



TO:

National Institutes of Health
9000 Rockville Pike DOHS 13 South Drive
MSC 5760 Building 13 Room 3K04
Bethesda, MD 20892
FAX: (301) 480-0701

FROM: Centers for Disease Control and Prevention, Division of Select Agents and Toxins

DATE: August 8, 2014

RE: Joint CDC and FBI Investigation of Vials labeled "Variola" and other Vials Discovered on the NIH Bethesda, MD Campus

Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the United States Department of Health and Human Services (HHS) has 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. These requirements can be found at 42 CFR Part 73. 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. See 42 CFR § 73.18. The above referenced regulations and supporting guidance information may be found at <http://www.selectagents.gov/>.

Background

On July 1, 2014,

_____ for the NIH Bethesda, MD campus registered entity notified the CDC DSAT of the discovery of vials possibly containing Variola virus (the material) on the NIH Bethesda campus.

In response to this notification, CDC DSAT and the Federal Bureau of Investigation (FBI) conducted a joint investigation at the NIH Bethesda, MD campus, from July 7 - 9, 2014, to gather the facts regarding the discovery of the material, how the material was secured upon discovery, the security environment the material was in prior to its discovery, and what actions the NIH Bethesda, MD campus is, or will be, taking to prevent any future incidents of this type.

The following CDC DSAT personnel participated in the investigation (CDC DSAT Investigation Team):

The following personnel from the HHS Office of General Counsel participated in the investigation:

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[Redacted text block]

The following FBI personnel participated in the investigation:

The following Food and Drug Administration (FDA) and NIH personnel were present at some point during the investigation:

The following personnel from the CDC Division of High-Consequence Pathogens and Pathology assisted in the laboratory investigation:

The CDC DSAT investigation team was on the NIH Bethesda, MD campus at 10 a.m. on July 7, 2014 and started a joint investigation of the incident with the FBI. In addition, on July 7, personnel from the CDC Division of High-Consequence Pathogens and Pathology assisted the FBI in reviewing the labels on the vials, establishing a preliminary inventory of the vials, and the transfer of sixteen of the vials to the CDC in Atlanta, GA. The CDC DSAT and FBI investigation continued on July 8. On July 9, 2014, one member of the CDC DSAT team remained onsite with FBI personnel to witness the destruction of some of the vials and the transfer of the remainder of the vials to the FBI for transport to the U.S. Department of Homeland Security's National Bioforensic Analysis Center.

During the CDC DSAT and FBI joint investigation, seven FDA and NIH staff were interviewed (see Appendix A), including all four FDA and NIH personnel that were associated with the discovery or

subsequent handling of the material. Records were obtained that included access records to building 13 room 3W84B, where the material was secured upon discovery.

The observations and findings during the joint CDC and FBI inspection are provided below.

Description of the Event

Based on interviews with FDA and NIH personnel associated with the discovery or subsequent handling of the material (Appendix A), events transpired on July 1, 2014 as follows (a graphical time line of these events is provided as Appendix B):

- Between approximately 11:30 a.m. and 12:30 p.m. an FDA investigator, [redacted] is in cold storage room 3C16 in building 29A, determining what pieces of equipment will be moved to the FDA White Oak Facility in Silver Spring, MD (photos of the cold room, a room generally held at 4° C and used for extended storage of materials or equipment requiring refrigeration, are provided as Appendix D).
- At approximately 12:30 p.m., [redacted] investigates the contents of 12 brown cardboard boxes located on a shelf in the back left corner of the cold room (photos are provided as Appendix D). In the first box opened, he sees, among the other glass vials with typed labels, a vial of lyophilized material bearing the typed label: "variola." [redacted] immediately closes the box, exits the cold room, and proceeds to laboratory 3C22 to wash his hands.
- At approximately 1:00 p.m., [redacted] goes to the office of a second FDA investigator, [redacted] a virologist, and describes to him the aforementioned events and discovery of the vial labeled "variola."
- At approximately 1:00 p.m., [redacted] return to cold storage room 3C16. They reopen the box identified by [redacted] and further examine the contents, identifying a second vial labeled "variola."
- Between approximately 1:00 p.m. and 1:30 p.m., [redacted] look through additional boxes, finding vials with labels such as "Q-fever," "rickettsia," and an additional vial labeled "variola."
- At approximately 1:30 p.m., [redacted] finish their investigation of the boxes, leave them in the cold room, exit to wash their hands in nearby laboratory 3C22, and go to the office of [redacted] supervisor, [redacted] was not in her office. [redacted] emails her indicating that he would like to have a discussion upon her return.
- Between 4:30 p.m. and 5:00 p.m., [redacted] emails [redacted] indicating that she has returned to her office and is available to talk.
- At approximately 5:00 p.m., [redacted] goes to the office of [redacted] the two then proceed to [redacted] office and inform her of the aforementioned events leading to the discovery of the vials labeled "variola."
- [redacted] informs [redacted] that she would be contacting the director of the NIH Division of Occupational Health and Safety (DOHS), [redacted] return to their offices.
- At approximately 5:30 p.m. [redacted] contacts [redacted] tells her to bring the material to the DOHS office on the third floor of building 13.
- At approximately 5:35 p.m. [redacted] contacts [redacted] and the two of them meet in the cold storage room 3C16. They do not open any boxes, and wearing a lab coat and gloves, place all 12 boxes into a larger cardboard box. The used lab coats and gloves are also placed into the larger box with the 12 smaller boxes. The larger box is sealed with clear packaging tape, and [redacted] alone hand-carries the material to the NIH DOHS office on the 3rd floor of building 13. An aerial view of the route taken between building 29A and building 13 is provided as Appendix C.

- At approximately 5:50 p.m., [redacted] arrives and meets [redacted] at the NIH DOHS office. [redacted] initiates a chain of custody form to document the transfer of the material from FDA to NIH. [redacted] and [redacted] proceed to the BSL2 laboratory, building 13 room 3W84. [redacted] disarms and opens the door to room 3W84. [redacted] hands over the material to [redacted] who takes the material into 3W84. [redacted] remains outside of 3W84, but watches through the window as [redacted] disarms and enters BSL3 laboratory, 3W84B, and places the material in the biosafety cabinet within 3W84B. [redacted] walks back to her office in the building 29 complex and notifies her supervisor,
- Between 6:00 p.m. and 6:08 p.m. [redacted] tries three times to get in contact with the FBI. The FBI makes contact with [redacted] at 6:28 p.m.
- At 6:35 p.m. [redacted] calls and notifies the CDC DSAT director.

According to access logs provided by NIH, no personnel accessed BSL3 lab 3W84B after 5:51 p.m. July 1, 2014 until 10:54 a.m. July 7, 2014 when the joint CDC Division of High-Consequence Pathogens and Pathology and the FBI team started the photo documentation and preliminary inventory of the vials.

Description of the Security Environment of the Material upon Discovery and Prior to Its Transfer to FBI Custody

At the time of its discovery, the material was in an unsecure, shared cold storage room, 3C16, on the third floor of building 29A. Once discovered, the material was packaged in a larger cardboard box and transported to a BSL3 laboratory in building 13, room 3W84B.

Security of Campus

- Buildings 29, 29A, and 29B (building 29 complex) and building 13 reside on a closed campus. The campus is protected by a perimeter fence, surveillance cameras, guards at the entrances, as well as roving security.
- Security is managed by a Security Operations Center which monitors alarms and directs response (NIH Division of Police).

Security of Building 29 Complex

- The building 29 complex consists of 3 buildings, 29, 29A, and 29B, linked by common hallways.
- There are 13 exterior doors to the building 29 complex (4 have card readers and guards; the remaining doors are keyed).
- Access to the building 29 complex is limited to FDA, NIH, and HHS employees with access to the NIH campus.
- With the exception of laboratory 3A03 in building 29A, which is registered with the Federal Select Agent Program¹ and has access controls administered by NIH, access to all other areas within the building 29 complex is administered by the FDA.
- There are four video cameras on the outside of the building. The video cameras do not completely cover the building perimeter.

¹ The Federal Select Agent Program, a joint effort of the CDC's DSAT and the Animal and Plant Health Inspection Services' Agriculture Select Agent Services, has regulatory oversight of the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal or plant health or to animal or plant products.

- During business hours there are five guards on duty (four at access points and one roving guard); after business hours there are three guards on duty (two at access points and one roving guard).

Security of Cold Room 3C16

- 3C16 is located on the 3rd floor of building 29A.
- The cold room is accessed from a common hallway, across from a suite of laboratories.
- The space is currently shared between the laboratories of two FDA investigators and [redacted]. They are from different FDA divisions. [redacted] and [redacted] did not know who may have stored material in this room before 1992. [redacted] thought the material was in the room before he began using the room in the 1990s.
- At the time of the discovery, the room was not locked and there is no indication that it has been locked in the past.
- There is no means to determine who may have entered the room (e.g. card key readers, access logs, or video cameras).
- There was no means to determine who was responsible for the storage area or who owned material inside room 3C16.

Security of laboratory 3W84B in Building 13

- During work hours when the building is occupied, there are two secured doors.
- After work hours, the main points of entry to building and an additional door are automatically locked.
- Access to the BSL3 laboratory is restricted by three different electronic mechanisms and the room is monitored by an intrusion detection system. The BSL3 laboratory is within a BSL2 laboratory, room 3W84.
- Personnel who had access to the BSL3 laboratory (3W84B), after a Security Risk Assessment previously conducted by the FBI, have been approved by the Federal Select Agent Program for access to select agents and toxins; and are enrolled in the NIH Bethesda, MD campus personnel reliability program.
- Between July 4 and 7, 2014 there were two FBI agents stationed at the access point to BSL2 laboratory 3W84.
- Three NIH and FDA personnel knew that the material found in building 29A was stored inside the building 13 BSL3 laboratory 3W84B. [redacted] both knew its location and had access. [redacted] was present when it was stored, however she stated she did not tell anyone and when asked, could not recall the room number. [redacted] did not know the storage location.
- No one entered laboratory 3W84B after 5:51 p.m., July 1, 2014 until 10:54 a.m., July 7, 2014 when the personnel from the CDC Division of High-Consequence Pathogens and Pathology and the FBI entered the room to begin their inventory of the materials contained in the box.

Description of Biosafety and Security Oversight for Building 29A

Access to the building 29 complex is administered by and limited to FDA, NIH, and HHS employees with access to the NIH Bethesda campus. With the exception of laboratory 3A03 in building 29A, which is registered with the Federal Select Agent Program and has access controls administered by NIH, access to all other areas within the building 29 complex is administered by the FDA.

[redacted] indicated that as a tenant, work conducted by FDA researchers is subject to review and approval by the NIH Institutional Biosafety Committee (IBC) and must adhere to the stipulations of the IBC as well as overall NIH biosafety requirements. However [redacted] said that NIH does not

perform laboratory inspections of the FDA labs, with the exception that they do laboratory safety surveys when active work is being conducted if the laboratories are registered with the NIH Recombinant DNA Advisory Committee (RAC).

Interviews with [redacted] indicated that NIH is in charge of the safety oversight of the work being conducted in the building 29 complex. They indicated that, annually, people from NIH inspect their laboratories, but to their knowledge the NIH personnel have never inspected cold rooms in the building 29 complex.

When interviewing [redacted] for the building 29 complex, she likewise indicated that NIH manages safety for the building 29 complex [redacted] indicated that in the 11 months she had worked there, she had never done a laboratory inspection or been in the 3C16 cold storage room. According to "Response to CDC Memo of July 11, 2014" the FDA biosafety specialist serves as a liaison between FDA research staff and the NIH DOHS.

We also asked who had "ownership of cold room." [redacted] is listed on the door as a point of contact. However, [redacted] indicated that there is no formal agreement or policy assigning any one person responsibility for the contents of the room [redacted] indicated that the cold rooms are officially assigned to different divisions and groups. [redacted] echoed the sentiment that cold rooms are shared storage spaces but indicated that there is no centralized assignment of the cold room space. [redacted] said that people voluntarily list themselves as the contact person in case there are problems with the cold room. There was no biological hazard signage on the door.

On July 11, 2014, CDC DSAT requested that [redacted] provide additional information to better understand the relationship between the FDA building 29 complex and NIH, the biosafety and security responsibilities for oversight of the building 29 complex, and any additional measures that have been taken to ensure that no additional regulated materials exist on the NIH Bethesda, MD campus in areas not registered with the Federal Select Agent Program (Appendix F).

The information provided by [redacted] in response to the CDC DSAT request was received on July 18, 2014 and includes an update on the actions taken to ensure there is no more of this type of material in unregistered space on the NIH Bethesda campus (see below for a summary of those actions).

Description of progress made, since July 1, 2014, in assessing the contents of cold storage rooms in buildings 29, 29A, and 29B along with other laboratory and storage areas on the NIH Bethesda, MD campus.

On July 1, 2014, and July 8, 2014, respectively, FDA personnel and DSAT personnel separately searched cold room 3C16 where the material was discovered; with no additional material of this type being found.

[redacted] and [redacted] provided documents indicating that on July 3 and 8 they examined all other cold rooms in the building 29 complex looking for additional unassigned biological material and found none.

As of July 18, 2014, NIH and FDA created a new "attestation" document requiring FDA PIs to check their laboratory, its contents and all associated freezers, refrigerators, cold rooms, storage cabinets for select agents on the NIH Bethesda, MD campus.

Effective July 18, 2014, FDA ceased moving material from the building 29 complex to its White Oak facility until the attestation is completed by each FDA PI. This includes the materials already transferred from NIH to the FDA White Oak campus. Furthermore, before any more material is moved from the NIH

campus to the White Oak campus, FDA is requiring that the entire contents of each storage container be visually surveyed and any select agent be identified and handled in accordance with the NIH safety plan.

Effective July 18, 2014, NIH created a new "attestation" statement requiring all NIH Institutes and Centers (IC) Scientific Directors to attest, by September 30, 2014, that all IC laboratories, contents, and all associated freezers, refrigerators, cold rooms, storage cabinets had been surveyed for select agents and other potentially hazardous biological materials. All human pathogenic organisms that require BL2 level 2 containment and above, and biological toxins, venoms, or poisons will be recorded and inventoried as to location and reported to NIH/DOHS.

NIH has directed a 'clean sweep' of all NIH laboratories, clinical spaces, and offices associated with laboratories to be completed by September 30, 2014. This will include identification and labeling of material. It will also include assigning a responsible person for the material or destruction if it's not needed. Phase 2 of this plan is under development and will address policy review and revision, potential changes to the NIH Table of Penalties, and establishment of enhanced management responsibilities.

After the "clean sweep," NIH/DOHS will perform systematic compliance checks of all the laboratory spaces, all freezers and refrigerators, cold rooms, dry storage areas, etc. including review of the inventories for potentially hazardous biological materials.

For areas registered with the Federal Select Agent Program, DOHS will provide follow-up compliance checks of storage areas during annual surveys of registered laboratories (those conducting infectious disease and recombinant nucleic acid research). Safety specialists will document compliance checks.

Findings

The cold room where the glass vials were found has been used by numerous investigators since at least 1992 and likely since the building was constructed in 1968. Though the room had the capability of being locked, interviewed FDA personnel indicated that the room had never been locked to their knowledge, going back to at least 1992.

There were no access logs or inventory records for any material or equipment in the cold room where the vials were found.

The material found by FDA personnel and transferred to _____ consisted of a total of 327 glass vials of lyophilized material in 12 boxes.

At least nine of the 327 vials had labels indicating that they were potentially select agents (six Variola major virus or Variola minor viruses, one Russian Spring and Summer Encephalitis virus, one Eastern Equine Encephalitis virus, and one *Coxiella burnetii*):

1. "Variola- Lee Strain, 2nd egg passage, CAM 20% in milk, 2.5cc, 11FEB47" one vial
2. "Variola- Kim Strain, 2nd egg passage, CAM 20% in milk, 2.5cc, 11FEB47" one vial
- 3 - 4. "Alastrim, CAM3, 20% suspension, 0.5cc dried, 7APR59" two vials
- 5 - 6. "Variola-Yamada, 32 egg pass, 20% CAM, susp. In H2O, 2cc, 10FEB54" two vials
7. "RSSE 45, 10%MB, 1.0cc, 1/26/57" one Vial
8. "EEE 462" one vial
9. "Q fever (Dyer strain)" one vial

One vial was labeled "RMSF." Until December 4, 2012, Rocky Mountain Spotted Fever or *Rickettsia rickettsii* was listed as a select agent.

On July 7, 2014, vials 1 - 7 along with 9 other vials that could not be identified by their labels were sent to the CDC Poxvirus and Rabies Branch BSL-4 laboratory (a total of 16 vials). One vial labeled "NOR. SPL. ANT. Lot 1 1.0ml 11/19/59" was found breached and destroyed by submersion in Microchem.

On July 9, 2014, 31 vials, four labeled "Vaccinia WR 10% IN 20% NRS 2mol pass 1.0ml 4/17/52 and 27 additional vials labeled "NOR. SPL. ANT. Lot 1 1.0ml 11/19/59" were destroyed using the autoclave in the building 13 BSL2 laboratory 3W84. The remainder of the vials, including vials 8 and 9, were moved to the U.S. Department of Homeland Security's National Bioforensic Analysis Center on July 9, 2014 (a total of 279 vials).

On July 8, 2014, the CDC Division of High-Consequence Pathogens and Pathology confirmed by using two variola-specific PCR assays that all six vials that were labeled "Variola" or "Alastrim" contained Variola virus genetic material.

On July 10, 2014, the CDC Division of High-Consequence Pathogens and Pathology confirmed that the Variola virus in at least two of the six vials was viable, therefore confirming that the material was a select agent.

The 12 boxes were marked on the outside with a series of Roman numerals and letters, IA - IH, IIA - IIC, and IIF - IIH. Based upon the numbering system, there may be at least two boxes that are not accounted for (i.e. IID and IIE). All other lettering on the outside of the boxes had been previously marked through. Although some of the marked out lettering was legible (e.g., Measles, Enders strain, Rubella, bent tip pipettes), none of the boxes contained information that identified the source of the material (e.g. PI name or organization). Photos are presented as Appendix D.

The dates on the labels on the vials ranged from the 1946 to the 1964. While the vast majority of the labels did not contain any information identifying any particular source of the material (e.g. PI name or organization), some of the labels contained possible names or potential sources (e.g. Department of Biologics Research WRAIR, WRAMC L13, Microbiological Associates Bethesda, Maryland).

Interviews with _____ revealed that the boxes may have been in cold room 29A/3C16 where the material was discovered since at least the early 1990's, but no one was aware of the owner or source of the material.

The location in which the material was found does not meet the requirements of the select agent regulations (42 CFR Part 73) for the possession of select agents in general and for Variola virus in particular, and there were significant vulnerabilities with access control and accountability.

After discovery, though the location in which the material was stored did not meet the specific additional requirements of the select agent regulations required for possession of Variola virus, the investigation team did not identify any significant vulnerability for the short time it was secured in the building 13 BSL3 laboratory, room 3W84B.

When moved from building 29A to building 13, the vials were not packaged and transported in a manner sufficient to prevent their release from the transport container (cardboard box) in the event of an accident, and, had any of the six glass vials containing the Variola virus been breached, there would have been nothing to contain the agent and prevent its release to the surrounding environment. During the initial inspection of the vials on July 7, 2014 it was noted that one vial labeled "NOR. SPL. ANT." (presumably Normal Spleen Antigen) had been breached. It is not known when this breach occurred but this could have occurred during the movement on July 1, 2014 to building 13. In her interview,

indicated that she heard the vials clinking together as she transported them from building 29A to building 13.

Section 202 (a) of Public Law 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, signed into law on June 12, 2002, directed the HHS Secretary to provide written guidance within 30 days of enactment of the bill on how facilities in possession of select agents shall notify the Secretary of possession. CDC on July 12, 2002 published a notice that states that each facility should designate a responsible facility official (RFO) to complete the notification of possession form by September 10, 2002. The notice stated that to complete the notification form the RFO would need to inventory its facility and consult with others (e.g. principal investigators) as necessary to obtain information required for the notification form. Variola major was listed on that notification form. Neither NIH nor FDA identified the possession of Variola major.

The select agent regulations (42 CFR Part 73) became effective on February 7, 2003. These regulations require the registration of the possession, use, and transfer of select agents and toxins including Variola major and Variola minor virus. The registration application submitted by NIH as required under the select agent regulations did not include Variola major and Variola minor virus.

Assessment of the Root Cause and Next Steps

Failure of past NIH and FDA actions to fully identify and account for material labeled as potentially select agents and toxins on the NIH Bethesda campus, specifically the failure to have oversight and accountability for material in a shared storage space (e.g. walk in cooler) were ownership of the material is not clear or unknown.

DSAT is referring this incident to the HHS Office of Inspector General for further investigation and possible action.

In order to address the findings noted above, please provide DSAT by August 22, 2014, the following:

- 1. An updated security and incident response plan to address appropriate security and safety of select agents, or potential select agents, after identification in unregistered areas and during transfer between unregistered space and registered space.**
- 2. A copy of the completed "Phase 2" of NIH's plan, currently in development, aimed to address review and revision to NIH policies, potential changes to the NIH Table of Penalties, and establishment of enhanced management responsibilities at all levels of NIH. If the plan is not completed by August 22, 2014 please indicate when it will be completed and provide the completed plan by that date.**
- 3. Please clarify how the Biological Material Survey Attestation and the Phase I of the NIH Potential Hazardous Biological Materials Management Plan will address identification and the accountability for biological materials where ownership is not clear or unknown (e.g. the current incident where there was no Principal Investigator or other personnel specifically assigned to account for the collection containing Variola virus).**

In addition, please provide the date by which NIH/DOHS will provide documentation that it has completed under Phase I of the NIH Potential Hazardous Biological Materials Management Plan the

systematic compliance checks of all the laboratory spaces, all freezers and refrigerators, cold rooms, dry storage areas, etc. and has reviewed all inventories for potentially hazardous biological materials and the results of these checks with respect to select agents and toxins.

Please contact
any questions regarding this report.

if you have

Sincerely,

Captain, USPHS (Ret.)
Department of Health and Human Services
Centers for Disease Control and Prevention