



Doc 15



July 10, 2014

United States  
Department of  
Agriculture

[REDACTED] (Responsible Official)  
Centers for Disease Control & Prevention  
1600 Clifton Rd NE, Mailstop A-46  
Atlanta, GA 30333  
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**RE: Entity Inspection Report**

Animal and Plant  
Health Inspection  
Service

Dear [REDACTED]

Veterinary Services

On June 19, 2014, the Centers for Disease Control and Prevention (CDC) submitted a "Report of Theft, Loss, or Release of Select Agents and Toxins (Form 3)" regarding the potential release of [REDACTED] outside of select agent registered space. In response to the Form 3 submission, the APHIS Agriculture Select Agent Services (AgSAS) performed an inspection of the Centers for Disease Control & Prevention (CDC), in Atlanta, Georgia, from June 23-July 3, 2014.

National Import  
Export Services

Agriculture Select  
Agent Services

4700 River Road  
Mailstop 22, Unit 2  
Room 1A-07  
Riverdale, MD 20737

The following AgSAS personnel participated in the inspection: [REDACTED] and [REDACTED]. From the CDC, Division of Select Agents and Toxins (DSAT), the following senior inspectors assisted the AgSAS team: [REDACTED] and [REDACTED].

Telephone:  
(301) 851-3300  
option 3

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(301) 734-3652

On June 24, 2014, the AgSAS team held an entrance conference with interested individuals at the CDC facility. On July 2, 2014, the AgSAS inspection team provided an exit briefing to the Responsible Official (RO), senior CDC managers, and CDC laboratory personnel impacted by the incident. During the exit conference, the AgSAS inspection team outlined the deficiencies found during the inspection so that CDC could immediately begin taking corrective actions.

During the inspection, AgSAS and DSAT inspectors interviewed 31 potentially exposed persons including laboratory employees from affected laboratories, CDC management, and occupational health employees. The AgSAS team inspected select agent registered areas in Building [REDACTED] and non-registered areas in Building [REDACTED] and [REDACTED] in which the BA samples were prepared, manipulated, and stored. The observations and findings discovered during the AgSAS inspection are provided below.



Veterinary Services – Safeguarding American Agriculture  
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**1. Requirement:** 9 CFR 121.12 *Biosafety*

**Observation:** The use of inadequate inactivation protocols within the Bioterrorism Rapid Response and Advanced Technology Laboratory (BRRAT) registered areas resulted in release of live select agents. The validated inactivation protocol is titled "Ethanol/formic acid extraction procedure" and is detailed in the BioTyper User manual, Version 2.0 by Bruker Daltonik GmbH and indicates this protocol is for "inactivating biological material without spore formation." The BRRAT laboratory further modified this protocol and failed to include important sections of the protocol which were required to fully inactivate [REDACTED]. Additionally, the revised protocol was not validated. There was no oversight on the use of the inactivation protocol by the principal investigators in either laboratory.

**Observation:** Use of personal protective equipment (PPE) is inconsistent in unregistered laboratories. Signage on laboratory entrances has a PPE requirement, but no PPE was identified. PPE in non-registered areas in Buildings [REDACTED] and [REDACTED] is not required. Rooms [REDACTED] and [REDACTED] are considered by the Principal Investigator (PI) to be BSL-1 laboratories. Room [REDACTED] is a BSL-2 laboratory; gloves are worn but only to prevent contamination of sample.

**2. Requirement:** 9 CFR 121.14 (d)(12) *Incident Response, Decontamination Procedures* and 9 CFR 121.15(a) *Training*

**Observation: (Registered laboratory rooms)** The disinfectant used for surface decontamination of vials and Ziploc bags within Building [REDACTED] was expired based on the dates listed on containers. All bleach disinfectant towels (Clorox® Dispatch® Hospital Cleaner Disinfectant Towels with Bleach) observed within the laboratory suite had expired February 19, 2014. This observation included one open container of disinfectant towelettes in the hallway [REDACTED], one open container in the anteroom [REDACTED] and three unopened containers on a shelf in anteroom [REDACTED]. Disinfectant used for work surface decontamination in [REDACTED] was expired. One bottle of Bleach-Rite® spray expired December 14, 2014. The researchers could not remember if they used the expired bleach to decontaminate benches after the potential release was identified. The same expired bleach was found in Room [REDACTED] [REDACTED]. The contact time of application of the disinfection on surfaces was not consistent. Laboratory workers decontaminated the floors in [REDACTED] with spore-klenz but not the work areas because they were told that BRRAT decontaminated those areas.

**Observation: (Non-registered rooms and areas)** There were inconsistencies with chemicals used and contact time as well as who was responsible to perform the decontamination. In Building [REDACTED], Rooms [REDACTED] and [REDACTED] were decontaminated by CDC personnel with spore-klenz on floors and work counters on June 18 and 19, 2014. Building [REDACTED] Room [REDACTED] was decontaminated by different CDC personnel with a 10% bleach solution with a contact time of 20 minutes for surfaces.

**Observation:** Laboratorians in registered laboratories were not appropriately trained in use of the inactivation protocol and the protocol was communicated inaccurately between the two registered laboratories with no oversight by supervisors and principal investigators. No formal approval process was in place for a new inactivation procedure

involving select agents that could result in removal of select agents from BSL3 containment.

**Observation:** The BRRAT personnel registered for [REDACTED] were not appropriately trained in the characteristics, properties, and risk of the agent. The laboratorians using the inactivation protocol did not recognize the unique biology of bacterial endo-spore formers when considering the use of the inactivation protocol. The protocol used had a requirement to filter the solution when inactivating spore-formers. The BRRAT laboratory performed this step but still sent the unfiltered viable solutions to the unregistered CDC laboratory. The CDC laboratory that gave BRRAT this protocol is also registered for BA but did not give adequate instructions and limitations to the BRRAT laboratory when they provided the protocol.

**3. Requirement:** 9 CFR 121.12 *Occupational Health Program*

**Observation:** The CDC Occupational Health Program requires the use of the CDC Occupational Health Clinic to assess and respond to any laboratory incidents with laboratory workers. Our findings indicated that this clinic was inadequately prepared to respond to the exposure of a large number of individuals. Individuals reported in interviews that the health clinic appeared overwhelmed, understaffed, and not in possession of enough information to appropriately assess exposures. This led to individuals departing the clinic without knowing the status of their risk of exposure. According to one laboratorian, they were not examined by anyone in the clinic for 5 days after potential exposure and notification. This example is highlighted as a concern because the laboratorian manipulated potentially contaminated plates without proper PPE, close to their face, on an open bench in direct contact with their ungloved hands. The clinic management was not informed in a timely manner of the scope of the incident and the numbers of potentially exposed workers in order to adequately build capacity to fully provide the services needed. The clinic management did not request that CDC management increase staff even though it was evident they were overwhelmed.

Some supervisors were informed that their staff should self-monitor instead of going to the clinic. Some CDC employees were told by the clinic that they were not in danger yet their laboratories and hallways were decontaminated by the Environmental Health Safety Chemical Office (EHSCO) staff which concerned the employees since this action seemed to be inconsistent with the information given by the clinic. These examples point out the inconsistencies and communication problems identified following the incident.

**4. Requirement:** 9 CFR 121.14 *Incident Response* and 9 CFR 121.9 *Responsible Official*

**Observation:** Actions following the incident demonstrated lack of managerial control after initial immediate response, resulting in delays in decontamination and lockdown of affected areas, unclear objectives for mid-level managers and their subordinates, and general confusion amongst responders and personnel potentially exposed to the agent. Observations by inspectors as well as employee interviews revealed a lack of communication between CDC divisions. Laboratory personnel were unclear as to who they should contact for procedures involving decontamination of space/equipment or for additional information on the incident. Interviews with health and safety personnel indicated there was no clear focus of who was leading the decontamination effort. Interviews with Alternate Responsible Officials indicated they had little knowledge of the

incident and no active involvement in the response. Confusion as to the appropriate decontamination chemical was identified in interviews. There was no clear decision so each laboratory decontaminated its own laboratory work surfaces independently.

**Observation:** There was no documentation of retrieval of agents/materials (MALDI plates and vials) from Buildings [REDACTED] (non-registered areas) after the potential release was identified on June 13, 2014. Also there was no documentation of where these materials were placed within registered space (Building [REDACTED] Suite [REDACTED]) after movement from unregistered space.

**Observation:** Interviews indicated that the unregistered laboratory located in Building [REDACTED] Room [REDACTED] which contained one of the MALDI plates, was not appropriately secured on the day that the release was identified on June 13, 2014. This allowed individuals without Security Risk Assessment (SRA) approval as required for access to select agents and toxins continued access to space containing or exposed to [REDACTED] from June 14-17, 2014. This also led to additional potentially exposed personnel reporting to the occupational health clinic for further evaluation. CDC security did not lock the BRRAT suite laboratory (registered areas) until sometime on Monday, June 16, 2014, in the afternoon. At the end of the inspection, it was still unclear to the AgSAS inspection team at which point the rooms in Buildings [REDACTED] and [REDACTED] (non-registered areas) were locked to prevent persons from entering. Signage indicating possible exposures to [REDACTED] was not placed on laboratories in Buildings [REDACTED] and [REDACTED] until Wednesday, June 18, 2014.

**Observation:** There was a delay in decisions in the choice of appropriate chemical disinfectant for [REDACTED]. There was disagreement between the research staff, EHSCO staff and the Clinical and Environmental Microbiology Branch who were assisting with the incident response. This resulted in each laboratory using its own preference for chemical decontamination of surfaces and which surfaces to decontaminate. The laboratories' preference was 10% bleach, the EHSCO preference was peracetate. The EHSCO did not decontaminate any work surfaces; they only decontaminated the laboratory floors and outside hallways which was insufficient.

##### 5. Requirement: 9 CFR 121.19 *Notifications of Theft, Loss, and Release*

**Observation:** Numerous discrepancies on submitted Form 3 were noted at the time of inspection:

- Section 2 listed [REDACTED] quantity of 1 release. A total of 7 specimens potentially contaminated with [REDACTED] were identified by CDC: 3 MALDI plates two in Building [REDACTED], 1 in Building [REDACTED], 2 vials in Building [REDACTED] and 2 vials in Building [REDACTED] Rm [REDACTED]. The actual count was 4 MALDI plates, 8 inactivation vials, and 16 microtube [REDACTED] vials.
- Narrative of events in Building [REDACTED] indicated the chemical hood in Room [REDACTED] was utilized for removal of flakes from MALDI plate. The chemical hood actually used is located in Room [REDACTED].
- Vials delivered to Building [REDACTED] were stored in refrigerators # [REDACTED] and # [REDACTED], Room [REDACTED]. These locations were omitted from the submitted Form 3.
- Room [REDACTED] in Building [REDACTED] was utilized for centrifugation of vials and preparation of MALDI plates. This location was omitted from the submitted Form 3.

- Transfer of materials between buildings/laboratories was indicated to have occurred within primary and secondary containment devices. The AgSAS Inspection indicated materials were transferred within two plastic Ziploc bags which do not meet the “durable” requirement for secondary containment.
- The narrative describes disinfectants used as a combination of bleach and ethanol. Form 3, Section 3, line 29 indicates peracetic acid was utilized for all affected work surfaces. The AgSAS team identified that peracetic was only used on the floors and in some laboratories and on no work surfaces.

**6. Requirement: 9 CFR 121.10 Restricting access to select agents and toxins, security risk assessments**

**Observation: (Non-registered rooms and areas)** In Building [REDACTED], the MALDI plates and microtubes of [REDACTED] were stored in unlocked refrigerators # [REDACTED] and # [REDACTED] located in hallway [REDACTED] prior to transfer back to registered space. This hallway was unrestricted and laboratory workers were freely passing through this area at the time of inspection. There was no signage on these refrigerators indicating they should not be opened. The key to the refrigerator was located in the lock at the time of the inspection. At the request of the AgSAS team, the refrigerators were locked, the keys secured and the refrigerators were subsequently decontaminated.

**Observation:** At the onset of the AgSAS inspection on June 24, 2014, the inspection team identified 4 missing MALDI plates, 16 [REDACTED] microtubes and 8 inactivation tubes based on interviews with laboratory staff. On June 27, 2014, the 4 MALDI plates and 8 inactivation tubes were located in the BRRAT laboratory by the AgSAS inspection team and CDC management. Also on June 27, 2014, 8 microtubes were found in unregistered space in a bottle containing 20% bleach and these were subsequently autoclaved. On July 2, 2014, the remaining 8 missing [REDACTED] microtubes were located by the AgSAS inspection team and the RO, in the packing material of the container holding the MALDI plates in the BRRAT laboratory.

**Observation:** Building [REDACTED] Room [REDACTED] is another unregistered laboratory which was potentially contaminated and unlocked at the time of the AgSAS inspection. There was no signage on the door to this room prohibiting entry. A sign was present alerting users of the room that inactivated [REDACTED] was handled in the room and that potentially exposed persons should consult with the occupational health clinic but it did not prohibit entry.

**7. Requirement: 9 CFR 121.17 Records**

**Observation:** Upon identification of the potential release, no documentation was created for intra-entity transfer of materials back to select agent registered space, including a lack of verification of material and quantities to be transferred. The identified [REDACTED] materials were returned in packages to the BRRAT laboratory on June 13 and 14, 2014. The BRRAT laboratory did not open the retrieved packages from the unregistered areas in Building [REDACTED] refrigerator [REDACTED] containing the MALDI plates and the [REDACTED] micro tubes to verify that all [REDACTED] material had been returned. This verification was only done at the request of the AgSAS team on July 2, 2014.

**In order to address the findings as noted above, please provide to the AgSAS by July 25, 2014, the following:**

1. Provide the appropriate inactivation protocols for inactivation of [REDACTED] to be used in the future by CDC, with validation data. Indicate the time period needed to obtain this information.
2. Provide a plan to train and provide refresher training of laboratory personnel with access to [REDACTED] on the appropriate use of the inactivation protocol. This plan should include procedures to document correct use of the protocol and oversight of individuals using the protocol. Additionally, the plan should also provide refresher training to [REDACTED] to all individuals with access to [REDACTED]. Submit the training records to AgSAS after completion.
3. Provide a plan to update all laboratory areas with appropriate disinfectants. Provide SOPs on appropriate use of disinfectants for select agents and toxins registered in the specific laboratories, as well as processes to train personnel in registered laboratories on appropriate disinfection methods.
4. Provide a plan for corrections in the management response to this incident. The plan should include communications between the RO and CDC management on the appropriate actions and responses to address a potential release in both registered and non-registered areas. The plan should also include communications to impacted CDC employees, as well as coordination with the RO, Occupational Health personnel, CDC security personnel, and CDC senior management officials, to affect a coordinated, uniform response and actions to the incident.
5. Provide an updated security and incident response plan to address appropriate security of select agents during transfer between unregistered space and registered space. These updates should include plans to expeditiously secure all potentially exposed sites and control access to the potentially contaminated areas.
6. Provide a corrected Form 3, Theft, Loss, and Release Report.
7. Provide the intra-entity process to AgSAS.

Please contact [REDACTED] by phone at [REDACTED] or by email at [REDACTED] if you have any questions regarding this report.

[REDACTED]

[REDACTED]

National Director  
Agriculture Select Agent Services