



Doc. 9

United States
Department of
Agriculture

May 30, 2013

Animal and Plant
Health Inspection
Service

[REDACTED]
Responsible Official
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mail Stop A-22
Atlanta, Georgia 30333

Veterinary Services

National Center for
Import and Export

4700 River Road,
Unit 2, Mailstop 22,
Cub. 1A07
Riverdale, MD 20737

(301) 851-3300, 1
FAX (301) 734-3652

[REDACTED]
The Animal and Plant Health Inspection Service (APHIS), Agricultural Select Agent Program (ASAP) and the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) conducted an APHIS-Led CDC joint inspection April 24, 2013 at the Centers for Disease Control and Prevention for BSL3, [REDACTED] and [REDACTED]. ASAP and DSAT have completed the review of the facility inspection. ASAP has no questions at this time but CDC requires additional information from you. Please provide this information to DSAT within 14 calendar days of receipt of this letter.

If there are any questions in reference to this correspondence please contact [REDACTED] at [REDACTED] with the Centers for Disease Control and Prevention, Division of Select Agents and Toxins.

Sincerely,

[REDACTED]

Staff Veterinary Medical Officer
Agricultural Select Agent Program



Safeguarding American Agriculture

APHIS is an agency of USDA's Marketing and Regulatory Programs
An Equal Opportunity Provider and Employer

Federal Relay Service
(Voice/TTY/ASCII/Spanish)
1-800-877-8339



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
Select Agent Program
Riverdale, Maryland



May 10, 2013

[REDACTED] (Responsible Official)

Centers for Disease Control and Prevention
1600 Clifton Road, NE, Mailstop A-22
Atlanta, GA 30333
FAX (404) 639-0437

RE: Facility Inspection Report: Centers for Disease Control and Prevention

As a result of 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 requirements regarding possession, use, and transfer of select agents and toxins. These requirements were published in the Federal Register by HHS (42 CFR Part 73) and by USDA (7 CFR Part 331 and 9 CFR Part 121). CDC inspects entities to evaluate if they meet the requirements set forth in 42 CFR 73 ("Possession, Use and Transfer of Select Agents and Toxins: Final Rule"). The regulations and supporting information may be found at: <http://www.selectagents.gov/>.

Inspectors from the CDC Select Agent Program visited your facility located at 1600 Clifton Road, NE, Mailstop A-22 Atlanta, GA 30333 on April 24, 2013. A list of the laboratories inspected on these dates is on file with this letter at CDC.

The following personnel from the CDC and APHIS Select Agent Programs inspected the facility:

[REDACTED] Lead Inspector (APHIS)
[REDACTED] Inspector
[REDACTED] Inspector
[REDACTED] Inspector

Individuals from Centers for Disease Control and Prevention present during the inspection included:

[REDACTED] ARO, Safety and Occupational Health Specialist
[REDACTED] PI
[REDACTED] Director, DLPP
[REDACTED] Laboratorian
[REDACTED] Laboratorian
[REDACTED] Building Manager, FMEO
[REDACTED] Assistant Director, FMEO
[REDACTED] OSHE Biosafety Team Member
[REDACTED] ARO

During the same visit departures from nationally recognized safety standards and/or deviations from requirements of 42 CFR Part 73 were also noted. Please address each of the items described in Attachment 1 and include in your response the specific actions or changes you will adopt to correct these deficiencies. Provide a detailed response to this office within 14 calendar days of receipt of this letter. Failure to fully respond to this request may result in withdrawal of your facility registration for the possession, transfer or receipt of select agents.

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

We appreciate your assistance during this inspection.

Sincerely,

[REDACTED]
[REDACTED]

Captain, USPHS (Ret.)
Director, Division of Select
Agents and Toxins
Department of Health and Human
Services
Centers for Disease Control and
Prevention

[REDACTED]
[REDACTED]

Director, Agriculture Select Agent
Program
United States Department of
Agriculture
Animal and Plant Health
Inspection Service

Attachment: 1:
List of Facility Departures

Attachment: 2:
BSL-3/ABSL-3 Verification

Attachment 1: Facility Departures

Deficiencies noted on April 24, 2013 at Centers for Disease Control and Prevention (citations from 29 CFR Part 1910.1450, 29 CFR Part 1910.1200, or 42 CFR Part 73 specifying each requirement are given in brackets).

- 1 Requirement:** The security plan must: describe procedures for how the Responsible Official will be informed of suspicious activity that may be criminal in nature and related to the entity, its personnel, and its select agents or toxins; [Section 11(c)(8)]

Observation: The security plan contained procedures describing how the Responsible Official (RO) will be informed of suspicious activity, but did not describe procedures indicating how the RO will be informed of suspicious activity that may be criminal in nature, and related to the entity, its personnel, and its select agents or toxins. Please update the security plan to include procedures describing how the RO will be informed of suspicious activity that may be criminal in nature, and provide a copy of the updated section of the security plan.

- 2 Requirement:** The security plan must: contain provisions for information security that ensure controls are in place that are designed to prevent malicious code (such as, but not limited to, computer virus, worms, spyware) from compromising the confidentiality, integrity, or availability of information systems which manage access to registered spaces in §11 or records in §17. [Section 11(c)(9)(iii)]

Observation: Information technology controls, such as antivirus programs, are in place to prevent the compromise of information systems that manage access to registered spaces; however, these controls were not described in the security plan. Please update the security plan accordingly and provide a copy of the updated section(s).

- 3 Requirement:** The security plan must: contain provisions for information security that establish a robust configuration management practice for information systems to include regular patching and updates made to operating systems and individual applications. [Section 11(c)(9)(iv)]

Observation: A robust configuration management practice is in place for the entity information systems to include regular patching and updates made to operating systems and individual applications; however, this practice was not described in the security plan. Please update the security plan to include these provisions as described and provide a copy of the updated section(s).

- 4 Requirement:** Entities with Tier 1 select agents and toxins must have the following additional incident response policies or procedures: The incident response plan must fully describe the entity's response procedures for failure of intrusion detection or alarm system; and [Section 14 (e)(1)]

Observation: The incident response plan did not describe response procedures for the failure of intrusion detection or alarm system. Please update the incident response plan to include the entity's procedures in case of a failure of an intrusion or alarm system, and provide a copy of the updated section(s).

- 5 Requirement:** An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: 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), including: The name and characteristics (e.g., strain designation, GenBank Accession number, etc.). [Section 17(a)(1)(i)]

Observation: Inspectors were told that evidentiary material identified as containing select agents may be stored in [REDACTED]. Please demonstrate what information will be captured in your inventory for any select agent material stored in this room, e.g., an inventory template.

Attachment 1: Facility Departures

- 6 **Requirement:** An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: accurate, current inventory for each toxin held, including: The name and characteristics. [Section 17(a)(3)(i)]

Observation: Inspectors were told that evidentiary material identified as containing toxins may be stored in [REDACTED]. Please demonstrate what information will be captured in your inventory for any select toxin material stored in this room, e.g., an inventory template.

- 7 **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)]. BSCs should be certified at least annually to assure correct performance. [BMBL: (BSL-3) D10]

Observation: Certification for the two Class III biological safety cabinets (BSCs) in [REDACTED] performed 9/24/2012, did not document testing of interlocks and alarms. Please describe the interlocks and alarms that are part of the design of these BSCs, and provide documentation that they have been tested and are working as designed.

- 8 **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)]. The BSL-3 facility design, operational parameters, and procedures must be verified and documented prior to operation. Facilities must be re-verified and documented at least annually. [BMBL: (BSL-3) D15]

Observation: Documentation of annual BSL3 re-verification was provided but did not include items d), e), g), and j) of Section IV contained in "BSL-3/ABSL-3 Annual Verification" (Attachment 2). Please provide documentation that these items have been verified within the last 12 months.

**Attachment 2: BSL-3/ABSL-3
Verification**

BSL-3/ABSL-3 Verification

- BSL-3 D9: "The laboratory shall be designed such that under failure conditions the airflow will not be reversed."
- ABSL-3 D6: "The ABSL-3 animal facility shall be designed such that under failure conditions the airflow will not be reversed."
- BSL-3 D15: "The BSL-3 facility design, operational parameters and procedures must be verified and documented prior to operation. Facilities must be re-verified and documented at least annually."
- ABSL-3 D14: "The ABSL-3 facility design and operational procedures must be documented. The facility must be tested to verify that the design and operational parameters have been met prior to use. Facilities should be re-verified at least annually against these procedures as modified by operational experience."

The Federal Select Agent Program Policy is based on the above BMBL Standards as currently published and is subject to change. Current policy:

I. BSL-3/ABSL-3 Initial HVAC Verification (BMBL: BSL-3 D9/ABSL-3 D6)

Initial HVAC design verification must be performed and documented by someone with experience and expertise with the HVAC system prior to operation. This initial HVAC design verification ensures that secondary containment is maintained under failure conditions to prevent possible exposure of personnel outside the containment boundary. After HVAC verification is initially documented, the testing need not be repeated, providing no major changes have been made to, or major problems noted with, the HVAC system. See Section II below for details on major changes and major problems which may require repeat HVAC verification.

Documentation must be provided of verification of HVAC design functionality under failure conditions. The failure conditions for verification include:

a. Mechanical failure of exhaust fan or fan component(s):

- If redundant fans are present, the ability to transition to the alternate fan without reversal of air flow from potentially contaminated laboratory space into "clean" areas surrounding the laboratory must be verified.
- If no redundancy is present in the laboratory HVAC system, the capacity to transition from sustained inward air flow into the laboratory to a "static" condition, i.e., no air flow out of the laboratory must be verified.

b. Simultaneous power failure supporting supply and exhaust fan components:

- If emergency power supply is available for the laboratory HVAC system, the ability to transition from "normal" power to the backup system without a reversal of air flow from the laboratory should be verified.
- If no backup power supply is available, the ability of the HVAC system to transition to a "static" condition, i.e., no outward air flow, should be verified.

c. Return from power failure to "normal" operating conditions:

- If emergency power supply is available, it should be verified that the ability exists to

**Attachment 2: BSL-3/ABSL-3
Verification**

transition from backup power to normal power without a reversal of air flow from the laboratory.

If no backup power supply is available, the ability of the HVAC system to return to normal operating conditions, without a reversal of air flow from laboratory spaces to clean areas surrounding the laboratory should be verified.

II. BSL-3/ABSL-3 Repeat HVAC Verification (BMBL: BSL-3 D9/ABSL-3 D6)

Once the BSL-3/ABSL-3 HVAC verification has been completed and approved by CDC/DSAT or APHIS/ASAP, HVAC failure conditions testing need not be repeated, providing there have been no major changes made to the HVAC system and no major problems noted with HVAC performance. Examples of major changes to the HVAC system which may require re-verification of HVAC design functionality under failure conditions by someone with experience and expertise with the system include: replacement of exhaust or supply fans that serve the BSL-3/ABSL-3 containment areas, replacement of ductwork valves or dampers that serve these areas, replacement or repair of HVAC system control wiring, building automation system logic programming changes, structural changes to the BSL-3/ABSL-3 rooms, or addition or removal of hard-ducted BSCs or fume hoods. Examples of major problems with HVAC performance that may require re-verification of HVAC design functionality under failure conditions include: frequent failures of the HVAC system, supply-exhaust interlocking system failure, observation that directional air flow is reversed under normal conditions, observation that HVAC alarms are not working, or that any BSCs with an HVAC connection are not working properly.

III. Acceptance Criteria for HVAC Verification (BMBL: BSL-3 D9/ABSL-3 D6)

The documentation provided must demonstrate that under exhaust fan or normal power failure conditions, or during normal power start-up, there is no reversal of air which originates within the BSL-3/ABSL-3 laboratory or vivarium room that travels all of the way outside the containment boundary. A facility may be considered to pass the HVAC verification tests as long as laboratory air does not exit the containment barrier of the facility. The BSL-3 anteroom is considered to be within the containment envelope. A positive pressure excursion is not necessarily an airflow reversal; if a brief, weak positive pressure excursion is noted, a repeat test may be performed with airflow observation using an airflow indicator such as a smokestick, or dry ice in a container of water, at the base of the closed laboratory door to confirm whether airflow reversal is occurring.

**IV. BSL-3/ABSL-3 Initial Facility Verification and Annual Re-verification
(BMBL: BSL-3 D15/ABSL-3 D14)**

In addition to initial HVAC verification and re-verification as described above, the following are the minimum facility verification requirements that an entity is expected to perform and document initially for a BSL-3 or ABSL-3 laboratory and again at least annually. Some entities may choose to perform additional facility verification beside what is listed below.

- a. The means of detecting air flow (telltale, magnehelic or digital gauge, Baulin-Tube®, etc.) has been confirmed to accurately reflect observed air flow. It is recommended, but not required, that digital or magnehelic gauges be calibrated annually.
- b. Inward directional airflow has been confirmed by observation for the laboratory.
- c. Decontamination systems (autoclave, room decontamination systems, digesters, liquid effluent systems, etc.) have been confirmed to be operating correctly.

**Attachment 2: BSL-3/ABSL-3
Verification**

- d. If a Building Automation System has the capacity to monitor and record performance measurements, e.g., differential pressures, the entity is encouraged to capture and store data from potential failure events, drills, etc. This information may provide verification of system performance. In addition, any programmed BAS alarms should be verified for proper functioning.
- e. All alarms (fire, air flow, security, etc.) have been checked and are functioning according to established specifications.
- f. Laboratory HVAC HEPA filters, if present, have been certified annually.
- g. Exhaust fan motors have been checked and routine maintenance conducted.
- h. The laboratory has been checked for unsealed penetrations, cracks, breaks, etc. and these have been repaired if present.
- i. All biological safety cabinets have been certified annually.
- j. Seals on centrifuges, Class III cabinets, gloves on Class III cabinets, etc. have been checked and replaced if required.
- k. Drench showers, eye wash stations, and hands free sinks have been confirmed to be operating properly.

If there are any questions about this policy, please contact the CDC DSAT Facility Specialist [REDACTED] at [REDACTED] or [REDACTED] or the APHIS/ASAP Facility Specialist [REDACTED] at [REDACTED] or [REDACTED]

[REDACTED]

From: [REDACTED] - APHIS
Sent: Thursday, May 30, 2013 5:15 PM
To: [REDACTED]
Cc: [REDACTED] - APHIS
Subject: Facility Inspection of 4-24-2013 and Request for additional information
Attachments: CDC IR 4-24-13.pdf

Dear Ms. Jones,

Enclosed is the APHIS-Led CDC joint Inspection of April 24, 2013 at the Centers for Disease Control and Prevention for BSL3, [REDACTED] CDC requires additional information from you. Please provide this information to DSAT within 14 calendar days of receipt of this letter.

Best Regards,

[REDACTED]
Program Analyst
APHIS Select Agent Program
[REDACTED]