Form Approved
OMB Control No. 0920-0576
Exp. Date xx/xx/2020

Security Plan Guidance

(42 CFR § 73.11, 7 CFR § 331.11, and 9 CFR § 121.11)

(March 2017)

Centers for Disease Control and Prevention (CDC)
Division of Select Agents and Toxins (DSAT)
Animal and Plant Health Inspection Service (APHIS)
Agriculture Select Agent Services (AgSAS)

Contents

Introduction

Section 11 of the select agent regulations (42 CFR § 73.11, 7 CFR § 331.11, and 9 CFR § 121.11) requires a registered entity to develop and implement a written security plan that is:

1. Sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release, and
2. Designed according to a site-specific risk assessment, providing graded protection.

The purpose of this guidance document is to assist an entity in developing and implementing its site-specific security plan. Extra requirements for entities registered to use or possess Tier 1 biological select agents and toxins (BSAT) can be found in the Tier 1 guidance document. As used in this document, the word "must" means a regulatory requirement. The use of the word "should" or "consider" is a suggested method to meet that requirement based on generally recognized security "best practices." Implementation is performance-based and entities may find other ways to meet a regulatory requirement.

This document addresses the select agent regulations with regard to security with one exception: Entities with Tier 1 BSAT have pre-access suitably and ongoing suitability assessment requirements which are addressed in the Guidance for Suitability Assessments.

Section 11(a) – Creating a Site-Specific Written Security Plan

Section 11(a) of the select agent regulations require entities to develop and implement a written site-specific security plan. A security plan is a documented, systematic set of policies and procedures to achieve security goals that protect BSAT from theft, loss, or release. Plans also include agreements or arrangements with extra-entity organizations such as local law enforcement. Plans may be a single document or incorporate other documents and policies and procedures that work to achieve those security goals.

Entities should establish specific policies which support their plan. Security policies should document strategies, principles, and rules which the entity follows to manage its security risks. Effective policies provide a clear means of establishing behavioral expectations. They cover the spectrum from directives to standard operating procedures. As part of security program management, the entity should consider formally documenting security policies covering all operational controls.

Background checks and other personnel security measures, if practical, should be vetted through the entity's legal and human resources department. See the FSAP Guidance for Suitability Assessments for additional information.

An effective security plan should be based on the following principles:

- The security plan should result from collaboration between scientific facilities and security personnel.
- It is built upon well documented operational processes.
- It should account for and secure all biological select agents or toxins from creation or acquisition to destruction.
- It complements other plans such as biosafety, disaster recovery, continuity of operations and others.
- It does not violate any laws. Laws to consider when creating the security plan should include the Americans with Disabilities Act, OSHA safety standards, and local building and fire codes.
- The entity should provide security plan training so every person understands his or her responsibilities.
- It requires reporting of all suspected security incidents and suspicious activities.
- It is reviewed at least annually and updated whenever conditions change.
- It is based on a site-specific risk assessment.

Security Plan Roles and Responsibilities

The security program should define each individual's roles and responsibilities in the system and solicit their input for improvements.

An entity should be aware of, and collaborate with, the personnel responsible for and/or impacting security. This may include:

- Responsible Official (RO) / Alternate Responsible Official (ARO)
- Facility key control and/or access control personnel
- Alarm companies
- Campus security personnel
- Security personnel who observe video
- Local law enforcement or other response forces
- FBI – Weapons of Mass Destruction (WMD) coordinator

Key Entity Leadership

Certain parties should be involved in the process of designing and implementing the security plan. These include but are not limited to:

- Principal Investigator (PI)
- Responsible Official (RO)
- Alternate Responsible Official (ARO)
- Security staff
- Institutional Biosafety Committee
- Laboratory Management

Security Plan Team

Each person brings an important perspective as a subject matter expert in their own specialty. This group should collaborate to develop a site-specific security plan. Plans also include agreements or arrangements with extra-entity organizations such as local law enforcement.

Entities should form a team of entity subject matter experts (SMEs), supporting security professionals, and stakeholders. The team should include entity professionals who are experts on the potential consequences of a theft, loss, or release of a select agent or toxin and the daily operations of the entity. Entities are also encouraged to include federal partners (i.e., the FBI) as well.

Entity personnel should provide:

- Standard Operating Procedures (SOPs), policies, and other organizational controls which can reinforce or be affected by security measures
- Public health consequences of the select agent and toxin
- Operational requirements
- Value of the select agent or toxin work to the organization

- Knowledge of current security systems

Facility and support personnel should provide:

- Facility wide security measures
- Personnel hiring practices (background checks, reference checks, education verifications)
- Planned upgrades to the facility
- Constraints which affect security (fire code, ordinances, federal laws)

Local, state, and federal law enforcement and security personnel members may be able to provide:

- Known threats to the entities
- Assistance with identifying vulnerabilities
- Assistance with designing or vetting the mitigating factors
- Economic and psychological impacts of the select agents or toxins

Once the team is formed, members should be consulted on a regular basis, including during the plan development. The team should meet annually as part of the security plan review.

Section 11(b) – Site-Specific Risk Assessment

Section 11(b) of the select agent regulations states: "The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use." Graded protection is a result of mitigating the hazards (threat and natural) and the vulnerabilities based on the consequences of a select agent or toxin in its current form.

The cornerstone of a good security plan is a site-specific risk assessment. It forms the logical basis for physical and personnel security measures employed to achieve graded security. It should indicate what risks have been identified, and of those, which have been mitigated and any residual risks acceptable to the entity. It does not necessarily have to account for accidental hazards accounted for in a biosafety plan.

Figure 1: Determining Risk

Risk comes from the interaction of threats/hazards, vulnerabilities, and consequence (**Figure 2**). There are many methods to capture these interactions, including qualitative, quantitative, or probabilistic analysis, among others. Any assessment which captures and relates these interactions is sufficient. The Security Risk Assessment Tool is available to assist the entities.

Conducting a Risk Assessment

Understand and Assess Threats

A threat is a person or organizations whose actions may cause the theft or release of a select agent or toxin. The threat may target the agent directly (e.g. theft), may cause damage to the entity as the result of their action (e.g. animal rights extremists and eco-terrorists damaging containment), and may act on their own or collude with others. Threats can be captured as a 'probability of attack.'

Threats are generally determined in 3 different ways:

- Entities are encouraged to reach out to law enforcement and other experts to determine threats.
- An expert or group of experts model 'threats' in general, often using Design Basis Threat (DBT)[1]. This capability is most common in federal and state facilities but may be available in larger entities.
- Historical data, including statistics on past local events (crimes), terrorist events worldwide, social science research into terrorists' behavior, official accounts, and/or terrorists own writings about motivation and intent.

Insider Threats

An insider threat comes from personnel within the organization who have inside information regarding the organization's security, data to include Select Agent and Toxin inventory, access to biocontainment and computers. The goals of such threats often involve fraud, information theft, intellectual property theft, theft and/or misuse of Select Agents and toxins and computer system sabotage.

[1] A profile of the type, composition, and capabilities of an adversary.

External Threats

An external threat originates outside of the organization. These threats may include hackers, outages, and other emergencies.

Natural Hazards

See the Incident Response Guide for resources to help you to determine if you are in a risk area for natural hazards. As with threats, entities should assess the impacts of the hazard to the select agent or toxin as well as the entity as whole.

Understand and Assess Vulnerabilities

Vulnerability is the relative susceptibility of select agents or toxins to a threat or natural hazard. Vulnerabilities are a threat capability that can be applied which results in the theft or release of the agent or a natural hazard that can impact the select agent or toxin. Vulnerabilities are often captured as "probability of effectiveness" (PE) of a particular system. Below are some best practices in conducting vulnerability assessment:

- Exercises/after action reviews
- Assessments by subject matter experts (SMEs)
- Scenarios and path development with SMEs and entity members
- Modeling (primarily with natural hazards)
- Simulations (primarily with natural hazards)

Understand and Assess Consequence

Consequence is the impact of the theft or release of the agents. It is the impact on public, animal, or plant health and safety, and the potential for economic and psychological impacts. Entities should consider:

- The communicability of the agent.
- The agent's mortality and morbidity rates.
- Present availability of known countermeasures to the agent or toxin.
- The type of work being conducted on the select agent or toxin:
    - **Low risk** generally includes select agents or toxins that are handled in a diagnostic, non-propagative manner (e.g., single specimen, no culture). This may also include small quantities of select agents or toxins that are endemic in the environment.
    - **Moderate risk** includes select agents or toxins that are handled in a propagative manner or in amounts greater than a diagnostic sample. This risk level includes activities that work only with the amounts necessary for experiments at hand (e.g., specimen cultured for diagnostic purposes or produced only in amounts required for the research or experiments being conducted).
    - **High risk** includes select agents or toxins that are handled in large or highly purified quantities. It would also include those select agents or toxins used in higher risk procedures such as aerosolization, centrifugation, animal inoculation, or restricted experiments (as defined by section 13 of the select agent regulations).

Key point: Unless there is sufficient data available to project a particular threat's capability to enhance an agent, entities do not have to consider what a threat "could" do to make an agent more virulent. Current characteristics are sufficient for this assessment.

Assess Risk

A sufficient risk assessment should reflect the interactions of threat, vulnerability and consequence. In implementing a risk assessment, threat, vulnerability, and consequence may be captured as discrete variables, dependent variables (i.e., probability), or other methods. Also, entities may use a quantitative or qualitative means depending on the amount of information available. See Risk Analysis Methods for more information and examples of qualitative risk assessment. For guidance on mitigating the impacts of a natural hazard, see the Incident Response Guide.

Communicating Risks

After the risk assessment is completed, the key entity leadership should determine if the current risk level is acceptable. If the risk level is deemed unacceptable, then the entity is obligated to develop a means to mitigate the risk. Some common risk mitigation measures are given below. It should be noted that any activity involving a select agent or toxin will involve some level of unmitigated risk. The only way to eliminate risk completely would be to not undertake this work.

Manage the risk: Mitigation measures

If the risk is not acceptable, the entity has multiple paths to mitigate the risks. Options include:

- Employ additional security measures.
- Change the work with the select agent or toxin to reduce risk.
- Decrease the quantity of toxin on hand, possessing only the amounts necessary for the work.
- Change how the select agent or toxin is stored (e.g., not lyophilized).
- When a toxin is a by-product of a larger process, immediately autoclave the agent or destroy the toxin.
- Document any risks which have not been mitigated and why.

Document and Update the Risk Assessment

The entity should document the risk assessment and review it as threats change. The security plan should be updated to reflect the changes based on the risk assessment, as should any drills and exercises that are impacted by the change.

Section 11(c) – Planning Requirements

Section 11(c)(1) of the select agent regulations requires the security plan to describe procedures for physical security, inventory control, and information systems control. These descriptions should reflect the policies implemented at the entity. This section explains different methods for ensuring that the entity's security plan complies with the regulations.

Effective inventory control measures for select agents and toxins can deter and detect a variety of insider threats. How the inventory audits are conducted and inventory is maintained must be described in the entity's security plan and inventory records must meet the requirements of section 17 of the select agent regulations. The security requirement includes:

- Current accounting of any animals or plants intentionally or accidentally exposed to a select agent.
- An accurate and current inventory for each select agent or toxin in long-term storage.
- Labeling and identifying select agents and toxins in the entity inventory in a way that leaves no question that the entity's inventory is accurately reflected in the inventory records.
- Accounting for select agents and toxins from acquisition to destruction.
- See Inventory Audits for more detailed instructions on maintaining effective inventory control

Access Control

Section 11(c)(2) – Provisions for Access and Safeguarding

Section 11(c)(2) of the select agent regulations require the security plan to describe how the select agent or toxin is physically secured against unauthorized access. The security plan is performance based and should complement the Incident Response Plan and Biosafety Plan. An effective physical security plan deters, detects, delays, and responds to threats identified by the site-specific risk assessment. A successful security plan creates sufficient time between detection and the completion of an attack for response force to arrive. The physical security plan should include:

- Security barriers which both deter intrusion and deny access (except by access approved personnel) to the areas containing select agents and toxins:
    - Perimeter fences
    - Walls
    - Locked doors
    - Security windows
    - Trained person (e.g., security guard, trained laboratorians, or escorts)
- Biosafety measures and other environmental factors which increase security such as:
    - Access or locking system which denies access to BSAT, e.g. mechanical locks, card key access systems or biometrics
    - Tamper-evident devices for select agents and toxins held in long-term storage
- A balanced approach so that all access points, including windows and emergency exits, are secured at the same level
- A procedure or process to keep the number of alarms to a minimum

Create a system which limits access to select agents and toxins to those approved by the HHS Secretary or APHIS Administrator for access to select agents and toxins. The access control system should:

- Include provisions to limit unescorted/unrestricted access to the registered areas to those who have been approved by the HHS Secretary or APHIS Administrator to have access to select agents and toxins.
- Include provisions for the safeguarding of animals and plants exposed to or infected with select agents.
- Regularly review and update access logs.
- Be modified when access requirements change or be responsive to changes in personnel's access requirements during personnel changes.

Remain flexible enough so non-approved personnel can be escorted if needed. See Non-Tier 1 Barrier Scenarios for a visual representation of adequate physical security barriers. See Intrusion Detection Systems for a chart that defines and explains the use of various IDS options.

Section 11(c)(3) – Provisions for Cleaning, Maintenance, and Repairs

The security plan must state how cleaning, maintenance, and repairs will be accomplished in areas where BSAT are stored or used. When allowing maintenance, cleaning, or repair personnel (whether in-house or contract services) into a registered area, an entity should practice one or more of the following:

1) Use only access approved individuals.
2) Provide an access approved individual as an escort to the non-approved individual.
3) If the non-approved individual will not be escorted, install additional security measures (e.g., additional lock and key, cipher lock, or tamper alarms interfaced with the facility intrusion detection system) to prohibit access to select agents and toxins by non-approved individual; or
4) Remove the select agent or toxin to a different area that is appropriately registered.

Section 17 (Records) of the select agent regulations requires that access logs must be in place to record the name and date/time of entry into the registered area, including the name of an escort.

Section 11(d)(2) – Escort Provisions

The security plan must contain provisions which allow non-approved persons access to registered spaces that store BSAT only when escorted by an access approved person. The escort must be dedicated to observing the escorted person. No other duties may be performed during the time that the individual is serving as an escort. The escort must understand what to observe for (e.g., accessing select agents and toxins). Non-approved persons are not allowed to have access to an agent, even if escorted by an access approved person. The escort's responsibilities include:

- Serving as a physical barrier between the non-SRA approved person and select agents and toxins.
- Being knowledgeable about the entity's security policies.
- Training non-SRA approved persons on emergency protocols and risks related to the BSAT before they enter the registered space.
- Executing safety protocols as necessary.
- Receive approval for escorted access and notifying the RO when escorted entry has concluded.

See the Security Risk Assessment FAQs for more information about escort provisions.

Section 11(d)(6) – Prevent Sharing Access Credentials

The security plan must state that any person accessing select agents and toxins will not share their unique means of access (such as key cards and passwords) with any other person. This should include how the entity prevents:

- "Piggybacking" or "tailgating" on another access approved person's access card.
- Key card, password or badge sharing.

Challenge all individuals who tailgate or piggyback a secured access entry point.

Section 11(c)(5) – Identification, Key, Keycard, Combination, and Password Management

The security plan must describe the procedures for changing access after personnel changes in order to prevent access by personnel who have previous approved access to select agents and toxins. This can include:

- Deactivating card key access.
- Deactivating email, network, and local machine computer accounts which provide access to information.
- Surrendering key cards and badges.
- Surrendering keys and key cards when people leave or change duties.

The security plan must indicate that the following incidents must be reported to the RO:

- Any loss or compromise of keys, passwords, and combinations.
- Any suspicious persons or activities.
- Any loss or theft of a select agent or toxin.
- Any release of a select agent or toxin.
- Any sign that inventory or use records for select agents and toxins have been altered or otherwise compromised.

Unauthorized or Suspicious Persons

Section 11(c)(4) – Reporting and Removing Unauthorized or Suspicious Persons

An "unauthorized person" is not approved to have access to select agents and toxins or is not authorized by the entity to be in a particular area or be involved in particular conduct. A "suspicious person" is any individual who has no valid reason to be in or around the areas where select agents and toxins are possessed or used.

The security plan must describe the process for identifying and removing unauthorized and suspicious persons. It must also require follow-up actions such as reporting the information to the RO; and the RO reporting the information to entity security personnel, and possibly contacting local law enforcement agencies or FSAP, as appropriate.

Unauthorized and suspicious persons attempting to gain entry into registered areas without proper credentials should be identified, challenged and removed immediately. The RO must be notified immediately (see Section 11(d)(7) for more details).

The entity should consider:

- Integrating an access control measure (e.g., card key) into an alarm system which notifies a responder when an unauthorized person attempts to gain access (similar to an IDS, but does not involve an actual break in).
- Having a badge system which clearly identifies who does and does not have approved access to select agents and toxins.
- Provide training on how to remove unauthorized personnel (e.g., procedures for notification of security personnel and/or local law enforcement).

See RO Reporting for more detailed instructions for what activities should be reported to the RO.

Access Approval

Section 11(c)(7)

Section 11(c)(7) requires the entity to ensure that all individuals with access approval from the HHS Secretary or APHIS Administrator understand and comply with the security procedures. All approved individuals should undergo training that covers general security as well as security training as it applies to their specific work. See the Training Requirements guidance document for general information on training provisions.

Section 11(d)(1)

Create a system which limits access to select agents and toxins to those approved by the HHS Secretary or APHIS Administrator for access to select agents and toxins. Individuals must have passed a security risk assessment and have written approval from either the HHS Secretary or APHIS administrator before they obtain access to any select agents or toxins.

RO Reporting

Section 11(c)(8) – Suspicious Activities

The security plan must describe procedures for how the RO will be informed of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents and toxins. Individuals with access to select agents and toxins must be aware of the protocol for reporting suspicious or criminal activity. The plan must also describe procedures for how the entity will notify the appropriate federal, state, or local law enforcement agencies of such activity. Identify who best can respond to the circumstances during the security portion of the risk assessment.

Include in the security plan the procedures for how the entity will notify the appropriate Federal, State, or local law enforcement agencies of any suspicious or criminal activity.

Suspicious activity of a criminal nature includes:

- Those activities so identified in the site-specific security risk assessment.
- Insider:
    - Attempts to create additional select agent or toxin inventory not authorized or required.
    - Attempts to "cover up" and not report select agent or toxin inventory discrepancies.
    - Attempts to remove select agent or toxin inventory without authorization.
    - Attempts by "restricted" persons to intentionally access registered areas containing a select agent or toxin.
- Outsider:
    - Indirect threats against the entity receives by email, letter, telephone, or website postings.
    - Unauthorized attempts to purchase or transfer a select agent or toxin.
    - Attempts to coerce entity personnel into a criminal act.
    - Intimidation of entity personnel based on their scientific work (for example, eco-terrorism).
    - Requests for access to laboratories for no apparent legitimate purpose, or for purposes that don't seem legitimate.
    - Unauthorized attempts to probe or gain access to proprietary information systems particularly access control systems (for example, attempts by unauthorized individuals to gain physical or electronic access to systems)
    - Theft of identification documents, identification cards, key cards, or other items required to access registered areas.
    - Personnel representing themselves as government personnel (federal, state, local) attempting to gain access to the facility or obtain sensitive information that cannot or will not present appropriate identification.
    - Use of fraudulent documents or identification to request access.

Section 11(d)(7) – Reporting to the RO

Require that individuals with access approval from the HHS Secretary or Administrator immediately report any of the following to the Responsible Official:

- Any loss or compromise of keys, passwords, combination, 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.

Information Systems Security Controls

Section 11(c)(9) – Information Systems Security Controls

Please see the Information Systems Security Controls Guidance for details about meeting the requirements of this section of the regulations.

Shipping and Transfers

Section 11(c)(10) Shipping and Transfers

The security plan must contain provisions and policies for shipping, receiving, and storage of select agents and toxins. This includes procedures for receiving, monitoring, and shipping of all select agents and toxins.

With exception of exports out of the country, shipments containing select agents and toxins between entities must be authorized by FSAP, coordinated through an APHIS/CDC Form 2, and tracked so the receiving entity knows when the shipment will arrive. Both the sender (unless the sender is outside of the United States) and the recipient (unless the recipient is outside the United States) of the package must be approved for access to select agent or toxins.

The individual who packages the BSAT for shipment must have an SRA approval.

The package containing select agents and toxins is not considered "received" by the entity until the intended recipient takes possession of the package. The intended recipient must have SRA approval and, if the agent is Tier 1, have gone through the entity's pre-access suitability and is subject to the entity's ongoing assessment.

When received by the intended recipient, the shipment should immediately be secured in a registered space. Ideally, the shipment is taken to the receiving laboratory; however the package may be temporarily stored in other registered spaces.

Shipping and receiving areas must be registered if the select agents or toxins packages are identified or accessed. For example:

- If packaging or un-packaging of a select agent or toxin is performed in these areas.
- If the plan to temporarily store identified select agents.

If select agent or toxin packages are not identified or accessed, the shipping and receiving area may not need to be registered.

The entity must also have a written contingency plan for receipt and security for unexpected shipments. An "unexpected shipment" is when an entity receives a legitimate shipment of a select agent that it had neither requested nor coordinated for. The entity must have a contingency plan to have approved personnel gain control of the unexpected shipment of BSAT without delay and secure it in a registered area.

Section 11(d)(5) – Intra-Entity Transfers

An intra-entity transfer is a physical transfer of select agents or toxins that takes place between two individual with access approval, preferably two SRA approved PIs, at the same registered entity, and e.g., a PI removes a select agent or toxin from his long term storage and gives it to another PI at the same entity.

Entities that conduct intra-entity transfers must describe in their security plan how these transfers will take place, including chain-of-custody documents and provisions for safeguarding the select agents and toxins against theft, loss, or release. Please see the example intra-entity transfer form to see what information should be captured

according to section 17 (Records) of the select agent regulations. Transfers must include a chain-of-custody document and ensure that select agents and toxins will not be left unattended. See the sample Intra-Entity Transfer Form for an example. The entity is not required to cover intra-entity transfers in the security plan if they do not conduct them.

Section 11(d)(4) – Inspection of Suspicious Packages

A suspicious package is any package or item that enters or leaves registered areas that does not appear to be consistent with what is expected during normal daily operations.

The entity should consider the following indicators of suspicious packages:

- Misspelled words
- Addressed to a title only or an incorrect title
- Badly taped or sealed
- Lopsided or uneven
- Oily stains, discolorations, or crystallization on the wrapper
- Excessive tape or string
- Protruding wires
- Return address does not exist or does not make sense

The security plan must describe how the entity will inspect packages based on the site-specific risk assessment. The entity should inspect all packages and items before they are brought into or removed from areas where select agents and toxins are used or stored (registered laboratory, etc.). Suspicious packages should be inspected visually or with noninvasive techniques before they are brought into, or removed from the area where select agents and toxins are stored or used. See the USPS guidelines for recognizing suspicious packages for more detailed information.

Section 11(d) – Security Requirements

This section describes the policies and procedures that the entity must implement in order to be in compliance with the select agent regulations. There are many ways to adequately meet the requirements below.

Storage

Section 11(d)(3) – Storage Control

The entity is required to "provide for the control of select agents and toxins by requiring freezers, refrigerators, cabinets, and other containers where select agents or toxins are stored to be secured against unauthorized access (e.g., card access system, lock boxes)." See Access Control Devices for more information on methods of securing BSAT against unauthorized access.

There are many ways that the entity can comply with this requirement. Typically physical locks, key card access, biometrics, or some combination of those provide adequate storage control. Tier 1 select agents and toxins require more stringent conditions. See the Tier 1 guidance document for more information.

Section 11(d)(8) – Separate Registered Space from Public Space

The storage or laboratories that contain select agents and toxins must not be publicly accessible. Public areas are places where the general public may congregate or transit. Areas where select agents and toxins are used or stored must be registered and personnel with access to the registered space must have approval from the HHS Secretary or the APHIS administrator.

Section 11(e) – Inventory Audits

An inventory audit is an examination of a portion of the inventory or collection sufficient to verify that inventory controls are effective. **Note:** This inventory is not a part of the requirements of section 17. Section 11(e) of the select agent regulations requires the entity to perform a complete inventory audit for all BSAT under the control of a PI whenever:

1. The BSAT is physically relocated to another registered space.
2. There is a change (departure or new arrival) of the PI in control of the BSAT.
3. There is a theft or loss of BSAT under the control of the PI.

Entities have discretion on how they conduct these audits. The depth of an audit should depend on the circumstances. Entities should consider the following when determining the depth of an entity audit:

1. The timing of the inventory audit.
2. The circumstances that require the inventory audit. For example, an 'emergency' movement to another location (freezer malfunction) may result in a focus on counting full racks and a confirmation of a targeted, smaller number of vials. In the case of a shipment to a new building or campus where there is sufficient time to plan, entities are encouraged to inventory more thoroughly.
3. The criteria used to determine which samples are audited. In the case of a large inventory, the entity may choose to focus on the most recently manipulated samples. In the case of a small inventory, the entity may choose to focus on the entire inventory.
4. Any additional storage measures. If the material is stored in tamper evident systems, the entity may choose to count the sealed containers instead of the individual vials within those containers.

5. The size of the collection being audited and the manner it is stored. Inventories which are intermixed with other samples may require a 'vial by vial' audit.

See the Inventory Audit Conditions table for more detailed instructions for when an inventory audit is necessary.

Keep audit records in accordance with section 73.17(c). Changes to the inventory must be recorded in accordance with section 73.17(a) as well.

Section 11(f) – Tier 1 Requirements

Please see the Tier 1 guidance document for details about meeting the enhanced security requirements for the possession of Tier 1 select agents and toxins.

Section 11(h) – Review and Revision

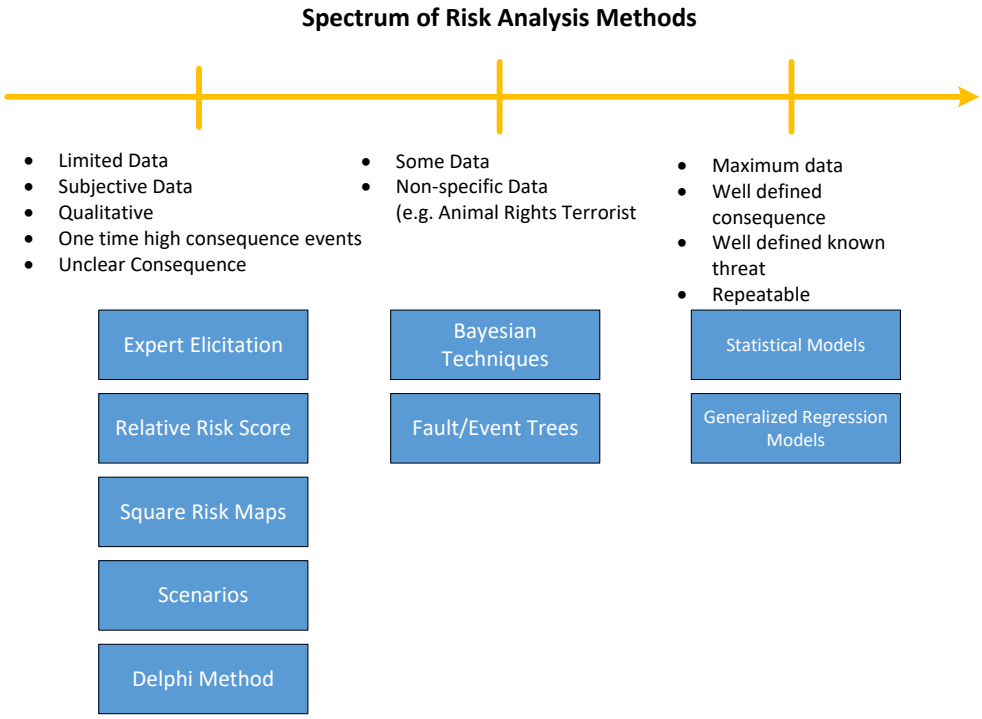
The security plan should be reviewed at least annually and revised as necessary. Some events that may necessitate the review and revision of the security document include:

- Theft, loss, or release of a select agent or toxin
- Changes to entity registration
- Changes to the registered space
- Changes to relevant entity personnel

Don't forget to update any training assessments, drills, or exercises that may change along with a change to the security plan.

Appendix I: Risk Assessment Methods

There are several methods for determining risk. Any recordable method will do, as long as the entity determines risk as the intersection between threat, likelihood, and consequence. The National Academies of Science describes different methods of risk analysis as being on a spectrum, like those in the following table. More qualitative methods are on the left while quantitative, data-reliant methods are toward the right.



For example, the square risk map is a qualitative analysis method that relies on a common sense understanding of the combination of threat and vulnerability with the consequence of such an incident occurring.

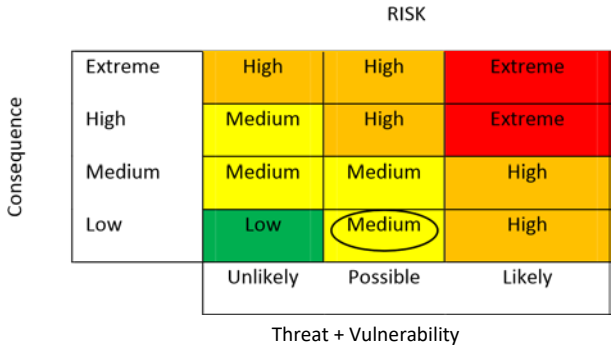


Figure 2. Square Risk Maps assess risk by comparing the threat and vulnerability of a situation to the consequence. The risk is assessed as Low, Medium, High, or Extreme.

Similarly, the relative risk score method numerically scores threats and vulnerabilities compared to the consequence of a given scenario and plots the risk according to a set range of risk levels.

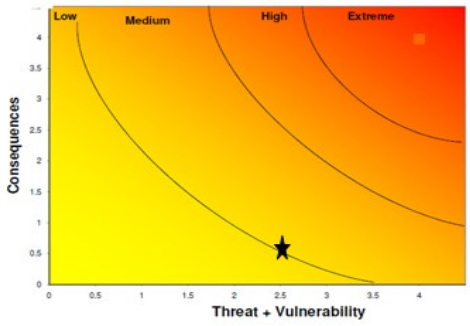


Figure 3. Example "Relative Risk Score"- This method assesses risk by numerically scoring threats and vulnerabilities compared to the consequence of a given scenario.

Appendix II: Access Control Devices

Lock Type	Physical Security Requirement	Additional SRA Requirements
Mechanical Key	• All keys must be tracked in a log. • Change locks if key is lost or compromised. • All keys must be returned when people quit or are terminated. • Log access and retain for 3 years. • If the key is secured in a key box, the key box key must meet the requirements above.	• All personnel with access to the key must have SRAs. • If in a key box, all personnel with access to the key box key must have an SRA. • If there is no IDS, the following people must have SRAs: • All personnel with access to a master key. • All personnel with access to a facility or building grand master. • Entity locksmiths if they have or can make the key and the key can be traced to the door.
Cipher Key/Combination lock	• Change the code or lock when personnel quit or are terminated. Changes must be reflected in a log. • Change the code or lock in the event of compromise. • Log access to registered areas and retain access records for 3 years.	• All personnel with the code/combination or access to the code/combination must have SRAs. • If there is no IDS, the following people must have SRAs: • All personnel who can change the code.
Card Key	• Maintain electronic or physical logs of access to registered areas for 3 years. • The log must be capable of being printed. • The access control network must meet the information security requirements.	• All personnel with card-key which can open door • (includes facility wide keys)
Card Key+ Pin	• Maintain electronic logs of access for 3 years. • The access control network must meet the information security requirements.	• No additional requirement
Biometrics	• Maintain electronic logs of access for 3 years. • The access control network must meet the information security requirements.	• No additional requirement
Multiple kinds of access control (i.e., Card Key and Mechanical Lock on same door)	• All the requirements for each type of access control systems when or if used.	• All the SRA requirements for both systems unless use of the access control device triggers the IDS (use of a mechanical key in Card-Key door will often trigger a 'forced door' alarm. The same alarm if someone broke the door down).
Remote opening (e.g., someone 'buzzes' a person in)	• Maintain electronic logs of access for 3 years. • The access control network must meet the information security requirements.	• No additional requirement
"Emergency" card key kept with First Responders	• Log of access. • Inventory of key. • Notification of the RO and FSAP in the event of its use.	• No SRA requirement for first responders
Emergency mechanical key or Card-Key in Knox Box (key stored in secured 'box' only accessible to first responders)	• Maintain electronic logs of access for 3 years. • Notification of the RO and FSAP in the event of its use.	• No SRA requirement for first responders

Appendix III: Intrusion Detection Systems

Systems	Definition	Possible Uses	Questionable Uses	Dependencies
Infrared motion detector	A device that detects a change in ambient temperature (heat sensor)	-Inside registered areas -Along a hall that leads to registered areas -Doors that lead to registered areas -Storage freezers	-Areas where things are heated (warming) - Very large areas	Ensure that system is focused at key areas and not 'randomly' located throughout entity
Contact Switches	Devices that alarm when a circuit is broken (door or window opened)	-Inside registered areas -Along a hall that leads to registered areas -Doors that lead to registered areas -Storage freezers	Areas with glass windows or doors that provide direct access to registered area	Ensure the emergency exit has an alarm and windows have sensors
Broken Glass Sensors	A device that detects the sound frequencies generated by breaking glass.	-Laboratories with glass windows which provide access to registered space	-Entities where there are frequent severe storms -Entities with synthetic windows	Ensure all the doors also have a sensor.
Acoustic Motion Sensor (emits sounds)	An active device that detects motion by transmitting sounds that reflects off objects	-Inside registered areas -Along a hall that leads to registered areas -Doors that lead to registered areas -Storage freezers	-Animal rooms -Rooms where equipment is continuously left on or after work hours (i.e., shakers, incubators) - Very large areas	Ensure that system is focused at key areas and not 'randomly' located throughout entity
Acoustic Sensor (listens for sounds)	A passive device that monitors the sounds to determine when an intrusion occurs and/or to determine the nature of the intrusion	-Inside registered areas -Along a hall that leads to registered areas	-Animal rooms - Rooms where equipment is continuously left on or after work hours (i.e., shakers, incubators) -Entities without exterior sound dampening	Ensure exterior noises do not set the alarm off (i.e., animals in the laboratory next door)

Appendix IV: Example Intra-Entity Transfer Form that Captures the Section 17 Requirements

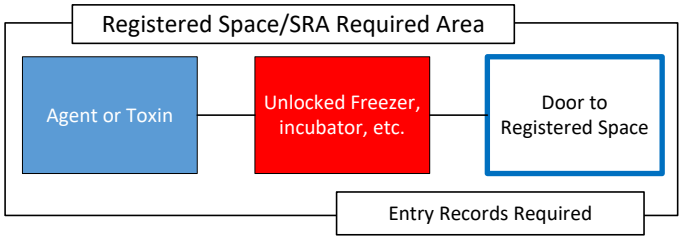
SELECT AGENT/TOXIN	STRAIN / CHARACTERISTICS	QUANTITY TRANSFERRED	DATE OF TRANSFER	SENDER	RECIPIENT

Comments:

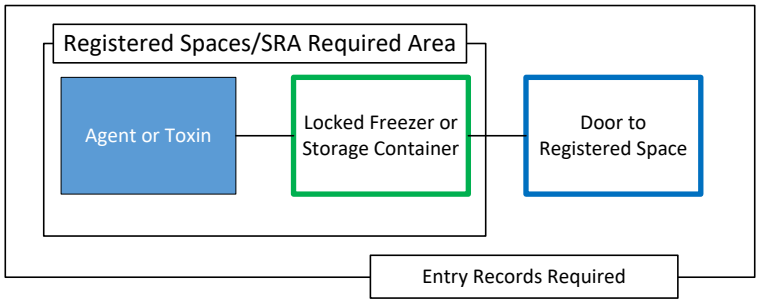
_____
_____
_____
_____
_____
_____

Appendix V: Scenarios (Non-Tier 1 Barriers and Access Controls):

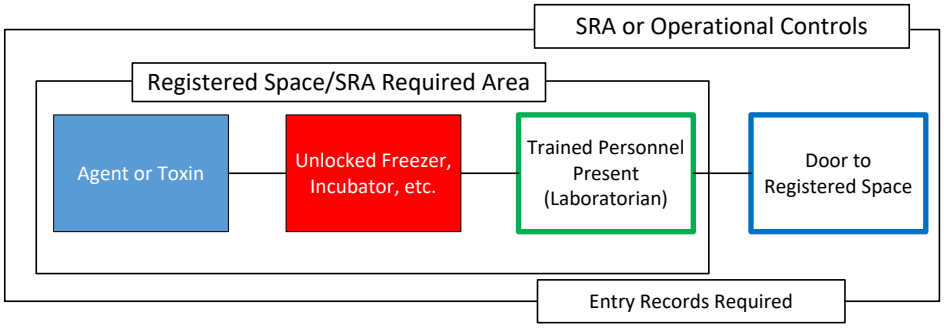
Scenario 1: Typical Working Facility



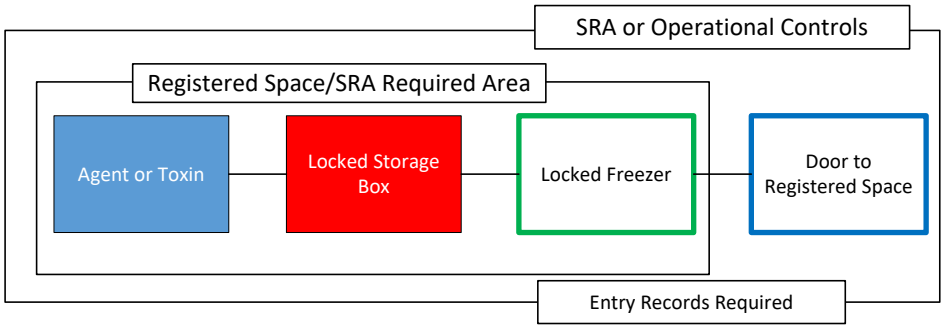
Scenario 2: Storage Only



Scenario 3: Working with Select Agent or Toxin in Shared Space



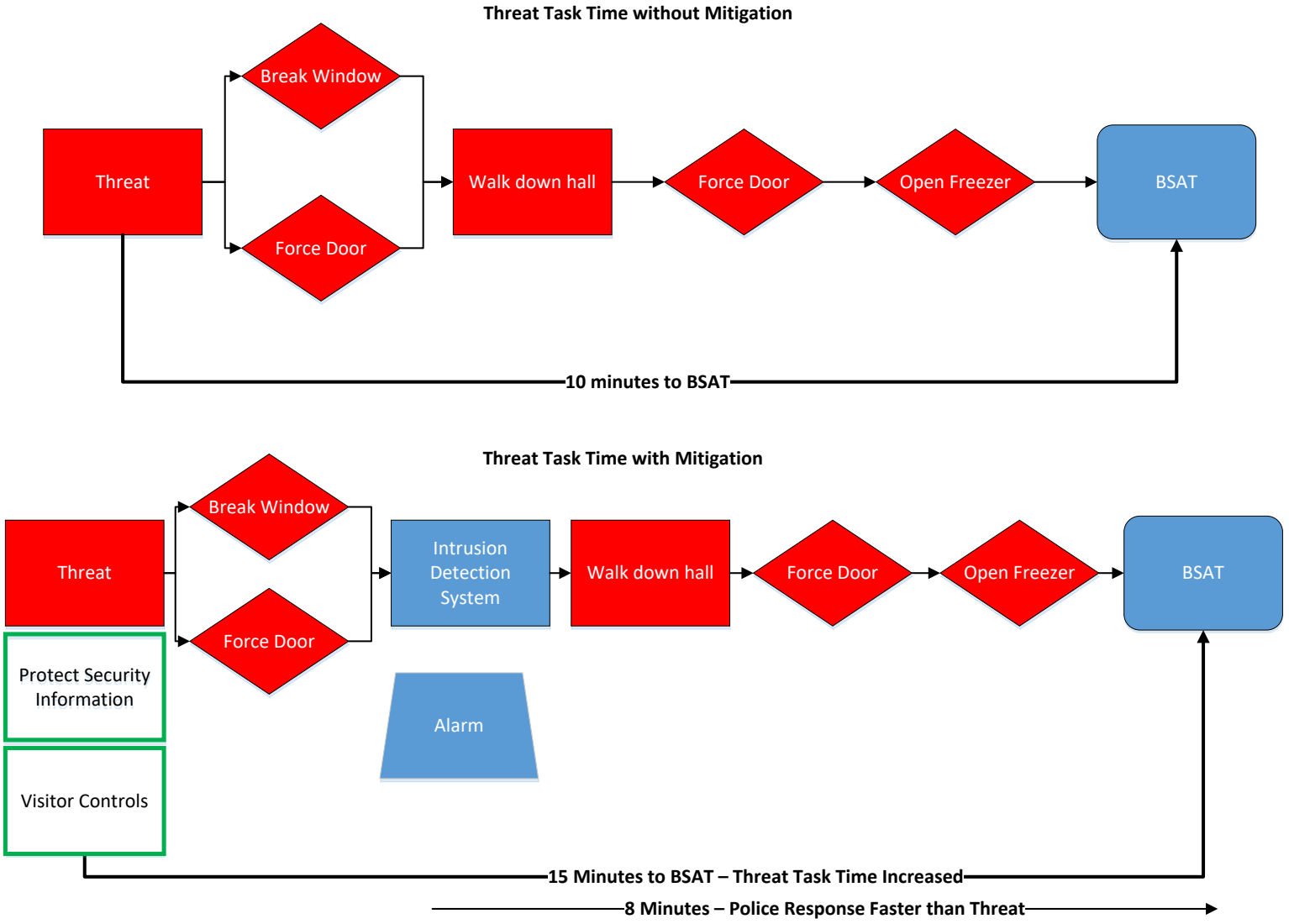
Scenario 4: Locked Box Inside Freezer



Operational controls are controls in place specifically to prevent unauthorized access to any select agent or toxin. Appropriate operational controls are based on the nature of all work in the registered area, the physical features in the area, and the entity's risk assessment.

Outsider Threat

Barriers deter but cannot be relied on to stop an outsider. The outsider cannot be stopped by locks, doors or other barriers, only delayed. The only thing that will stop an outsider is a response force.



Example Select Agent or Toxin Inventory Form that Captures the Section 17 Requirements

AGENT OR TOXIN NAME: CHARACTERISTICS:

QUANTITY ACQUIRED: DATE OF ACQUISITION: SOURCE OF ACQUISITION:

INITIAL QUANTITY:

WHERE STORED:

BUILDING: ROOM: FREEZER:

INVENTORY OF USAGE

CURRENT QUANTITY	DATE REMOVED FROM STORAGE	QUANTITY REMOVED	REMOVED BY	USED BY	DATE RETURNED TO STORAGE	QUANTITY RETURNED	RETURNED BY	PURPOSE OF USE	DATE DESTROYED	QUANTITY REMAINING

Comments/Discrepancies: _____
_____
_____
_____
_____

Inventory Audit Conditions

Circumstance	Suggested audit
Emergency movement inside the same registered area	Audit not required if there is no evidence loss or theft.
Emergency movement to a different registered area	100% check of sealed containers for indication of tampering. 10% of the entire inventory which is not sealed. Audit commences after the move is complete.
Loss	100% of all samples in that PI's collection and/or any other inventory in shared freezer space. Audit commences immediately (within 48 hours) after the event.
Theft	100% of all samples in that PI's collection and/or any other inventory in the shared freezer or space. Audit commences immediately (within 48 hours) after the event.
Addition or removal of a PI from the registration. Or Transfer of inventory from or to another PI.	100% of the samples in that PI's collection. 100% check of sealed containers for indication of tampering. Audit commences as soon as possible after the arrival/removal of the investigator or as soon as practical thereafter.
Planned movement to a different registered area	100% check of sealed containers for indication of tampering. 10% of the entire inventory which is not sealed. Audit commences after the move is complete.
Planned movement to a different registered area a different building, campus, facility.	100% of all samples manipulated since the last inventory. 100% check of sealed containers for indication of tampering. Audit commences after the move is complete.

Entities may also choose to consider inventory when following conditions occur:

Condition	Inventory
Laboratorian or support staff removal from registration	10% of the samples in that PI's collection that the individual worked with. 100% check of sealed containers for indication of tampering. Audit commences as soon as practical after the person is removed.
Destruction of agents	100% of the agents being destroyed.