ), and 9 CFR Part 121 (USDA-VS). The Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins (DSAT) inspects entities to evaluate whether they meet the regulatory requirements set forth in 42 CFR Part 73, and the Animal and Plant Health Inspection Service (APHIS) Agriculture Select Agent Services (AgSAS) inspects entities to evaluate whether they meet the regulatory requirements set forth in 7 CFR Part 331 and 9 CFR Part 121. The above referenced regulations and supporting guidance information may be found at http://www.selectagents.gov/.

DSAT inspectors visited your facility located at [redacted] from May 26, 2015 to May 28, 2015. A list of laboratories inspected on these dates is on file with this letter at CDC.

The following personnel from the CDC Select Agent Program inspected the facility:

[redacted]

The following person from the Federal Bureau of Investigation inspected the facility:

[redacted]

Individuals from Life Science Test Facility present during the inspection included:

[redacted]

[redacted]

During the inspection, departures from regulatory requirements cited above were noted. Please address each of the items described in Attachment 1 (List of Entity Departures) and include in your response the specific actions or changes to be adopted to correct these departures. A detailed response should be received by this office not later than 14 calendar days from receipt of this letter. An electronic copy of your response should be sent to the lead inspector. Failure to fully respond may result in the initiation of proceedings for the withdrawal of your facility registration to possess, use, or transfer select agents and toxins.

Effective immediately, all shipments of "inactivated" *B. anthracis* preparations are to be suspended, except in support of the ongoing investigation. Any "inactivated" *B. anthracis* preparations are to be considered a select agent until proven otherwise. Before any shipments of inactivated preparations can occur, LSTF must submit definitive proof that the procedures implemented ensure that no viable organisms are present in the preparations.

Please be advised that all newly discovered spore preparations determined to be viable must be added to LSTF's inventory as required in Section 17 of the Select Agent Regulations.

If you have any questions concerning this correspondence please contact [redacted] at [redacted]

Sincerely,

Robbin S. Weyant, PhD, RBP (ABSA)
Captain, USPHS (Ret.)
Director, Division of Select
Agents and Toxins
Department of Health and Human
Services
Centers for Disease Control and
Prevention

Attachment: 1:
List of Entity Departures

Departures noted during the period of May 26, 2015 to May 28, 2015 at Life Science Test Facility (LSTF) (citations from 42 CFR Part 73 specifying each requirement are given in brackets).

1 **Requirement:** The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. [Section 12(a)]

Observation: The Standard Operating Procedures for the irradiation of *B. anthracis* spore suspensions did not account for the variable amounts of spores treated in the gamma cell irradiator. This resulted in inactivation failures that led to the transfer of viable B. anthracis to non-registered entities.

Please provide an updated standard operating procedure, as part of or referenced in LSTF's biosafety plan, in which all steps in the preparation of the spore suspensions have been verified to not inhibit their inactivation.

2 **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). [Section 12(b)]

Observation: The method used for inactivation of the *B. anthracis* spore suspensions, Cobalt 60 gamma irradiation, was not validated using standardized control spore samples at varying concentrations, volumes, and levels of irradiation before creating spore suspensions that would be released from the facility. As a result, viable *B. anthracis* spore suspensions were shipped from LSTF as inactivated samples in April 2015, December 2014, October 2014, and March 2014.

Please provide documentation validating the method of inactivation to ensure that each preparation does not contain viable spores or cells after irradiation. Please include, but not limited to, the following: (1) How LSTF will determine that the parameters of the irradiation protocols are adequate; and (2) How LSTF will determine that post-irradiation sample preparations are completely sterile.

3 **Requirement:** Except as provided in paragraphs (c) and (d) of this section, a select agent or toxin may only be transferred to individuals or entities registered to possess, use, or transfer that agent or toxin. A select agent or toxin may only be transferred under the conditions of this section and must be authorized by CDC or APHIS prior to the transfer. [Section 16(a)]

Observation: As of June 5, 2015, Life Science Test Facility has sent unauthorized shipments of live *B. anthracis* to 52 laboratories located across 19 U.S. states (including the District of Columbia), from January 2005 to May 2015, totaling 74 unauthorized shipments. The *B. anthracis* preparations that are currently known to contain viable organisms after gamma irradiation inactivation include: Ames lot 1667, Ames lot 70, Ames lot 516, Canadian Bison lot 822, Jamaican lot 810, Scotland lot 806, and Zimbabwe lot 794.

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