



## **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 Services  
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. This document supersedes the Select Agents and Toxins Security Plan Template, dated March 8, 2007. Submit comments directly to the Select Agent Program at:

CDC: [LRSAT@cdc.gov](mailto:LRSAT@cdc.gov)

APHIS: [AgSAS@aphis.usda.gov](mailto:AgSAS@aphis.usda.gov)

## **Notice to User**

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 sample language section whenever possible. However, some areas are entity specific, and sample language could not be provided. The user has the option to accept the sample language exactly as it is written, provided it is an exact fit for the entity. If the sample 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 Guidance for Select Agent or Toxin Facilities, it is advisable that the entity review those sections. An entity may find the information document useful when developing and writing the site-specific risk security plan.

The template follows the order of the inspection checklists used by APHIS and CDC inspectors 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.

# 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 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
2016	
2017	
2018	
2019	
2020	

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# 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)**). Please include all documents or policies cited in this document with this security plan (for example, Information Security policy, Intra-Entity transfer SOP, etc.).

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

**Instructions to the entity:** The risk assessment can be part of the Security Plan or under a separate cover. Entities are strongly encouraged to use the Security Risk Assessments Tool that can be found on the select agent web-site: [www.selectagents.gov/guidance-securityrisk.html](http://www.selectagents.gov/guidance-securityrisk.html). (See pages 5-8 of the Security Guidance for Select Agent or Toxin Facilities)

1. Describe who was involved in the Risk Assessment Process (i.e., Principal Investigator, Security Staff, Responsible Official, Alternate Responsible Official, Local law enforcement, Federal Bureau of Investigation (FBI)'s Weapons of Mass Destruction Directorate, etc.).
2. Describe the threats to select agents or toxins and how they were determined. Natural disasters should also be included in the threat assessment.
3. Describe how the threat can get access to the select agent or toxin (e.g., the path taken to gain access) (Reference Appendix I, page 30 and Appendix II, page 32 of the Security Guidance for Select Agent or Toxin Facilities).
4. Describe the consequence of the agent. This may be mortality, morbidity, or other measures.

#### **Agent-Specific Risk Assessment:**

This entity has reviewed the APHIS/CDC Security Guidance for Select Agent or Toxin Facilities.

Using the definitions in the APHIS/CDC Security Guidance for Select Agent or Toxin Facilities, 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 Guidance for Select Agent or Toxin Facilities. Considering all the threats listed in the APHIS/CDC Security Guidance for Select Agent or Toxin Facilities (man, nature, incident), the **probability** of their occurring are:

Man	Nature	Incident
<input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High	<input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High	<input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High

Considering all the threats listed in the APHIS/CDC Security Guidance for Select Agent or Toxin Facilities (man, nature, incident), the **consequences** should they occur are:

Man	Nature	Incident
<input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High	<input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High	<input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High

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

**Vulnerability Assessment:**

Based on a review of the APHIS/CDC Security Guidance for Select Agent or Toxin Facilities, 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:** Describe the applicable requirements found in Section 11(d) and (f), or address the requirements of Section 11(d)/(f) or address them individually within the security plan.

**Inventory Control:** Describe inventory accountability procedures for the following:

- Select Agent Inventory. Reference is Section 17 (a)(1)(i-v); 17(a)(2) and 17(a)(6)
- Select Toxin Inventory. Reference is Section 17 (a)(3)(i-vi, x) and 17(a)(6)
- Accountability of animals, including arthropods, or plants accidentally exposed to a select agent. For investigations involving plants or animals, Describe the accountability up to and including the disposition. (Section 17(a)(2))

See [Guidance on the Inventory Requirements for Select Agents and Toxins](#) and page 20 of the [Security Guidance for Select Agent or Toxin Facilities](#).

**Information Systems Control:** Describe the applicable requirements found in Section 11(c) (9) or address the requirements of Section 11(c) (9) or address them individually within the security plan. See [Information Systems Security Control Guidance Document](#) relating to information systems

### IV. Access Control (**Section 10(b), Section 11(c)(2), Section 17(a)(4) and 17(a)(5)**)

**Access Control:** Describe how the entity limits access to personnel approved by the HHS Secretary of Administrator. See pages 12-14 and Appendix III of the [Security Guidance for Select Agent or Toxin Facilities](#). Describe the control of access to select agents and toxins, including the safeguarding of animals, including arthropods, or plants intentionally or accidentally exposed to or infected with a select agent, against unauthorized access, theft, loss or release.

If all registered areas within an entity have the same security features, then indicate so. If not, identify the features by each unique registered area

1. For entities with electronic access (card keys, biometrics), describe who manages access control and how they are notified when an individual has been granted access approval. Also, if there are electronic master keys, describe how they are controlled.
2. For entities with mechanical locks (even if dual locks with electronic readers), describe key control procedures. If the lock has a master key or facility master key, describe how that key is controlled as well.
3. For entities with key locks to freezers housing select agents or toxins, describe key control procedures.
4. Describe how access is recorded.
5. If a person is employed a barrier, describe procedures.

Describe the following (if applicable):

- Shared equipment: This includes incubators, or centrifuges with individuals who are conducting non-select agent work, the entity should describe procedures which control access when the equipment is used for select agents and toxins. If they are locked, discuss key control procedures.
- Autoclaves: If the autoclave is outside registered space, the entity must include procedures for autoclaving material (Reference page 9 of the [Security Guidance for Select Agent or Toxin Facilities](#)).
- Shared Space: If the space is shared, describe procedures which control access when used for select agents and toxins (Reference Appendix X, page 40 in the [Security Guidance for Select Agent or Toxin Facilities](#)).
- Swing Space: If the access to space is separated by time (swung) between Select Agent or Toxin work and other work, describe procedures which control access when used for select agents and toxins. Also describe method of inactivating the space. (Reference Appendix X, page 40 in the [Security Guidance for Select Agent or Toxin Facilities](#)).

V. Routine Cleaning, Maintenance and Repairs (**Section 11(c)(3)**) (See page 13 of the [Security Guidance for Select Agent or Toxin Facilities](#) and describe in your plan how your laboratory addresses these provisions).

VI. Unauthorized or Suspicious Persons (Removal) (**Section 11(c)(4)**) (See page 14 of the [Security Guidance for Select Agent or Toxin Facilities](#) and describe in your plan how your laboratory addresses these provisions).

VII. Loss or Compromise of Keys, Passwords, Combinations Changing Access Numbers or Locks Following Staff Changes (**Section 11(c)(5)**) . (See page 14 of the [Security Guidance for Select Agent or Toxin Facilities](#) and describe in your plan how your laboratory addresses these provisions).

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)) (See page 14 and 27 of the Security Guidance for Select Agent or Toxin Facilities and describe in your plan how your laboratory addresses these provisions).

IX. Understanding and Complying with Security Procedures (**Section 11(c)(7), Section 15(a), (c) and (d); Tier 1, Section 15(b)**) (See page 23 of the [Security Guidance for Select Agent or Toxin Facilities](#) and describe in your plan how your laboratory addresses these provisions).

X. Suspicious Activity of a Criminal Nature (**Section 11(c)(8)**) (See page 27 of the [Security Guidance for Select Agent or Toxin Facilities](#) and describe in your plan how your laboratory addresses these provisions).

**XI. Information Security (Section 11(c)(9))** See [Information Systems Security Control Guidance Document](#) relating to information systems and describe in your plan how your laboratory addresses the security of electronic and hard copy data. If the entity has SOPs or policies which cover the requirements, they must be attached to this plan.

1. Describe how all external connections to systems which manage security for the registered space are isolated or have controls that permit and monitor only authorized and authenticated users (e.g., external logins, “VPNs,” physically separate media, etc.)
2. Describe the controls which allow only authorized and authenticated users access to select agent and toxin related information, files, equipment (e.g., servers or mass storage devices) and applications as necessary to fulfill their roles and responsibilities.
3. Describe how access is modified when the user’s roles and responsibilities change or when their access to select agents and toxins is suspended or revoked.
4. Describe controls that are in place that are designed to prevent malicious code (such as, but not limited to, computer virus, worms, spyware) from compromising the confidentiality, integrity, or availability of information systems which manage access to registered spaces. This description should include any anti-virus software or security suite running on the systems. The security plan should also include if the network is isolated physically or virtually.
5. Describe configuration management practices for information systems to include regular patching and updates made to operating systems and individual applications. Describe how new software is approved and how patches are applied.
6. Describe procedures that provide backup security measures in the event that access control systems, surveillance devices, and/or systems that manage the requirements of section 17 of the select agent regulations are rendered inoperable

**XII. Shipping/Receiving and Unexpected Shipments (Section 11(c)(10))** (See page 25 of the [Security Guidance for Select Agent or Toxin Facilities](#) )

- Describe where select agents or toxins are packaged.
- Describe how the entity secures containers on site.
- Describe or attach contingency procedures for unexpected shipments.

**XIII. Security Requirements (Section 11(d))** Paragraph (d) covers features that must be in place in the entity.

**XIV. Access Approval (Section 11(d)(1))** If not covered in “IV. Access Control” describe how access is limited to personnel approved by the HHS Secretary or Administrator. See pages 12-14 and Appendix III of the [Security Guidance for Select Agent or Toxin Facilities](#).

**XV. Unescorted Access for Cleaning, Maintenance, and Repair Personnel (Section 11(d)(2))** (See page 13 of the [Security Guidance for Select Agent or Toxin Facilities](#), and [Guidance for Escort Procedures for Registered Entities that can be found on the select agent web-site: www.selectagents.gov/guidance-escort.html for additional information.](#))

XVI. Means of Securing Select Agents and Toxins (**Section 11(d)(3)**) If not covered in “IV. Access Control” describe methods for securing agents or toxins. (See review pages 12, 13, 19 and Appendix III of the [Security Guidance for Select Agent or Toxin Facilities](#). If all registered areas within an entity have the same security features, then indicate so. If not, identify the features by each unique registered area.)

XVII. Inspection of Packages (**Section 11(d)(4)**). (See page 24 of the [Security Guidance for Select Agent or Toxin Facilities](#) and describe in your plan how your laboratory addresses these provisions)

XVIII. Intra-entity Transfers (**Section 11(d)(5)**) If the entity has an SOP which covers this, attach it to the plan (See page 26 of the [Security Guidance for Select Agent or Toxin Facilities](#). Examples of the forms are available in the [Security Guidance for Select Agent or Toxin Facilities- Appendix IX](#)).

XIX. Sharing Access (**Section 11(d)(6)**) (See page 13 of the [Security Guidance for Select Agent or Toxin Facilities](#) and describe in your plan how your laboratory addresses these provisions)

XX. Reporting Requirements to the Entity’s Responsible Official (**Sections 11 (d)(7)(i-v)**) (See pages 14 and 27 of the [Security Guidance for Select Agent or Toxin Facilities](#) and describe in your plan how your laboratory addresses these provisions).

XXI. Public Access Areas (**Section 11(d)(8)**) (Reference page 15 of the [Security Guidance for Select Agent or Toxin Facilities](#) and describe in your plan how your laboratory addresses these provisions).

XXII. Complete Inventory Audits (**Section 11(e)**) (See page 21 of the [Security Guidance for Select Agent or Toxin Facilities](#) and describe in your plan how your laboratory addresses these provisions).

XXIII. Tier 1 Select Agents and Toxins (**Section 11(f)**)

**Section 11(f)(1)- Pre-access Suitability Assessment:** (See [Guidance for Suitability Assessments](#) and please use the [Suitability Plan Template](#) for this section).

**Section 11(f)(2)- Coordination of safety and security personnel:** See page 5 and 10 of the [Security Guidance for Select Agent or Toxin Facilities](#) and describe in your plan how your laboratory addresses these provisions).

**Section 11(f)(3)(i-iii)- Self and Peer-reporting, Training and Ongoing suitability monitoring:** See [Guidance for Suitability Assessments](#) and please use the [Suitability Plan Template](#) for this section:

**Section 11(f)(4)(i-viii)- Tier 1 Enhanced Security Requirements**

(i)- Describe procedures that will limit access to a Tier 1 select agent or toxin to only those individuals who are approved by the HHS Secretary or Administrator and are enrolled in the entity suitability program (See page 18 and Appendix IV of the [Security Guidance for Select Agent or Toxin Facilities](#)).

(ii)- Describe procedures that limit access to laboratory and storage facilities outside of normal business hours to only those specifically approved by the Responsible Official or designee: (See page 19 of the [Security Guidance for Select Agent or Toxin Facilities](#)).

(iii)- Describe procedures for allowing visitors, their property, and vehicles at the entry and exit points to the registered space, or at other designated points of entry to the building, facility, or compound that are based on the entity's site-specific risk assessment; ∴ (See page 19 of the [Security Guidance for Select Agent or Toxin Facilities](#)).

(iv)- Describe Barriers: (See page 15 and Appendix IV of the Security Guidance for Select Agent or Toxin Facilities).

1st Barrier:

2nd Barrier:

3rd Barrier:

Describe how 1 barrier limits access to the SRA personnel who are enrolled in the entity's suitability program.

Describe how at least one of the security barriers is monitored in such a way as to detect intentional and unintentional circumventing of established access control measures

(v)- Describe - Intrusion Detection System (IDS): (See page 16 and Appendix V of the [Security Guidance for Select Agent or Toxin Facilities](#)).

- The location or how it will protect registered space or areas that reasonably afford access to the registered space. For example, if the doors to the registered space are the target for the monitors, then all doors to the registered area must be covered by the system.
- Under what conditions the alarm code is changed.

(vi)- Describe how the IDS is monitored (Reference page 16 of the [Security Guidance for Select Agent or Toxin Facilities](#)).

- Describe the type and location of the sensors
- Describe who monitors the IDS
- Describe if or how they interpret the alarm (do they confirm the alarm)?
- Under what conditions do they notify the response force (all alarms, after approval by entity personnel, etc.)

(vii)- Describe procedures to ensure that security is maintained in the event of the failure of access control systems due to power disruption affecting registered Reference page 17 of the Security Guidance for Select Agent or Toxin Facilities).

(viii (A) and (B))- Describe response time: (Reference page 16 of the Security Guidance for Select Agent or Toxin Facilities).

If response time is less than 15 minutes, state how it was determined. (coordination/MOU with response force, drills, etc.)

If barriers “sufficient to delay unauthorized access until the response force arrives” describe how it was determined.

XXV. Drills and Exercises (**Section 11(h)**)(See page 9 of the [Security Guidance for Select Agent or Toxin Facilities](#) and describe in your plan how your laboratory addresses these provisions).