



APHIS/CDC
GUIDANCE DOCUMENT
for
REPORTING POTENTIAL
THEFT, LOSS, RELEASE, or OCCUPATIONAL EXPOSURE

DRAFT

Public reporting burden: Public reporting burden of this collection of information is estimated to average 30 minutes 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 D-74, Atlanta, Georgia 30329; ATTN: PRA (0920-0576).

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Document Change History

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2.0	Jun 2016	Major update to document to include additional guidance.	

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INTRODUCTION

An entity is required by regulation (7 CFR § 331.19, 9 CFR § 121.19, and 42 CFR § 73.19) to notify the Animal and Plant Health Inspection Service (APHIS) or the Centers for Disease Control and Prevention (CDC) immediately upon discovery of a theft (unauthorized removal of select agent or toxin), loss (failure to account for select agent or toxin), or release (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a select agent or toxin. In addition, clinical or diagnostic laboratories and other entities that possess a select agent or toxin contained in a specimen presented for diagnosis, verification, or proficiency testing must report the theft, loss, or release of a select agent or toxin. This document has been developed by the Federal Select Agent Program (FSAP) to provide you with guidance on notifying the FSAP of reportable incidents.

After the initial notification, this form (APHIS/CDC Form 3) must be sent to either APHIS or CDC within seven calendar days after the discovery of the theft, loss, or release of a select agent or toxin:

**Animal and Plant Health Inspection Service
Agriculture Select Agent Services**
4700 River Road, Unit 2,
Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652
E-mail: AgSAS@aphis.usda.gov

**Centers for Disease Control and Prevention
Division of Select Agents and Toxins**
1600 Clifton Road, NE
Mailstop A-46
Atlanta, GA 30329
FAX: 404-471-8375
Email: form3@cdc.gov

For a theft or loss of a select agent or toxin, the entity must also notify the appropriate local, state, or federal law enforcement agencies. While not specifically addressed by the select agent regulations, in cases of a release of a select agent or toxin, an entity should also notify the appropriate local, state, and federal health agencies.

PURPOSE

This form should be used by the Responsible Official (FSAP registered entities) or the Laboratory Supervisor (non-registered entities) to report the theft, loss, or release of a select agent or toxin. In addition, an incident which has the potential to be a theft, loss, or release may be reported using this form. A copy of the completed form and attachments must be maintained by a registered entity for three years.

INSTRUCTIONS

Any laboratory (registered or non-registered) that has questions regarding the APHIS/CDC Form 3 or submission of the APHIS/CDC Form 3 can send an e-mail with their questions to form3@cdc.gov. A member of the Form 3 Team from CDC or APHIS will contact you and provide assistance. A supplementary guidance document with scenario-based reporting examples of theft, loss or release can be found under the Form 3 Tab at <http://www.selectagents.gov>.

Reporting Incidents

Upon discovery of a theft, loss, or release of a select agent or toxin, entities must report all incidents as specified below.

- An entity must immediately notify their lead agency; i.e., APHIS or CDC, by telephone, fax, or e-mail. (The contact information is provided below.)
 - If the entity is not registered with either APHIS or CDC (such as an unregistered clinical or diagnostic facility), then it may notify either Agency.
 - If a responsible official (RO) has a reasonable belief that a theft, loss, or release has occurred, the RO is urged to notify either APHIS or CDC to make the FSAP aware of a potential incident. This will help the FSAP respond quickly if an incident is confirmed.

- o If a registered entity is unsure whether a report is required, it should contact their lead agency immediately.
- Entities must report thefts or losses even if the select agent or toxin is subsequently recovered and/or the responsible parties are identified.
- The initial report should include as much information as possible about the incident. If a release occurred, the entity must provide the number of individuals potentially exposed, actions taken to respond to the release such as medical intervention and biocontainment, and hazards posed by the release such as an estimate of the severity of the event and the expected impact to public health or agricultural.
- Information should be submitted as it becomes known, but no later than 24 hours.
- Within seven days, the entity must submit a complete APHIS/CDC Form 3 to the lead agency; or to either APHIS or CDC if the entity is not registered with either agency. All appropriate data fields should be completed. Supporting documentation, such as access logs, standard operating procedures, and the follow up investigation, should be provided regarding the reported incident. The form and supporting documentation may be submitted by either e-mail, fax or mail.

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APHIS/CDC Form 3 Definitions

Accession Number – A unique, identifying number in the National Select Agent Registry (NSAR) database that is assigned to each document to facilitate tracking, referencing and retrieval of documents.

Animal and Plant Health Inspection Service (APHIS) – A multi-faceted Agency with a broad mission area that includes protecting and promoting U.S. agricultural health, regulating genetically engineered organisms, administering the Animal Welfare Act and carrying out wildlife damage management activities. These efforts support the overall mission of USDA, which is to protect and promote food, agriculture, natural resources and related issues.

Biosafety Level (BSL) – A BSL is a level of containment (ascending 1 through 4) is primarily defined by risk criteria addressing infectivity, severity of disease, transmissibility, and the nature of the work being conducted. Another important risk factor for agents that cause moderate to severe disease is the origin of the agent, whether indigenous or exotic. Each level of containment describes the microbiological practices, safety equipment and facility safeguards for the corresponding level of risk associated with handling a particular agent.

Centers for Disease Control and Prevention (CDC) – One of the major operating components of the Department of Health and Human Services and its mission is to collaborate to create the expertise, information, and tools that people and communities need to protect their health – through health promotion, prevention of disease, injury and disability, and preparedness for new health threats.

Contaminated – The presence of blood, infectious materials, potentially infected materials, toxins, or prions on an item or surface.

Decontamination – A process that consists of cleaning combined with disinfection or sterilization.

Disposition – A form of removal of a select agent or toxin from an entity.

Entity – Any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

Exposure – Any event which results in any person in a registered entity facility or lab not being appropriately protected in the presence of an agent or toxin.

Facility – As used in this document, a “facility” is the physical structure where a select agent or toxin is used, manipulated, and/or stored. An entity can be composed of multiple facilities, and a facility may contain multiple suites/rooms where work is performed and/or select agents or toxins are stored.

Federal Select Agent Program (FSAP) – The FSAP is jointly comprised of the Centers for Disease Control and Prevention/Division of Select Agents and Toxins and the Animal and Plant Health Inspection Service/Agriculture Select Agent Services. The FSAP oversees the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal or plant health or to animal or plant products.

Federal Bureau of Investigation (FBI) – The federal department, which protects and defends the United States against terrorist and foreign intelligence threats, upholds and enforces the criminal laws of the United States, and provides leadership and criminal justice services to federal, state, municipal, and international agencies and partners.

Forced Entry – entry into a building or room illegally with intent to commit a crime by force, especially theft.

Incident – an event that results in or has the potential to result in infection, injury or exposure to a select agent or toxin for entity personnel or impact the health of the public.

Insider Threat – A malicious threat to an organization that comes from people within the organization, such as employees, former employees, contractors or business associates, who have inside information concerning the organization's security practices, data and computer systems. The threat may involve fraud, the theft of confidential or commercially valuable information, the theft of intellectual property, or the sabotage of computer systems.

Lab acquired infection (LAI) – an infection acquired through laboratory or laboratory–related activities regardless whether they are symptomatic or asymptomatic in nature.

Loss – A failure to account for select agent or toxin.

Medical Surveillance – the systematic assessment of employees exposed or potentially exposed to occupational hazards. This assessment monitors individuals for adverse health effects and determines the effectiveness of exposure prevention strategies.

Occupational exposure – A reasonably anticipated skin, eye, mucous membrane, or parenteral contact infectious or potentially infectious materials that may result from the performance of an employee's duties. For example, a sharps injury from a needle being used in select agent or toxin work would be considered an occupational exposure.

Personal Protective Equipment (PPE) – Safety equipment used for personal protection including such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or goggles, or other garment or equipment designed to protect the wearer's body from injury and/ or infection.

Primary containment barriers – Specialized items designed or engineered for the capture or containment of hazardous biological agents. Examples include biological safety cabinets, trunnion centrifuge cups, and aerosol-containing blenders. For the purposes of assessing a potential select agent release, the laboratory room may be considered a primary containment barrier in facilities meeting the requirements of biosafety level-4 (BSL-4) or BSL-3Ag as described in CDC/NIH Biosafety in Microbiological or Biomedical Laboratories, 5th edition.

Principal Investigator (PI) – The individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

Prophylaxis – measures taken to prevent disease, especially by specified means or against a specified disease.

Select Agent or Toxin (SAT) – A biological agent or toxin listed in 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331.

Registered entity – An entity that is registered with the Federal Select Agent Program (FSAP).

Release – A discharge of a select agent or toxin outside the primary containment barrier due to a failure in the containment system, an accidental spill, occupational exposure, or a theft. Any incident that results in the activation of a post exposure medical surveillance/prophylaxis protocol should be reported as a release.

Responsible Official (RO) – the individual designated by an entity with the authority and control to ensure compliance with the select agent regulations.

Risk assessment – A systematic process of evaluating the potential risks that may be involved in a projected activity or undertaking.

Theft – To take select agents or toxins without permission or right, especially secretly or by force.

Tier 1 Select Agents and Toxins – A subset of select agents and toxins designated in the select agent regulations as “Tier 1” because these agents and toxins present the greatest risk of deliberate misuse with the most significant potential for mass casualties or deleterious effects on the economy, critical infrastructure, or public confidence. This list can be found in the instructions for [Section 3](#) in this document and at SelectAgents.gov.

Severity –

None – No threat to entity personnel or the health of the public, or agriculture.

Negligible – Insignificant threat to entity personnel or the health of the public, or agriculture.

Low – Small threat to entity personnel or the health of the public, or agriculture.

Moderate – A threat to entity personnel or the health of the public, or agriculture.

High – Significant threat to entity personnel or the health of the public, or agriculture.

Section A – Entity Information

Block A1 – Name of Entity:

- For an entity registered with FSAP, please provide the name of your entity exactly as it appears on your entity’s current certificate of registration.
 - If you do not know your entity’s registration name, please contact your Responsible Official.
- For a non-registered entity, please provide the complete name of your entity under which the entity conducts its operations
- Do not abbreviate the entity name (e.g. International Business Machine Corporation instead of IBM).

Block A2 – Entity Registration Number:

- For an entity registered with FSAP, please enter the registration number exactly as it appears on your entity’s current certificate of registration. Please do not provide the entity’s application number; provide only the thirteen digit registration number (e.g. A00000000-0000 or C00000000-0000).
 - If you do not know your entity’s current registration number, please contact your Responsible Official.
- For an entity not registered with the FSAP, please leave this box blank.

Blocks A3-A6 – Entity’s Physical Address:

- For an entity registered with FSAP, please provide your entity’s complete address, exactly as it appears on your current certificate of registration.
- For a non-registered entity, please provide the complete physical address of your entity.
- P.O. Box address is not acceptable.
- Provide only the five digit zip code.

Block A7 – Responsible Official or Laboratory Supervisor Name:

- For an entity registered with FSAP, please provide the complete name of your entity’s Responsible Official (RO), exactly as it appears on the current certificate of registration.

- For a non-registered entity, please provide the full legal name of your entity's Facility or Laboratory Supervisor or the individual who supervises the laboratory that handled or manipulated the identified select agent or toxin (e.g., Microbiology Supervisor).
 - For the purposes of the APHIS/CDC Form 3, the term "full legal name" refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.
 - For the purposes of the APHIS/CDC Form 3, the term "Facility or Laboratory Supervisor" refers to the person ultimately responsible for the overall operation and administration of the laboratory and who ensures that quality standardized testing methods provide accurate and reliable results.

Block A8 – Name of Principal Investigator:

- For an entity registered with FSAP, please provide the complete name of Principal Investigator the SAT is registered under.
- For a non-registered entity, please provide the full legal name of the person responsible for the area that the incident occurred (e.g., Microbiology Section leader or Supervisor).

Block A9 – Telephone #:

- Provide the telephone number including the area code for the individual listed in *Block 15*; including any extension.

Block A10 – FAX #:

- Provide the 10-digit Fax number for the individual listed in *Block 15*.

Block A11 – E-mail Address:

- Provide the email address for the individual listed in *Block 15*.
- Print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included.

Section B – Incident Information

Block B1 – Date and Time of Incident

- Enter the date and approximate time that the incident occurred.
- Enter only one date and one approximate time in Block B1.

Block B2 – Date of Immediate Notification:

- Enter the date that FSAP was notified of the incident
- Enter only one date in Block 2

Block B3 – Type of Immediate Notification:

- Select the type of immediate notification given to FSAP.
- Select all that apply.

Block B4 – Location of Incident:

- Provide the building and room number where the incident occurred.
- Describe the location within the room the incident occurred (e.g., freezer, open bench, incubator, etc.).

Block B5 – Select Agent or Toxin Name:

- List all select agents and/or toxins involved in the incident.
- Do not abbreviate the name of a select agent or toxin.
- Use the name of the select agent or toxin exactly as it appears in the select agent regulations ([Select Agent/Toxin List](#)).
- Do not list an agent or toxin that is not a select agent or toxin.

Block B6 – Strain Designation of Select Agent or Toxin:

- List the strain designation(s) for all select agents and/or toxins only if known, otherwise leave blank.

Note: For the purposes of the APHIS/CDC Form 3, the term “strain” refers to a group of organisms of the same species, sharing certain hereditary characteristics not typical of the entire species but minor enough not to warrant classification as a separate breed or variety. Resistance to specific antibiotics is a feature of certain strains of bacteria. For select agents that have been genetically modified such as introduction of an antibiotic resistant gene, you would note that in the characterization of agent column.

Block B7– Quantity/amount of Select Agent or Toxin:

- For each select agent or toxin listed, enter the total volume or quantity of the SAT involved in the incident.
 - For example, if one vial with a volume of 50 µL; you would enter ‘50 µL’ in the space provided.
 - Another example, if you have two agar slants or plates; you would enter ‘2’ in the space provided.

Block B8 – Type of Incident

- Theft
 - Select if the incident is a theft.
 - Proceed to Section C and complete the requested information.
- Loss
 - Select if the incident meets the above definition for a loss.
 - Proceed to Section D and complete the requested information.
- Release/Potential Exposure
 - Select if the incident does or may meet the regulatory definition of a release.
 - Proceed to Section E and complete the requested information.
- Not a Theft/Loss/Release Incident
 - Select if the incident is not a theft, loss, or release.
 - Proceed to Section F and complete the requested information.

Block B9 – Severity of Incident

- Select the level of severity that is warranted for the incident.

Block B10 –Biosafety Level

- Select the biosafety level of the location the incident occurred. Select all that apply.

Block B11 – APHIS/CDC Form 2

- Select 'yes', if the sample involved was part of an APHIS/CDC Form 2 transfer. Otherwise, select 'no'.
- **Note:** If yes, additional information may be required.

Block B12 – APHIS/CDC Form 4

Select 'yes', if the sample was a clinical/diagnostic specimen and an APHIS/CDC Form 4 was completed. Otherwise, select 'no'. **Note:** If yes, additional information may be required.

Section C – Report of Potential Theft

Block C1 – Type of Theft:

- Select the type of theft that occurred.
 - Select Force Entry if a forced entry was involved.
 - Select Insider Threat if the incident involved a person or persons within the organization, such as employees, former employees, contractors or business associates, who have inside information concerning the organization's security practices, data and computer systems.

Block C2 – Local Law Enforcement Notified:

- Select 'yes', if the entity notified local law enforcement of the theft. Otherwise select 'no'.
- If yes, fill out requested information for C3-C5.

Block C3 – Local Law Enforcement Agency:

- Provide the full name of the local law enforcement agency that to which the theft was reported.

Block C4 – Local Law Enforcement Agent Name:

- If applicable, provide the full name of the local law enforcement representative who is in charge of the response for the incident.

Block C5 – Local Law Enforcement Contact Information:

- Provide the contact information (e-mail and telephone number) for the person listed in Block C4.

Block C6 – FBI Notified:

- Select 'yes', if the entity notified the FBI of the theft. Otherwise select 'no'.
- If yes, fill out requested information for C7-C8.

Block C7 – FBI Agent Name:

- Provide the full name of the FBI agent who is in charge of the response for the incident.

Block C8 – FBI Agent Contact Information:

- Provide the contact information (e-mail and telephone number) for the person listed in Block C7.

Block C9 – SAT material recovered:

- Select 'yes', if the entity recovered the SAT. Otherwise select 'no'.

Block C10 – Potential Exposure:

- Select 'yes', if you have reason to believe that an exposure occurred during the theft. Otherwise select 'no'.
- If yes, proceed to Section E5-E12 and fill in the requested information.

Signature:

- For all entities, the individual named in Block A7 (RO, ARO, Facility Director or Laboratory Supervisor), must print, sign and date signature line.

Section D – Report of Potential Loss

Block D1 – Type of Loss:

- Select the type of loss that occurred
 - Select Inventory/recordkeeping discrepancy, if there was an error in the inventory records that misrepresented the amount or type of SAT that are present at the entity.
 - Select Sample lost/discarded at entity, if a SAT was intentionally or intentionally misplaced or disposed of at the entity.
 - Select Sample lost in transit, if a SAT was lost while in transit to the entity. Also, fill out Appendix B for additional information.

Block D2 – Local Law Enforcement Notified:

- Select 'yes', if the entity notified local Law Enforcement of the theft. Otherwise select 'no'.
- If yes, fill out requested information for D3-D5.

Block D3 – Local Law Enforcement Agency:

- Provide the full legal name of the local law enforcement agency to which the loss was reported.

Block D4 – Local Law Enforcement Agent Name:

- Provide the full name of the local law enforcement agent who is in charge of the response for the incident.

Block D5 – Local Law Enforcement Contact Information:

- Provide the contact information (e-mail and telephone number) for the person listed in Block D4.

Block D6 – FBI Notified:

- Select 'yes', if the entity notified the FBI of the theft. Otherwise select 'no'.
- If yes, fill out requested information for D7-D8.

Block D7 – FBI Agent Name:

- Provide the full name of the FBI agent who is in charge of the response for the incident.

Block D8 – FBI Agent Contact Information:

- Provide the contact information (e-mail and telephone number) for the person listed in Block D7.

Block D9 – SAT material recovered:

- Select 'yes', if the entity recovered the SAT and enter the date the material was recovered in Section D10.
- Otherwise select 'no'.

Block D10 – SAT material missing:

- Enter the estimated duration of time the SAT material was loss before being found. i.e. (two days, 3 weeks, 1 hour, not recovered, etc.)
- If yes was selected for D9, enter in the date the SAT material was recovered.

Block D11 – Inventory/audit:

- Enter the date of the last inventory/audit that was performed according to the FSAP regulations.

Block D12 – Potential Exposure:

- Select 'yes', if you have reason to believe that an occupational exposure occurred during the loss. Otherwise select 'no'.
- If yes, proceed to Section E5-E12 and fill in the requested information.

Signature:

- For all entities, the individual named in Block A7 (RO, ARO, Facility Director or Laboratory Supervisor), must print, sign and date signature line.

Section E – Report of Potential Release/Exposure

Block E1 – Type of Release:

- Select the type of release that occurred
 - Select Animal bite/scratch, if an entity personnel was scratched or bitten by an animal used in SAT work.
 - Select Equipment/mechanical failure, if there was an equipment or mechanical failure while SAT work was being performed causing a breach of primary containment.
 - Select PPE failure, if there was a breach in PPE at any point in a location where SAT is being worked with or stored.
 - Select Package damaged in transit, if the entity received a SAT package that was damaged in transit.
 - Select Spills, if SAT was spilled while transporting or being worked with.
 - Select Needle sticks/sharps, if an entity personnel was stuck or pricked by a needle or sharps while working with SAT.
 - Select Work performed on open bench, if an entity personnel worked with SAT on an open bench top instead of inside a BSC.
 - Select Unintended Animal infection, if an animal was unintentionally infected by SAT at the entity.
 - Select Unintended Plant Agent Release, if a plant agent was released outside of primary containment.
 - Select Inactivation Failure, if there was a release due to a failure in the inactivation process.
 - Select 'Other', if the incident was not covered by one of the above releases. Please indicate in the space provided an explanation.

Block E2 – Release outside containment

- Select 'yes', if there was a release outside the containment barriers resulting in possible agricultural/environmental/public health threat.
- Otherwise select 'no' or 'n/a' if there was no release outside of laboratory containment.

Block E3 –PPE worn during incident

- Select the type of PPE used at the time of the incident. Select all that apply. If a respirator was used, please indicate which type of respirator was in use at the time of the incident.

Block E4 –Potential Exposures

- Select 'yes', if the incident resulted in potential exposures. Otherwise select 'no' or 'n/a' if there was no release.

- If yes, please indicate how many individuals/animals/plants were exposed during the release.
- If yes, proceed to Section E5-E12 and fill out the required information.

Block E5 – Lab Acquired Infection/Outbreak:

- Select 'yes', if the incident resulted in a laboratory acquired infection or an infection/outbreak in agriculture or in the environment. Otherwise select 'no' or 'n/a'.

Block E6 – Medical Surveillance Initiated:

- Select 'yes', if medical surveillance has been initiated. Otherwise select 'no; or 'n/a'.

Block E7 – Prophylaxis or Treatment:

- Select 'yes', if prophylaxis has been provided to the individuals/animals/plants exposed to the incident. Otherwise select 'no' or 'n/a'.

Block E8 – Internal Investigation:

- Select 'yes', if an internal investigation has been initiated to identify the root cause and review laboratory procedures and policies. Otherwise, select 'no'.
- If yes is selected please provide additional details on what has been initiated to lessen the likelihood of reoccurrences of this type of incident at the entity.

Block E9 – Hazards:

- Describe the any hazards posed to humans, other than illness that may have been a result of incident.

Block E10 – Estimated Extent of Release:

- Describe how many individuals/animals/plants that may have been exposed are considered, high-risk, medium-risk or low-risk.

Block E11 – Decontamination Summary:

- Describe how the exposed laboratory area and work surfaces were decontaminated.

Block E12 – Medical Surveillance Summary:

- Describe the medical surveillance provided to the affected individuals exposed to the SAT and how many were potentially exposed.

Signature:

- For all entities, the individual named in Block A7 (RO, ARO, Facility Director or Laboratory Supervisor), must print, sign and date signature line.

Section F – Report of Potential Non-Theft/Loss/Release Incident

Block F1 – Type of Non-TLR Incident:

- Select the type of incident that occurred:
 - Select Found Material not in Inventory, if the entity found SAT material in non-registered space.

Note: For the purposes of the APHIS/CDC Form 3, the term “found material” refers to select agents or toxins that were discovered that were not in inventory.

➤ Select Near Miss event, if the incident was a near miss, not meeting the criteria for a TLR.

- Proceed to F4 to fill in the required information.
- Select Inactivation failure, if the incident was a failure of the inactivation process.
- Proceed to F5 to fill in the required information.

Block F2 –Found material added to Inventory

- Select 'yes', if the incident resulted in found material being added to the entity inventory. Otherwise select 'no' or 'n/a' if there was no release.
- If yes, please ensure that your entity is registered to retain the SAT found.
- If no, proceed to Block F3.

Block F3 –Not registered for found material

- Select the type of disposition that will be done:
 - Select 'Destroyed on site', if the entity will destroy the material on location. Please provide documentation that shows the found material has been destroyed.
 - Select 'Destroyed offsite', if the entity has a third party waste management company or must move the found material from secured location to be destroyed. Please provide documentation that shows the found material has been destroyed.
 - Select 'Transferred', if the entity will transfer the found material to an entity registered to retain the found material.

Block F4 –Other Near Misses

- Select 'yes', if there were any other similar near misses that occurred in the past year at the entity. Otherwise select 'no'.
- If yes, please provide details of the near misses in the events timeline in Appendix A.

Block F5 –Inactivation Failure

- Select 'yes', if the incident was a resulted of a failure to inactivate a SAT.
- Otherwise select 'no' or 'n/a'.
- If yes, please provide a description of the events in the events timeline in Appendix A.

Block F6 –Potential Exposures

- Select 'yes', if the incident resulted in potential exposures. Otherwise select 'no' or 'n/a' if there was no release.
- If yes, please indicate how many individuals were exposed during the release.
- If yes, proceed to Section E5-E12 and fill out the required information.

Signature:

- For all entities, the individual named in Block A7 (RO, ARO, Facility Director or Laboratory Supervisor), must print, sign and date signature line.

Appendix A – Events Timeline

Provide a detailed summary of events including a timeline of what occurred and when. For a discovery of a select agent or toxin in unregistered locations, include your entity's plan of action to assure no future discoveries, how discovered agents were found and disposition of the discovered agents, inventory reconciliation and assurance that the discovered material was safeguarded against unauthorized access, theft, loss, or release.

Appendix B- Sample Loss During Transit

Complete Appendix B if the incident occurred during transfer. Please complete only sections 1 and 2 of the APHIS/CDC Form 3 and provide a copy of the relevant APHIS/CDC Form 2.

Block 1 – Transfer Authorization Number:

- Provide the CEA number that is listed on the top of both pages of the APHIS/CDC Form 2.

Block 2 – Date Shipped:

- Provide the exact date that is listed on *Block 32* of APHIS/CDC Form 2.

Block 3 – Name of Carrier:

- Provide the name of the commercial carrier (e.g., World Courier, etc.) or individual hand-carrier that will deliver all packages indicated in *Block 36* of the APHIS/CDC Form 2.

Block 4 – Airway Bill/Tracking Number:

- Provide the shipment tracking number (s) (e.g., airway bill number, bill of lading number, tracking number, etc...) found on *Block 40* on the APHIS/CDC Form 2.

Block 5 – Package Description:

- Provide the detailed description of how the select agents and/or toxins were packaged for shipment. The description should include items such as the size, shape, and a description of the packaging and the number and type of inner packages as listed on *Block 38* on the APHIS/CDC Form 2.

Block 6 – Requestor received Package:

- Select 'yes', if the requestor (or receiving entity) received the package containing the SAT. Otherwise, select 'no'.
- If yes, please indicate the date of receipt.

Block 7 – Opened package:

- Select 'yes', if the package containing the SAT was opened. Otherwise, select 'no'.
- If yes, include a brief description in the summary in *Block 5*.

Block 8 – Sender Notified:

- Select 'yes', if the Sender of the SAT was notified of the incident. Otherwise, select 'no'.

Block 9 – Carrier Notified:

- Select 'yes', if the Carrier/Courier was notified of the incident involving SAT. Otherwise, select 'no'.

Signature:

- For all entities, the individual named in *Block A7* (RO, ARO, Facility Director or Laboratory Supervisor), must print, sign and date signature line.

For additional information or questions about submitting an incident report, please contact the DSAT Form 3 team, Point of contact: Von McClee at 404-718-2000 or visit the FSAP website at <http://www.selectagents.gov/form3.html>.