

APHIS/CDC Form 1 (Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins)

For the previous system NSAR, the system captured Section 1A, Section 4, and Section 6A as shown below. The rest of the information was saved into the system as pdf for the submitted APHIS/CDC Form 1.

For Section 1,

The screenshot shows the 'Create Entity' form in the NSAR system. The form is divided into two main sections: 'Entity Information' and 'Address Information'. The 'Entity Information' section includes fields for Name, Application Number, Lead Agency (a dropdown menu), File Owner (a dropdown menu), Entity Status (a dropdown menu), and SRA Status. The 'Address Information' section includes a checkbox for 'Mailing Address is same as Physical Address', and two sets of address fields (Physical and Mailing) for Address Line 1, Address Line 2, City, State (a dropdown menu), ZIP Code, and Country (a dropdown menu). A note at the bottom of the address section states: 'Note: State and ZIP Code are only required if the Country selected is United States.' The user's name 'zoz1' and session expiration time '5:35:25 PM' are visible at the top of the page.

For Section 4,

The screenshot shows the 'Entity Staff' search results page in the NSAR system. The page displays a table of staff members with the following columns: Personnel Group ID, Name, Role, DOJ Number, Date of Birth, SRA Status, Active, Tracking Number, and Latest Approved. The table contains 7 rows of data. The SRA Status dropdown menu is open, showing options: Unrestricted, Denied, Pending Approval, and Restricted. The Active dropdown menu is also open, showing options: Yes, No, and N/A. The search criteria include Date of Birth (12/17/1969) and SRA Status (Unrestricted).

Personnel Group ID	Name	Role	DOJ Number	Date of Birth	SRA Status	Active	Tracking Number	Latest Approved
17686	Doe, John	Laboratorian	C-JD-047011		Pending	Yes	070415	Yes
53659	Doe, John	Laboratorian	C-JD-047011		Pending	Yes	182523	Yes
17686	Douby, Quincy	Laboratorian		12/17/1969	Pending	Yes	182523	Yes
37683	Gilliam, Mike	PL ARO	C-MS-040485	12/14/1977	Unrestricted	Yes		Yes
17684	McCarthy, Jim	PL RO	C-JM-040484	12/06/1977	Unrestricted	Yes	179602	Yes
17682	O'Hara, Randall (inactive)	PI (inactive)		12/13/2005	Pending	No		Yes
46902	Orrb, Andrew	PI	C-AG-040483	02/08/1966	Unrestricted	Yes	182523	Yes

For Section 6A,

NSAR - Entity Agents

Summary Registrations Amends Chain Inspections Transfers Clinical Diagnostics Information Staff Agents Lab Info

Search Criteria

Filter Option: Latest Approved Only

Agent: African horse sickness virus, African swine fever virus, Camel pox virus, Classical swine fever virus, Francisella tularensis

Labs: Building: Facility Annex 3, Room: 223; Building: test, Room: test room; Building: other building, Room: other room; Building: OMB Lab 1, Room: 111; Building: OMB 1, Room: 217

Active: Yes, No, N/A

P.I.: Gillilan, Mike; McCarthy, Jim; OHara, Randall (inactive); Omb, Andrew; Omb, Bill

Tracking Number: []

Agent Group ID: []

Viable: Yes, No, N/A

Genomic: Yes, No, N/A

Recombinant DNA: Yes, No, N/A

Small Animal: []

Sort Criteria

First: Agent, Ascending, Descending

Second: - Select a Second -, Ascending, Descending

Third: - Select a Third -, Ascending, Descending

Fourth: - Select a Fourth -, Ascending, Descending

Fifth: - Select a Fifth -, Ascending, Descending

Sixth: - Select a Sixth -, Ascending, Descending

Seventh: - Select a Seventh -, Ascending, Descending

Eighth: - Select an Eighth -, Ascending, Descending

Ninth: - Select a Ninth -, Ascending, Descending

For eFSAP, the new system will capture all information from the APHIS/CDC Form 1 as noted below in the screenshots.

Section 1 - Form 1 Data Completion

Entity Information

Entry Application Number: cb41d946-e45f-e711-80d1-001d98003fe2

Current Registration Number: []

Entity Name: Lori Bane's Entity

Physical Address: [] City: [] State: -- Select an option -- Zip Code: []

Additional Physical Address(es): []

Type of Entity: []

Entry Abstract: Provide a summary of the overall institution mission, functions, and size. This information can include a general estimated number of employees, square footage of entire campus or facility, number of laboratories, overall scope of research, and any international collaborations. Specialized areas of research, education, or expertise can be highlighted. Include a brief description of the management structure of the institution related to oversight of the select agent facility/facilities. Provide a brief summary of the select agent and toxin work at the entity including mission, function, and size. Note: Information specific to select agents and toxins will be required in later sections of this application.

https://webapp.ipsasest.com/web/Form1/Default/Section4?entityId=... Section 4 | CDC IPSAS eCFR - Code of Federal Regul...

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Save All

New Person

Last Name: Last Name (include suffix e.g. Jr. III) **First Name:** First Name

DOJ Number: **Date of Birth:** mm/dd/yyyy

Business E-mail Address: e.g. user@website.com **Title:** Tier 1 Access Inventory

Business Telephone #: **Business Fax #:** **Emergency Telephone #:**

Mailing Address (NOT a post office box): **City:** **State:** -- Select an option -- **Zip:**

Assign Roles

Primary Roles

RO ARO Owner/Controller PI

Laboratorian Animal Care Staff Unescorted visitors

Support Roles

Signature Required

I certify that information and training on safety, security, and incident response for working with select agents and toxins has been or will be provided to the individuals listed above before they have access to select agents and toxins. Training will address the needs of the individual, the work being performed, and risks posed by the select agents and/or toxins. Annual refresher training will be provided for these individuals. Written records and the means used to verify that the individuals understood the training will be maintained for at least three years.

RO Signature: **Date:**

Lori Bane

Division of Select Agents and Toxins

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I certify that the following requirements are in effect and contain all information required by the Select Agent regulations [7 CFR 331, 9 CFR 121, and 42 CFR 73]:

Security, Biosafety and Incident Response

There is a written, site-specific security plan designed according to a site-specific risk assessment that provides graded protection in accordance with the risk of the select agent and/or toxin.

There is a written, agent-specific, and site-specific biosafety plan commensurate with the risk of the select agent and/or toxin that contains sufficient information and documentation to describe the biosafety and containment procedures.

There is a written, site-specific incident response plan commensurate with the hazards of the select agent and/or toxin that fully describe the entity's response procedures to include the theft, loss or release of a select agent and/or toxin, inventory discrepancies, security breaches, natural disasters and emergencies.

The security, biosafety and incident response plans are reviewed annually and revised as necessary, including after any drill or exercise and after any incident.

Laboratory specific drills or exercises are conducted at least annually to validate or test the effectiveness of the security, biosafety and incident response plans.

Training

Individuals with access approval, authorized visitors, and escorted personnel are provided training on safety, security, and incident response for select agents and/or toxins, as appropriate for their role, as defined in 7 CFR 331.15, 9 CFR 121.15, and 42 CFR 73.15.

Records

Complete records are maintained for at least 3 years that include but are not limited to: an accurate, current inventory for each select agent and/or toxin possessed, information about all entries into areas containing select agent and/or toxin, and a current list of all individuals that have been granted access approval.

Responsible Official Duties & APHIS/CDC Program Notification

The Responsible Official will:

Ensure annual inspections are conducted for each laboratory and storage area where select agent and/or toxin are stored or used to assess compliance with the requirements of the select agent regulations.

Submit an amendment for any change in circumstances to the certificate of registration, including but not limited to: adding or removing individuals, addition of a suite/room prior to use or storage of select agent and/or toxin and any changes to Responsible or Alternate Responsible Official contact

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Section 3 - Select Agents and Toxins

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Type of Agents
 Current Historical

Agent Toxin Name	Agency	Tier 1	Possessed
Add New Agent/Toxin			
Select an Agent/Toxin:			

+ Add

Centers for Disease Control and Prevention

Help and Support Help and Support Other Links

Division of Select Agents and Toxins
 1600 Clifton Road, NE, Mailstop A-46
 Atlanta, GA 30329
 Telephone: 404-718-2000
 404-488-7100 (after hours)
 Fax: 404-718-2096
 Email: LRSAT@cdc.gov

Animal and Plant Health Inspection Service
 Agriculture Select Agent Services
 4700 River Road, Unit 2, Mailstop 1A07
 Riverdale, MD 20737
 Telephone: 301-851-3300 opt. 3 (voice only)
 Fax: 301-734-3652
 Email: AgSAS@aphis.usda.gov

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Section 4 - New Person

Last Name: First Name: DOJ Number: Date of Birth: Business E-mail Address: Title: Mailing Address (NOT a post office box): City: State: Zip: Assign Roles Primary Roles Support Roles

RO ARO Owner/Controller PI Laboratorian Animal Care Staff Unescorted visitors

Signature Required

I certify that information and training on safety, security, and incident response for working with select agents and toxins has been or will be provided to the individuals listed above before they have access to select agents and toxins. Training will address the needs of the individual, the work being performed, and risks posed by the select agents and/or toxins. Annual refresher training will be provided for these individuals. Written records and the means used to verify that the individuals understood the training will be maintained for at least three years.

RO Signature: Date: Lori Bane

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The fields are grayed out for

- SECTION 1
- SECTION 2
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- SECTION 4
- SECTION 5A
- SECTION 5B
- SECTION 5C
- SECTION 6
- SECTION 7A & 7C
- SECTION 7B

Section 5A - Entity-Wide Security Assessment and Incident Response

SAVE

1. This facility is: (check all that apply)

Must answer one of the below

- Government owned
- Entity owned
- Rented/leased
- Shared with another entity or program
- Other

2. Does the entity have a security officer or other individual(s) identified to assist the RO in security matters?

- Yes No

3. A threat assessment has been conducted:

- Yes No
- a. Were local law enforcement or federal agencies consulted in developing the threat assessment?
 - Yes No
- b. Has there been a break-in at the entity in the last three years?
 - Yes No
- c. Have there been any direct threats against the entity or its scientists in the last three years?
 - Yes No
- d. Have there been protests at the entity in the last three years?
 - Yes No

4. Insider risk assessment

Must answer one of the below

a. As a condition of granting unescorted access, the entity, or another organization on behalf of the entity, verifies (check all that apply):

- Educational background
- Previous work references
- Criminal history (beyond the security risk assessment approved by the Federal Select Agent Program)
- Other
- None

b. Does the entity have policies and procedures for self and peer reporting?

- Yes No

c. Does the entity have additional requirements for personnel suitability to retain access to select agents or toxins?

- Yes No

5. Natural hazards



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Section 5B - Entity-Wide Biosafety/Biocontainment

SAVE

1. Describe the program or expertise used to develop and implement the biosafety and biocontainment procedures described in the site-specific biosafety or biocontainment plan.

2. Laboratory personnel must demonstrate proficiency in laboratory procedures prior to working with select agents and/or toxins.

- Yes No

3. Appropriate Personal Protective Equipment (PPE) for the select agent and/or toxin and the work performed is required.

- Yes No

4. Individuals with access to Tier 1 select agent and/or toxin are enrolled in an occupational health program.

- Yes No

5. Laboratory personnel with access to non Tier 1 select agent and/or toxin are enrolled in an occupational health program as appropriate.

- Yes No

6. There are policies for the safe handling of sharps.

- Yes No

7. There is a spill protocol in place appropriate to the select agent and/or toxin risk.

- Yes No

8. There is an effective, integrated pest management program in place.

- Yes No

Centers for Disease Control and Prevention

Help and Support

Help and Support

Other Links

Division of Select Agents and Toxins
1600 Clifton Road, NE, Mailstop A-46
Atlanta, GA 30329

Animal and Plant Health Inspection Service
Agriculture Select Agent Services
4700 River Road, Unit 2, Mailstop 22, Cubicle 1A07

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Section 5C - Entry Requirements for Federal Select Agent Program Inspectors

SECTION 1 **SECTION 2** **SECTION 3** **SECTION 4** **SECTION 5A** **SECTION 5B** **SECTION 5C** **SECTION 6** **SECTION 7A & 7C** **SECTION 7B**

1. Describe procedures for entry to the facility, such as gate location, visitor reception area, and parking for inspectors performing a site visit.

2. Identification requirements:
Must answer one of the below
 Government ID
 Other ID

3. Are there security clearance requirements?
 Yes No

4. Is respiratory protection required?
 Yes No

5. List other PPE required (indicate what will be provided by the entity).

6. Medical documentation required:
 Yes No

7. Is entity specific training required?
 Yes No

8. Describe any additional entry requirements for inspectors.

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Section 6 | CDC IPSAS

1. What security features are present outside of the building(s) where select agents and/or toxins are used or stored? (Check all that apply):
Must answer one of the below
 Security lighting
 Bars/security film on windows
 Exterior intrusion detection system
 Perimeter fence
 Roving guards
 Video surveillance of all access points
 Vehicle screening
 Other
 None

2. How is access to building(s) or other area(s) housing registered room(s)/suite(s) controlled? (Check all that apply):
Must answer one of the below
 Lock and key
 Card access system
 Biometric system
 Card access system w/ PIN
 Other
 Guards
 None

3. What additional security features are present in the interior of the building(s) where select agents and/or toxins are used or stored? (Check all that apply):
Must answer one of the below
 Additional locked doors
 Card access system
 Card access system with PIN
 Biometric System
 Intrusion detection system
 Video surveillance
 Other

Division of Select...
1600 Clifton Road,
Atlanta, GA 30339
Telephone: 404-718-7111
404-488-7100 (after hours)
Fax: 404-718-2096
Email: LRSAT@cdc.gov

Biosafety Levels

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SECTION 1 **Section 7A & 7C - Principal Investigator (PI) Information and Select Agent and Toxin Locations**

SECTION 2

SECTION 3 **Assign Agents / Toxins to Location & PI** Collapse

SECTION 4

SECTION 5A

SECTION 5B

SECTION 5C

SECTION 6

SECTION 7A & 7C

SECTION 7B

Use CTRL+Left Mouse Click to select multiple agents/toxins.

Assigned PI	Select Agent / Toxin / Regulated Nucleic Acid	Building	Room / Suite
Non Tier 1 Lori Bane		123	

No rooms assigned

Work Details

NOTIFICATION

There are no Saved Agents / Toxins or work items for the Entity. You can create one by clicking the "Open" button at the top right of the page.



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SECTION 1 **Section 7B - Strain or Serotype Designation Information** SAVE

SECTION 2 **Add Agent / Strain or Serotype** Open

SECTION 3 Search Agents

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SECTION 5B

SECTION 5C

SECTION 6

SECTION 7A & 7C

SECTION 7B

Saved Agents / Strain or Serotypes

Agent/Toxin	Strain or Serotype	Assigned PI	Entity Wide

Centers for Disease Control and Prevention

Help and Support

Division of Select Agents and Toxins
1600 Clifton Road, NE, Mailstop A-46
Atlanta, GA 30333
Telephone: 404-718-2000
404-488-7100 (after hours)
Fax: 404-718-2096
Email: LRSAT@cdc.gov

Animal and Plant Health Inspection Service
Agriculture Select Agent Services
4700 River Road, Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
Telephone: 301-851-3300 opt. 3 (voice only)
Fax: 301-734-3652
Email: AgSAS@aphis.usda.gov

Other Links

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Division of Field Epidemiology

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Notifications -

Locations

Collapse

Add work

2. Provide an estimate of the maximum quantities (e.g., number of Petri dishes or total volume of liquid media) and concentration of each organism grown at a given time (e.g., 2 - 250 ml flasks of 105 cfu/ml). If select agent will not be propagated, indicate "no propagation of agent".

Agent	Maximum Quantity / Concentration
Bacillus anthracis	<input type="text"/>

3. Provide an estimate of the maximum quantity of functional toxin held by the PI at any one time (e.g., 500 mg, 100 ml x 100 ug/ml).

Toxin	Maximum Quantity / Concentration
	<input type="text"/>

4. Equipment that may produce infectious agent or toxin aerosols (e.g., ultracentrifuge, flow cytometer, cell sorter, plate washer) is contained in primary barrier devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory.

Yes No

5. Inventory record is reconciled:

Annually
 Other (specify frequency)

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APHIS/CDC Form 2: Request to Transfer Select Agents and Toxins

The same information that is collected in NSAR is same information being collected in eFSAP. There were no changes in the IT structure.

APHIS/CDC Form 3, Report of Theft, Loss, or Release of Select Agents and Toxins

Data for the APHIS/CDC Form 3 were not collected in NSAR. The pdf of the form was scanned into the system. The below screen prints show what will be collected in eFSAP.

The screenshot shows a web browser window with the URL <https://webapp.ipsastest.com/web/Form3/Default/Index?enti>. The browser tabs include "Federal Select Agent Program ..." and "Form 3 | CDC IPSAS". The page title is "Section A - ENTITY INFORMATION".

1. Name of Entity: ACG (252 of 255 characters left)

2. Entity Registration/NRE Number: (empty)

3. Physical Address: 1234 Maple (245 of 255 characters left)

4. City: Onekama (43 of 50 characters left)

5. State: Michigan

6. Zip Code: 48236-____

7. Name of Responsible Official or Laboratory Supervisor: Rick Smith (245 of 255 characters left)

8. Name of Principal Investigator: (empty)

9. Telephone Number: (734)123-4564ext.____

10. Fax Number: (123)456-4656ext.____

11. E-mail address: nick@acg.com (38 of 50 characters left)

Section B - INCIDENT INFORMATION

The screenshot shows the same web browser window as above, but the page title is "Section B - INCIDENT INFORMATION".

1. Date and Time of Incident:

Date: mm/dd/yyyy

Time: Hour: [dropdown], Minute: [dropdown], am/pm: [dropdown]

2. Date of Immediate Notification: mm/dd/yyyy

3. Type of Immediate Notification:

- Email
- Fax
- Telephone
- eFSAP

4. Location of Incident: (empty)

5. Name of Select Agent or Toxin: [dropdown]

6. Strain Designation: (empty)

7. Quantity: (empty)

+ Add Row

Name of Select Agent or Toxin **Strain Designation** **Quantity**

Name of Select Agent or Toxin Strain Designation Quantity

8. Type of Incident:

Must answer at least one of the below

- Theft
- Loss
- Release/ Potential Exposure

Note:

Please complete Appendix A, event timeline, to provide details on the theft/loss/release incident.

9. Severity of the incident:

--Select an option--

10. What Biosafety Level did the incident occur?

Must answer at least one of the below

- | | | |
|---------------------------------|------------------------------------|------------------------------------|
| <input type="checkbox"/> BSL2 | <input type="checkbox"/> NIHBL2 | <input type="checkbox"/> NIHBL3-LS |
| <input type="checkbox"/> BSL3 | <input type="checkbox"/> NIHBL3 | <input type="checkbox"/> NIHBL4-LS |
| <input type="checkbox"/> BSL4 | <input type="checkbox"/> NIHBL4 | <input type="checkbox"/> ACL2 |
| <input type="checkbox"/> ABSL2 | <input type="checkbox"/> NIHBL2N | <input type="checkbox"/> ACL3 |
| <input type="checkbox"/> ABSL3 | <input type="checkbox"/> NIHBL3N | <input type="checkbox"/> ACL4 |
| <input type="checkbox"/> BSL3Ag | <input type="checkbox"/> NIHBL4N | <input type="checkbox"/> PPQ Agent |
| <input type="checkbox"/> ABSL4 | <input type="checkbox"/> NIHBL2-LS | |

11. Is this incident associated with an APHIS/CDC Form 2:

12. Is this incident associated with an APHIS/CDC Form 4:

- | | | |
|---------------------------------|------------------------------------|------------------------------------|
| <input type="checkbox"/> ABSL2 | <input type="checkbox"/> NIHBL2N | <input type="checkbox"/> ACL3 |
| <input type="checkbox"/> ABSL3 | <input type="checkbox"/> NIHBL3N | <input type="checkbox"/> ACL4 |
| <input type="checkbox"/> BSL3Ag | <input type="checkbox"/> NIHBL4N | <input type="checkbox"/> PPQ Agent |
| <input type="checkbox"/> ABSL4 | <input type="checkbox"/> NIHBL2-LS | |

Transfer

11. Is this incident associated with an APHIS/CDC Form 2:

- Yes
- No

12. Is this incident associated with an APHIS/CDC Form 4:

- Yes
- No

Appendix A - EVENTS TIMELINE

Provide a detailed summary of events, including a timeline of what occurred.

Save Draft Immediate Notification Initiate Submit

Section C - REPORT OF THEFT

1. Type of Theft:
 Forced Entry
 Insider/Insider-assisted access
 Unauthorized access

2. Has Local Law Enforcement been Notified:
 Yes
 No

3. Local Law Enforcement Agency:

4. Local Law Enforcement Agent Name:

5. Local Law Enforcement Contact Information (phone/email):

6. Has the FBI been Notified:
 Yes
 No

6. Has the FBI been Notified:
 Yes
 No

7. FBI Agent Name:

8. FBI Agent Contact information (phone/email):

9. Was the stolen BSAT material recovered:
 Yes
 No

10. Was there a potential exposure:
 Yes
 No
 Unsure

Appendix A - EVENTS TIMELINE

Section D - REPORT OF LOSS

1. Type of Loss:

- Inventory/Recordkeeping error
- Sample lost/discarded at entity
- Sample lost in transit
- Other

2. Has Local Law Enforcement been Notified:

- Yes
- No

3. Local Law Enforcement Agency:

After yu, Inc.
241 of 255 characters left

4. Local Law Enforcement Agent Name:

Eyeon Yu
247 of 255 characters left

5. Local Law Enforcement Contact Information (phone/email):

123-234-3456
243 of 255 characters left

6. Was the FBI Notified:

After yu, Inc.
241 of 255 characters left

6. Was the FBI Notified:

- Yes
- No

7. FBI Agent Name:

Al Cuffedup
244 of 255 characters left

8. FBI Agent Contact Information (phone/email):

234-898-1871
243 of 255 characters left

9. Was the lost BSAT material found?

- Yes
- No

10. How long was the BSAT material missing?

Date Recovered: Duration of loss(hrs/days)

11. Give the date of the last inventory/audit performed, which meets the FSAP regulatory requirement:

12. Was there a potential exposure:

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7. FBI Agent Name:

 244 of 255 characters left

8. FBI Agent Contact Information (phone/email):

 243 of 255 characters left

9. Was the lost BSAT material found?
 Yes
 No

10. How long was the BSAT material missing?
Date Recovered:
Duration of loss(hrs/days)

11. Give the date of the last inventory/audit performed, which meets the FSAP regulatory requirement:

12. Was there a potential exposure:
 Yes
 No
 Unsure

Appendix A - EVENTS TIMELINE



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Section E - REPORT OF RELEASE

1. Type of Potential Exposure/Release(choose all that apply):

<input type="checkbox"/> Animal bite/scratch	<input type="checkbox"/> Equipment/mechanical failure
<input type="checkbox"/> PPE failure	<input type="checkbox"/> Package damaged in transit (fill out Appendix B)
<input type="checkbox"/> Spill	<input type="checkbox"/> Unintended Animal Infection
<input type="checkbox"/> Needle stick/Sharps	<input type="checkbox"/> Unintended Plant Pathogen Release
<input type="checkbox"/> Decontamination failure	<input checked="" type="checkbox"/> Work performed on an open bench
<input type="checkbox"/> Inactivation failure	<input type="checkbox"/> Other

2. Was there a release outside containment barriers? (choose all that apply)

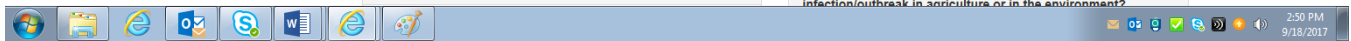
Release outside primary containment (e.g., biosafety cabinet, leaking storage vial within storage unit)

Release beyond secondary containment (e.g., laboratory)

Release outside all containment barriers of the facility (e.g., resulting in possible agricultural/environmental/public health threat)

3. What PPE was worn at the time of the incident? (choose all that apply)

<input checked="" type="checkbox"/> Hand Protection (e.g., gloves)	<input type="checkbox"/> Foot Protection (e.g., booties, shoe covers)
<input type="checkbox"/> Head Protectors/Covers	<input type="checkbox"/> Eye/Face Protection (e.g., goggles, face shield)
<input type="checkbox"/> Body Protection	<input checked="" type="checkbox"/> Respiratory Protection:
	Type: <input type="text" value="N-95"/>
	<input type="checkbox"/> Other



4. Did the release result in potential exposure(s)?

5. Did the release result in a laboratory acquired infection or an infection/outbreak in agriculture or in the environment?

4. Did the release result in potential exposure(s)?

Yes

If yes, how many individuals/animals/plants were exposed?

1

No

5. Did the release result in a laboratory acquired infection or an infection/outbreak in agriculture or in the environment?

Yes

No

Not currently known

6. Has medical surveillance been initiated?

Yes

No

7. Has prophylaxis or treatment been provided?

Yes

No

8. Has an internal investigation been initiated to lessen the likelihood of recurrences of incident involving the select agents and toxins at this entity?

Yes (if yes, please provide additional details.)

No

Details:

Additional training was conducted with the staff.

9. Other than a potential for occupational illness, what other hazards have been identified as a result of this incident?

Broken glass on floor

3979 of 4000 characters left

10. Provide a brief summary of how the laboratory and work surfaces were decontaminated after the incident.

10 percent bleach

3983 of 4000 characters left

11. Provide a brief summary of the medical surveillance conducted (do not provide names or confidential information).

Went to occupational health and was prescribed antibiotics

1942 of 2000 characters left

Appendix A - EVENTS TIMELINE

APHIS/CDC Form 4: Report of the Identification of a Select Agent or Toxin

Outside the entity information and select agent identified, data for the APHIS/CDC Form 4 were not collected in NSAR. The pdf of the form was scanned into the system. The below screen prints show what will be collected in eFSAP.

SECTION A – REFERENCE LABORATORY INFORMATION

1. Name of individual completing Sections C and D

2. E-mail address:

3. Telephone #:

4. APHIS or CDC Registration #: Registered Entity

5. Responsible Official or Laboratory Supervisor name (if same as field 1 then skip to field 9):

6. E-mail address:

7. Telephone #:

8. Fax #:

9. Entity name:

10. Address (NOT a post office address):

11. City:

12. State: -- Select an option--

13. Zip Code:

For the below screen print, this is found in Section B of the form.

SECTION B – SELECT AGENT OR TOXIN IDENTIFIED FROM CLINICAL/DIAGNOSTIC SPECIMEN(S)

1. Select Agent or Toxin Identified:

2. Date identified:

3. Case/patient/sample ID #(s):

4. # of samples received:

5. Sample type received:

6. Case/patient origin (zip code):

7. Type of test performed (e.g., PCR, mouse bioassay, ELISA):

8. Dispositions of select agent or toxin by entity listed in Block A9 (complete all that apply):

Transferred

Destroyed

Retained

9. Were any of the samples containing a select agent or toxin handled outside of primary containment which may have led to an unintentional release and/or exposure to the select agent or toxin?

No Yes

10. Do you anticipate receiving additional samples/specimens for this case/patient that originate from the initial case (e.g., patient, environmental sample)?

No Yes

11. Has the sender(s) (i.e., sample provider(s)) of the specimen(s) been notified of the identification of the select agent or toxin? No Yes N/A

11. Has the sender(s) (i.e., sample provider(s)) of the specimen(s) been notified of the identification of the select agent or toxin? No

Yes N/A

Note

Please request completed and signed Sections C & D from each facility that was in possession of the specimen(s).

12. Sample Provider Entity Name:

13. Sample Provider Point of Contact:

14. Sample Provider E-mail Address:

15. Sample Provider Contact Number:

16. Comments / Notes:

This is a required field

Signature

Certification: I hereby certify that the information contained in Sections C and D of this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 7 CFR 331, 9 CFR 121, or 42 CFR 73 may result in civil or criminal penalties, including imprisonment.

Public reporting burden: Public reporting burden of providing this information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D74, Atlanta, Georgia 30329; ATTN: PRA (0920-0576).

Signature of Respondent:

Date Signed:

For the below screen print, this is found in Section C of the form.

SECTION C – SAMPLE PROVIDER INFORMATION

1. Name of individual completing Sections C and D: 2. E-mail Address: 3. Telephone #:

4.

Registered Entity APHIS or CDC Registration #:

Clinical or Diagnostic Laboratory (NRE # (provided by APHIS or CDC):

5. Responsible Official or Laboratory Supervisor name (if same as field 1 then skip to field 9):

6. E-mail address: 7. Telephone #: 8. Fax #:

9. Entity Name:

10. Address (NOT a post office address):

11. City: 12. State: 13. Zip Code:

For the below screen prints, this is found in Section D of the form.

SECTION D – SPECIMENS CONTAINING SELECT AGENT OR TOXIN PROVIDED TO REFERENCE LABORATORY

1. Select Agent or Toxin Identified: <input type="text"/>	2. Date notified of select agent or toxin identification: <input type="text" value="mm/dd/yyyy"/>
3. Case/patient/sample ID #(s): <input type="text"/>	4. # of samples shipped: <input type="text"/>
5. Sample type provided: <input type="text"/>	6. Case/patient/sample origin (zip code): <input type="text"/>
7. Date sample(s) shipped to Reference Laboratory: <input type="text" value="mm/dd/yyyy"/>	8. Name of Reference Laboratory: <input type="text"/>

9. Disposition of any remaining select agent or toxin by entity listed in Block C9:

<input type="checkbox"/> Destroyed	Method: <input type="text"/>	Date: <input type="text" value="mm/dd/yyyy"/>
<input type="checkbox"/> Retained	Name: <input type="text"/>	
<input type="checkbox"/> Not applicable, the entire specimen was transferred to the Reference Laboratory.		

10. Were any of the samples containing a select agent or toxin handled outside of primary containment which may have led to an unintentional release and/or exposure to the select agent or toxin?
 No Yes

Information
If Yes, you are required under 7 CFR Part 331.19, 9 CFR Part 121.19, and 42 CFR Part 73.19 to complete and submit an APHIS/CDC Form 3

11. Was your entity the source of the sample(s)?
 No Yes

Information
If Yes, skip to field 18

12. Do you anticipate receiving additional samples/specimens for this case/patient that originate from the initial case (e.g., patient, environmental sample)?
 No Yes

Information
If Yes, please refer to the guidance instructions at www.selectagents.gov for further directions.

13. Has the sender(s) (i.e., sample provider(s)) of the specimen(s) been notified of the identification of the select agent or toxin? No Yes

Note
Please notify senders about Section C & D requirements that are a prerequisite of the exemption.

14. Sample Provider Entity Name:

15. Sample Provider Point of Contact: **16. Sample Provider E-mail Address:** **17. Sample Provider Contact Number:**

18. Comments / Notes:

Signature

Certification: I hereby certify that the information contained in Sections C and D of this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 7 CFR 331, 9 CFR 121, or 42 CFR 73 may result in civil or criminal penalties, including imprisonment.

Public reporting burden: Public reporting burden of providing this information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDCIATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D74, Atlanta, Georgia 30329; ATTN: PRA (0920-0576).

Signature of Respondent: **Date Signed:**

APHIS/CDC Form 5: Request for Exemption of Select Agents and Toxins for an Investigational Product

Similar to NSAR, the form will not be available in the new system. Applicants will still complete the pdf available on the Federal Select Agent Program website.