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

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

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 Federal Select Agent Program is jointly comprised of the Centers for Disease Control and Prevention(CDC), Division of Select Agents and Toxins(DSAT) and the Animal and Plant Health Inspection Service(APHIS), Agriculture Select Agent Services(AgSAS). CDC DSAT inspects entities to evaluate whether they meet the regulatory requirements set forth in 42 CFR Part 73. APHIS 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/.

The Federal Select Agent Program will provide inspection findings through eFSAP. Inspection findings may include departures from regulatory requirements, general concerns, concerns related to amendments, requests for additional information, or issues under review. Inspection departures fall within three categories: immediate actions, preliminary, and final. Descriptions of each type of inspection finding are available on the following page.

You may dispute departures resulting from your inspection. Within 14 calendar days from receipt of a departure, you may email your dispute request to the DSAT Operations Branch Chief(lrsat@cdc.gov) or the AgSAS Operations Unit Director(AgSAS@aphis.usda.gov).The request must specify the departures that you are disputing. Upon receipt of your inspection findings, you have 30 calendar days to provide a written statement that clearly states why you consider the disputed departures(s) to be in error. You may include documentation in support of your dispute. The DSAT Operations Branch Chief or the AgSAS Operations Unit Director will attempt to resolve the dispute with you within 30 calendar days of the receipt of the written statement. The resolution of a dispute may include discussions with the entity or additional site visits. If the resolution of a dispute results in a change to an observation or required corrective action, FSAP will update the departure within eFSAP.

(b)(6)

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Description of Inspection findings Definitions

Departures: Deviations from the select agent regulations that pose a threat to human, plant, or animal health, animal or plant products, and / or security of select agent or toxin. Inspection departures from regulatory requirements fall within three general categories:

Immediate Action Departure: A serious deviation from the select agent regulations that requires the immediate attention of an entity. The entity must take immediate action to ensure that select agents and toxins are secured and handled safely.A detailed response to the departure must be submitted through eFSAP within the stipulated resolution timeframe.

Preliminary Departure: A brief description of an inspection finding that is subject to change before final inspection findings are provided. A response to preliminary departures is not required.

Final Departure: Deviations from the select agent regulations, including the corrective action(s) to be taken in response. A detailed response to the departure must be submitted through eFSAP within the stipulated resolution timeframe.

General Concerns: Observations that fall outside the select agent regulations but may be important considerations for the entity. No response is required.

Concerns Related to Amendments: Concerns related to an entity's request to amend its registration. These concerns must be addressed prior to the approval of the amendment. Corrective actions are submitted as part of the amendment rather than as part of the inspection.

Issues Under Review: Additional information collected in relation to the inspection that is still under review. Additional inspection findings may be communicated upon complete review.

Requests for Information: Requests for additional information needed to complete the inspection process. A detailed response to the request must be submitted through eFSAP within the stipulated resolution timeframe.

Inspection Findings

The findings below are presented in order of their **relative severity – highest to lowest**. Repetition of departures, as shown on future inspections, will be considered more serious and may result in compliance actions.

Departure
UID: 42-12-38300.1 42 CFR 73 - 12(b)

Response Due:	07/19/2019	**Departure Type:**	Immediate Action
Severity Level:	Serious	**Repeat Departure:**	No
Status:	Open		

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).

Observation:
USAMRIID reported 2 breaches of containment resulting [redacted] These combined [redacted] demonstrate a failure of USAMRIID to implement and maintain containment procedures sufficient to contain select agents or toxins in [redacted] generated by BSL-3 and BSL-4 laboratory operations.

Corrective Action:
Effective immediately, USAMRIID must cease all work involving select agents and toxins in registered laboratory areas from which [redacted] until the root cause investigation has been conducted for each incident and the results have been submitted to FSAP for review.

Departure
UID: 42-12-38200

42 CFR 73 - 12(a)

Response Due:	08/29/2019	**Departure Type:**	Final
Severity Level:	Serious	**Repeat Departure:**	No
Status:	Open		

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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.

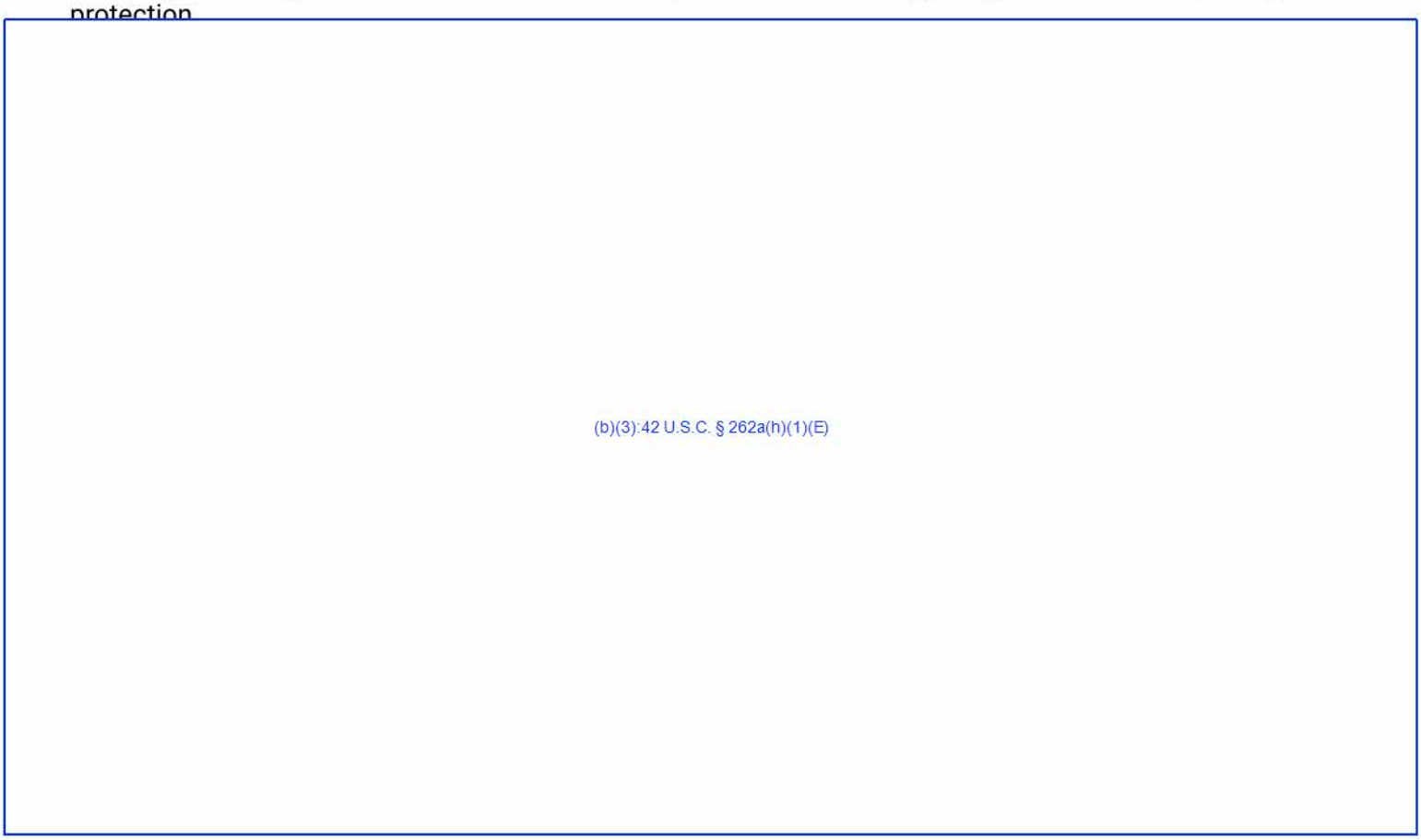
Observation:
USAMRIID has systematically failed to ensure implementation of biosafety and containment procedures commensurate with the risks associated with working with select agents and toxins. Specifically:

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

1. In building entity personnel deliberately deviated from standard operating procedures by propping open the door to the autoclave room while removing large amounts of biohazardous waste from the adjacent ABSL-3 room This deviation increases the risk of contaminated air from room escaping and being drawn into the autoclave room, where individuals typically do not wear respiratory protection.



(b)(3):42 U.S.C. § 262a(h)(1)(E)

Corrective Action:
Provide the measures implemented to ensure the biosafety and containment procedures described in the biosafety plan and referrenced SOPs are implemented. Provide confirmation that staff have been trained on the aforementioned procedures.

Departure
UID: 42-11-00100

42 CFR 73 - 11(a)

Response Due:	08/29/2019	**Departure Type:**	Final
Severity Level:	Moderate	**Repeat Departure:**	No
Status:	Open		

Requirement:
An individual or entity required to register under this part must develop and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Departure
UID: 42-17-01200

42 CFR 73 - 17(a)(3)

Response Due:	08/29/2019	**Departure Type:**	Final
Severity Level:	Moderate	**Repeat Departure:**	No
Status:	Open		

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.

Observation:
(b)(6) did not maintain an accurate or current inventory for (b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(6) recieved and used toxin, but there was no record created to meet the requirements of 17(a)(3) .

Corrective Action:
Provide an updated record that accurately reflects (b)(6) current (b)(3):42 U.S.C. § 262a(h)(1)(E) inventory, and the measures implemented to ensure that a complete inventory record of select toxins is maintained.

Departure
UID: 42-12-26000

42 CFR 73 - 12(b)

Response Due:	08/29/2019	**Departure Type:**	Final
Severity Level:	Low	**Repeat Departure:**	No
Status:	Open		

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).

Observation:
Laboratories in building [redacted] did not have a sealed surface to facilitate cleaning and decontamination. Specifically: Building [redacted] /Room [redacted] had cracks around the conduit box; Building [redacted] /Room [redacted] had cracks in the ceiling; and Building [redacted] / Room [redacted] had a crack in the seam above the biological safety cabinet. [BMBL: (BSL-3) D3]

(b)(3):42 U.S.C. § 262a(h)(1)(E)
(b)(3):42 U.S.C. § 262a(h)(1)(E)
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(b)(3):42 U.S.C. § 262a(h)(1)(E)
(b)(3):42 U.S.C. § 262a(h)(1)(E)

Corrective Action:
Provide evidence (e.g. work order or photo) that cracks in the above laboratories are sealed to facilitate decontamination.

Departure
UID: 42-12-41500

42 CFR 73 - 12(b)

Response Due:	08/29/2019	**Departure Type:**	Final
Severity Level:	Low	**Repeat Departure:**	Yes
Status:	Open		

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).

Observation:
The signage posted in the BSL3 and ABSL3 laboratories did not include the current entry and exit procedures for the modified PPE practices used by personnel. [BMBL: (BSL-3/ABSL-3) A9]

Corrective Action:
Provide confirmation that all laboratories have signage posted that includes the current entry and exit procedures for the PPE practices used by personnel.

General Concern
UID: 42-12-41500.1 42 CFR 73 - 12(b)

Observation:
There was no biohazard sign, contact information, nor biosafety level posted upon entry into ABSL3 lab [redacted] Signage on the door stated that the lab has been "out of use" since May 2018, but the area will be used for BSAT waste storage, if needed. The entity should ensure signage is posted and includes appropriate information if BSAT is stored or used in the lab.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

General Concern
UID: 42-12-48500 42 CFR 73 - 12(a)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Observation:
In BSL-2 room [redacted] the [redacted] (b)(3):42 U.S.C. § 262a(h)(1)(E) is not removable. Consider implementing administrative controls to ensure the machine is only used for non-BSAT or ensure the machine is contained in the biosafety cabinet prior to use with select agents and toxins.

General Concern
UID: 42-12-63200 42 CFR 73 - 12(b)

Observation:
During smoke testing of the downdraft tables, the laminar airflow associated with the tabletop was disrupted by exhaust air deflecting off of a wall behind the unit(s). Turbulent flow should be avoided during the use of all primary containment devices as contaminated material may spread to the operator and the laboratory space in an unpredictable manner.

General Concern
UID: 42-12-42600

42 CFR 73 - 12(b)

Observation:
Several activities, including doffing PPE upon exit from active ABSL-3 laboratories, include personnel holding the laboratory door ajar for an extended period of time. During smoke testing, smoke exited ABSL-3 laboratories and entered the corridor while the door was held open for a brief period of time (~5-10 secs). While the contaminated air did not escape the suite containment area, individuals inside the containment suite not wearing respiratory protection are at increased risk of exposure and occupational illness. Consider incorporating additional parameters when doffing PPE across the door threshold (e.g. decrease time door is held ajar, increase distance of personnel in the corridor who are not wearing respiratory protection, include a requirement for respiratory protection in adjacent areas, etc.) to ensure personnel in the corridor are not exposed to contaminated air exiting the ABSL-3 laboratory.

General Concern
UID: 42-12-44300

42 CFR 73 - 12(a)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Observation:
In building [redacted] suite [redacted] room [redacted] the FACS Counter II is not inside a HEPA-filtered primary containment device. The instrument fluidics line filters were changed on 11/14/18, and the instrument is ready to be used. There is no posted signage or SOPs indicating that it should only be used inside a primary containment device. Consider implementing administrative controls to ensure the machine is only used for non-BSAT or ensure the machine is contained in a primary barrier device prior to use with BSAT.

General Concern
UID: 42-12-45400

42 CFR 73 - 12(b)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Observation:
USAMRIID has not implemented the use of a durable leak proof container to transport and secure biohazardous materials to be decontaminated in the autoclave located in the basement of building [redacted] A large bag of waste was transported by hand to the autoclave located in the basement. The waste originated from ABSL3 Room [redacted] (Building [redacted] floor), where there is an ongoing NHP [redacted] study. The waste was not transported in a durable leak proof container, which creates the potential for spills or leaks, and the bag may be easily punctured. Additionally, bags of contaminated PPE are stored on the floor inside several containment suites inside building [redacted] Although these areas are located in registered space, personnel are not required to wear respiratory protection or gloves in the corridors, which increases the risk of exposure if the bag is punctured or spills. Consider additional PPE or using durable storage containers for contaminated waste.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

General Concern
UID: 42-12-37600

42 CFR 73 - 12(a)(3)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Observation:
The entity Safety Manual for BSL Suite (Bldg. USAMRIID) Appendix 14 (Cleaning of Suite) states: "Expired Microchem and bleach may be used for mopping and filling drains but not for more than one year beyond the original expiration date. Bottles will be clearly marked with the extended one year expiration and will indicate 'for mopping and drains only.'" Because expired disinfectants are maintained in the same suite as the appropriate chemical disinfectants, a worker may inadvertently use the expired disinfectant for decontamination purposes resulting in ineffective decontamination. Consider removing expired disinfectants to prevent accidental misuse.

General Concern
UID: 42-12-38300

42 CFR 73 - 12(b)

Observation:
The entity plugged several floor drains throughout registered space and placed orange cones over the plugs to designate these areas. The orange cones are raised above floor level, causing a potential trip hazard. The entity should ensure these hazards are mitigated to avoid the potential for personnel transporting select agent or toxin material to trip and spill BSAT, leading to a potential exposure for themselves and/or others.

General Concern
UID: 42-12-38200.1

42 CFR 73 - 12(a)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Observation:
The entity has different PPE postures for entering BSL-3 laboratories in buildings and , has changed the PPE posture and doffing procedures several times over the past 12 months, permits a variety of situational PPE postures in some suites, and has implemented a multi-stepped doffing procedure in BSL-3 suites including multiple handwashes in different rooms. This has caused the occurrences of doffing SOP deviations to increase from previous inspections. Consider standardizing PPE postures based on risk assessment to reduce confusion, deviation from SOPs, and thereby the risk for contamination and exposure.