Select Agents and Toxins Security Plan Template

7 CFR Part 331.11, 9 CFR Part 121.11, 42 CFR Part 73.11

Prepared by

U.S. Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)
Division of Select Agents and Toxins
Atlanta, GA

U.S. Department of Agriculture
Animal and Plant Health Inspection Service (APHIS)
Agriculture Select Agent Program
Riverdale, MD

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Preface

Intent: The intent of this document is to provide possible practices and procedures that entities may use to assist them in developing and implementing the written security plan required by the select agent regulations. However, the ideas and suggestions provided in this document do not constitute or establish minimum acceptable standards that would automatically meet the requirements of title 7 of the *Code of Federal Regulations* (CFR) part 331.11, 9 CFR 121.11, or 42 CFR 73.11.

Revisions: This is a living document subject to ongoing improvement. Feedback or suggestions for improvement from Registered Select Agent entities are welcomed. Submit comments directly to the Select Agent Program at:

CDC: LRSAT@cdc.gov

APHIS: Agricultural.Select.Agent.Program@aphis.usda.gov.

Notice to User

The attached document is a sample written security plan. This document was prepared as a reference guide and template to assist entities in the development of a site-specific security plan required by the Select Agent Regulations (7 CFR 331.11, 9 CFR 121.11, or 42 CFR 73.11). The purpose of this guide is to offer assistance in structuring a security plan and assist in identifying the information that should be provided. The user is not limited as to what information to provide.

Within the proposed template every effort was made to provide a proposed language section whenever possible. However, some areas are entity specific, and proposed language could not be provided. The user has the option to accept the proposed language exactly as it is written, provided it is an exact fit for the entity. If the proposed language is not an exact fit, the entity may change it to best meet the needs of their facility.

When reference is made to the Security Information Document, it is advisable that the entity review those sections. An entity may find the information document useful when writing the site-specific risk assessment.

The template follows the order of the inspection checklists used by APHIS and CDC and also follows the order found in Section 11 of the select agent regulations.

Formatting of title pages, table of contents, signature pages, tables, charts, and graphics is at the discretion of the user.

Table of Contents

Certification and Approvals

The Security Plan has been developed by:

_____ _____

Name and Title Date

The Security Plan for this facility has been prepared with the intent of being in compliance with the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* and 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73. This plan is required to be reviewed annually, or updated when changes occur.

_____ _____

Signature of Authorized Responsible Official Date

_____

Print Name

ANNUAL REVIEW VERIFICATION	
VERIFICATION DATE	SIGNATURE
2006	
2007	
2008	

SELECT AGENTS AND TOXINS SECURITY PLAN TEMPLATE
7 CFR Part 331.11, 9 CFR Part 121.11, 42 CFR Part 73.11

I. Written Security Plan (Section 11 (a))

This is the written security plan for (name of entity). This written plan addresses and meets the requirements of the Select Agent Final Regulations (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73.).

II. Site-Specific Risk Assessment (Section 11 (b))

For the purpose of the written security plan, the entity need only provide a summary of the site-specific risk assessment as follows:

Agent-Specific Risk Assessment:

This entity has reviewed the APHIS/CDC Security Information Document.

Using the definitions in the APHIS/CDC Security Information Document, the overall agent-specific risk for this entity is:

- ☐ Low
- ☐ Moderate
- ☐ High
- ☐ Highest

Instructions to entity: Please explain the rationale for your agent-specific risk assessment.

Note: Instead of stating the overall risk for agents in the entity's inventory, the entity may want to evaluate each agent independently and conduct the agent-specific risk assessment based on that approach.

Threat Assessment:

This entity has reviewed the APHIS/CDC Security Information Document.

Considering all the threats listed in the APHIS/CDC Security Information Document (man, nature, incident), the probability of their occurring are:

Man	Nature	Incident
☐ Low ☐ Moderate ☐ High	☐ Low ☐ Moderate ☐ High	☐ Low ☐ Moderate ☐ High

Considering all the threats listed in the APHIS/CDC Security Information Document (man, nature, incident), the consequences should they occur are:

Man	Nature	Incident
☐ Low ☐ Moderate ☐ High	☐ Low ☐ Moderate ☐ High	☐ Low ☐ Moderate ☐ High

Instructions to entity: Please explain the rationale for your threat assessment.

Vulnerability Assessment

Based on a review of the APHIS/CDC Security Information Document, the security weaknesses and deficiencies identified at this facility, and the corrective measures considered, the overall vulnerability at this entity is:

☐ Low
☐ Moderate
☐ High

Instructions to entity: Please explain the rationale for your vulnerability assessment.

Graded Protection (Mitigation Measures)

Considerations: Physical security includes any device or protection capability that limits access to select agent activity areas starting from the select agent activity area and working outwards. A device may include locks on storage units, locks on laboratory doors, electronic monitoring systems (including CCTV), card-key access, etc., in any combination. Physical barriers also include the laboratory walls (floor to ceiling), a room

within a room, secured storage rooms, secured storage units, building perimeter walls and fences, security guards, security patrols, etc., in any combination.

Instructions to entity: Please explain the rationale for the measures you determined that addresses the graded protection.

Entity Security Consensus Meeting:

The relevant staff members at this entity (such as the Principal Investigator, Security Staff, Responsible Official, Alternate Responsible Official, Institutional Biosafety Committee and Laboratory Management) have met and concluded that based upon the agent, threat and vulnerability assessments the following security measures are necessary to prevent the theft, loss, and release of select agents and toxins (list all measures below):

1.
2.
3.

III. Physical Security, Inventory Control, and Information Systems Control (Section 11 (c)(1))

Physical Security

Considerations: The requirements for the security plan as described in Section 11 requires a detailed written description of security procedures and protocols to safeguard select agents and toxins. In order to have a comprehensive written plan, the entity needs to articulate its security systems and procedures tailored to site-specific characteristics and requirements including on-going programs and operational needs. Most important is to mitigate the risks of loss, theft or release of select agents and toxins.

Instructions to the entity: Please describe in your plan how your laboratory addresses physical security.

Inventory Control

Considerations: If the entity receives select agents and toxins, the security plan should describe how select agents and toxins are handled and accounted for in the inventory once received. This should include the identification of a receiving area where select agent material is delivered by the courier. This descriptive narrative should also include assurances that the intra-entity transfers of select agents and toxins are safeguarded and accounted for while in transport (chain of custody). The entity should have written

procedures from both a biosafety and security perspective when select agents and toxins are transported from one building to another or from one floor to another. In short, the inventory must accurately reflect the transfer and receipt of all select agents and toxins.

Instructions to the entity: Please review the APHIS/CDC Security Information Document relating to inventory requirements and describe in your plan how your laboratory addresses inventory tracking for each of the following requirements:

Select Agent Inventory. Reference is Section 17 (a)(1)(i-v) and (a)(6)

Toxin Inventory. Reference is Section 17 (a)(2)(i-vi, x) and (a)(6)

Intra-entity Transfer Inventory. Reference is Section 17 (a)(2)(vii and viii)

Information Systems Control

Considerations: Information security includes procedures and protocols for information systems control such as electronic storage (computers) and hardcopy records (logbooks, registrations, inventories, etc.). Both are required to be secured under controlled access. Electronic storage requires appropriate safeguards such as passwords, firewalls, secured space, a back-up mechanism, etc. An electronic storage device can be a network and/or a stand-alone unit. The entity is required to describe what procedures are in place to prevent unauthorized access to select agent and toxin information.

Instructions to the entity: Please review the APHIS/CDC Security Information Document relating to information systems and describe in your plan how your laboratory addresses the security of electronic and hard copy data.

IV. Access Control (Section 10 (b), Section 11 (c)(2), and Section 17 (a)(4))

Access Control, SRA Approval and Recording Access

Considerations: Any individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g., ability to carry, possess, use, transfer, or manipulate) or the ability to gain possession of a select agent or toxin. Access controls include basic security devices such as padlocks and keys to the more elaborate devices such as card keys and biometrics. The results of the site-specific risk assessment can guide the entity in deciding what security devices to use.

Anyone requiring access to restricted areas where select agents and toxins are possessed, used, or transferred must have an approved Security Risk Assessment (SRA) and be listed on the entity's

APHIS/CDC Form 1, Section 4B. Authorized visitors must be escorted at all times by an SRA-approved individual.

Access can be recorded electronically through the use of card keys and biometric readers or through the use of manual methods such as log books. Entities should ensure all access logs accurately reflect the name, date, and time of entry. Piggybacking and tailgating on another individual's electronic access will result in an entry not being recorded. The Responsible Official, Alternate Responsible Official, or the Principal Investigator should closely monitor access to the select agent laboratories, and if piggybacking or tailgating is observed, it should be stopped immediately and raise the concern for additional training. All access logs must be retained for 3 years.

Instructions to the entity: Please review the APHIS/CDC Security Information Document relating to access control and describe in your plan how access is controlled at the entity.

V. Routine Cleaning, Maintenance and Repairs (Section 11 (c)(3))

Cleaning, Maintenance and Repair Provisions

Considerations: The entity's security plan must contain provisions for routine cleaning, maintenance, and repairs. The Responsible Official should be aware when cleaning, maintenance, and repairs are performed. Consideration should be given to ensure that cleaning and maintenance services take place as a scheduled event. The entity should also make provisions for after-hours emergencies such as a broken water line in the select agent laboratory or failure of major equipment. The entity needs to be sensitive to who is providing the cleaning and maintenance services (staff or contract employees?). Cleaning and maintenance staff must also receive training before they enter these spaces. Refer to section 15 (a) in the CFR.

Instructions to the entity: Please review the APHIS/CDC Security Information Document relating to cleaning, maintenance, and repair, and describe in your plan how your laboratory addresses these provisions.

VI. Unauthorized or Suspicious Persons (Removal) (Section 11 (c)(4))

Proposed language: SRA-approved individuals are required to remove all unauthorized and suspicious persons in and around the select agent area immediately and report them immediately to the Responsible Official, Alternate Responsible Official, and other management as appropriate. SRA-approved individuals also have the responsibility to police restricted areas and keep out other departmental staffs that do not belong.

Individuals at this facility who are approved by the HHS Secretary or APHIS Administrator receive annual training regarding the removal of unauthorized or suspicious persons and the reporting requirements. Staff members at this facility have been trained to challenge individuals who have no Identification badges or displayed credentials. Training also includes reporting and follow-up requirements and identification verification procedures.

VII. Loss or Compromise of Keys, Passwords, Combinations Changing Access Numbers or Locks Following Staff Changes (Section 11 (c)(5))

Proposed Language: Upon loss or compromise of keys, passwords, and combinations or upon staff changes, access to select agents controlled by electronic means (including computer passwords and combinations) are changed immediately. Access to select agents that are controlled by standard lock and key will have locks replaced immediately, including the purchase or replacement of lock boxes.

When keys and access cards have been inadvertently left at home, the Responsible Official will ensure that a temporary access pass is issued for the day.

Inventory of select agents will be conducted prior to the issuance of new card-key codes, combinations, and keys to SRA-approved individuals.

VIII. Reporting Unauthorized or Suspicious Persons or Activities Loss, Theft or Release of Select Agents or Toxins Alteration of Inventory Records (Section 11 (c)(6))

Proposed Language: All entity personnel, whether authorized to possess, use, or transfer select agents or not, are instructed to immediately report any suspicious persons or activities to the Responsible Official and/or the Alternate Responsible Official.

Any suspected loss or theft of a select agent or toxin must be immediately reported to the Responsible Official or the Alternate Responsible Official. Upon notification of a loss or theft, the Responsible Official or the Alternate Responsible Official has the authority to suspend all select agent activity, disable all card-keys to the select agent activity area, and notify APHIS/CDC as appropriate. APHIS/CDC Form 3 (Report of Theft, Loss or Release of Select Biological Agents and Toxins) must be completed and submitted to APHIS/CDC as appropriate within 7 days.

If for any reason there is suspicion that the inventory and use records of the select agents or toxins have been altered or compromised, it must be reported to the Responsible Official or the Alternate Responsible Official. The Responsible Official or the Alternate Responsible Official will immediately initiate an investigation to further determine what has occurred. APHIS/CDC will be notified immediately in situations where a theft or loss has occurred. When directed, local law enforcement and/or the FBI will be consulted.

IX. Understanding and Complying with Security Procedures (Section 11 (c)(7) and Section 15)

Proposed Language: At this facility, training is conducted that addresses the needs of the individuals, the work they will do, and the risks posed by select agents and toxins. Training is also provided regarding the security procedures associated with select agents and toxins. This information is presented in a formal class setting. Validation of understanding the information is accomplished with a test.

All persons authorized to work with select agents and toxins shall review and be familiar with this site-specific security plan.

X. Access Approval (Section 11 (d)(1))

Proposed Language: At this facility, all personnel working with select agents and toxins are approved by the APHIS Administrator or HHS Secretary (SRA) approved) and are listed on APHIS/CDC Form 1, Section 4B.

XI. Unescorted Access for Cleaning, Maintenance, and Repair Personnel (Section 11 (d)(2))

Proposed Language: At this facility, unapproved individuals such as maintenance, cleaning, and repair personnel cannot enter select agent areas for cleaning and repairs unescorted.

Note: Please review the APHIS/CDC Security Information Document relating to cleaning, maintenance and repair and describe in your plan how your laboratory addresses these provisions.

XII. Means of Securing Select Agents and Toxins (Section 11 (d)(3))

Proposed Language:

Select agent areas are isolated from public access. Access to all areas where select agents and toxins are possessed, used, or transferred is controlled by (insert means of security here) for personnel who are SRA approved. These laboratories are locked and monitored at all times. No other facility personnel have access to these areas. Within the freezer unit, select agents are secured by a lock and key. The key and key log is controlled by the Responsible Official. A log (manual or electronic) is maintained that records name, date, and

time of entry. Logbooks are maintained and secured in a locked file cabinet by the Responsible Official. Select agents and toxins are possessed, used or transferred in Room(s)_____. Select agents and toxins are stored in Room(s) _____.

The select agent laboratory has a motion-activated alarm that is armed when the last person leaves the lab. Alarms and video cameras are monitored by the security staff on duty. Video cameras are security surveillance tools and not subject to recordkeeping requirements at this facility. (Note: The devices listed in this paragraph are examples of proposed language if a laboratory had an alarm and video surveillance system).

XIII. Inspection of Packages (Section 11 (d)(4))

Proposed language: All packages, containers, carts, bags, and briefcases that appear to be a suspicious nature are inspected by the Principal Investigator or his designee. This applies to all packages of a suspicious nature entering or leaving the select agent areas.

XIV. Intra-entity Transfers (Section 11 (d)(5))

Proposed Language: All intra-entity transfers at this facility will be handled by the Responsible Official, who will ensure that the facility intra-entity transfer form is used along with chain of custody and that the transfer or receipt of the select agent and toxin is accurately reflected on the inventory. This responsibility, at the discretion of the Responsible Official may be delegated to a Biosafety Professional provided this individual is SRA approved. All biosafety and security provisions will be worked out and discussed prior to any intra-entity transfer at this facility. Police escort may be necessary to ensure transfers are conducted in a secure manner (e.g., between floors, buildings, etc). (Examples of the forms are available in the Select Agent and Toxin Security Information Document.)

XV. Sharing Access (Section 11 (d)(6))

Proposed language: At this facility, individuals approved for unescorted access are not to share their unique means of access such as passwords, PIN numbers, keys, and key cards that allow access to the area(s) where select agents and toxins are possessed, used, or transferred.

XVI. Reporting Requirements to the Entity's Responsible Official (Sections 11 (d)(7)(i) through (v))

Proposed Language: At this facility, the following must be reported to the Responsible Official:

- Any loss or compromise of keys, passwords, combinations, etc.
- Any suspicious persons or activities
- Any loss or theft of select agents or toxins

- Any release of a select agent or toxin
- Any sign that inventory or use records for select agents or toxins have been altered or otherwise compromised

Once reported, the Responsible Official will take action to make all appropriate notifications and complete all forms, including the required follow-up.

XVII. Public Access Areas (Section 11 (d)(8))

Proposed Language: At this facility, rooms where select agents and toxins are possessed, used, or transferred are separate from public access areas.

XVIII. Select Agent Reference Document (Section 11 (e))

Proposed Language: The document entitled *Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents*, published in Morbidity and Mortality Weekly Report (December 6, 2002; 51:RR-19:1-6) is available at this facility and is on file in the Responsible Official's office.

XIX. Drills and Exercises (Section 11 (f))

Proposed Language: Drills and exercises conducted at this facility that satisfy the requirements of the Biosafety, Security, and Incident Response Plans are conducted on an annual basis and the drills conducted by this facility are summarized as an attachment to our incident response plan. All written plans at this facility are updated annually and when drills and exercises warrant update.

XX. Retention of Records (Section 17 (c))

Proposed Language: Records relating to security are required to be retained for 3 years and include the following: Inventory, transfers, theft, loss and release, Responsible Official's records, security, biosafety, incident response, and training. Security cameras at this facility are used as security monitoring devices.