

**From:** (b)(6) USARMY MEDCOM USAMRIID (US)  
**To:** Edwin, Samuel (CDC/OPHPR/DSAT)  
**Cc:** (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) CDC/OPHPR/DSAT  
**Subject:** 21 May CDC Site Visit visit - logistics  
**Date:** Saturday, May 19, 2018 11:45:32 AM

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Hi (b)(6)

(b)(3):42 U.S.C. §  
262a(h)(1)(E)

We are making arrangements to have a van available to drive CDC personnel to Building (b)(6) on Monday-Tuesday.

I highly recommend the team bring appropriate footwear to change into. We have been experiencing a significant amount of rain and it is very muddy at this location.

Please ensure the team contacts me on my cell when they re en route:

(b)(6)

Thank you and we will see your team Monday.

Much appreciated,

(b)(6)

&

FSAP Responsible Official  
US Army Medical Research Institute of Infectious Diseases (USAMRIID)  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
Cell: (b)(6)  
E-mail: (b)(6)@mail.mil

Sent from my iPhone

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) CIV USARMY HQDA OTIG (USA); (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)  
(b)(6) CIV USARMY HQDA OTIG (US); (b)(6) CIV USARMY HQDA OTIG (US); (b)(6)  
(b)(6) CIV USN NAVSURFWARGEN DAH VA (USA); (b)(6) CIV USARMY MEDCOM USAMRIID  
(US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CTR USARMY MEDCOM  
USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) CIV  
USARMY USAMC (USA); (b)(6) CIV USARMY MEDCOM USAMRMC (US); (b)(6) CIV USARMY  
MEDCOM USAMRMC (US)  
**Subject:** Call to DAIG/CDC to discuss schedule and final planning items (RE: 18-29 March 2019 Inspection)  
(UNCLASSIFIED)  
**Attachments:** [CDC DAIG Schedule 18-29 MAR 2019 DRAFT 7.xlsx](#)  
[BSL4 inspection planning March2019 v2.xlsx](#)  
[List of Inspectors 18-29Mar19 ver5.docx](#)

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CLASSIFICATION: UNCLASSIFIED

Dial-In Number:  
Compassion (b)(6)  
DSN (b)(6) (b)(6) for Overseas DSN  
\*\*\* The Conference ID and PIN are needed to dial in\*\*\*  
Conference ID (b)(6) Pin Code (b)(6)

CLASSIFICATION: UNCLASSIFIED

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** Edwin, Samuel (CDC/OPHPR/DSAT (b)(6) CDC/OPHPR/DSAT)  
**Cc:** (b)(6) CDC/OPHPR/DSAT; (b)(6) CDC/OPHPR/DSAT; (b)(6) (CDC/OPHPR/DSAT); (b)(6) DC/OPHPR/DSAT; (b)(6) CIV USARMY USAG (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) CTR USARMY MEDCOM USAMRIID (US); (b)(6) LTC USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US); USARMY Ft Detrick MEDCOM USAMRIID Mailbox EOC (b)(6) D CIV USARMY MEDCOM USAMRIID (US); (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) I CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CTR USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY USAG (US); (b)(6) CIV USARMY USAG (US); (b)(6) CIV USARMY USAG (US); (b)(6) CIV USARMY ID-SUSTAINMENT (US); (b)(6) CIV USARMY MEDCOM USAMRMC (US); (b)(6) CIV USARMY MEDCOM USAMRMC (US); (b)(6) CIV USARMY MEDCOM USAMRMC (US); (b)(6) CPT USARMY MEDCOM USAMRIID (US); (b)(6) SSG USARMY 555 ENG BDE (US); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CTR USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRMC (US); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CTR USARMY (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CPT USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY ID-SUSTAINMENT (US); (b)(6) COL USARMY USAG (US); (b)(6) CIV USARMY USAG (US); (b)(6) CIV USARMY USAG (US)

**Subject:** CDC - FSAP inspectors onsite at USAMRIID Monday afternoon 5/21/18 (UNCLASSIFIED)  
**Date:** Friday, May 18, 2018 6:34:32 PM  
**Importance:** High

CLASSIFICATION: UNCLASSIFIED

Dr. Edwin,

USAMRIID Biosafety will work with US Army Garrison Safety to develop a risk assessment to identify any potential exposures (BSAT or Chemicals) to USAG personnel working in the Steam Sterilization Plant (SSP) and mitigating factors in place to lower the residual risk.

Also acknowledging the message below from (b)(6)

"FSAP has decided to send a small contingent of inspectors to USAMRIID next week to complete the information gathering aspects of our review. Currently the inspection team will consist of myself (b)(6) (b)(6) with the possibility of representatives from AgSAS to join us in these efforts. We wanted to give you advanced notice that we will be traveling to Frederick on Monday morning (5/21) and intend to be onsite Monday afternoon. Our visit will continue into Tuesday where we hope to lay eyes on the areas impacted by the (b)(6) and interact with facilities and biosafety personnel regarding the current and next steps USAMRIID is taking to resolve the issues. I cannot confirm at this time exactly when we will be onsite Monday but will send you a message once where in route from the airport to Fort Detrick to narrow down our arrival window."

(b)(3):42 U.S.C. § 262a(h)(1)(D)

Please contact me upon your arrival and I will meet your team at the USAMRIID (b)(3):42 U.S.C. § 262a(h)(1)(E) Building

(b)(3):42 U.S.C. § 262a(h)(1)(E) Cell: (b)(6)

Thank you,

(b)(6)

(b)(6) Biosecurity Directorate &

FSAP Responsible Official  
US Army Medical Research Institute of Infectious Diseases (USAMRIID)  
1425 Porter Street  
Fort Detrick, MD 21702

Office Phone: (b)(6)  
Office Mobile: (b)(6)  
E-mail: (b)(6)@mail.mil

-----Original Message-----

From: Edwin, Samuel (CDC/OPHPR/DSAT) [mailto:mhq2@cdc.gov]

Sent: Friday, May 18, 2018 4:37 PM

To: (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov; (b)(6) CIV USARMY MEDCOM  
USAMRIID (US) (b)(6)@mail.mil

Cc: (b)(6) (CDC/OPHPR/DSA) (b)(6)@cdc.gov; (b)(6) (CDC/OPHPR/DSAT)

(b)(6)@cdc.gov; (b)(6) (CDC/OPHPR/DSA) (b)(6)@cdc.gov; (b)(6)

(CDC/OPHPR/DSAT) (b)(6)

Subject: [Non-DoD Source] RE: FSAP inspectors onsite Monday afternoon 5/21/18

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

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Hi (b)(6)

Please conduct a risk assessment to identify any potential exposures (BSAT or Chemicals) and mitigating factors in place to lower the residual risk. Thank you. Don't hesitate to contact us if you have additional questions.

Respectfully,

Sam

Samuel S. Edwin, Ph.D.

Director,

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Phone: (b)(6)

E-mail: (b)(6)@cdc.gov <Caution-mailto:(b)(6)@cdc.gov>

From: (b)(6) (CDC/OPHPR/DSAT)

Sent: Friday, May 18, 2018 4:17 PM

To: (b)(6) civ@mail.mil; (b)(6) civ@mail.mil

Cc: (b)(6) CDC/OPHPR/DSAT <clo2@cdc.gov>; Edwin, Samuel (CDC/OPHPR/DSAT)

(b)(6)@cdc.gov; (b)(6) (CDC/OPHPR/DSAT) (b)(6)

(CDC/OPHPR/DSAT) (b)(6)@cdc.gov; (b)(6) CDC/OPHPR/DSAT (b)(6)@cdc.gov

Subject: FSAP inspectors onsite Monday afternoon 5/21/18

Good Afternoon (b)(6)

I appreciate the information provided in this afternoon's conference call. FSAP has decided to send a small contingent of inspectors to USAMRIID next week to complete the information gathering aspects of our review. Currently the inspection team will consist of (b)(6) with the possibility of representatives from AgSAS to join us in these efforts. We wanted to give you advanced notice that we will be traveling to Frederick on Monday morning (5/21) and intend to be onsite Monday afternoon. Our visit will continue into Tuesday where we hope to lay eyes on the areas impacted by the (b)(6) and interact with facilities and biosafety personnel regarding the current and next steps USAMRIID is taking to resolve the issues. I cannot confirm at this time exactly when we will be onsite Monday but will send you a message once where in route from the airport to Fort Detrick to narrow down our arrival window.

(b)(3):42 U.S.C. § 262a(h)(1)(D)

Thank you for your cooperation and please let me know if any additional information is needed from FSAP regarding our site visit ahead of our arrival.

Sincerely,

(b)(6)

Division of Select Agents and Toxins  
Office of Public Health Preparedness and Response  
Centers for Disease Control and Prevention  
1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: (b)(6) Fax: (b)(6)

DSAT Vision: To be the preeminent resource for the safety and security of biological agents and toxins.

This document is intended for the exclusive use of the recipient named above. It may contain sensitive information that is protected privileged, or confidential, and it should not be disseminated, distributed, or copied. If you think you have received this document in error, please notify the sender immediately and destroy the original, thank you.

CLASSIFICATION: UNCLASSIFIED

**From:** (b)(6) IV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) CDC/DDPHSIS/CPR/DSAT (b)(6) (CDC/DDPHSIS/CPR/DSAT)  
**Cc:** (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM  
USAMRIID (US)  
**Subject:** CDC Inspection 26-28 March 2019 (UNCLASSIFIED)  
**Date:** Monday, February 11, 2019 1:16:10 PM

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CLASSIFICATION: UNCLASSIFIED

(b)(6)

Can you provide the names of the CDC personnel who will be conducting the inspection 26-28 March? We would like to ensure we have the JPAS Visit Requests. So far, we have only received one Visit Request for (b)(6)

Of these personnel, who will be going into BSL-4? We would like to ensure we have the training/occupational health clearances scheduled for entry into containment.

Thank you.

(b)(6)

(b)(6)

Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office

(b)(6)

Mobile

(b)(6)

E-mail

(b)(6)

civ@mail.mil

CLASSIFICATION: UNCLASSIFIED

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) CIV USARMY HQDA OTIG (USA); (b)(6) CDC/DDPHSIS/CPR/DSAT  
**Cc:** (b)(6) CIV USARMY HQDA OTIG (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) CTR USARMY MEDCOM USAMRIID (USA); (b)(6) (CDC/DDPHSIS/CPR/DSAT)  
**Subject:** CDC/DAIG Inspection Schedule (version 12) (UNCLASSIFIED)  
**Date:** Tuesday, March 12, 2019 12:07:18 PM  
**Attachments:** CDC DAIG Schedule 18-29 MAR 2019 DRAFT 12.xlsx

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CLASSIFICATION: UNCLASSIFIED

(b)(6)

Please see updated DAIG/CDC Inspection schedule (version 12). I'm currently working on another update (version 13), but these are minor edits.

(b)(6) - as requested, we placed BSL-4 refresher training in the first week for the DAIG team. It is currently scheduled, Monday 18 March at 1300.

Thank you,

(b)(6)

(b)(6) Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6)@civ@mail.mil

CLASSIFICATION: UNCLASSIFIED





Fort Detrick, MD 21702

Office (b)(6)

Mobile (b)(6)

E-mail: (b)(6) [civ@mail.mil](mailto:(b)(6)@mail.mil)

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) CDC/OPHPR/DSAT  
**Cc:** (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) (CDC/OPHPR/DSAT) (b)(6)  
(b)(6) CDC/OPHPR/DSAT; (b)(6) CDC/OPHPR/DSAT  
**Subject:** FW: CDC (UNCLASSIFIED)  
**Date:** Monday, August 27, 2018 8:48:38 AM

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(b)(6)

Please have the personnel attending the 12-13 Sept CDC inspection at USAMRIID fax the Visit Request for the following personnel to (b)(6)

Fax: (b)(6)

(b)(6)  
(b)(6)  
(b)(6)  
(b)(6)

Please direct any questions to:

(b)(6)

Personnel Security Manager  
OPSEC Officer  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter St., Room (b)(6)  
Fort Detrick, MD 21702  
Office: (b)(6)  
Fax: (b)(6)  
(b)(6) (b)(6)  
E-mail: (b)(6)@mail.mil

(b)(3):42 U.S.C. §  
262a(h)(1)(E)

Thank you,

(b)(6)

(b)(6) Biosecurity Directorate &  
FSAP Responsible Official  
US Army Medical Research Institute of Infectious Diseases (USAMRIID)  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6)civ@mail.mil

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6)  
**To:** (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)  
(b)(6) CIV USARMY HQDA OTIG (USA); (b)(6) CIV USARMY HQDA OTIG (US) (b)(6)  
(b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**Subject:** FW: DAIG/CDC Inspection Schedule (UNCLASSIFIED)  
**Date:** Monday, February 11, 2019 2:48:19 PM  
**Attachments:** [DAIGCDC Inspection Schedule .msg](#)

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CLASSIFICATION: UNCLASSIFIED

Thank you,

(b)(6)

(b)(6) Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6) civ@mail.mil

CLASSIFICATION: UNCLASSIFIED

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) CIV USARMY HQDA OTIG (US); (b)(6) CIV USARMY HQDA OTIG (US); (b)(6)  
(b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) (CDC/DDPHSIS/CPR/DSAT)  
**Cc:** (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CTR USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) LTC USARMY MEDCOM USAMRIID (USA)  
**Subject:** FW: DAIG/CDC Schedule - Prep for 18-29 March Inspection (Request a Teleconference 11-15 Feb) (UNCLASSIFIED)  
**Date:** Thursday, February 7, 2019 5:11:44 PM

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CLASSIFICATION: UNCLASSIFIED

Dear CDC/DAIG Team Leads,

Are you available 13 Feb from 1100-1200 EST for a teleconference to discuss the inspection schedule?

Thank you.

(b)(6)  
(b)(6)  
(b)(6) Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6)@mail.mil

-----Original Message-----

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**Sent:** Thursday, February 7, 2019 12:54 PM  
**To:** (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6)@mail.mil; (b)(6)@mail.mil; (b)(6) CTR USARMY MEDCOM USAMRIID (US); (b)(6)@mail.mil; (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6)@mail.mil; (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6)@mail.mil  
**Cc:** (b)(6) CIV USARMY HQDA OTIG (US); (b)(6)@mail.mil; (b)(6) CIV USARMY HQDA OTIG (US); (b)(6)@mail.mil; (b)(6) (CDC/OPHPR/DSAT)@cdc.gov; (b)(6) (CDC/DDPHSIS/CPR/DSAT)@cdc.gov; (b)(6) USARMY MEDCOM USAMRIID (USA); (b)(6)@mail.mil  
**Subject:** DAIG/CDC Schedule - Prep for 18-29 March Inspection (Request a Teleconference 11-15 Feb) (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Team,

The DAIG would like to set up a teleconference to discuss the DAIG/CDC Schedule. I've cc:d the DAIG and CDC Team Leads so we can come up with a date for the teleconference. The DAIG is out of the office next week, so it may be the following week (11-15 February.)

Specifically the DAIG and CDC have asked,

- 1) What studies will be going on in containment during the inspection (18-29 March)
- 2) Will all 3 BSL-4 suites be active at the time of the inspection?

Please provide dates/times you are available 11-15 Feb and I will set up a calendar invite/dial in number.

Thank you,

(b)(6)

(b)(6)

Biosecurity Directorate Federal Select Agent Program Responsible Official US Army Medical

Research Institute of Infectious Diseases

1425 Porter Street

Fort Detrick, MD 21702

Office: (b)(6)

Mobile: (b)(6)

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CLASSIFICATION: UNCLASSIFIED

CLASSIFICATION: UNCLASSIFIED

(b)(6)

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) CDC/DDPHSIS/CPR/DSAT  
**Cc:** (b)(6) USARMY MEDCOM USAMRIID (USA)  
**Subject:** Photos requested by CDC (UNCLASSIFIED)  
**Date:** Friday, March 29, 2019 8:45:16 AM  
**Attachments:** [DSC 6598.jpg](#)  
[DSC 6605.jpg](#)  
[DSC 6607.jpg](#)  
[DSC 6608.jpg](#)  
[DSC 6614.jpg](#)  
[DSC 6619.jpg](#)  
[DSC 6620.jpg](#)  
[DSC 6624.jpg](#)  
[DSC 6628.jpg](#)  
[DSC 6386b.jpg](#)  
[DSC 6396.jpg](#)  
[DSC 6397.jpg](#)  
[DSC 6403.jpg](#)  
[DSC 6514.jpg](#)  
[DSC 6515.jpg](#)  
[DSC 6517.jpg](#)  
[DSC 6519.jpg](#)  
[DSC 6522.jpg](#)  
[DSC 6533.jpg](#)  
[DSC 6542.jpg](#)  
[DSC 6596.jpg](#)

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CLASSIFICATION: UNCLASSIFIED

(b)(6)

Please see attached photos from our [tour](#). These have been cleared by Physical Security for release.

Thank you,

(b)(6)

(b)(6) Biosecurity Directorate

Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)

Mobile: (b)(6)

E-mail: (b)(6).civ@mail.mil

CLASSIFICATION: UNCLASSIFIED

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) CIV USARMY HQDA OTIG (US); (b)(6) CIV USARMY HQDA OTIG (USA); (b)(6)  
(b)(6) (CDC/DDPHSIS/CPR/DSAT)  
**Cc:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**Subject:** Pictures of [redacted] Tour (UNCLASSIFIED)  
**Date:** Wednesday, March 27, 2019 10:43 AM C. §  
262a(h)(1)(D)

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CLASSIFICATION: UNCLASSIFIED

Team,

We have photos for the [redacted] tour available. If there are any specific photos you would like, please let me know and we can review them.

(b)(3):42 U.S.C. § 262a(h)(1)(D)

Thank you,

[redacted]  
(b)(6)

(b)(6) Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6)@mail.mil

CLASSIFICATION: UNCLASSIFIED



**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) (CDC/DDPHSIS/CPR/DSAT)  
**Cc:** (b)(6) LTC USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) CTR USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (USA)  
**Subject:** RE: [Non-DoD Source] 7086 USAMRIID Inspection (UNCLASSIFIED)  
**Date:** Thursday, February 14, 2019 1:27:09 PM

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CLASSIFICATION: UNCLASSIFIED

(b)(6)

Great, thank you for this information.

Thank you,

(b)(6)

(b)(6) Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6).civ@mail.mil

-----Original Message-----

From: (b)(6) (CDC/DDPHSIS/CPR/DSAT) [mailto:(b)(6)@cdc.gov]  
Sent: Thursday, February 14, 2019 1:20 PM  
To: (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) civ@mail.mil  
Cc: (b)(6) LTC USARMY MEDCOM USAMRIID (USA); (b)(6) @mail.mil; (b)(6) (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) @mail.mil; (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) @mail.mil; (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) .civ@mail.mil; (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) civ@mail.mil; (b)(6) CTR USARMY MEDCOM USAMRIID (USA); (b)(6) tr@mail.mil; (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) civ@mail.mil  
Subject: [Non-DoD Source] 7086 USAMRIID Inspection

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

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Good afternoon (b)(6)

As an FYI, I was told the security clearances were/will be sent to (b)(6) today. Also, we have a tentative staffing:

\*  
\*  
\*  
\*  
\*

(b)(6)

You should be able to see the inspection in the inspection tab of eFSAP now. This will serve as the NOI, we no longer upload paper copies since all the same information is in the inspection tab. You will see the inspection shows 4 days (T-Th, with Friday being the flex as need day). Since this is technically a follow-up inspection to the (b)(3):42 U.S.C. § 262a(h)(1)(D) it is marked as compliance. Eventually, you will be able to see the checklists we will use on inspection. Since you are registered for a (b)(3):42 U.S.C. § 262a(h)(1)(E), it is possible that AgSAS will send an inspector as well. I do not anticipate that, but you could see an addition.

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

If you upload any documents into eFSAP related to this inspection, you can tag the item with inspection number, 7086. Any plans (Bio, Sec, or IR) or relevant (b)(3):42 U.S.C. § 262a(h)(1)(D) BSL-4 SOP can be uploaded and tagged with the inspection number. The exception would be the following: prior to our arrival, we are requesting that you upload your BSL-4 suite floor plans into eFSAP. From your homepage, please go to upload and upload as a non-form: facilities, facilities sub: Floorplans, and put the suite name in the description (b)(3):42 U.S.C. § 262a(h)(1)(E)

While onsite, we plan on inspecting the (b)(3):42 U.S.C. § 262a(h)(1)(D) and associated records, the active BSL-4 areas and associated records, conduct a targeted inventory of select agent that has been worked with in the BSL4/ABSL4, and the ABSL3 that is associated with (b)(3):42 U.S.C. § review plans / SOPs updates, review training records since Oct 1, 2018, conduct a HVAC/facility review associated with the BSL4 areas, conduct a security review, and review implementation of corrective actions since our last inspection in October. Additionally, we may ask for formal interviews with entity personnel.

Please let me know if you have any questions.

Regards,

(b)(6)

(b)(6)

Senior Microbiologist / Inspector

Operations Branch

Division of Select Agents and Toxins

Center for Preparedness and Response

Centers for Disease Control and Prevention (CDC)

1600 Clifton Road, NE, MS A-46, Atlanta, GA 30329

(b)(6)

Office

(b)(6)

Cell

(b)(6)

@cdc.gov | Telework: Monday/Wednesday/Friday

< Caution-[http://www.cdc.gov/24-7/?s\\_cid=24-7\\_010&source=govdelivery](http://www.cdc.gov/24-7/?s_cid=24-7_010&source=govdelivery) >

CLASSIFICATION: UNCLASSIFIED

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) (CDC/DDPHSIS/CPR/DSAT)  
**Cc:** (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) LTC USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) LTC USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CTR USARMY MEDCOM USAMRIID (US); (b)(6) (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**Subject:** RE: [Non-DoD Source] CDC / DSAT Inspection Team Adjustment (UNCLASSIFIED)  
**Date:** Wednesday, March 13, 2019 2:50:48 PM

---

CLASSIFICATION: UNCLASSIFIED

(b)(6)

Thanks for the notification, we will add (b)(6) to the list of CDC inspectors.

Thank you,

(b)(6)

Deputy Director, Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6).civ@mail.mil

-----Original Message-----  
From: (b)(6) (CDC/DDPHSIS/CPR/DSAT) [mailto:(b)(6)@cdc.gov]  
Sent: Wednesday, March 13, 2019 2:42 PM  
To: (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) civ@mail.mil  
Subject: [Non-DoD Source] CDC / DSAT Inspection Team Adjustment

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

---

Hi (b)(6)

Just as an FYI, our management decided to add another inspector to our team. This will allow me flexibility, as needed, to finalize eFSAP, registration or any other questions that may come up while we are onsite. Her name is (b)(6). Our security team has already requested a perm cert be sent to (b)(6) on her behalf. I have passed on the training, etc to her as well.

(b)(6)

Again, (b)(6) is not going into BSL-4, she could potentially go into the BSL-3/ABSL-3 as necessary. I just wanted to let you know we would have another.

Regards,

(b)(6)

(b)(6)

Senior Microbiologist / Inspector

Operations Branch

Division of Select Agents and Toxins

Center for Preparedness and Response

Centers for Disease Control and Prevention (CDC)

1600 Clifton Road, NE, MS A-46, Atlanta, GA 30329

(b)(6) Office | (b)(6) Cell

(b)(6)@cdc.gov | Telework: Monday/Wednesday/Friday

< Caution-[http://www.cdc.gov/24-7/?s\\_cid=24-7\\_010&source=govdelivery](http://www.cdc.gov/24-7/?s_cid=24-7_010&source=govdelivery) >

CLASSIFICATION: UNCLASSIFIED

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) (CDC/DDPHSIS/CPR/DSAT)  
**Cc:** (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) (b)(6)  
**Subject:** RE: [Non-DoD Source] Inspection Training (UNCLASSIFIED)  
**Date:** Tuesday, March 19, 2019 3:27:00 PM  
**Attachments:** [Occupational Health Requirements for USAMRIID Visitors entering containment.docx](#)

CLASSIFICATION: UNCLASSIFIED

Hi (b)(6)

Currently, I am only tracking (b)(6) for BSL-3.

If you want clearance for yourself and (b)(6), please review the training and let me know when completed. You will also need to bring the Occupational Health requirements as shown in the attached memorandum.

Thank you,

(b)(6)  
 (b)(6) Biosecurity Directorate  
 Federal Select Agent Program Responsible Official  
 US Army Medical Research Institute of Infectious Diseases  
 1425 Porter Street  
 Fort Detrick, MD 21702

Office: (b)(6)  
 Mobile: (b)(6)  
 E-mail: (b)(6).civ@mail.mil

-----Original Message-----

From: (b)(6) (CDC/DDPHSIS/CPR/DSAT) [mailto:(b)(6)@cdc.gov]  
 Sent: Tuesday, March 19, 2019 2:21 PM  
 To: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6).civ@mail.mil  
 Cc: (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov; (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov; (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov; (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov; (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov; (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov; (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov; (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov  
 Subject: RE: [Non-DoD Source] Inspection Training (UNCLASSIFIED)

Hi (b)(6)

If needed (b)(6) y and/or I will go into BSL-3 space.

Thanks,

(b)(6)

(b)(6)

Senior Microbiologist / Inspector  
Operations Branch  
Division of Select Agents and Toxins  
Center for Preparedness and Response

Centers for Disease Control and Prevention (CDC)  
1600 Clifton Road, NE, MS A-46, Atlanta, GA 30329

(b)(6) Office | (b)(6) Cell | (b)(6) @cdc.gov | Telework: Monday/Wednesday/Friday

-----Original Message-----

From: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6).civ@mail.mil>  
Sent: Tuesday, March 19, 2019 1:38 PM  
To: (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov>  
Cc: (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov>; (b)(6) (CDC/DDPHSIS/CPR/DSA) (b)(6)@cdc.gov>; (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov>; (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov>; (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov>; (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6).civ@mail.mil>  
Subject: RE: [Non-DoD Source] Inspection Training (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

CLASSIFICATION: UNCLASSIFIED

(b)(6)

Thanks for the follow up.

I am tracking the following personnel going into containment, is this correct?

- (1) (b)(6) BSL-4
- (2) (b)(6) BSL-4
- (3) (b)(6) s (BSL-3)

If John Holcomb is not going into containment space, he does not need to take the training.

I'll standby for (b)(6) training completion date.

Thank you

(b)(6)

Deputy Director, Biosecurity Directorate Federal Select Agent Program Responsible Official US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6).civ@mail.mil

-----Original Message-----

(b)(6)

From: (b)(6) (CDC/DDPHSIS/CPR/DSAT) [mailto:(b)(6)@cdc.gov]  
Sent: Tuesday, March 19, 2019 12:56 PM  
To: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6)@cdc.gov; (b)(6)@cdc.gov; (b)(6)@cdc.gov; (b)(6)@cdc.gov; (b)(6)@cdc.gov; (b)(6)@cdc.gov  
Cc: (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov; (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov; (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov; (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov; (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov  
Subject: [Non-DoD Source] Inspection Training

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

---

Good afternoon (b)(6)

(b)(6) and I have reviewed the training slides. I have not yet received confirmation from (b)(6) but I suspect I will soon.

Since (b)(6) is not going into space, do you need anything from him?

Thanks,

(b)(6)

(b)(6)

Senior Microbiologist / Inspector  
Operations Branch  
Division of Select Agents and Toxins  
Center for Preparedness and Response  
  
Centers for Disease Control and Prevention (CDC)



1600 Clifton Road, NE, MS A-46, Atlanta, GA 30329

(b)(6)

Office

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@cdc.gov

| Telework: Monday/Wednesday/Friday

< Caution-[http://www.cdc.gov/24-7/?s\\_cid=24-7\\_010&source=govdelivery](http://www.cdc.gov/24-7/?s_cid=24-7_010&source=govdelivery) >

CLASSIFICATION: UNCLASSIFIED

CLASSIFICATION: UNCLASSIFIED

CLASSIFICATION: UNCLASSIFIED

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) (CDC/OPHPR/DSAT) (b)(6) (CDC/OPHPR/DSAT)  
**Cc:** (b)(6) USARMY MEDCOM USAMRIID (US) (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**Subject:** RE: [Non-DoD Source] (b)(6) USAMRIID visit (UNCLASSIFIED)  
**Date:** Tuesday, October 16, 2018 1:19:01 PM

---

CLASSIFICATION: UNCLASSIFIED

(b)(6)

Ok, thanks for the clarification.

(b)(6)

(b)(6) Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6)@mail.mil

-----Original Message-----

From: (b)(6) (CDC/OPHPR/DSAT) [mailto:(b)(6)@cdc.gov]  
Sent: Tuesday, October 16, 2018 1:04 PM  
To: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6)@mail.mil>;  
(b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov>  
C (b)(6) USARMY MEDCOM USAMRIID (US) (b)(6)@mail.mil>; (b)(6)@mail.mil>  
(b)(6) USARMY MEDCOM USAMRIID (US) (b)(6)@mail.mil>  
D CIV USARMY MEDCOM USAMRIID (US) (b)(6)@mail.mil>  
Subject: RE: [Non-DoD Source] (b)(6) USAMRIID visit (UNCLASSIFIED)

Hi (b)(6)

The inspection team will be:

(b)(6)

In the confusion of requests for (b)(6) and (b)(6) security clearances, our liaison mistakenly sent their names again instead of (b)(6). This request was corrected this morning and (b)(6) clearances should be on the way.

All 4 inspectors may take part in all parts of the inspection, both BSAT and IPP.

Regards,

(b)(6)

-----Original Message-----

From: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6)@mail.mil>  
Sent: Tuesday, October 16, 2018 12:57 PM

To: (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov  
Cc: (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov (b)(6) LTC USARMY MEDCOM USAMRIID (US) (b)(6) mil@mail.mil; (b)(6) USARMY MEDCOM USAMRIID (US) (b)(6) mil@mail.mil; (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail.mil  
Subject: FW: [Non-DoD Source] (b)(6) -USAMRIID visit (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Hi (b)(6)

Can you confirm who will be inspecting from the CDC (22-25 Oct)? We just received visitor requests for:

(b)(6)

Is (b)(6) attending for the Import Permit Inspection?

Thank you,

(b)(6)

(b)(6) Biosecurity Directorate Federal Select Agent Program Responsible Official US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6) civ@mail.mil

-----Original Message-----

From: (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
Sent: Tuesday, October 16, 2018 7:29 AM  
To: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail.mil  
Cc: (b)(6) USARMY MEDCOM USAMRIID (US) (b)(6) @mail.mil (b)(6)  
CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail.mil  
Subject: FW: [Non-DoD Source] (b)(6) -USAMRIID visit (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Hi (b)(6)

I received the visit requests for these individuals from CDC. I did not have (b)(6) on the list of attendees and I did not receive (b)(6)

Was there a change in personnel coming?

Thanks, (b)(6)

(b)(6), SAPPC, SPIPC  
Personnel Security Manager  
OPSEC Officer  
US Army Medical Research Institute of Infectious Diseases

1425 Porter St., Room [redacted]  
Fort Detrick, MD 21702 (b)(3):42 U.S.C. § 262a(h)(1)(E)  
Office: [redacted] (b)(6)  
Fax: [redacted] (b)(6)  
JPAS SMO: [redacted] (b)(3):42 U.S.C. § 262a(h)(1)(E)  
EMAIL: [redacted] (b)(6) civ@mail mil  
SIPRNET [redacted] (b)(6) civ@mail.smil mil

-----Original Message-----

From: [redacted] (b)(6) CDC/OCOO/OSSAM) (CTR) [mailto:[redacted] (b)(6)@cdc.gov]  
Sent: Monday, October 15, 2018 8:06 AM  
To: [redacted] (b)(6) CIV USARMY MEDCOM USAMRIID (US) [redacted] (b)(6) civ@mail mil>  
Subject: [Non-DoD Source] [redacted] (b)(6) USAMRIID visit

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

Please see the attached requests for visit 10/22-10/26

[redacted] (b)(6)

Personnel Security Assistant

Centers for Disease Control and Prevention

Security Services Office (SSO)

Office of Safety, Security, and Asset Management (OSSAM)

Office of the Chief Operating Officer (OCOO)

[redacted] (b)(6)

< Caution-mailto:[redacted] (b)(6)@cdc.gov > [redacted] (b)(6) office [redacted] (b)(6) fax

CLASSIFICATION: UNCLASSIFIED  
CLASSIFICATION: UNCLASSIFIED  
CLASSIFICATION: UNCLASSIFIED

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) (CDC/OPHPR/DSAT)  
**Cc:** (b)(6) (CDC/OPHPR/DSAT); (b)(6) CIV USARMY HQDA OTIG (US); (b)(6) CIV USARMY HQDA OTIG (US); (b)(6) (CDC/OPHPR/DSAT); (b)(6) (CDC/OPHPR/DSAT)  
**Subject:** RE: [Non-DoD Source] RE: CDC/DAIG Visit 12-13 Sept 2018 - In processing items and Schedule  
**Date:** Friday, August 31, 2018 9:31:11 PM

(b)(6)

Ok, for now I'll put all BSL-3 labs on the schedule and we can always dial back.

Thanks,

(b)(6)

**From:** (b)(6) (CDC/OPHPR/DSAT) [mailto:(b)(6)@cdc.gov]  
**Sent:** Friday, August 31, 2018 9:20 PM  
**To:** (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail.mil>  
**Cc:** (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov>; (b)(6) CIV USARMY HQDA OTIG (US) (b)(6) civ@mail.mil>; (b)(6) CIV USARMY HQDA OTIG (US) (b)(6) civ@mail.mil>; (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov>; (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov>

**Subject:** Re: [Non-DoD Source] RE: CDC/DAIG Visit 12-13 Sept 2018 - In processing items and Schedule

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Hi (b)(6)

Honestly, I don't know. Depending on the flow of the inspection, we may need to lay eyes on a few or all space with modified procedures.

We really won't know until we get into the inspection.

(b)(6)

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail.mil>  
**Date:** August 31, 2018 at 7:57:27 PM EDT  
**To:** (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov>  
**Cc:** (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov>; (b)(6) CIV USARMY HQDA OTIG (US) (b)(6) civ@mail.mil>; (b)(6) CIV USARMY HQDA OTIG (US) (b)(6) civ@mail.mil>; (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov>; (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov>

**Subject:** Re: [Non-DoD Source] RE: CDC/DAIG Visit 12-13 Sept 2018 - In processing items and Schedule

(b)(6)

Great thanks! I will upload the documents early next week.  
Do you want me to schedule time to enter all BSL-3 spaces or do you just want to see the ones we plan to open first?

Thank you

(b)(6)

Deputy Director, Biosecurity Directorate &  
FSAP Responsible Official  
US Army Medical Research Institute of Infectious Diseases (USAMRIID)  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)

Mobile: (b)(6)

Cell: (b)(6)

E-mail: (b)(6) <[redacted]@mail.mil> <Caution-mailto:[redacted]@mail.mil>

Sent from my iPhone

On Aug 31, 2018, at 1:32 PM (b)(6) (CDC/OPHPR/DSAT) <[redacted]@cdc.gov <Caution-mailto:[redacted]@cdc.gov>> wrote:

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

Hi (b)(6)

From FSAP, we will not want to limit our team flexibility, so all of us may go into space. Additionally, all of us may want additional PPE or respiratory protection depending on what we come across. We can bring N-95s and/or PAPRs if necessary. I am not sure how much space we will need to actual enter, but I cannot give specifics until we are on site. I don't anticipate all with the modified procedures, but it is possible.

For points 1 and 2 below, if you have any records (e.g. training records or additionally modified SOPs) & you have not sent them as part of the response to the Form 3 RFI or in responses to the inspection report, feel free to upload in eFSAP tagged with the inspection number in the general discussion box.

Our primary objective will be to clarify any outstanding items in the open inspection report and Form 3 RFI as well as to review implementation and training on the new – modified procedures (points 1a-c below). We hope to cover all point and discuss any issue or progress you have made toward bringing all registered space back online.

Feel free to upload required training documents for the FSAP team in eFSAP tagged with the inspection number or any other information you want us to have associated with the inspection.

Please let me know if you have any questions,

(b)(6)

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
<[redacted]@mail.mil <Caution-mailto:[redacted]@mail.mil>>

**Sent:** Friday, August 31, 2018 8:53 AM



USAMRIID (US) (b)(6).civ@mail.mil < Caution-  
mailto:(b)(6).civ@mail.mil > >; (b)(6) CIV USARMY MEDCOM  
USAMRIID (US) (b)(6).civ@mail.mil < Caution-  
mailto:(b)(6).civ@mail.mil > >

**Subject:** CDC/DAIG Visit 12-13 Sept 2018 - In processing items and Schedule

Dear CDC and DAIG Teams,

I am planning the in-processing documents and inspection schedule for the 12-13 September 2018 CDC/DAIG inspection of USAMRIID.

Please let me know if you concur with the following scope of the visit or if there are other items you would like me to add to the schedule:

The focus of the 12-13 CDC Inspection is the following:

1) Modified BSL-3 Procedures

- a. Training for Modified BSL-3 (review the training slides/Sign in Rosters)
- b. Interviews with personnel who have received modified BSL-3 training
- c. Review of new SOP's related to Modified BSL-3 Procedures
- d. Tour of the BSL-3 laboratories to view the engineering controls
- e. Review of the validation studies for (b)(3):42 U.S.C. § 262a(h)(1)(D)

being collected (b)(6) and discharged to the (b)(6)

(b)(3):42  
U.S.C. §  
262a(h)(1)(E)

- f. Review of the Regulated Medical Waste collection and autoclave procedures

(b)(3):42 U.S.C. §  
262a(h)(1)(E)

(b)(3):42  
U.S.C. §  
262a(h)(1)(E)

2) Review of any documentation regarding the (b)(6)

(b)(3):42 U.S.C. §  
262a(h)(1)(D)

(b)(3):42 U.S.C. § 262a(h)(1)(D)

Please provide the names of the personnel on your teams who will be entering the containment laboratories during the visit. I will send these personnel the Visitor Access Forms and Laboratory Entry Training.

I am working on a schedule for the visit. Since this is a 2 day visit, will your teams want to visit all modified BSL-3 laboratories or just a select number?

Currently, there are no activities in the BSL-3 modified laboratories that require respiratory protection. Will any of your team members opt to wear respiratory protection? If so, we will incorporate Respiratory Protection Training and a brief - hands on demonstration of PAPR/Respirator Use on the first day of the visit.

Thank you,

(b)(6)

(b)(6) Biosecurity Directorate &

FSAP Responsible Official

US Army Medical Research Institute of Infectious Diseases (USAMRIID)

1425 Porter Street

Fort Detrick, MD 21702

Office: (b)(6)

Mobile: (b)(6)

E-mail: (b)(6)@mail.mil < Caution-

mailto:(b)(6).civ@mail.mil > < Caution-Caution-

mailto:(b)(6).civ@mail.mil < Caution-



**From:** (b)(6) C CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) CDC/OPHPR/DSAT  
**Cc:** (b)(6) (CDC/OPHPR/DSAT); (b)(6) (CDC/OPHPR/DSAT)  
**Subject:** Re: [Non-DoD Source] RE: Schedule CDC Visit to review the (b)(6) USAMRIID  
**Date:** Monday, August 13, 2018 7:42:21 AM

(b)(3):42 U.S.C. §  
262a(h)(1)(D)

(b)(6)

Thank you for the update. I will see you this week!

Thank you,

(b)(6)

Deputy Director, Biosecurity Directorate &  
FSAP Responsible Official  
US Army Medical Research Institute of Infectious Diseases (USAMRIID)  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
Cell: (b)(6)  
E-mail: (b)(6) civ@mail.mil

Sent from my iPhone

On Aug 13, 2018, at 7:38 AM, (b)(6) (CDC/OPHPR/DSAT) (b)(6) @cdc.gov> wrote:

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

Good Morning (b)(6)

After internal discussions on Friday and over the weekend, we believe that it is best that we keep our scheduled September inspection in place and then follow this trip with an additional inspection the week of Oct. 22. We understand that th (b)(6)

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

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

(b)(6) may be in place but not operational at the time of the Sept site visit but the inspection will serve as an onsite status update and allow the FSAP an opportunity to assess the corrective actions and select agent activities you will have brought back on-line to that point (b)(6) will be reaching out to you and your team as we approach the Sept inspection date and we are open to further discussion this week at the RO training workshop here in Atlanta.

Best regards and safe travels this week,

(b)(6)

(b)(6)

Supervisory Microbiologist  
Division of Select Agents and Toxins  
Office of Public Health Preparedness and Response  
Centers for Disease Control and Prevention  
1600 Clifton Road, NE MS A-46  
Atlanta, GA 30329

Tel: (b)(6) Fax: (b)(6)

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
(b)(6).civ@mail.mil>

**Sent:** Sunday, August 12, 2018 10:46 AM

**To:** (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov; (b)(6) (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov; Form 3 (CDC) <form3@cdc.gov>; (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov

**Cc:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
(b)(6).civ@mail.mil> (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
(b)(6).civ@mail.mil>; (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
(b)(6).civ@mail.mil> (b)(6) CIV USARMY MEDCOM USAMRIID  
(US) (b)(6).civ@mail.mil> (b)(6) CIV USARMY MEDCOM  
USAMRIID (US) (b)(6).civ@mail.mil> (b)(6) LTC USARMY  
MEDCOM USAMRIID (US) (b)(6).mil@mail.mil> (b)(6) CIV  
USARMY MEDCOM USAMRIID (US) (b)(6).civ@mail.mil> (b)(6)  
C CIV USARMY MEDCOM USAMRIID (US) (b)(6).civ@mail.mil> (b)(6)  
(b)(6) CTR USARMY MEDCOM USAMRIID (US) (b)(6).ctr@mail.mil>;  
(b)(6) CIV USARMY MEDCOM USAMRMC (US) (b)(6).civ@mail.mil>;  
(b)(6) COL USARMY MEDCOM USAMRIID (US) (b)(6).mil@mail.mil>;  
(b)(6) COL USARMY MEDCOM USAMRIID (US) (b)(6).mil@mail.mil>;  
(b)(6) CIV USARMY MEDCOM USAMRIID (US)  
(b)(6).civ@mail.mil> (b)(6) CTR USARMY MEDCOM  
USAMRIID (US) (b)(6).ctr@mail.mil> (b)(6) CTR USARMY  
(US) (b)(6).r@mail.mil>; (b)(6) CIV USARMY MEDCOM  
USAMRIID (US) (b)(6).civ@mail.mil>; (b)(6) CIV USARMY MEDCOM  
USAMRIID (US) (b)(6).civ@mail.mil>

**Subject:** Schedule CDC Visit to review the (b)(3):42 U.S.C. § 262a(h)(1)(D) - USAMRIID

Dear (b)(6)

Thank you for taking the time to speak with our team on Friday. After review of our schedule, it would be best if your team can schedule a site visit to review the (b)(3):42 U.S.C. § 262a(h)(1)(D)

(b)(3):42 U.S.C. § 262a(h)(1)(D) the week of 22 October 2018.

Please let me know if this works for your team.

Thank you,

(b)(6)

(b)(6) Biosecurity Directorate &  
FSAP Responsible Official

US Army Medical Research Institute of Infectious Diseases (USAMRIID)

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) (CDC/OPHPR/DSAT)  
**Cc:** (b)(3):42 (b)(6) USARMY MEDCOM USAMRIID (US)  
**Subject:** U.S.C. § 262a(h)(1)(D) RE: [Non-DoD Source] RE: USAMRIID CDC/DAIG Inspection (week of 22 October 2018) - BSL-3 Modified and & Import Permit (UNCLASSIFIED)  
**Date:** D) /Wednesday, October 10, 2018 1:18:36 PM

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CLASSIFICATION: UNCLASSIFIED

(b)(6)

Thanks for the feedback. I will review with our team to see if there is any training we can streamline for inspectors. I'm not sure if we can do this for the October visit, but possibly future visits. I need to cross-reference the Army Regulations to ensure we are covering all the required training.

Thank you,

(b)(6)

(b)(6) Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office (b)(6)  
Mobile (b)(6)  
E-mail (b)(6) civ@mail.mil

-----Original Message-----

**From:** (b)(6) (CDC/OPHPR/DSAT) [mailto:(b)(6)@cdc.gov]  
**Sent:** Wednesday, October 10, 2018 7:40 AM  
**To:** (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail.mil  
**Cc:** (b)(6) USARMY MEDCOM USAMRIID (US) <(b)(6)@mil>  
**Subject:** RE: [Non-DoD Source] RE: USAMRIID CDC/DAIG Inspection (week of 22 October 2018) - BSL-3 Modified and & Import Permit (UNCLASSIFIED)  
**Modified on:** (b)(3):42 U.S.C. § 262a(h)(1)(D) (b)(6)  
**Good morning:** (b)(6)

There are multiple different examples.

The simplest we see is a simple 1 page read and sign. Something to the effect of:

You are about to enter secured laboratories. You must follow the instructions of your escorts and remain in view of your escorts at all times. You may not touch anything in the laboratory. If you need to see something, please ask your escorts to touch or open a container. In the event of an emergency, follow the instructions of your escort. If something happens to your escort, call XXXXX from the phone in the lab your escort will show you. If we need to evacuate the building, the assembly area is XXXXX. Failure to follow the instructions of your escort or our entity security force may result in your removal from our facilities.

This laboratory contains respiratory pathogens that can cause severe illness and/or death in humans. A list of the agents that could be in each laboratory as well as their specific illness presentations are in the training packet (see MSDS sheets). While your risk for entering the space will be lower, if you experience signs of illness, such as a fever of X, respiratory illness, [other symptoms] within X days, call our health clinic at XXXX. If you go to your local hospital or physician for this illness, please give them the below information (e.g. you entered a laboratory containing a high risk virus or bacterial pathogen within the past X days, please contact the health clinic at

XXXXX). You will be given specific entry and exit instructions including PPE instructions before entering containment at each specific suite as well as agent information specific for that suite.

By signing this, you agree that you have been provided the security, incident response, and biosafety briefing above, have had the chance to review the agent specific risks, have been provided the opportunity to ask questions, and you understand the training that was provided.

Depending on the entity, we see expansions off this type of basic training.

Entities may give use the MSDS for the agents or provide a ppt of the agents with basic symptoms.

Entities may show us a map of evacuation routes.

Entities may posts the PPE and provide the respiratory protection training.

Entities sometimes give visitors a card to give their physicians with the contact information of the entity health clinic and a statement about the person could have been exposed to a high risk pathogen.

That pretty much covers the basics.

I hope that helps.

(b)(6)

-----Original Message-----

From: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail.mil>

Sent: Tuesday, October 9, 2018 2:54 PM

To: (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov>

Subject: RE: [Non-DoD Source] RE: USAMRIID CDC/DAIG Inspection (week of 22 October 2018) - BSL-3

(b)(3) Modified Card & Import Permit (UNCLASSIFIED)  
262a(h)(1)(D)

CLASSIFICATION: UNCLASSIFIED

(b)(6)

Can you provide me an example of what other entities require for inspectors for training? (i.e. title of training or documentation to sign?)

Thank you,

(b)(6)

Deputy Director, Biosecurity Directorate Federal Select Agent Program Responsible Official US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)

Mobile:

E-mail: (b)(6) civ@mail.mil

-----Original Message-----

From: (b)(6) (CDC/OPHPR/DSAT) [mailto:(b)(6)@cdc.gov]

Sent: Tuesday, October 9, 2018 12:47 PM

To: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail.mil>  
Subject: [Non-DoD Source] RE: USAMRIID CDC/DAIG Inspection (week of 22 October 2018) - BSL-3 Modified and (b)(6) & Import Permit (UNCLASSIFIED)

(b)(3):42 U.S.C.  
§ 262a(h)(1)(D)

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

---

Hi (b)(6)

I have a question. I had talked with (b)(6) about this previously, but is there a reason USAMRIID gives inspectors or visitors this training set?

A significant amount of the training is irrelevant to inspectors and is designed for those who would actually work at USAMRIID. We actually go to entities that have a single page visitor training that adequate for our purposes.

From my previous talks, it seemed like USAMRIID may modify to lighten the load on both sides, but I'm not sure if USAMRIID wants to do.

Just food for thought.

(b)(6)

---

From: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail.mil>  
Date: October 9, 2018 at 11:21:09 AM EDT  
To: (b)(6) CDC/OPHPR/DSAT (b)(6) cdc.gov>  
Subject: RE: USAMRIID CDC/DAIG Inspection (week of 22 October 2018) - BSL-3 Modified and (b)(6) & Import Permit (UNCLASSIFIED)

(b)(3):42 U.S.C.  
§ 262a(h)(1)(D)

CLASSIFICATION: UNCLASSIFIED

(b)(6)

I have reached out to our team to get a list of training and documentation needed. Here are some initial thoughts, but I will provide you an official response after I get feedback from everyone.

Personal Security - Full Name, SSN, DOB, security clearance information (hardcopy) Physical Security - need to get signed Visitor Access Memos (sample attached) so that we can get a picture ID and PIN Biosafety - In person PAPR & BSL-4 Suit Training (all other training see below) Select Agent Management - training (see below) Competent Medical Authority - respiratory protection clearance card Responsible Official - needs to be on-site

I am thinking we would just pick a date annually and send inspectors the following on-line training. This way your team would always be up to date and do not need to waste time with on-line training after your arrival:

- Incident Response Training
- Agent Specific Training
- Select Agent Management Training
- Blood borne Pathogens Training
- Chemical Hygiene Training

Laboratory Essential Training  
Respiratory Protection Training  
Safe Laboratory Operations

Thank you.

(b)(6)

(b)(6) Biosecurity Directorate Federal Select Agent Program Responsible Official US Army Medical  
Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6)@mail.mil

-----Original Message-----

From: (b)(6) (CDC/OPHPR/DSAT) [Caution-mailto:(b)(6)@cdc.gov < Caution-mailto:(b)(6)@cdc.gov >]

Sent: Tuesday, October 2, 2018 5:09 PM

To: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6)@mail.mil>

Cc: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6)@mail.mil>

Subject: [Non-DoD Source] Re: USAMRIID CDC/DAIG Inspection (week of 22 October 2018) - BSL-3 Modified and CEDS & Import Permit (UNCLASSIFIED)

Hi (b)(6) (b)(3):42 U.S.C. § 262a(h)(1)(D)

I have a general question about inspections, not specific for this inspection. We will eventually inspect your facility by unannounced inspection. Obviously, like at other entities, this will mean that we will not send in clearances prior to arrival to tip the entity off. While we have legal authority under 42 CFR 73.18 to inspect all BSAT registered space, I would like clarification on what we would need to bring with us when we arrive for an unannounced to expedite entry.

Just planning for the future. Our upper leadership has at times wondered why all inspections are not unannounced.

Regards,

(b)(6)

From: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6)@mail.mil>

Date: October 2, 2018 at 3:59:27 PM EDT

To: (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov, (b)(6) (CDC/OPHPR/DSAT)

(b)(6)@cdc.gov> (b)(6) CIV USARMY HQDA OTIG (US) (b)(6)@mail.mil>,

(b)(6) CIV USARMY HQDA OTIG (US) (b)(6)@mail.mil> (b)(6)

(CDC/OPHPR/DSAT) (b)(6)@cdc.gov> (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov (b)(6)

(CDC/OPHPR/DSAT) (b)(6)@cdc.gov> (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov>

Cc: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6)@mail.mil> (b)(6)

(b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6)@mail.mil> (b)(6)

CIV USARMY MEDCOM USAMRIID (US) (b)(6)@mail.mil>, USARMY Ft Detrick

MEDCOM USAMRMC List BSAT (b)(6)@mail.mil>

Subject: USAMRIID CDC/DAIG Inspection (week of 22 October 2018) - BSL-3 Modified and CEDS & Import

Permit (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Dear CDC and DAIG Team,

I want to ensure we have the appropriate Visitor Access documentation and training on file as we plan the upcoming CDC and DAIG Inspection the week of 22 October 2018.

Purpose of Inspection:

- 1) Review the BSL-3 Modified procedures
- 2) Review/approve the (b)(3);42 U.S.C. § 262a(h)(1)(D)
- 3) Import Permit Inspection for PI (b)(6)s - Permit 2018-06-043 (25 October - only)

Please confirm the dates of the visit: 22 October - 26 October 2018

Please confirm the inspectors will be:

(b)(6) CDC DSAT Inspector  
(b)(6) CDC DSAT Inspector  
(b)(6) CDC DSAT Inspector

(b)(6) DAIG Inspector  
(b)(6) DAIG Inspector

(b)(6) - CDC Import Permit Inspector (25 October - only) (b)(6) - CDC Import Permit Inspector (25 October - only)

Thank you.

(b)(6)

(b)(6) Biosecurity Directorate Federal Select Agent Program Responsible Official US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6)civ@mail.mil

CLASSIFICATION: UNCLASSIFIED

CLASSIFICATION: UNCLASSIFIED

CLASSIFICATION: UNCLASSIFIED

CLASSIFICATION: UNCLASSIFIED

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) (CDC/DDPHSIS/CPR/DSAT)  
**Cc:** (b)(6) USARMY MEDCOM USAMRIID (USA)  
**Subject:** RE: [Non-DoD Source] Tuesday AM (UNCLASSIFIED)  
**Date:** Monday, March 25, 2019 6:33:12 PM

---

CLASSIFICATION: UNCLASSIFIED

(b)(6)  
I'll see you at the (b)(6) at 0800. If you need anything, my cell phone is: (b)(6)

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

(b)(6)  
(b)(6), Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6) civ@mail.mil

-----Original Message-----

**From:** (b)(6) LTC USARMY MEDCOM USAMRIID (USA)  
**Sent:** Monday, March 25, 2019 6:21 PM  
**To:** (b)(6) (CDC/DDPHSIS/CPR/DSAT) <(b)(6)@cdc.gov>  
**Cc:** (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail.mil  
**Subject:** RE: [Non-DoD Source] Tuesday AM (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Good afternoon (b)(6)

Good to hear you have arrived to Frederick (sorry for the rain!!). You will park at the designated parking spot (one of the orange cones) near the (b)(6) entry point.

See you in the morning. (b)(3):42 U.S.C. § 262a(h)(1)(E)

Best regards,  
(b)(6)

-----Original Message-----

**From:** (b)(6) (CDC/DDPHSIS/CPR/DSAT) [mailto:(b)(6)@cdc.gov]  
**Sent:** Monday, March 25, 2019 6:15 PM  
**To:** (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail.mil (b)(6)  
(b)(6) CIV USARMY MEDCOM USAMRIID (USA) (b)(3):42 U.S.C. mil@mail.mil  
**Subject:** [Non-DoD Source] Tuesday AM

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.



---

Good Evening (b)(6)

We have arrived in rainy Frederick. As an FYI, we will be in 2 automobiles in the morning when we arrive. I'm not sure if you need to know for parking considerations.

Please let me know if we need anything else for the morning. See you at 8:00.

(b)(6)

(b)(6)

Senior Microbiologist / Inspector

Operations Branch

Division of Select Agents and Toxins

Center for Preparedness and Response

Centers for Disease Control and Prevention (CDC)

1600 Clifton Road, NE, MS A-46, Atlanta, GA 30329

(b)(6) Office | (b)(6) Cell

(b)(6)@cdc.gov | Telework: Monday/Wednesday/Friday

< Caution-[http://www.cdc.gov/24-7/?s\\_cid=24-7\\_010&source=govdelivery](http://www.cdc.gov/24-7/?s_cid=24-7_010&source=govdelivery) >

CLASSIFICATION: UNCLASSIFIED  
CLASSIFICATION: UNCLASSIFIED

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) CDC/DDPHSIS/CPR/DSAT); (b)(6) CIV USARMY HQDA OTIG (US)  
**Cc:** (b)(6) CIV USARMY HQDA OTIG (US); (b)(6) USARMY MEDCOM USAMRIID (USA)  
**Subject:** (b)(6) RE: 18-29 March DAIG Inspection (UNCLASSIFIED)  
**Date:** Thursday, January 10, 2019 8:57:27 AM

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CLASSIFICATION: UNCLASSIFIED

(b)(6)

Thank you for the update. We will keep you posted with our (b)(3) BSL-4 status. We are still working on the biological validations of the (b)(3):42 U.S.C. § 262a(h)(1)(D)

(b)(3):42 U.S.C. § 262a(h)(1)(D)

Thank you.

(b)(6)

Deputy Director, Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6) civ@mail.mil

-----Original Message-----

**From:** (b)(6) CDC/DDPHSIS/CPR/DSAT) [mailto:(b)(6)@cdc.gov]  
**Sent:** Thursday, January 10, 2019 6:59 AM  
**To:** (b)(6) CIV USARMY HQDA OTIG (US)  
(b)(6) civ@mail.mil> (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail mil>  
**Cc:** (b)(6) CIV USARMY HQDA OTIG (US) (b)(6) @mail mil>; (b)(6) USARMY MEDCOM USAMRIID (USA) (b)(6) @mail.mil>  
**Subject:** [Non-DoD Source] RE: 18-29 March DAIG Inspection (UNCLASSIFIED)

Good morning (b)(6)

Thank you for copying me on your scheduling emails with DAIG.

As an FYI, FSAP has a tentative window the 2nd week of DAIG's inspection in the hopes that you (b)(3):42 U.S.C. § 262a(h)(1)(D) will be in place and the BSL-4 is operational. We don't want to add to your burden by showing up if th (b)(3):42 U.S.C. § 262a(h)(1)(D) are (b)(3):42 U.S.C. § 262a(h)(1)(D) not ready & the BSL-4 is still in shutdown. However, if you do have (b)(3):42 U.S.C. § 262a(h)(1)(D) is place that would allow you to start bringing the BSL-4 online, then we would want to have our team onsite with DAIG to reduce the inspection burden.

So please keep us posted on your BSL-4 (b)(3):42 U.S.C. § 262a(h)(1)(D) progress.

Regards,

(b)(6)

(b)(6)

Senior Microbiologist  
Operations Branch  
Division of Select Agents and Toxins  
Center for Preparedness and Response

Centers for Disease Control and Prevention (CDC)  
1600 Clifton Road, NE, MS A-46, Atlanta, GA 30329

(b)(6) Office | (b)(6) Cell  
(b)(6)@cdc.gov | Telework: Monday/Wednesday/Friday

-----Original Message-----

From: (b)(6) CIV USARMY HQDA OTIG (US)

(b)(6) civ@mail.mil>

Sent: Wednesday, January 9, 2019 2:56 PM

To: (b)(6) CIV USARMY MEDCOM USAMRIID (US)

(b)(6) civ@mail.mil>

Cc: (b)(6) CIV USARMY HQDA OTIG (US)

(b)(6) civ@mail.mil>; (b)(6) USARMY MEDCOM

USAMRIID (USA) <(b)(6)@mail.mil>; (b)(6) CIV USARMY

MEDCOM USAMRIID (US) (b)(6) civ@mail.mil> (b)(6)

USARMY MEDCOM USAMRIID (USA) (b)(6) mil@mail.mil>; (b)(6)

(b)(6) CIV USARMY MEDCOM USAMRIID (US) <(b)(6)@mail.mil>;

(b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov> (b)(6)

(CDC/DDPHSIS/CPR/DSAT (b)(6)@cdc.gov> (b)(6)

(CDC/DDPHSIS/CPR/DSAT (b)(6)@cdc.gov> (b)(6) CIV USARMY MEDCOM

USAMRIID (US) (b)(6) civ@mail.mil>

Subject: RE: 18-29 March DAIG Inspection (UNCLASSIFIED)

(b)(6)

Yes, it is for both BSL-3 and -4. The time proposed looks good.  
Thank you!

Best,

(b)(6)

-----Original Message-----

From: (b)(6) CIV USARMY MEDCOM USAMRIID (US)

(b)(6) civ@mail.mil>

Sent: Wednesday, January 9, 2019 2:52 PM

To: (b)(6) CIV USARMY HQDA OTIG (US)

(b)(6) civ@mail.mil>

Cc: (b)(6) CIV USARMY HQDA OTIG (US)

(b)(6) civ@mail.mil> (b)(6) USARMY MEDCOM

USAMRIID (USA) (b)(6)@mail.mil>; (b)(6) CIV USARMY

MEDCOM USAMRIID (US) (b)(6) civ@mail.mil> (b)(6)

USARMY MEDCOM USAMRIID (USA) (b)(6) mil@mail mil> (b)(6)  
(b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail.mil>;  
(b)(6) (CDC/DDPHSIS/CPR/DSAT (b)(6) @cdc.gov> (b)(6)  
(CDC/OPHPR/DSAT (b)(6) @cdc.gov> (b)(6) (CDC/OPHPR/DSAT)  
(b)(6) @cdc.gov> (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
(b)(6) civ@mail.mil>  
Subject: RE: 18-29 March DAIG Inspection (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

(b)(6)

Certainly, we can work on a schedule for you to review. Will this inspection cover both BSL-3 and BSL-4?

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

We are working on conference room availability. We can meet the team at the (b)(6) at 0830 and start the presentations at 0900 on 18 March. Does that work for you?

I've cc:d our CDC Team for visibility.

Thank you.

(b)(6)

(b)(6) Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6) civ@mail.mil

-----Original Message-----

From: (b)(6) CIV USARMY HQDA OTIG (US)  
Sent: Wednesday, January 9, 2019 10:44 AM  
To: (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
<(b)(6) civ@mail mil>  
Cc: (b)(6) CIV USARMY HQDA OTIG (US)  
(b)(6) civ@mail mil> (b)(6) TC USARMY MEDCOM  
USAMRIID (USA) (b)(6) mil@mail.mil>  
Subject: 18-29 March DAIG Inspection

(b)(6)

Could we start working on tentative schedule for the inspection? What time and where do you propose the in brief to be held on the 18th?

Best,

(b)(6)

-----Original Message-----

From: (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
(b)(6) civ@mail mil>  
Sent: Monday, January 7, 2019 1:54 PM

To: (b)(6) CIV USARMY HQDA OTIG (US)  
(b)(6).civ@mail.mil>  
Cc: (b)(6) CIV USARMY HQDA OTIG (US)  
(b)(6).civ@mail.mil> (b)(6) LTC USARMY MEDCOM  
USAMRIID (USA) (b)(6).mil@mail.mil>  
Subject: RE: New year and inspection (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

(b)(6)

We are operational in BSL-3 under the modified procedure (b)(3):42 going

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

(b)(6) We are still working on getting the (b)(3):42 U.S.C. § 262a(h)(1)(D)  
system up and running. We are conducting biovalidation testing this week.

When this system is up (hopefully end of January) we will be open under  
limited operations for BSL-3 and BSL-4 (probably only one BSL-4 suite.)

The (b)(3):42  
U.S.C. §  
262a(h)(1)(D) is not expected to be operational until beginning of March.

We are still planning for the CDC/DAIG inspection to occur 18-29 March 2019.

Thank you,

(b)(6)

(b)(6) Biosecurity Directorate

Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)

Mobil: (b)(6)

E-mail: (b)(6).civ@mail.mil

-----Original Message-----

From: (b)(6) CIV USARMY HQDA OTIG (US)  
Sent: Monday, January 7, 2019 12:45 PM  
To: (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
(b)(6).civ@mail.mil>  
Cc: (b)(6) CIV USARMY HQDA OTIG (US)  
(b)(6).civ@mail.mil>  
Subject: New year and inspection

(b)(6)

Happy New Year! May this one be the best :) and may all the troubles go  
away.

Quick status check with you....Our regular inspection is coming up and I  
need to know how to proceed. Will you be operational in March? What are the  
projections? And are you currently under the (b)(3):42 U.S.C. §  
262a(h)(1)(E)

Thank you,

(b)(6)

**From:** [Edwin Samuel \(CDC/OPHPR/DSAT\)](#)  
**To:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**Cc:** (b)(6) CDC/OPHPR/DSAT (b)(6) USARMY MEDCOM USAMRIID (US)  
**Subject:** Re: 21 May CDC Site Visit visit - logistics  
**Date:** Saturday, May 19, 2018 12:54:00 PM

---

Thank you (b)(6) I have forwarded the message to my staff.

Respectfully,

(b)(6)

---

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
(b)(6) civ@mail.mil>  
**Date:** May 19, 2018 at 11:45:31 AM EDT  
**To:** (b)(6) (CDC/OPHPR/DSAT) (b)(6) @cdc.gov>  
**Cc:** (b)(6) (CDC/OPHPR/DSAT) (b)(6) @cdc.gov>, (b)(6) USARMY  
MEDCOM USAMRIID (US) (b)(6) .mil@mail.mil>  
**Subject:** 21 May CDC Site Visit visit - logistics

Hi (b)(6)

(b)(3);42 U.S.C. §  
262a(h)(1)(E)

We are making arrangements to have a van available to drive CDC personnel to Building (b)(6) on Monday-Tuesday.

I highly recommend the team bring appropriate footwear to change into. We have been experiencing a significant amount of rain and it is very muddy at this location.

Please ensure the team contacts me on my cell when they re en route:

(b)(6)

Thank you and we will see your team Monday.

Much appreciated,

(b)(6)

(b)(6) Biosecurity Directorate &

FSAP Responsible Official

US Army Medical Research Institute of Infectious Diseases (USAMRIID)

1425 Porter Street

Fort Detrick, MD 21702

Office: (b)(6)

Mobile:

Cell: (b)(6)

E-mail: (b)(6) civ@mail.mil

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) (CDC/DDPHSIS/CPR/DSAT)  
**Cc:** (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) CTR USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (USA)  
**Subject:** RE: Call to DAIG/CDC to discuss schedule and final planning items (RE: 18-29 March 2019 Inspection) (UNCLASSIFIED)  
**Date:** Thursday, March 7, 2019 6:08:06 PM

---

CLASSIFICATION: UNCLASSIFIED

(b)(6)  
Ok, thanks. I have cc'd the Biosafety Division so they will know to have 2 suits available.

Thank you,

(b)(6)  
(b)(6) Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6)@mail.mil

-----Original Message-----

From: (b)(6) (CDC/DDPHSIS/CPR/DSAT) [mailto:(b)(6)@cdc.gov]  
Sent: Thursday, March 7, 2019 12:03 PM  
To: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail.mil>  
Subject: [Non-DoD Source] Re: Call to DAIG/CDC to discuss schedule and final planning items (RE: 18-29 March 2019 Inspection) (UNCLASSIFIED)

Hi (b)(6)

I talked to (b)(6)

Neither have a suit, so they will need to use a USAMRIID suit. (b)(6) said he is a medium.

(b)(6)

---

From: (b)(6) CIV USARMY MEDCOM USAMRIID (US) <(b)(6) civ@mail.mil>  
Date: March 6, 2019 at 11:00:42 PM EST  
To: (b)(6) CIV USARMY HQDA OTIG (USA) (b)(6) civ@mail.mil> (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov> (b)(6) CIV USARMY HQDA OTIG (US) (b)(6) civ@mail.mil> (b)(6) CIV USARMY HQDA OTIG (USA) (b)(6) civ@mail.mil> (b)(6) CIV USN NAVSURFWARCEN DAH VA (USA) (b)(6)@navy.mil> (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail.mil (b)(6) CIV USARMY MEDCOM USAMRIID (US)

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) CDC/DDPHSIS/CPR/DSAT  
**Cc:** (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**Subject:** RE: CDC Inspection 26-28 March 2019 (UNCLASSIFIED)  
**Date:** Monday, February 11, 2019 1:38:19 PM

---

CLASSIFICATION: UNCLASSIFIED

(b)(6)  
Great, thanks for the follow up.

Thank you.

(b)(6)

(b)(6) Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6)@mail.mil

-----Original Message-----

**From:** (b)(6) (CDC/DDPHSIS/CPR/DSAT) [mailto:(b)(6)@cdc.gov]  
**Sent:** Monday, February 11, 2019 1:35 PM  
**To:** (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6)@mail.mil  
**Cc:** (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6)@mail.mil; (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6)@mail.mil  
**Subject:** [Non-DoD Source] RE: CDC Inspection 26-28 March 2019 (UNCLASSIFIED)

Hi (b)(6)

We have not confirmed our staffing yet or our exact travel days. Our security officer requested that 15 or 20 individuals have our security clearances forwarded to (b)(6) for a permcert for the year, but I am not sure if that has occurred. I saw an email last week asking for an update. We will staff the inspection from that group.

As of today, I can confirm that (b)(6) and I will be there, and (b)(6) will not (b)(6)'s suit trained, through USAMRIID's training program. I am guessing we will have another suit trained person attend. I will not be going into the BSL4, I am anticipating 1-2 more people coming with use that are not suit trained. I am expecting FSAP will be able to split into 2 teams of 2, plus perhaps a security or facilities expert for a team of 5 total. We will probably finish staffing in the next few weeks.

Regards,

(b)(6)

-----Original Message-----

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6)@mail.mil  
**Sent:** Monday, February 11, 2019 1:10 PM



To: (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov> (b)(6)  
(CDC/DDPHSIS/CPR/DSAT (b)(6)@cdc.gov>  
Cc: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail mil>;  
(b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail mil>  
Subject: CDC Inspection 26-28 March 2019 (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

(b)(6)

Can you provide the names of the CDC personnel who will be conducting the inspection 26-28 March? We would like to ensure we have the JPAS Visit Requests. So far, we have only received one Visit Request for JT Paulley.

Of these personnel, who will be going into BSL-4? We would like to ensure we have the training/occupational health clearances scheduled for entry into containment.

Thank you,

(b)(6)

Deputy Director, Biosecurity Directorate Federal Select Agent Program Responsible Official US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6).civ@mail.mil

CLASSIFICATION: UNCLASSIFIED

CLASSIFICATION: UNCLASSIFIED

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) CDC/DDPHSIS/CPR/DSAT  
**Cc:** (b)(6) USARMY MEDCOM USAMRIID (US)  
**Subject:** RE: DAIG/CDC Inspection - List of studies 18-29 March 2019 (UNCLASSIFIED)  
**Date:** Tuesday, March 5, 2019 7:05:19 PM  
**Attachments:** [List of Inspectors 18-29Mar19 ver4.docx](#)

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CLASSIFICATION: UNCLASSIFIED

(b)(6)

Will (b)(6) go into BSL-4?

Currently, I'm only tracking (b)(6)

Thank you,

(b)(6)

Deputy Director, Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)

Mobile: (b)(6)

E-mail: (b)(6)

-----Original Message-----

From: (b)(6) (CDC/DDPHSIS/CPR/DSAT) [mailto:(b)(6)@cdc.gov]

Sent: Tuesday, March 5, 2019 6:39 AM

To: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6).civ@mail.mil>

Subject: [Non-DoD Source] RE: DAIG/CDC Inspection - List of studies 18-29 March 2019 (UNCLASSIFIED)

Hi (b)(6)

Your list looks good for DSAT, with the caveat that if something comes up, all inspectors besides John Holcomb may go into a BSL-3 if necessary.

Thanks,

(b)(6)

(b)(6)

Senior Microbiologist / Inspector  
Operations Branch  
Division of Select Agents and Toxins  
Center for Preparedness and Response

Centers for Disease Control and Prevention (CDC)  
1600 Clifton Road, NE, MS A-46, Atlanta, GA 30329

(b)(6) Office | (b)(6) Cell  
(b)(6)@cdc.gov | Telework: Monday/Wednesday/Friday

-----Original Message-----

From: (b)(6) CIV USARMY MEDCOM USAMRIID (US) - (b)(6) civ@mail.mil>  
Sent: Monday, March 4, 2019 6:43 PM  
To: (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov> (b)(6) CIV USARMY HQDA OTIG (USA) (b)(6) civ@mail.mil>  
Cc: (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov> (b)(6) CIV USARMY HQDA OTIG (US) (b)(6) civ@mail.mil>; (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) civ@mail.mil>; (b)(6) CIV USARMY MEDCOM USAMRIID (USA) (b)(6) civ@mail.mil>; (b)(6) CTR USARMY MEDCOM USAMRIID (US) (b)(6)@mail.mil> (b)(6) USARMY MEDCOM USAMRIID (USA) (b)(6)@mail.mil>; USARMY Ft Detrick MEDCOM USAMRMC List BSAT <usarmy (b)(6)@mail.mil>  
Subject: DAIG/CDC Inspection - List of studies 18-29 March 2019 (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

(b)(6)

As requested, please see attached list of studies going on in BSL-3 and BSL-4 containment during the CDC/DAIG inspection (18-29 March 2019). Please note, this list may be subject to change and as soon as I have updated information, I will pass this along.

Also, can your teams review the attached "List of Inspectors," specifically which inspectors will enter BSL-3 and BSL-4? This will help as we are tracking the training and occupational health requirements.

(b)(6) - I've also uploaded this information into eFSAP under the Inspections Tab.)

Thank you,

(b)(6)

(b)(6) PhD, RBP

Deputy Director, Biosecurity Directorate Federal Select Agent Program Responsible Official US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6) civ@mail.mil

CLASSIFICATION: UNCLASSIFIED  
CLASSIFICATION: UNCLASSIFIED

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) (CDC/DDPHSIS/CPR/DSAT)  
**Cc:** (b)(6) USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) A COL USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) CTR USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY HQDA OTIG (US); (b)(6) APHIS; (b)(6) APHIS; (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) CIV USARMY HQDA OTIG (USA); (b)(6) COL USARMY MEDCOM USAMRIID (USA); (b)(6) COL USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (US); USARMY Ft Detrick MEDCOM USAMRMC List BSAT; (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) M CIV USARMY MEDCOM USAMRIID (US); USARMY Ft Detrick MEDCOM USAMRIID List USAMRIID OPERATIONS  
**Subject:** RE: Surprise Select Agent Inspection  
**Date:** Sunday, June 2, 2019 9:25:50 PM

---

(b)(6)  
Receipt acknowledged. I will meet you at the USAMRIID Entry Control Point in the morning. Will your team arrive at 0900 or earlier?  
  
We have reserved 5 parking spaces for your team and they will be marked with orange cones.  
  
We will work on getting a conference room space for your team tomorrow morning.

Please call me on my cell for any issues or concerns:

(b)(6)

Thank you,

(b)(6)

(b)(6), Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6) civ@mail.mil

-----Original Message-----

**From:** (b)(6) (CDC/DDPHSIS/CPR/DSAT) [mailto:(b)(6)@cdc.gov]  
**Sent:** Sunday, June 2, 2019 7:44 PM  
**To:** (b)(6) CIV USARMY MEDCOM USAMRIID (US) <(b)(6) civ@mail.mil>  
**Cc:** (b)(6) USARMY MEDCOM USAMRIID (USA) <(b)(6)@mail.mil>; (b)(6) (b)(6) CIV USARMY MEDCOM USAMRIID (US) <(b)(6) civ@mail.mil>; (b)(6) CIV USARMY MEDCOM USAMRIID (US) <(b)(6) civ@mail.mil>; (b)(6) CIV USARMY MEDCOM USAMRIID (USA) <(b)(6) civ@mail.mil>; (b)(6) CIV USARMY MEDCOM USAMRIID (USA) <(b)(6) civ@mail.mil>; (b)(6) CTR USARMY MEDCOM USAMRIID (USA) <(b)(6) ctr@mail.mil>; (b)(6) CIV USARMY HQDA OTIG (US) <(b)(6) civ@mail.mil>; (b)(6) APHIS <(b)(6)@aphis.usda.gov>; (b)(6) APHIS <(b)(6)@aphis.usda.gov>; (b)(6) (CDC/DDPHSIS/CPR/DSAT) <(b)(6)@cdc.gov>; (b)(6) (CDC/DDPHSIS/CPR/DSAT) <(b)(6)@cdc.gov>; (b)(6)

(CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov> (b)(6) CDC/DDPHSIS/CPR/DSAT (b)(6)@cdc.gov>;  
(b)(6) CDC/DDPHSIS/CPR/DSAT (b)(6)@cdc.gov (b)(6) (CDC/DDPHSIS/CPR/DSAT)  
(b)(6)@cdc.gov (b)(6) CIV USARMY HQDA OTIG (USA) (b)(6).civ@mail.mil>  
Subject: [Non-DoD Source] Surprise Select Agent Inspection

Good evening (b)(6)

This email is to let you know that a team of FSAP inspectors along with DAIG will be onsite for a surprise inspection of USAMRIID starting on June 3 at 9 AM in the morning.

The FSAP team includes:

DSAT

\* (b)(6)  
\*  
\*  
\*  
\*  
\*  
\* (b)(6) (Facilities)

AgSAS

\* (b)(6)  
\*

Also arriving at the same time will be (b)(6) from DAIG.

Speaking for the CDC / DSAT group, we have already reviewed the visitor training curriculum provided for the March 2019 inspection already. We will also have our fit for duty letter, our animal clearance letter (TB), and our respiratory fit cards as outlined in the Form 1 Section 5. All of DSAT inspectors have already had our security clearances sent in the PERM CERT.

When we arrive, we can have a short meeting with the responsible staff and then we would like to begin our inspections of space. We will be focusing primarily on BSL3/BSL2s during this inspection along with a facilities component.

Initial records we will be requesting:

- \* Biosafety plan and referenced SOPs
- \* Security plan and referenced SOPs
- \* Incident Response plan and referenced SOPs
- \* Copies of floor plans
- \* Form 3 - incident write up and corrective actions since January 2019
- \* Inactivation certificates for since January 2019
- \* We will also be coordinating for facility records with our mechanical engineer.
- \* We will also coordinate observing how your biosafety team reviews film (as indicated in your previous corrective responses)

Our typical work day is from 9 - 5, but this may be adjusted depending on your schedule. Not all staff will need to be with at all times. We do ask that at least 1 knowledgeable person escorts us into the different areas that can access the inventory. Also, we will need a conference room or area to store our belongs while onsite.

Please contact me at (b)(6) if you have any questions. I look forward to visiting your facility in the morning.

Regards,

(b)(6)

(b)(6)

Senior Microbiologist / Inspector

Operations Branch

Division of Select Agents and Toxins

Center for Preparedness and Response

Centers for Disease Control and Prevention (CDC)

1600 Clifton Road, NE, MS H21-7, Atlanta, GA 30329

(b)(6)

Office

(b)(6)

Cell

(b)(6)

@cdc.gov

| Telework: Monday/Wednesday/Friday

<[http://www.cdc.gov/24-7/?s\\_cid=24-7\\_010&source=govdelivery](http://www.cdc.gov/24-7/?s_cid=24-7_010&source=govdelivery)>

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) CDC/DDPHSIS/CPR/DSAT  
**Cc:** (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) CTR  
**Subject:** RE: Thursday schedule (UNCLASSIFIED)  
**Date:** Thursday, March 28, 2019 8:48:37 PM

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CLASSIFICATION: UNCLASSIFIED

(b)(6)

Sure, no problem. We will have a Facilities and Biosafety representatives touch base with you tomorrow to answer any additional questions regarding the (b)(6) unit.

Thank you,

(b)(6)

(b)(3):42 U.S.C. § 262a(h)(1)(D)

(b)(6), Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobil: (b)(6)  
E-mail: (b)(6)@mail.mil

-----Original Message-----

**From:** (b)(6) CDC/DDPHSIS/CPR/DSAT [mailto:(b)(6)@cdc.gov]  
**Sent:** Thursday, March 28, 2019 7:08 AM  
**To:** (b)(6) CIV USARMY MEDCOM USAMRIID (US) <(b)(6)@mail.mil>  
**Cc:** (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov>  
**Subject:** [Non-DoD Source] Thursday schedule

Good Morning (b)(6)

(b)(3):42 U.S.C. § 262a(h)(1)(D)

We need to meet with staff who are running the (b)(6) and hopefully some biosafety personnel to clarify a few questions we have about operations.

Thanks,

(b)(6)

CLASSIFICATION: UNCLASSIFIED



**From:** (b)(6) (CDC/OPHPR/DSAT)  
**To:** (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) (CDC/OPHPR/DSAT); Form 3 (CDC)  
**Cc:** (b)(6) LTC USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**Subject:** RE: USAMRIID Facility Inspection Report - Request extension  
**Date:** Friday, August 3, 2018 10:22:48 AM

---

Good Morning (b)(6)

We understand the extenuating circumstances USAMRIID is currently experiencing and the extension request is approved with a new response due date of Aug 31, 2018. Please let (b)(6) or myself know if you have any questions or concerns as you review the recent correspondence uploaded into eFSAP.

Respectfully,

(b)(6)

(b)(6)

Supervisory Microbiologist  
Division of Select Agents and Toxins  
Office of Public Health Preparedness and Response  
Centers for Disease Control and Prevention  
1600 Clifton Road, NE MS A-46  
Atlanta, GA 30329  
Tel: (b)(6); Fax: (b)(6)

DSAT Vision: To be the preeminent resource for the safety and security of biological agents and toxins. This document is intended for the exclusive use of the recipient named above. It may contain sensitive information that is protected privileged, or confidential, and it should not be disseminated, distributed, or copied. If you think you have received this document in error, please notify the sender immediately and destroy the original, thank you.

-----Original Message-----

From: (b)(6) CIV USARMY MEDCOM USAMRIID (US) <(b)(6).civ@mail.mil>  
Sent: Friday, August 3, 2018 9:29 AM  
To: (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov; (b)(6) (CDC/OPHPR/DSAT) (b)(6)@cdc.gov; Form 3 (CDC) <form3@cdc.gov>  
Cc: (b)(6) USARMY MEDCOM USAMRIID (US) <(b)(6)@mail.mil>; (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6).civ@mail.mil>; (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6).civ@mail.mil>; (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6).civ@mail.mil>; (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6).civ@mail.mil>; (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6).civ@mail.mil>; (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6).civ@mail.mil>; (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6).civ@mail.mil>; (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6).civ@mail.mil>  
Subject: USAMRIID Facility Inspection Report - Request extension

(b)(6)

Due to the autoclave incident that occurred 2 August and the RO/ARO workshop 14-17 August, I kindly request a 14 day extension to respond to the Facility Inspection Report dated August 1, 2018.

Request the new report deadline is Friday, 31 August.

Thank you,

(b)(6)

(b)(6)

Deputy Director, Biosecurity Directorate & FSAP Responsible Official US Army Medical Research Institute of Infectious Diseases (USAMRIID)  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)

Mobile: (b)(6)

E-mail: (b)(6)@mail.mil

-----Original Message-----

From: (b)(6) (CDC/OPHPR/DSAT) [mailto:(b)(6)@cdc.gov]

Sent: Tuesday, July 31, 2018 12:50 PM

To: (b)(6) CIV USARMY MEDCOM USAMRIID (US) <(b)(6)@mail.mil>

Subject: [Non-DoD Source] Forthcoming inadequate response letter today

Good Afternoon (b)(6)

I wanted to touch base ahead of uploading our response letter to you today to determine if you have been able to locate and review the correspondence from DSAT sent to USAMRIID on March 21, 2016. This letter is referenced in the current response letter as it highlights some of the PPE considerations DSAT would like USAMRIID to consider in developing revised PPE postures for the BSL-3 laboratories. If you do not have a copy of this letter I can resend the letter to you for your information, recognizing that only one section of the letter will apply to the current responses.

Best Regards,

(b)(6)

(b)(6)

Lead Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: (b)(6) Fax: (b)(6)

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) CDC/DDPHSIS/CPR/DSAT  
**Cc:** (b)(6) CIV USARMY HQDA OTIG (US); (b)(6) LTC USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) LTC USARMY MEDCOM USAMRIID (USA); USARMY Ft Detrick MEDCOM USAMRMC List BSAT; (b)(6) COL USARMY MEDCOM USAMRIID (USA); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) MAJ USARMY MEDCOM USAMRIID (USA)  
**Subject:** RE: USAMRIID Inspection Notification Memo 18-29 March 2019 (UNCLASSIFIED)  
**Date:** Tuesday, January 29, 2019 6:55:59 PM  
**Attachments:** CDC DAIG Schedule 18-29 MAR 2019 DRAFT 1.xlsx

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CLASSIFICATION: UNCLASSIFIED

(b)(6) (b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(3):42 U.S.C. § 262a(h)(1)(D)

Thank you for your input and notification that your team will be at USAMRIID on 26-28 March. We will adjust the schedule to include the (b)(6) and (b)(6) related events to the second week when your team is on-site. We will also move any CDC-related events to this time period to include FSAP and new USAMRIID discussions.

The (b)(3):42 U.S.C. § 262a(h)(1)(E) has been informed of the inspection and will be available both weeks.

Thank you,

(b)(6)

(b)(6) Biosecurity Directorate

Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6) civ@mail.mil

-----Original Message-----

From: (b)(6) (CDC/DDPHSIS/CPR/DSAT) [mailto:(b)(6)@cdc.gov]  
Sent: Tuesday, January 29, 2019 1:16 PM  
To: (b)(6) CIV USARMY MEDCOM USAMRIID (US) <(b)(6) civ@mail.mil>  
Cc: (b)(6) CIV USARMY HQDA OTIG (US) <(b)(6) @mail.mil>; (b)(6) USARMY MEDCOM USAMRIID (USA) <(b)(6) .mil@mail.mil>  
Subject: [Non-DoD Source] RE: USAMRIID Inspection Notification Memo 18-29 March 2019 (UNCLASSIFIED)

Hi (b)(6) (b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(D) Just a quick glance. Just a reminder, we won't be onsite the first week. I see a visit to the (b)(6) and to look at the (b)(6) on the 19th. I also see some mentions of the CDC team during the first week. FSAP will want to look at the (b)(6) as well. You may want to consider moving that to the 2nd week unless you don't mind showing it both weeks. (b)(3):42 U.S.C. § 262a(h)(1)(D)

Our tentative, unconfirmed travel currently has FSAP onsite on the March 26-28. This will be a targeted inspection from FSAP's point of view. Primarily, we will be inspecting the BSL4s and looking at you (b)(6) Secondly to that, we may look at ABSL-3 space that is sending (b)(6) Also, you mentioned that you may want to update FSAP on progress / developments with new USAMRIID and ask questions of our group. I believe you (b)(3):42 U.S.C. § 262a(h)(1)(D)

mentioned Dr. Edwin may be on site that week as well with the (b)(6) group. This would be a great time for any discussion or questions you may have as well.

Thank you for keeping FSAP in the loop.

Regards,

(b)(6)

**From:** (b)(6) USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) CDC/OPHPR/DSAT; (b)(6) CDC/OPHPR/DSAT; Form 3 (CDC (b)(6) (CDC/OPHPR/DSAT)  
**Cc:** (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) LTC USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CTR USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CTR USARMY MEDCOM USAMRIID (US); (b)(6) CTR USARMY (US); (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**Subject:** Schedule CDC Visit to review th (b)(6) - USAMRIID  
**Date:** Sunday, August 12, 2018 10:46:54 AM (b)(3):42 U.S.C. § 262a(h)(1)(D)

---

Dear (b)(6)

Thank you for taking the time to speak with our team on Friday. After review of our schedule, it would be best if your team can schedule a site visit to review the (b)(3):42 U.S.C. § 262a(h)(1)(D) the week of 22 October 2018.

Please let me know if this works for your team.

Thank you,

(b)(6)

(b)(6) Biosecurity Directorate &  
FSAP Responsible Official  
US Army Medical Research Institute of Infectious Diseases (USAMRIID)  
1425 Porter Street  
Fort Detrick, MD 21702  
Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6)

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (USA)  
**To:** (b)(6) (CDC/DDPHSIS/CPR/DSAT)  
**Subject:** TEDS 1a & 1b PI&D (UNCLASSIFIED)  
**Date:** Wednesday, June 5, 2019 2:00:16 PM  
**Attachments:** 26400-1 PID REV 2.pdf  
Vpak HPU Schematic 1.pdf (b)(3):42 U.S.C. § 262a(h)(1)(D)

---

CLASSIFICATION: UNCLASSIFIED

(b)(6)

(b)(6) had requested these drawing from our site visit today.

Thank you

(b)(6)

Engineering Technician Supervisor  
Facilities Management Office  
United States Army Medical Research  
Institute of Infectious Diseases  
Bldg (b)(6) Porter Street (b)(3):42 U.S.C. § 262a(h)(1)(E)  
Frederick MD. 21702  
Office Phone: (b)(6)  
Work Cell Phone (b)(6)  
Mobile Phone (b)(6)

CLASSIFICATION: UNCLASSIFIED

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) CDC/OPHPR/DSAT; (b)(6) (CDC/OPHPR/DSAT)  
**Cc:** (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**Subject:** Upcoming CDC Inspections  
**Date:** Wednesday, August 15, 2018 9:17:40 AM

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(b)(6)

Can you confirm the dates for the September and October inspections at USAMRIID?

Please provide the names of the inspectors and we can start working on facility clearances.

Will your team need access to both BSL3 and BSL4?

From our discussion this morning, the scope of both inspections will be focused on our modified BSL3 procedures and plan forward for our (b)(3):42 U.S.C. § 262a(h)(1)(D)

Dates discussed: 12-13 Sept (review modified procedures and any documentation related to the (b)(3):42 U.S.C. § 262a(h)(1)(D)

Week of 22 October (operational inspection of the (b)(6) — once it's on site) (b)(3):42 U.S.C. § 262a(h)(1)(D)

We are scheduled for our annual BSL4 inspection in December. Please confirm if your team plans to come back in December or if this inspection will be combined with the October inspection.

Thank you.

(b)(6)

(b)(6) Biosecurity Directorate &  
FSAP Responsible Official  
US Army Medical Research Institute of Infectious Diseases (USAMRIID)  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)

Mobile:

Cell: (b)(6)

E-mail: (b)(6) civ@mail.mil

Sent from my iPhone

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) (CDC/OPHPR/DSAT); (b)(6) CDC/OPHPR/DSAT  
**Cc:** Form 3 (CDC); (b)(6) CDC/OPHPR/DSAT; Edwin, Samuel (CDC/OPHPR/DSAT); USARMY Ft Detrick MEDCOM USAMRMC List BSAT; (b)(6) CIV USARMY HQDA OTIG (US); (b)(6) CIV USARMY HQDA OTIG (US); (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) LTC USARMY MEDCOM USAMRIID (US); (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRMC (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY USAG (US); (b)(6) CIV USARMY MEDCOM USAMRMC (US)  
**Subject:** USAMRIID Response to CDC Inspection Report dated 1 August 2018  
**Date:** Thursday, August 30, 2018 12:17:15 PM  
**Attachments:** [USAMRIID Response to CDC Inspection Report dated 1 Aug 2018.pdf](#)  
[Enclosure 1. Appendix 4 Potential Biological Releases and Decontamination Testing Monitoring.pdf](#)  
[Enclosure 2. USAMRIID Hydrostatic Test Report 7-26-2018.pdf](#)  
[Enclosure 3. Illustration of Piping Trench Building 375.pdf](#)  
[Enclosure 4. USAMRIID Emergency Management Plan 28 Aug 2018.pdf](#)  
[Enclosure 5. USAMRIID Biosafety Plan Change Request 3.pdf](#)

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(b)(6)

Please see attached USAMRIID Response to the CDC Inspection Report dated 1 August 2018. I have also uploaded these documents into eFSAP.

Please let me know if you have any questions or concerns.

Thank you,

(b)(6)

(b)(6) Biosecurity Directorate &  
FSAP Responsible Official  
US Army Medical Research Institute of Infectious Diseases (USAMRIID)  
1425 Porter Street  
Fort Detrick, MD 21702  
Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6)



**From:** (b)(6) C CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) CDC/DDPHSIS/CPR/DSAT; Edwin. Samuel (CDC/DDPHSIS/CPR/DSAT)  
**Cc:** (b)(6) COL USARMY MEDCOM USAMRIID (USA); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) USARMY MEDCOM USAMRIID (USA); (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) USARMY MEDCOM USAMRIID (USA); (b)(6) USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); USARMY Ft Detrick MEDCOM USAMRMC List BSAT; Form 3 (CDC); (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6) CIV USARMY MEDCOM USAMRIID (USA); (b)(6) (CDC/DDPHSIS/CPR/DSAT); (b)(6)  
**Subject:** USAMRIID Response to Facility Inspection Report dated: 9 Nov 2018 (UNCLASSIFIED)  
**Date:** Thursday, January 24, 2019 5:53:04 PM  
**Attachments:** [USAMRIID 5165 InadequateResponseLetter2.pdf](#)  
[RO - Signed Attestation Letter 20190124.pdf](#)  
[1 USAMRIID CEDS Functional Performance Testing 20191601 Merrick Signed.pdf](#)  
[2 CEDS Biovalidation report 20190124 FINAL.PDF](#)  
[3 USAMRIID Regulation 385-69, Biological Safety Program, 7 December 2018...pdf](#)  
[4 SA030600-11012018-Biological Challenge of CEDS using Bacterial Spores.pdf](#)  
[5 Form DD2977 - Deliberate Risk Assessment Worksheet SA 03-06.pdf](#)  
[\(b\)\(3\):42 U.S.C. § 30 Oct 2018.pdf](#)  
[7 Physical Security Plan \(CDC\) 10 October 2018 - FINAL.PDF](#)  
[8 USAMRIID Emergency Management Plan SIGNED October 2018.pdf](#)  
**Importance:** High

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CLASSIFICATION: UNCLASSIFIED

Dear (b)(6)

Please see attached response to the Facility Inspection Report dated 9 Nov 2018 which includes the following documents:

1. RO Signed attestation letter
2. Functional Performance Testing (Commissioning Documents)
3. Biovalidation of the (b)(3):42 U.S.C. § 262a(h)(1)(D)
4. USAMRIID Biosafety Plan, 7 Dec 2018
5. USAMRIID SOP, SA-03-06, 1 Nov 2018
6. Risk Assessment to USAMRIID SOP, SA-03-06, 11 Sep 2018
7. (b)(3):42 U.S.C. § 30 Oct 2018
8. Physical Security Plan, 10 Oct 2018
9. Emergency Management Plan, 18 Oct 2018

These documents have been uploaded into eFSAP.

Thank you for your continued guidance and support of USAMRIID and we look forward to your response.

(b)(6)

(b)(6)

(b)(6) Biosecurity Directorate  
Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6)@mail.mil

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
**To:** (b)(6) (CDC/DDPHSIS/CPR/DSAT)  
**Cc:** (b)(6) LTC USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (USA)  
**Subject:** Re: [Non-DoD Source] Re: USAMRIID requests (1) Reclama to 3-7 June report (2) Copy of 15 May 2019 DSAT Letter  
**Date:** Tuesday, August 6, 2019 9:55:33 PM

---

(b)(6)

Great thanks for the feedback.

Thank you,

(b)(6)

PhD, RBP

(b)(6)

Biosecurity Directorate &

FSAP Responsible Official

US Army Medical Research Institute of Infectious Diseases (USAMRIID)

1425 Porter Street

Fort Detrick, MD 21702

Office: (b)(6)

Mobile: (b)(6)

Cell: (b)(6)

E-mail: (b)(6) [civ@mail.mil](mailto:civ@mail.mil)

Sent from my iPhone

On Aug 6, 2019, at 9:47 PM, (b)(6) (CDC/DDPHSIS/CPR/DSAT)

(b)(6) [@cdc.gov](mailto:)> wrote:

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

---

Hi (b)(6)

(b)(5)

I will (b)(5)

Regards,

(b)(6)

Get Outlook for iOS < Caution-https://aka.ms/o0ukef >

---

**From:** (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
(b)(6).civ@mail.mil>  
**Sent:** Tuesday, August 6, 2019 7:28:12 PM  
**To:** (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov>  
**Cc:** (b)(6) LTC USARMY MEDCOM USAMRIID (USA)  
(b)(6)@mail.mil>; Dohm, David J CIV USARMY MEDCOM USAMRIID (USA)  
(b)(6).civ@mail.mil>  
**Subject:** USAMRIID requests (1) Reclama to 3-7 June report (2) Copy of 15 May 2019 DSAT Letter

Hi (b)(6)

(b)(5)

Thank you.

(b)(6)

PhD, RBP

Federal Select Agent Program Responsible Official

US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6) [civ@mail.mil](mailto:(b)(6).civ@mail.mil)

-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (USA)  
Sent: Tuesday, August 6, 2019 5:18 PM  
To: (b)(6) CIV USARMY MEDCOM USAMRIID (US)  
(b)(6).civ@mail.mil>  
Cc: (b)(6) CIV USARMY MEDCOM USAMRIID (USA)  
(b)(6).civ@mail.mil>  
Subject: CDC Letter dated 15 May (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Hi (b)(6)

CDC-DSAT's response to our June inspection report responses which (b)(5)

(b)(5)

Do you have a copy of that letter. Don't know if it is in the eFSAP or they send a separate letter. But I don't have a copy of it.  
If you have it please send me a copy.

Thank you,

(b)(6)

LTC, US Army, MS  
MS, Strategic Studies (Countering WMD)

(b)(6) Biosecurity

USAMRIID

(b)(6)

(office)  
(cell)  
(BB)

CLASSIFICATION: UNCLASSIFIED

**From:** (b)(6) CIV\_USARMY\_MEDCOM\_USAMRIID (US)  
**To:** (b)(6) CDC/DDPHSIS/CPR/DSAT  
**Cc:** (b)(6) LTC\_USARMY\_MEDCOM\_USAMRIID (USA)  
**Subject:** Re: [Non-DoD Source] USAMRIID adequate  
**Date:** Wednesday, February 6, 2019 10:03:32 AM

---

Matt,  
Thank you for the notification and the continued support.

Thank you,

(b)(6)

(b)(6)

Biosecurity Directorate &

FSAP Responsible Official

US Army Medical Research Institute of Infectious Diseases (USAMRIID)

1425 Porter Street

Fort Detrick, MD 21702

Office: (b)(6)

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E-mail: (b)(6) [civ@mail.mil](mailto:civ@mail.mil)

Sent from my iPhone

On Feb 6, 2019, at 8:25 AM, Ellison, Matthew L. (CDC/DDPHSIS/CPR/DSAT) <[ybr9@cdc.gov](mailto:ybr9@cdc.gov)> wrote:

Good morning Shelley,

I sent you an email last night, but the system returned it to me as still pending this morning.

(b)(5)

Regards,

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](mailto:lrsat@cdc.gov)) or the AgSAS Operations Unit Director([AgSAS@aphis.usda.gov](mailto: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)

Operations Branch Chief  
Division of Select Agents and Toxins  
of Health and Human Services  
Centers for Disease Control and Prevention

(b)(6)

Unit Director  
Agriculture Select Agent Services Department  
Animal and Plant Health Inspection Services  
United States Department of Agriculture

## **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: 42-12-62900

42 CFR 73 - 12(b)

Response Due: 04/19/2019

Severity Level: Serious

Status: Open

Departure Type:

Repeat Departure:

Immediate Action

No

### 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:

Inspectors observed an individual partially entering ABSL3 Room [redacted] multiple times without the required respiratory protection. During this time, other [redacted] in Room [redacted] were wearing PAPRs and performing procedures with a [redacted] non-human primate on a necropsy table; other infected non-human primates were housed in open caging. Entity plans and procedures require the use of a PAPR in animal rooms when infected animals are present. This deviation from entity procedures resulted in a respiratory occupational exposure to select agent aerosols. [BMBL: (ABSL-3) C3]

(b)(3);42 U.S.C. § 262a(h)(1)(E)

(b)(3);42 U.S.C. § 262a(h)(1)(E)

(b)(6)

(b)(3);42 U.S.C. § 262a(h)(1)(E)

### Corrective Action:

Provide an APHIS/CDC Form 3 for the occupational exposure described above. Additionally, provide the measures implemented to ensure all personnel entering areas where infectious materials and/or animals are housed or manipulated wear appropriate eye, face, and respiratory protection.

### Responses:

[redacted]  
(b)(6)

Submitted:  
04/15/2019

Receipt acknowledged. I would like to request an extension to the submission deadline to Friday, 26 April 2019.

Thank you,

[redacted]  
(b)(6)

Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: [redacted] (b)(6)

Mobile: [redacted] (b)(6)

E-mail: [redacted] (b)(6)

[redacted] (b)(6)

[redacted] (b)(3);42 U.S.C. § 262a(h)(1)(E); (b)(5)

[redacted] (b)(5)

[redacted] (b)(6)

[redacted] (b)(6)

Submitted:  
04/29/2019



Federal Select Agent Program Responsible Official  
US Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

Office: (b)(6)  
Mobile: (b)(6)  
E-mail: (b)(6)

(b)(6)

Submitted:  
04/29/2019

CORRECTION: (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) (b)(6)

(b)(6) Biosecurity Directorate Federal Select Agent Program  
Responsible Official US Army Medical Research Institute of Infectious  
Diseases 1425 Porter Street Fort Detrick, MD 21702 Office (b)(6)

(b)(6) E-mail:  
(b)(6)

(b)(6)

Submitted:  
05/31/2019

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(6)

Submitted:  
07/19/2019

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

Departure  
UID: 42-15-00500

42 CFR 73 - 15(d)

Response Due: 06/01/2019  
Severity Level: Serious  
Status: Open

Departure Type: Final  
Repeat Departure: No

**Requirement:**

The Responsible Official must ensure a record of the training provided to each individual with access to select agents and toxins and each escorted individual (e.g., laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

**Observation:**

The entity failed to ensure that the means used to verify that employees understood the provided training was effective. These failures were recognized through video review of laboratorians' working in BSL3 and ABSL3 laboratories and indicate the entity's means used to verify personnel understood the training has not been effective, leading to increased risk of occupational exposures. Specifically, (1) A laboratorian who had not donned appropriate respiratory protection was observed multiple times partially entering an ABSL3 room where non-human primates infected with (b)(3):42 U.S.C. § 262a(h)(1)(E) were housed in open caging. (2) A laboratorian was observed disposing of waste in a biohazardous waste bin in room [redacted] while not wearing gloves.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Corrective Action:**

Provide the measures implemented to ensure biosafety training for FSAP-approved individuals is understood.

**Responses:**

(b)(6)  
[redacted]  
(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

Submitted:  
05/31/2019

(b)(6)  
[redacted]  
(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

Submitted:  
07/19/2019

Departure  
UID: 42-12-43000

42 CFR 73 - 12(b)

Response Due: 06/01/2019  
Severity Level: Moderate  
Status: Open

Departure Type: Final  
Repeat Departure: No

**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:**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

A laboratorian was not wearing gloves while disposing of waste in a biohazardous waste bin in Bldg 1412, Suite [redacted] Room [redacted] [BMBL: (BSL-3) C4]

**Corrective Action:**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Provide: 1) Confirmation that relevant personnel have been trained to wear gloves to prevent exposure to hazardous materials. 2) The measures implemented to ensure personnel understand and follow the procedures .

**Responses:**

(b)(6)  
(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)  
Submitted: 05/31/2019

(b)(6)  
(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)  
Submitted: 07/19/2019

Departure  
UID: 42-12-64800

42 CFR 73 - 12(b)

<b>Response Due:</b>	06/01/2019	<b>Departure Type:</b>	Final
<b>Severity Level:</b>	Moderate	<b>Repeat Departure:</b>	No
<b>Status:</b>	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:**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

The procedures for the chemical effluent decontamination system were validated before putting the system online for use in both the [redacted] and [redacted] laboratories. However, there has been no means to verify the operational parameters of system are operating as intended. Specifically, there is no verification that 1) The measured ppm of the sodium hypochlorite totes is maintained during the potential 10 day storage period. 2) The flow rate of the sodium hypochlorite pump has maintained the 1.14 gal/minute initially validated. 3) The final ppm of sodium hypochlorite is at or above the minimum levels in the mixing tanks before the decontaminated effluent is pumped to the holding silos. [BMBL: (BSL-4) D14]

**Corrective Action:**

Provide: 1) Evidence the Chemical EDS is operating as intended. 2) The measures implemented to monitor the operational parameters on an ongoing basis.

**Responses:**

(b)(6)  
(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)  
Submitted: 05/31/2019

(b)(6)  
(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)  
Submitted: 07/19/2019

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

Departure  
UID: 42-12-37300

42 CFR 73 - 12(a)

<b>Response Due:</b>	06/01/2019	<b>Departure Type:</b>	Final
<b>Severity Level:</b>	Low	<b>Repeat Departure:</b>	No
<b>Status:</b>	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:**

The BSL3 and ABSL3 modified PPE procedures and associated signage do not include or reference donning and doffing procedures for the use of single or double gloves.

**Corrective Action:**

Provide written confirmation that: 1) This information has been added to the plan or that the plan references the SOPs where these procedures can be found. 2) Relevant entity personnel have been trained on the updated procedures.

**Responses:**

(b)(6)  
(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

Submitted:  
05/31/2019

(b)(6)  
(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

Submitted:  
07/19/2019

General Concern  
UID: 42-17-03400

42 CFR 73 - 17(b)

**Observation:**

In two instances, the number of select agent vials held in long term storage boxes did not match the count indicated in the inventory record. In both cases, the vials were found in a different box. Consider implementing a means to verify that all select agent vials are located in their designated box to avoid inventory discrepancies.

---

General Concern  
UID: 42-11-01700

42 CFR 73 - 11(c)(10)

**Observation:**

The security plan requires that the posted list of personnel approved to receive packages at the loading dock be updated monthly, but the posted list available was dated Sept 2018. This list was updated during the inspection.

Consider revising the security plan to meet current procedures.

---

General Concern  
UID: 42-11-02600

42 CFR 73 - 11(e)(1)

(b)(3):42 U.S.C. §  
262a(h)(1)(E)

**Observation:**

Select agent long term inventory was relocated in building [redacted] after the recent autoclave incident. The Biosurety team stated the entire freezers were relocated to a different room without unlocking or opening, thus ensuring the inventory remained accurate. Failure to conduct complete inventory audits upon the physical relocation of inventory could lead to departures in Section 11, or more serious departures, if select agent inventory is found to be inaccurate.

---

General Concern  
UID: 42-14-00100

42 CFR 73 - 14(a)

**Observation:**

The entity's biocontainment suites have individual incident response plans (IRP) that are not consistent with the main entity IRP. This inconsistency resulted in a failure of personnel to effectively implement their IRP during an emergency that occurred on February 9, 2018. The plans conflict on who should be contacted in the event of an incident. The suite SOPs state the biosafety team should be contacted, but the entity plan states that security should be contacted. This inconsistency resulted in a delay to an actual man-down emergency because the laboratorian called the biosafety contact per the suite SOP. When it was determined the emergency required an ambulance, entity security was unaware of the emergency

and unable to promptly open the gate, further delaying the response. Consider updating the procedures in these plans to provide consistent contact information.

---

General Concern  
UID: 42-11-03800

42 CFR 73 - 11(f)(4)(v)

**Observation:**

The entity uses a (b)(3):42 U.S.C. § 262a(h)(1)(E) that is no longer supported by the commercial vendor. Due to the construction and pending relocation to a new building, this system will not be upgraded or replaced. Although the system is currently working, the lack of future updates, patches, and support from the vendor may result in failure of the access control system and intrusion detection system, leading to potentially severe security departures under section 11 of the regulations.

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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](mailto:lrsat@cdc.gov)) or the AgSAS Operations Unit Director([AgSAS@aphis.usda.gov](mailto: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)

Operations Branch Chief  
Division of Select Agents and Toxins  
of Health and Human Services  
Centers for Disease Control and Prevention

(b)(6)

Unit Director  
Agriculture Select Agent Services Department  
Animal and Plant Health Inspection Services  
United States Department of Agriculture

## **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  
Severity Level: Serious  
Status: Open

Departure Type: Immediate Action  
Repeat Departure: No

### 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 in (b)(3):42 U.S.C. § 262a(h)(1)(E) and (b)(3):42 U.S.C. § 262a(h)(1)(D) on July 1 and July 11, 2019. These combined (b)(3):42 U.S.C. demonstrate a failure of USAMRIID to implement and maintain containment procedures sufficient to contain select agents or toxins (b)(3):42 U.S.C. § 262a(h)(1)(D) 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 (b)(3):42 U.S.C. § 262a(h)(1)(D) until the root cause investigation has been conducted for each incident and the results have been submitted to FSAP for review.

### Responses:

(b)(6)  
(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)  
Submitted: 07/15/2019

(b)(6)  
Root cause  
(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)  
Submitted: 07/15/2019

Science  
(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(6)

CLASSIFICATION: UNCLASSIFIED

Submitted:  
07/18/2019

Good morning (b)(6)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

Best regards,

(b)(6)

LTC, US Army, MS  
MS, Strategic Studies (Countering WMD)  
Director, Biosecurity  
USAMRIID

(b)(6)

(office)  
(cell)  
(BB)

-----Original Message-----

From: (b)(6) (CDC/DDPHSIS/CPR/DSAT)

[mailto:(b)(6)@cdc.gov]

Sent: Tuesday, July 16, 2019 10:59 PM

To: (b)(6) USARMY MEDCOM USAMRIID (USA)

(b)(6) mil@mail.mil>

Cc: (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov>;

(b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov>;

(b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(3):4 (b)(6)@cdc.gov>; (b)(6)

(b)(3):42 U.S.C. CIV USARMY MEDCOM USAMRIID (US)

(b)(6) civ@mail.mil> (b)(6) CIV USARMY

MEDCOM USAMRIID (USA) (b)(6) civ@mail.mil> (b)(6)

(b)(6) CIV USARMY MEDCOM USAMRIID (US)

(b)(6) civ@mail.mil> (b)(6) CIV USARMY MEDCOM

USAMRIID (US) (b)(6) civ@mail.mil> (b)(6) CIV

USARMY MEDCOM USAMRIID (USA) (b)(6) civ@mail.mil>;

(b)(6) CIV USARMY MEDCOM USAMRIID (USA)

(b)(6) civ@mail.mil> (b)(6) CTR USARMY

MEDCOM USAMRIID (USA) (b)(6) ctr@mail.mil>

Subject: [Non-DoD Source] RE: Immediate Action released in eFSAP

(UNCLASSIFIED)

Importance: High

Good Evening (b)(6)

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

Respectfully,

(b)(6)

Deputy Operations Branch Chief  
Division of Select Agents and Toxins  
Center for Preparedness and Response  
Centers for Disease Control and Prevention  
1600 Clifton Road, NE MS A-46  
Atlanta, GA 30329  
Tel: (b)(6); Fax: (b)(6)

-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (USA)  
(b)(6)@mail.mil>  
Sent: Monday, July 15, 2019 5:38 PM  
To: (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov>  
Cc: (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov>;  
(b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov>;  
(b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov>; (b)(6)  
(b)(6) CIV USARMY MEDCOM USAMRIID (US)  
(b)(6) civ@mail.mil>; (b)(6) CIV USARMY  
MEDCOM USAMRIID (USA) (b)(6) civ@mail.mil>; (b)(6)  
(b)(6) CIV USARMY MEDCOM USAMRIID (US)  
(b)(6) civ@mail.mil>; (b)(6) CIV USARMY MEDCOM  
USAMRIID (US) <(b)(6).civ@mail.mil> (b)(6) CIV  
USARMY MEDCOM USAMRIID (USA) (b)(6) civ@mail.mil>;  
(b)(3):42 U.S.C. § (b)(6) CIV USARMY MEDCOM USAMRIID (USA)  
(b)(6) civ@mail.mil>; (b)(6) CTR USARMY  
MEDCOM USAMRIID (USA) (b)(6) ctr@mail.mil>  
Subject: RE: Immediate Action released in eFSAP (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Good afternoon (b)(6)

In response to the immediate action, the following message has been submitted in the eFSAP.

-----  
Root cause

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

Science

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

Thank you,

(b)(6)

LTC, US Army, MS  
MS, Strategic Studies (Countering WMD)  
Director, Biosecurity  
USAMRIID

(b)(6) (office)  
(b)(6) (cell)  
(b)(6) (BB)

-----Original Message-----

From: (b)(6) (CDC/DDPHSIS/CPR/DSAT)  
[mailto:(b)(6)@cdc.gov]  
Sent: Friday, July 12, 2019 3:59 PM  
To: (b)(6) LTC USARMY MEDCOM USAMRIID (USA)  
(b)(6)@mail.mil> (b)(6) CIV USARMY  
MEDCOM USAMRIID (US) (b)(6).civ@mail.mil>  
Cc: (b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)2@cdc.gov>;  
(b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov>;  
(b)(6) (CDC/DDPHSIS/CPR/DSAT) (b)(6)@cdc.gov>  
Subject: [Non-DoD Source] Immediate Action released in eFSAP  
Importance: High

Good Afternoon (b)(6)

Please be advised that a significant immediate action item has been released in eFSAP that will require your prompt attention. Please log into eFSAP to view this action item and acknowledge receipt in the eFSAP discussion panel. The immediate action item was released under inspection #7087.

Respectfully,

(b)(6)

Deputy Operations Branch Chief  
Division of Select Agents and Toxins  
Center for Preparedness and Response  
Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: (b)(6); Fax: (b)(6)

(b)(6)

Submitted:  
08/28/2019

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(6)

Submitted:  
08/30/2019

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

Departure  
UID: 42-12-38200

42 CFR 73 - 12(a)

Response Due: 08/29/2019  
Severity Level: Serious  
Status: Open

Departure Type: Final  
Repeat Departure: No

**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)

1. In building [redacted] 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 ( [redacted] ) This deviation increases the risk of contaminated air from room [redacted] escaping and being drawn into the [redacted] where individuals typically do not wear respiratory protection.

(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)

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

**Corrective Action:**

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

**Responses:**

[redacted]

(b)(6)

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

Submitted:  
08/28/2019



(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(6)

Submitted:  
08/30/2019

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

Departure  
UID: 42-11-00100

42 CFR 73 - 11(a)

Response Due: 08/29/2019  
Severity Level: Moderate  
Status: Open

Departure Type: Final  
Repeat Departure: No

**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.

**Observation:**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

The entity failed to implement the security plan to safeguard against unauthorized access to select agents. Specifically, contaminated personal protective equipment worn while decontaminating select agent contaminated [redacted] was stored in open biohazard bags [redacted] in non-[redacted]. By storing regulated waste in this area, the entity did not limit access to those with access approval, and deviated from the standard operating procedure for securing this material.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Corrective Action:**

Describe the measures implemented to ensure regulated select agent waste is secured against unauthorized access by storing the waste in registered areas and limiting access using the standard operating procedure referenced in the security plan.

**Responses:**

(b)(6)

Submitted:  
08/28/2019

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(6)

Submitted:  
08/30/2019

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

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:**

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

**Observation:**

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

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

**Responses:**

(b)(6)

Submitted:  
08/14/2019

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(6)

Submitted:  
08/28/2019

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(6)

Submitted:  
08/28/2019

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(6)

Submitted:  
08/30/2019

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(6)

Submitted:  
08/06/2019

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)



(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

Departure  
UID: 42-12-26000

42 CFR 73 - 12(b)

Response Due: 08/29/2019  
Severity Level: Low  
Status: Open

Departure Type: Final  
Repeat Departure: No

**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] 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)

(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.

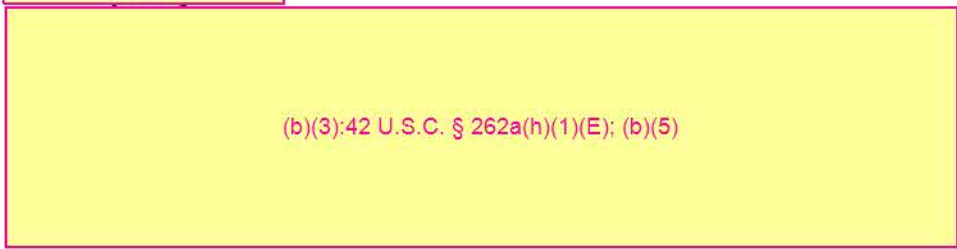
(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Responses:**

(b)(6)

Submitted:  
08/28/2019



(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(6)

Submitted:  
08/30/2019

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

Departure  
UID: 42-12-41500

42 CFR 73 - 12(b)

Response Due: 08/29/2019  
Severity Level: Low  
Status: Open

Departure Type: Final  
Repeat Departure: Yes

**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.

**Responses:**

(b)(6)

Submitted:  
08/28/2019

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(6)

Submitted:  
08/30/2019

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

General Concern  
UID: 42-12-41500.1

42 CFR 73 - 12(b)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Observation:**

There was no biohazard sign, contact information, nor biosafety level posted upon entry into ABSL3 lab (b)(6). 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.

General Concern

(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)

**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)

(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)

General Concern  
UID: 42-12-37600

42 CFR 73 - 12(a)(3)

**Observation:**

The entity Safety Manual for BSL3 [REDACTED] Suite (Bldg [REDACTED]) 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.

(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)

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)

**Observation:**

The entity has different PPE postures for entering BSL-3 laboratories in building [redacted] and [redacted] 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.

(b)(3):42 U.S.C. §  
262a(h)(1)(E)

(b)(3):42  
U.S.C. §  
262a(h)(1)(E)



**Memo of Record for USAMRIID Verification Inspection Conducted October 23-24, 2018**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Memo Prepared By:

(b)(6)

Division of Select Agents and Toxin

Center for Preparedness and Response

(b)(6) [@cdc.gov](mailto:(b)(6)@cdc.gov)

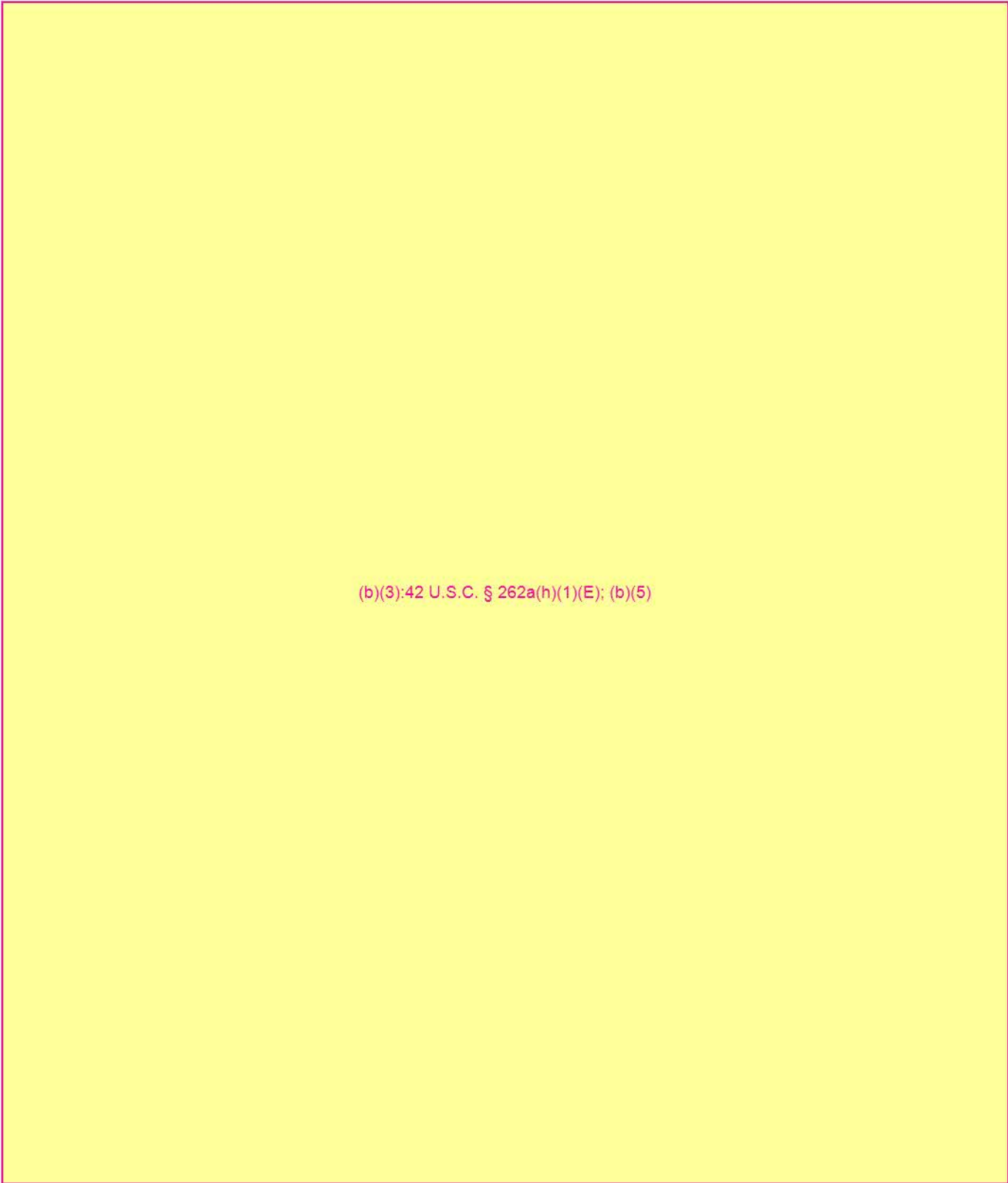
(b)(6)

**(Note: this memo was created from a summary email sent on November 2, 2018 at 7:17AM to**

(b)(6)

USAMRIID Site Visit Summary: May 21-22, 2018

Inspectors: (b)(6)



(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(5)

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(6)

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(6)



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



June 15, 2018

(b)(6) Responsible Official  
U.S. Army Medical Research in Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702

(b)(6) civ@mail.mil

cc (b)(6) mil@mail.mil, (b)(6) civ@mail.mil, (b)(6) civ@mail.mil,  
(b)(6) civ@mail.mil, (b)(6) civ@mail.mil, (b)(6) ctr@mail.mil,  
(b)(6) civ@mail.mil

Subject: **Entity Inspection Report:** U.S. Army Medical Research in Infectious Disease (USAMRIID)

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) and 7 CFR Part 331 and 9 CFR Part 121 (USDA). 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. AgSAS and DSAT comprise the Federal Select Agent Program (FSAP). The above referenced regulations and supporting guidance information may be found at <http://www.selectagents.gov/>.

Representatives from FSAP conducted a site visit of USAMRIID and associated support buildings in response to reported (b)(3):42 U.S.C. § 262a(h)(1)(E) on May 21-22, 2018. On May 30, 2018, USAMRIID suspended all work with select agents and toxins in (b)(3):42 U.S.C. § 262a(h)(1)(E) until such time as the containment of select agents and toxins can be assured. This action was due to the site visit and additional reports from USAMRIID of (b)(3):42 U.S.C. § 262a(h)(1)(E) Departures noted from the May 21-22, 2018 USAMRIID site visit are described below.

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

(b)(3):42  
U.S.C. §  
262a(h)(1)(E)

**Severity Level: High**

- 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:** USAMRIID failed to contain presumptively (b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(3):42 U.S.C. § 262a(h)(1)(E) where select agent work was being conducted due to multiple failure points (b)(3):42 U.S.C. § 262a(h)(1)(E). These failure points include (b)(3):42 U.S.C. § 262a(h)(1)(E). 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)

In summary

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Corrective Action:** Provide:

1.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

2. The action plan to address the (b)(3):42 U.S.C. § 262a(h)(1)(E) The action plan should include the steps taken to address (b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E) Additionally, the action plan should address (b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

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

(b)(3):42 U.S.C. § 262a(h)(1)(E)

3.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**2 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. [Section 12(a)]

**Requirement:** The biosafety plan must include the following provisions: Written procedures for each validated method used for disinfection, decontamination or destruction, as appropriate, of all contaminated or presumptively contaminated materials including, but not limited to: Cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents and toxins, personal protective equipment, animal caging systems and bedding (if applicable), animal carcasses or extracted tissues and fluids(if applicable), laboratory surfaces and equipment, and effluent material. [Section 12(a)(3)]

**Observation:**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

- USAMRIID's written procedures for

(b)(3):42 U.S.C. § 262a(h)(1)(E)

- 

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Corrective Action:** Provide:

1. Revised section(s) of the biosafety plan or supporting SOP(s) that includes clear and consistent

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

2. Validation information on the methods and

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

3. Documentation of training for laboratory staff on any revised procedures and biosafety considerations implemented for the

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42

The training documentation must include the name of the individuals, date of the training, content of the training, and a description of the means used to verify personnel understand the training.



**3 Requirement:** An individual or entity required to register under this part must develop and implement a written incident response plan based upon a site specific risk assessment. The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review. [Section 14(a)]

**Observation:** USAMRIID's incident response plan

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Corrective Action:** Provide an updated incident response plan that contains response procedures for (b)(3):42 U.S.C. § 262a(h)(1)(E) The procedures must be based on a site specific risk assessment and coordinated with entity-wide plans.

Within 14 days of the date of this letter, **USAMRIID must provide FSAP a detailed response to each regulatory departure including corrective actions or action plans implemented** to ensure compliance with the regulatory requirements noted in this report.

Contact (b)(6) with any questions concerning this correspondence.

Sincerely,

(b)(6)

Chief, Operations Branch  
Division of Select Agents and Toxins  
Centers for Disease Control and Prevention  
Department of Health and Human Services

(b)(6)

Unit Director  
Agriculture Select Agent Services  
Animal and Plant Health Inspection Service  
United States Department of Agriculture



DEPARTMENT OF THE ARMY  
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES  
1425 PORTER STREET  
FORT DETRICK, MARYLAND 21702-5011

June 28, 2018

Dr. Samuel Edwin  
Director, Division of Select Agents and Toxins  
Department of Health and Human Services  
Centers for Disease Control & Prevention  
1600 Clifton Road N.E., Mail Stop A-46  
Atlanta, GA 30329-4027

Dear Dr. Edwin:

Thank you for your letter dated 15 June 2018, containing your observations from the 21-22 May 2018 inspection of (b)(3):42 U.S.C. § 262a(h)(1)(E)

Building (b)(3):42 U.S.C. § 262a(h)(1)(E). The observations, requirements and responses are listed below:

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) and 7 CFR Part 331 and 9 CFR Part 121 (USDA). 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. AgSAS and DSAT comprise the Federal Select Agent Program (FSAP). The above referenced regulations and supporting guidance information may be found at <http://www.selectagents.gov/>.

Representatives from FSAP conducted a site visit of USAMRIID and (b)(3):42 U.S.C. §

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

On May 30, 2018, USAMRIID suspended all work with select agents and toxins in (b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

This action was due to (b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § Departures noted from the May 21-22, 2018 USAMRIID site visit are described below.

**Severity Level: High**

**1 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:** USAMRIID failed to contain presumptively (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)

Specifically:

(b)(3):42 U.S.C. § 262a(h)(1)(E)

In summary,

(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)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Corrective Action:** Provide:

1.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Response:** Please see Amended Form 3 (Enclosure 1) which includes the updated list of biological select agents and toxins (BSAT) that was used in containment laboratories since 8 June 2015, the date pump 2 was actively leaking.

The biological select agents and toxins (BSAT) include:

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.
- 9.
- 10.
- 11.
- 12.
- 13.
- 14.
- 15.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Additionally, the non-BSAT agents include:

1. Western equine encephalitis virus
2. Dobrava-Belgrade virus
3. Seoul virus
4. Chikungunya virus

2. The action plan to address

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Response:**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Response:**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**2 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. [Section 12(a)]

**Requirement:** The biosafety plan must include the following provisions: Written procedures for each validated method used for disinfection, decontamination or destruction, as appropriate, of all contaminated or presumptively contaminated materials including, but not limited to: Cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents and toxins, personal protective equipment, animal caging systems and bedding (if applicable), animal carcasses or extracted tissues and fluids(if applicable), laboratory surfaces and equipment, and effluent material. [Section 12(a)(3)]

**Observation:** USAMRIID failed to implement (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. § as written in the biosafety plan. The (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) 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)

**Corrective Action: Provide:**

1. Revised section(s) of the biosafety plan or supporting SOP(s) that includes clear and consistent treatment procedures for

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Response:**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

SOP's will be provided when available.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

2.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Response: USAMRIID completed**

(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)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Please see Enclosure 5,

(b)(3):42 U.S.C. § 262a(h)(1)(E)

3. Documentation of training for laboratory staff on any revised procedures and biosafety considerations implemented for the discharge of effluent from laboratories conducting select agent work. The training documentation must include the name of the individuals, date of the training, content of the training, and a description of the means used to verify personnel understand the training.

**Response:**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

DRAFT SOP's are being developed and personnel was training conducted on the

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Training and sign-in rosters are included.

Please see Enclosure 6, BSL-3 Modified Procedures Sign-In Rosters  
Please see Enclosure 7, BSL-3 Modified Procedures Training

**3 Requirement:** An individual or entity required to register under this part must develop and implement a written incident response plan based upon a site specific risk assessment. The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review. [Section 14(a)]

**Observation:** USAMRIID's incident response plan did not consider procedures for

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Corrective Action:** Provide an updated incident response plan that contains response procedures for (b)(3):42 U.S.C. § 262a(h)(1)(E). The procedures must be based on a site specific risk assessment and coordinated with entity-wide plans.

**Response:**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Please see Enclosure 8,

(b)(3):42 U.S.C. § 262a(h)(1)(E)



Please contact me if you have any additional questions or concerns. I can be reached by phone at (b)(6) or by e-mail at: (b)(6) [iv@mail.mil](mailto:(b)(6)@mail.mil). Thank you for your continued guidance and support of USAMRIID.

Respectfully,

(b)(6)  
(b)(6) Biosecurity  
Responsible Official

8 Enclosures

1. APHIS-CDC Form 3 USAMRIID 20180628 - amended
2. SSP Priorities List, 19 June 2018
3. (b)(3):42 U.S.C. § 262a(h)(1)(E)
4. (b)(3):42 U.S.C. § 262a(h)(1)(E)
5. (b)(3):42 U.S.C. § 262a(h)(1)(E)
6. BSL-3 Modified Procedures Sign-In Rosters
7. BSL-3 Modified Procedures Training
8. (b)(3):42 U.S.C. § 262a(h)(1)(E)



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



August 1, 2018

(b)(6) (Responsible Official)  
 U.S. Army Medical Research in Infectious Diseases  
 1425 Porter Street  
 Fort Detrick, MD 21702

(b)(6)

cc: (b)(6)

(b)(6)

**Subject: Facility Inspection Report Response: U.S. Army Medical Research in Infectious Disease (USAMRIID)**

Thank you for your response to the observations listed in the report from the June 15, 2018 inspection of your facility. We have received your responses dated June 28, 2018 and additional information is required. **Submit further documentation by August 17, 2018** for the following requirement(s).

**Appendix 1: List of Entity Departures**

**Requirement 1: Section 12(b)**

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

(b)(3):42 U.S.C. § 262a(h)(1)(E)

In regards to these ongoing efforts, provide:

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

**Requirement 2: Section 12(a), 12(a)(3)**

**Additional Information Required:** USAMRIID's responses indicate that (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)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Requirement 3: Section 14(a)**

**Additional information required:**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**DSAT's response to USAMRIID's phased plan to reinstate select agent work in BSL-3 and ABSL-3 registered laboratories provided June 27, 2018:**

(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)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Contact (b)(6) at (b)(6) or (b)(6) if you have any questions regarding this correspondence.

Sincerely,

(b)(6)

(b)(6)

Division of Select Agents and Toxins  
Office of Public Health Preparedness and Response  
Centers for Disease Control and Prevention

Phone: (b)(6)

Fax: (b)(6)

Email (b)(6)



DEPARTMENT OF THE ARMY  
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES  
1425 PORTER STREET  
FORT DETRICK, MARYLAND 21702-5011

August 31, 2018

Dr. Samuel Edwin  
Director, Division of Select Agents and Toxins  
Department of Health and Human Services  
Centers for Disease Control & Prevention  
1600 Clifton Road N.E., Mail Stop A-46  
Atlanta, GA 30329-4027

Dear Dr. Edwin:

The United States Army Medical Research Institute of Infectious Diseases (USAMRIID) provides the following response to the request for information dated August 1, 2018, regarding the Facility Inspection Report Response.

Appendix 1: List of Entity Departures Requirement 1: Section 12(b)

In regards to these ongoing efforts, provide:

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

**Response:** [Redacted] (b)(3):42 U.S.C. § 262a(h)(1)(E)  
[Redacted] (b)(3):42 U.S.C. § 262a(h)(1)(E)

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

**Response:** [Redacted] (b)(3):42 U.S.C. § 262a(h)(1)(E)  
[Redacted] (b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Requirement 2: Section 12(a), 12(a)(3)

3. Additional Information Required:

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Response:**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Response:**

(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)

**Requirement 3: Section 14(a)**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Response: Please see Enclosure 4**

(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)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Response:**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Response**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

9.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

**Response:**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Please contact me if you have any additional questions or concerns. I can be reached by phone at (b)(6) or by e-mail at (b)(6) [civ@mail.mil](mailto:civ@mail.mil). Thank you for your continued guidance and support of USAMRIID.



Respectfully,

(b)(6)

(b)(6)

Biosecurity

Responsible Official

5 Enclosures

1. Appendix 4 Potential Biological Releases and Decontamination Testing/Monitoring
2. USAMRIID Hydrostatic Test Report 7-26-2018
3. Illustration of Piping Trench Building 375
4. USAMRIID Emergency Management Plan, 28 Aug 2018
5. USAMRIID Biosafety Plan Change Request 3 (USAMRIID 385-69)



DEPARTMENT OF THE ARMY  
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES  
1425 PORTER STREET  
FORT DETRICK, MARYLAND 21702-5011

January 24, 2019

Dr. Samuel Edwin  
Director, Division of Select Agents and Toxins  
Department of Health and Human Services  
Centers for Disease Control & Prevention  
1600 Clifton Road N.E., Mail Stop A-46  
Atlanta, GA 30329-4027

Dear Dr. Edwin:

The United States Army Medical Research Institute of Infectious Diseases (USAMRIID) Responsible Official provides the following signed attestation letter in response to the Facility Inspection Report Response dated November 9, 2018:

a. (b)(3):42 U.S.C. § 262a(h)(1)(E)

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

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(Enclosures 2-5).

c. (b)(3):42 U.S.C. § 262a(h)(1)(E) (Enclosure 5).

d. The biosafety, security, and incident response plans address

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

such that these plan procedures are sufficient to prevent the theft, loss, release, or unauthorized access to a select agent or toxin (See Enclosures 3, 7-8).

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Please contact me if you have any additional questions or concerns. I can be reached by phone at (b)(6) or by e-mail at (b)(6).civ@mail.mil.

Thank you for your continued guidance and support of USAMRIID.

Respectfully,

(b)(6)

(b)(6)

Biosecurity

Responsible Official

8 Enclosures

1. Functional Performance Testing

FOR OFFICIAL USE ONLY

2. (b)(3):42 U.S.C. § 262a(h)(1)(E)
3. USAMRIID Biosafety Plan, 7 Dec 2018
4. USAMRIID SOP, SA-03-06, 1 Nov 2018
5. Risk Assessment to USAMRIID SOP, SA-03-06, 11 Sep 2018
6. (b)(3):42 U.S.C. § 262a(h)(1)(E) 30 Oct 2018
7. Physical Security Plan, 10 Oct 2018
8. Emergency Management Plan, 18 Oct 2018

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



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



(b)(6) Responsible Official  
U.S. Army Medical Research Institute of Infectious Diseases  
1425 Porter Street  
Fort Detrick, MD 21702  
(b)(6) civ@mail.mil  
(b)(6) mil@mail.mil (b)(6) civ@mail.mil; (b)(6) civ@mail.mil;  
(b)(6) civ@mail.mil (b)(6) civ@mail.mil; (b)(6) ctr@mail.mil;  
(b)(6) civ@mail.mil

RE: **Facility Inspection Report Response:** U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

Thank you for USAMRIID's responses concerning the Federal Select Agent Program (FSAP) reports of the inspections of your entity conducted May 21-22, 2018, and October 23-25, 2018. FSAP does not require any further response from you at this time.

Based on the corrective actions outlined in USAMRIID's responses, the June 28, 2018 suspension of USAMRIID's registration (b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

If you have any questions concerning this correspondence you may contact your designated FSAP representative. If you are unsure of who your designated representative is, please contact CDC at 404-718-2000 or APHIS at 301-851-3300.

Sincerely,

(b)(6)

Samuel S. Edwin, PhD  
Director, DSAT  
CDC, HHS

(b)(6)

Adis Dijab, DVM  
National Director, AgSAS  
APHIS, USDA