



United States  
Department of  
Agriculture

Animal and Plant  
Health Inspection  
Service

Veterinary Services

National Import and  
Export Services

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

(301) 851-3300, 3  
FAX (301) 734-3652

May 29, 2014

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

Dear [REDACTED]

The Animal and Plant Health Inspection Service (APHIS), Agricultural Select Agent Services (AgSAS) and the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) conducted an APHIS-Led CDC joint inspection, September 30, 2013, January 6-10, 2014 and January 13, 2014 at the Centers for Disease Control and Prevention. AgSAS and DSAT have completed the review and AgSAS does not have any questions at this time, but DSAT requires additional information from you. Please provide this information to DSAT no later than 14 calendar days from receipt of this letter. Please see the attached APHIS and CDC letters.

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

Sincerely,

[REDACTED]  
[REDACTED]  
Staff Veterinary Medical Officer  
Agricultural Select Agent Services



*Safeguarding American Agriculture*

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May 29, 2014

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

Dear [REDACTED]

The Animal and Plant Health Inspection Service (APHIS), Agricultural Select Agent Services (AgSAS) and the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) conducted an APHIS-Led CDC joint renewal inspection September 30, 2013, January 6-10, 2014 and January 13, 2014 at the Centers for Disease Control and Prevention. APHIS has completed the review of the facility inspection and requires no additional information. We have no questions at this time.

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

Sincerely,

[REDACTED]  
Staff Veterinary Medical Officer  
Agricultural Select Agent Services



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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

May 15, 2014

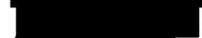
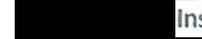
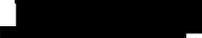
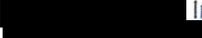
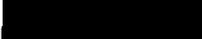
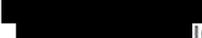
 (Responsible Official)  
Centers for Disease Control and Prevention  
1600 Clifton Road, NE, Mailstop A-22  
Atlanta, GA 30333  
FAX: (404) 639-0437

**RE: Entity Inspection Report: Centers for Disease Control and Prevention**

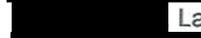
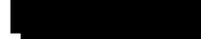
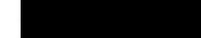
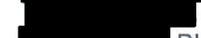
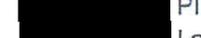
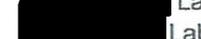
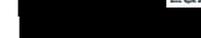
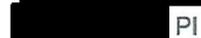
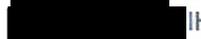
Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the United States Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) have established regulatory requirements for the possession, use, and transfer of biological 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/>.

AgSAS and DSAT inspectors visited your facility located at 1600 Clifton Road, NE, Mailstop A-22 Atlanta, GA 30333 on September 30, 2013 and January 06, 2014 to January 13, 2014. A list of laboratories inspected on these dates is on file with this letter at APHIS.

The following personnel from the APHIS Agriculture Select Agent Services and the CDC Division of Select Agents and Toxins inspected the facility:

-  Lead Inspector
-  Inspector
-  Inspector
-  Inspector
-  Inspector
-  Inspector
-  Inspector
-  Inspector

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

-  Support: Animal Care
-  Laboratorian
-  PI
-  PI
-  Chief, ACUPO
-  PI
-  Laboratorian
-  Laboratorian
-  ARO
-  PI
-  IH Team Lead
-  Physician/Acting Medical Director

[REDACTED] PI  
[REDACTED] Laboratorian  
[REDACTED] PI  
[REDACTED] Laboratorian  
[REDACTED] PI  
[REDACTED] Senior Advisor  
[REDACTED] Laboratorian  
[REDACTED] Laboratorian  
[REDACTED] Chief Nurse  
[REDACTED] RO  
[REDACTED] Laboratorian  
[REDACTED] NCEZID Safety Manager  
[REDACTED] Laboratorian  
[REDACTED] PI  
[REDACTED] Laboratorian  
[REDACTED] Director, ESHCO  
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[REDACTED] Laboratorian  
[REDACTED] PI  
[REDACTED] PI  
[REDACTED] Laboratorian  
[REDACTED] PI  
[REDACTED] Laboratorian  
[REDACTED] ARO  
[REDACTED] Shift Supervisor, [REDACTED]  
[REDACTED] Laboratorian

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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.

If you have any questions concerning this correspondence please contact APHIS Representative at [REDACTED] option 3.

Sincerely,

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

[REDACTED]  
[REDACTED]  
National Director, Agriculture Select  
Agent Services  
United States Department of  
Agriculture  
Animal and Plant Health  
Inspection Service

Attachment: 1:  
List of Entity Departures

### Attachment 1: Entity Departures

Departures noted from January 06, 2014 to January 13, 2014 at Centers for Disease Control and Prevention (citations from 42 CFR Part 73 specifying each requirement are given in brackets).

- 1 **Requirement:** A certificate of registration may be amended to reflect changes in circumstances (e.g., replacement of the Responsible Official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins). Prior to any change, the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application. [Section 7(h)(1)]

**Observation:** Inspectors noted that [REDACTED] spores were held in long term storage in [REDACTED] for PI [REDACTED] and [REDACTED]. This room was not registered for storage of select agents at the time of inspection. Amendment 223666 has been submitted, requesting the addition of storage to [REDACTED]. No further action is required.

- 2 **Requirement:** The security plan must: describe procedures for physical security, inventory control, and information systems control. [Section 11(c)(1)]

**Observation:** It was stated in interviews that the card reader for [REDACTED] Suite registered for PI [REDACTED] and [REDACTED] sometimes does not unlock the door to permit access for those with permission. PI [REDACTED] has a mechanical key that she shares with SRA approved laboratorians to allow entry into the laboratory when the card reader is not working. The security plan does not describe the use of mechanical keys. Please update the security plan for PI [REDACTED] to include procedures for use of mechanical keys and key control procedures in place and provide the updated section of this plan.

Inspectors were informed that new inventory control procedures were developed for PI [REDACTED] for transfer of select agents to a secondary location in order to address errors in inventory records noted during the inspection. Please provide documentation (such as an updated section) that the security plan for PI [REDACTED] has been updated to include current inventory control procedures.

- 3 **Requirement:** Entities with Tier 1 select agents and toxins must prescribe the following security enhancements: all registered space or areas that reasonably afford access to the registered space must be protected by an intrusion detection system (IDS) unless physically occupied. [Section 11(f)(4)(v)]

**Observation:** It was stated in interviews that the card reader for [REDACTED] Suite registered for PI [REDACTED] and [REDACTED] sometimes does not unlock the door to permit access for those with permission. [REDACTED] has a mechanical key that she shares with SRA approved laboratorians to allow entry into the laboratory when the card reader is not working. A forced door alarm serves as an intrusion detection system, transmitting an alarm to the Security Operations Centers in response to a "forced door" i.e., door opened without card reader approval. Please provide documentation that the security plan for PI [REDACTED] has been updated to describe how the intrusion detection system functions when the mechanical key is used to access the laboratory.

- 4 **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:** No evidence of PAPR training was provided for three individuals approved for access to [REDACTED] Suite registered for PI [REDACTED] and [REDACTED] did not provide evidence of PAPR training for 2013 and, at the time of inspection. I. [REDACTED] was medically cleared in 2012 but did not have evidence of PAPR training for 2012. Please provide evidence that [REDACTED] and [REDACTED] have received PAPR training within the last year, and describe the measures implemented to ensure PAPR training is provided annually, per entity policy, for all individuals with access to laboratories requiring the use of a PAPR.

**Attachment 1: Entity Departures**

- 5 **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:** A large water bath sonicator was present in ██████████ registered for PI ██████████ and was described as being used on a bench top with samples in specimen cups sealed with parafilm. Please provide a risk assessment for use of this sonicator with select agents that includes biocontainment measures, PPE worn at time of use, and any user training required.

A water bath sonicator was present in ██████████ registered for PI ██████████ and was described as being used with select agent in sealed tubes. Please provide a risk assessment for use of this sonicator with select agents that includes biocontainment measures (such as locating it inside a BSC), the vials or containers used for select agents and type of seal, PPE worn at time of use, and any user training required.

An IVIS imager was present in ██████████ registered for PI ██████████ and was described to be used with ██████████ infected prairie dogs. Please provide a risk assessment for use of the IVIS imager with ██████████ infected prairie dogs that includes biocontainment measures, PPE worn at time of use, and any user training required. Please also provide a copy of the IACUC approved protocol(s) that includes use of this equipment.

- 6 **Requirement:** The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program. [Section 12(d)]

**Observation:** An occupational health program with best practices is in place per interviews with laboratorians and occupational health professionals. It was stated that these procedures are mandated by PIs and specific to the work being conducted in their laboratories. However, the following written procedures were not available at the time of inspection. Please provide written procedures for 1) pre-placement examination, 2) exposure prevention, and 3) treatment for individuals with potential exposure to Tier 1 select agents and toxins for each PI group working with Tier 1 select agents and toxin.

- 7 **Requirement:** Entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings on how to identify and report suspicious behaviors. [Section 15(b)]

**Observation:** Records for insider threat awareness training in 2013 were not provided for ██████████ and ██████████. Please provide documentation that these individuals have received and understood this training.

- 8 **Requirement:** Refresher training must be provided annually for individuals with access approval from the HHS Secretary or Administrator or at such time as the registered individual or entity significantly amends its security, incident response, or biosafety plans. [Section 15(c)]

**Observation:** A record of refresher training including security, incident response, and biosafety was not provided for ██████████ in 2013. Please provide documentation the ██████████ has received refresher training within the last 12 months, and describe the measures implemented to ensure refresher training is provided annually.

- 9 **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 and/or synthetic nucleic acids, and recombinant and/or synthetic 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: [Section 17(a)(1)]

**Attachment 1: Entity Departures**

**Observation:** During review of inventory held by PI [REDACTED] and [REDACTED] it was observed that the vial count for some select agent samples was inaccurate. Specifically for DASH # 2000031283, spiked human sera for quantitative PCR, some vials in the inventory record were recorded as containing [REDACTED] but were negative controls (i.e., did not contain [REDACTED]). A group of 23 vials recorded as [REDACTED] was actually 22 vials of [REDACTED] and 1 blank. A group of 32 vials recorded as [REDACTED] was actually 29 vials of [REDACTED] and 3 negative controls. Please provide updated inventory records for the box containing these samples.

The inventory records for PI [REDACTED] for select agents stored in [REDACTED] and [REDACTED] did not accurately reflect the number of samples present at the time of inspection.

- Seventy vials of [REDACTED] lot date 10/3/2007 were recorded as located in [REDACTED]. However, there were only 60 vials present in [REDACTED] as 10 had been moved to [REDACTED] for retention but had not been subtracted from the total number recorded for [REDACTED].
- Two hundred and thirty-four vials of [REDACTED] lot date 1/1/2009 were recorded as located in [REDACTED]. However, there were only 214 vials present in [REDACTED] as 20 had been moved to [REDACTED] for retention but had not been subtracted from the total number recorded for [REDACTED].
- One hundred and twenty-eight vials of [REDACTED] lot date 3/3/2010, were recorded as located in [REDACTED]. The inventory record indicated 20 vials from this lot were removed for retention but this number was not subtracted from the total recorded for [REDACTED]. In actuality, there were only 118 vials present in [REDACTED] as 10 had been moved to [REDACTED] for retention.

Please provide updated inventory records for the bags containing these samples. Please note that issues with inventory records were also noted in the report resulting from the October 12-22, 2010 inspection of your facility.

- 10 **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: 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. [Section 17(a)(5)]

**Observation:** A manual log was in place to record entry of visitors into [REDACTED] Suite registered for PI [REDACTED]. Multiple entries made in March and April of 2012 included only a first name for both visitor and escort. In addition, there was no escort recorded for a visitor indicated by first name only on April 3, 2012. Please describe the measures implemented to ensure that both visitor and escort record full (first and last) names; alternatively, if only a first name only is recorded, please provide documentation that the visitor log contains a key that associates the first name with a full (first and last) name. Please describe the measures implemented to ensure that, when applicable, the name of the escort is captured.

A green book is used to capture visitor entry into [REDACTED] and [REDACTED] Suites registered for PI [REDACTED] and [REDACTED]. In October and November of 2011, multiple entries captured the name of the escort as ARB, first name only, or by initials. Please describe the measures implemented to ensure that the full name (first and last) of the escort is captured. If initials or another means will be used, please provide documentation that the visitor log book contains a key that associates initials or other means with a full (first and last) name.

Entry into [REDACTED] registered for PI [REDACTED] was not being recorded at the time of inspection. Entry into the freezer located in [REDACTED] and containing [REDACTED] and [REDACTED] was recorded. It was stated that a card reader had been order to restrict access and electronically record entry to [REDACTED]. Please provide documentation that a card reader has been installed and is now recording information for all entries into [REDACTED] or describe alternative measures implemented to ensure entry information is recorded.

**Attachment 1: Entity Departures**

- 11 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: A written explanation of any discrepancies. [Section 17 (a)(7)]

**Observation:** Please provide documentation that written explanations of the discrepancies between the number of select agent samples in the inventory logs versus the number of samples in the physical inventories, described this report (Observation 8) for PI [REDACTED] and [REDACTED] as well as PI [REDACTED] and [REDACTED] have been added to their respective inventory records.

- 12 Requirement:** The individual or entity must implement a system to ensure that all records and data bases created under this part are accurate, have controlled access, and that their authenticity may be verified. [Section 17(b)]

**Observation:** Please provide the procedures used to track inventory for PI [REDACTED] and [REDACTED] and describe how these procedures will prevent future errors in the inventory record.

- 13 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)]. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory. [BMBL: (BSL-2) A2]

**Observation:** Inventory stored in [REDACTED] and [REDACTED] registered for PI [REDACTED] and [REDACTED] was reviewed during the inspection. Afterwards, neither inspectors nor escorts washed hands or used an alternative method such as hand sanitizer upon exit. Please describe the measures implemented to ensure individuals comply with this safety standard.

- 14 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)]. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. Posted information must include: the laboratory's biosafety level, the supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the laboratory. [BMBL: (BSL-2) A9]

**Observation:** Signage at the entrance to [REDACTED] registered for PI [REDACTED] and [REDACTED] did not include the biohazard symbol, the biosafety level, or entry and exit procedures. Please provide evidence (such as copy of the updated sign and a photo of it in place) showing that signage for [REDACTED] has been updated to include this information.

- 15 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)]. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. [BMBL: (BSL-2) A11]

**Observation:** Inspectors observed variances in how laboratorians record long-term inventory for PI [REDACTED] and [REDACTED] resulting in inventory discrepancies. Please provide evidence (e.g., training curriculum and means to verify understanding) that personnel responsible for recording inventory held by PI [REDACTED] and [REDACTED] have been retrained on current inventory procedures; or, if new inventory procedures have been implemented for tracking inventory, they have trained on these new procedures.

**Attachment 1: Entity Departures**

- 16 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)]. When a procedure cannot be performed within a BSC, a combination of personal protective equipment and other containment devices, such as a centrifuge safety cup or sealed rotor, must be used. [BMBL: (BSL-3) B10]

**Observation:** A microcentrifuge on the bench top in [REDACTED] registered for PI [REDACTED] was described as being used to centrifuge serum from animals infected with [REDACTED]. Escorts stated the microcentrifuge was used on the bench top and samples were loaded and unloaded on the bench top. Please describe biocontainment measures implemented to comply with this safety standard or a risk assessment for this practice.

- 17 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)]. Laboratory doors must be self-closing and have locks in accordance with the institutional policies. [BMBL: (BSL-3) D1]

**Observation:** The door to [REDACTED] registered for PI [REDACTED] and [REDACTED] was not self-closing at the time of inspection. Escorts stated that inward airflow for this room varies and adjustment of the door closer is requested when the door is observed to not self-close. Please provide documentation (such as a statement from a laboratorian confirming this) that the door is now self-closing.

- 18 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)]. This system must provide sustained directional airflow by drawing air into the laboratory from "clean" areas toward "potentially contaminated" areas. [BMBL: (BSL-3) D9]

**Observation:** Room [REDACTED] registered to PI [REDACTED] had directional airflow from the BSL2 anteroom [REDACTED] into the BSL3 laboratory [REDACTED] at the time of inspection. Escorts stated that the airflow varies for this room, and it is sometimes observed as reversed such that air flows from the BSL3 laboratory [REDACTED] into the BSL2 anteroom [REDACTED]. A tell-tale is the means used to verify directional air flow and no audible alarm is present. Inspectors were informed that facilities personnel are contacted when there is an air flow reversal, and no work is performed until it is corrected. Facilities personnel stated that they have been alerted to an air flow reversal for [REDACTED] twice and were able to resolve the problem by adjusting the supply air damper. If there have been air flow reversals that occurred while work was ongoing, please describe the following for each instance: (1) how the laboratorian became aware of the problem, (2) the work being performed when the problem was discovered, (3) what actions the laboratorian took, (4) who was notified, and (5) provide any written documentation of the incident.

- 19 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)]. Provisions to assure proper safety cabinet performance and air system operation must be verified. [BMBL: (BSL-3) D10]

**Observation:** The BSC in [REDACTED] registered for PI [REDACTED] was not working at the time of the inspection. The blower did not turn on as evidenced by a lack of sound and a reading of 0" w.c. on the BSC's manometric gauge. This BSC housed a 2000 Geno/Grinder homogenizer. Please provide documentation (such as a photograph) that the BSC has been posted as not to be used until such time as repairs have been made and it is shown to be working and provide documentation (such as a completed work order) that the BSC has been repaired and is now functional and able to provide biocontainment for the homogenizer.

**Attachment 1: Entity Departures**

- 20 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)]. Equipment that may produce infectious aerosols must be contained in primary barrier devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory. These HEPA filters should be tested and/or replaced at least annually. [BMBL: (BSL-3) D12]

**Observation:** A shaking incubator used to grow bacteria was present in [REDACTED] registered for PI [REDACTED] and [REDACTED]. Per escort, this shaking incubator has an exhaust HEPA filter. Please provide documentation that this HEPA filter has been replaced or tested in 2011, 2012, and 2013.

A [REDACTED] ultracentrifuge present in [REDACTED] registered for PI [REDACTED] was described as being used to centrifuge [REDACTED]. Inspectors were informed that there was not a HEPA filter present on this ultracentrifuge and that a HEPA filter would be installed in February 2014. Please provide documentation (such as a completed work order) that a HEPA filter is now present on this ultracentrifuge. In addition, please describe the measures implemented to ensure that the HEPA filter is replaced or tested annually.

An ultracentrifuge present in [REDACTED] Suite registered for PI [REDACTED] was described as not used for select agents. Please provide documentation (such as a photograph) that this ultracentrifuge has been labeled as not to be used with select agents.