

INCIDENT FORM TO REPORT POTENTIAL THEFT. LOSS. RELEASE, OR OCCUPATIONAL EXPOSURE (APHIS/CDC FORM 3)

FORM APPROVED OMB NO. 0579-0213

INTRODUCTION

An entity is required by regulation (7 CFR 331.19, 9 CFR 121.19, and 42 CFR 73.19) to notify APHIS or 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 and/or toxin. In addition, clinical or diagnostic laboratories and other entities that possess, use or transfer a select agent or toxin contained in a specimen presented for diagnosis, verification, or proficiency testing must immediately report upon discovery of a theft, loss, or release of select agent or toxin. After the initial reporting, this form (APHIS/CDC Form 3) must be sent to APHIS or CDC within 7 calendar days after the discovery of theft, loss, or release of select agents or toxins:

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 theft or loss of select agents or toxins, the entity must also notify the appropriate local, state, or federal law enforcement agencies. For release of select agents or toxins, the entity should also notify the appropriate local, state, and federal health agencies.

PURPOSE

This form is to be used by the Responsible Official (registered entities) or the Laboratory Supervisor (non-registered entities) to report the theft, loss, or release of select agents or toxins. In addition, incidents which could have the potential for theft, loss, or release should be reported using this form. APHIS or CDC will make the final determination on whether an actual Theft, Loss, or Release has occurred. A copy of the completed form and attachments must be maintained by the entity for three years.

INSTRUCTIONS

Immediately notify APHIS or CDC via telephone, fax, or e-mail and appropriate local, state, or federal law enforcement agencies (theft or loss) or appropriate local, state, and federal health agencies (release).

- The Responsible Official (registered entities) or the Facility Director or Laboratory Supervisor (non-registered entities) must complete, sign and date this form. For registered entities, the information provided on this form should match the information submitted for the entity's certificate of registration.
 - For reporting of a theft or loss, complete sections 1 and 2. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified. Any laboratory incidents which have the potential for a theft or loss should also be reported (i.e. inventory discrepancy). For reporting a theft or loss that occurred during transfer, complete sections 1, 2, and Appendix B and include a copy of the approved APHIS/CDC Form "Request to Transfer Select Agents and Toxins."
 - For reporting a release of a select agent or toxin causing occupational exposure or a release of a select agent or toxin outside the primary barriers of the biocontainment area, complete sections 1, 2, and 3. For reporting a release that occurred during transfer, complete Sections 1, 2 and Appendix B and include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins." Any laboratory incidents which have the potential for a release should be reported even if the event remained in the primary or secondary barriers and a potential unconfirmed exposure has occurred (i.e. dropped inoculum plates in a laboratory, animal bite but skin not broken, etc.).
- The Responsible Official (registered entities) or the Facility Director or the Laboratory Supervisor (non-registered entities) must sign and send the Form 3 to APHIS or CDC within 7 calendar days of the theft, loss, or release.

Any laboratory (registered or non-registered) that has questions regarding the Form 3 or submission of the 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 scenario based guidance document on theft, loss or release can be found under the Form 3 Tab at http://www.selectagents.gov.