Select Agent Program Workshop
November 16, 2012

Agricultural Select Agent Program (USDA/APHIS)

CDC Select Agent Program (HHS/CDC)

Revisions to Regulations

- 11 (a) through 11 (c)(7): (b) and (c)(2) changed
- 11 (c) (8), (9), (10): New, applies to all entities
- 11 (d) Unchanged
- 11 (e): New, applies to all entities
- 11 (f): New, the Tier 1 requirements
- 11 (g): New, applies to all entities

CFR: Section 11(b)

- 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. A current security plan must be submitted for initial registration, renewal of registration, or when requested.

CFR: Section 11(c)(2)

- Contain provisions for 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.

CFR: Section 11(c)(8) (All)

- Describe procedures for how the Responsible Official will be informed of suspicious activity that may be criminal in nature and related to:
  - the entity
  - its personnel
  - its select agents or toxins
- Describe procedures for how the entity will notify the appropriate federal, state, or local law enforcement agencies of activity that may be criminal in nature.

CFR: Section 11(c)(8)
Why “may be criminal in nature”

- Covers the gap between suspicious and crime
- Broadens from “suspicious persons”
- The law can be confusing
  - What’s a ‘threat?’
  - Inchoate offenses
  - First amendment and animal rights terrorists

CFR: Section 11(c)(8) (All)

- Describe procedures for how the entity will notify the appropriate federal, state, **or** local law enforcement agencies of activity that may be criminal in nature.
  - Coordination, notification
  - "Who, what, where"

CFR: Section 11(c)(8)
All

- Describe procedures for how the entity will notify the appropriate federal, state, or local law enforcement agencies of activity that may be criminal in nature.
  - This can be anyone with the authority to legally investigate a crime
  - Police, state police, sheriff, FBI, campus police, military police (all good answers)
  - Security guards, DHS, PIs, Crime Stoppers (not good answers)

CFR Section 11(c) (10) Shipping and Receiving (All)

- Contain provisions and policies for shipping, receiving, and storage of select agents and toxins, including:
  - Documented procedures for receiving, monitoring, and shipping of all select agents and toxins
  - How the entity will secure containers on site
  - A written contingency plan for unexpected shipments

CFR Section 11(c) (10)
What is an “unexpected shipment?”

- Unexpected shipment- when an entity receives a shipment of a select agent that they had neither requested nor coordinated with the sender.
  - Receives package with select agent or toxin without authorization from Federal Select Agent Program (i.e., No APHIS/CDC Form 2).
  - The entity must have a contingency plan to have approved personnel gain control of the shipment without delay and secure it in a registered area.
  - What does ‘without delay’ mean? An approved person stops what they are doing and gets it.

CFR Section 11(e) (All)

- Entities must conduct complete inventory audits of all affected select agents and toxins in long-term storage when any of the following occur:
  - Upon the physical relocation of a collection or inventory of select agents or toxins for those select agents or toxins in the collection or inventory;
  - Upon the departure or arrival of a principal investigator for those select agents and toxins under the control of that principal investigator
  - In the event of a theft or loss of a select agent or toxin, all select agents and toxins under the control of that principal investigator.

CFR Section 11(e) (All)

- What's an inventory audit
  - An inventory audit is an examination of a portion of the inventory or collection sufficient to verify inventory controls are effective.
- Why? Insider threat
- What should they inventory?
  - Depends on the circumstances
  - Depends how the inventory is stored
- Requirement for current/accurate still exists

CFR Section 11(f) (2) (Tier 1)

- Describe procedures for how an entity's Responsible Official will coordinate their efforts with the entity's safety and security professionals to ensure security of Tier 1 select agents and toxins and share information.

CFR Section 11(f) (4) (i) (Tier 1)

- Procedures that will limit access to a Tier 1 select agent or toxin to only those individuals who have an current SRA, are approved for access and have had an entity-conducted pre-access suitability assessment, and are subject to the entity's procedures for ongoing suitability assessments
- Only people in the surety program can *access* the agent or toxin

CFR Section 11(f) (4)(iv) (Tier 1)

- Not the same as biocontainment barriers
- A minimum of three security barriers where each security barrier adds to the delay in reaching secured areas where select agents and toxins are used or stored. The final barrier must limit access to the select agent or toxin to only those individuals who are approved by the HHS Secretary or Administrator and enrolled in entity's Suitability Assessment Program.
- Access through the barrier only takes an approval by the HHS Secretary or Administrator (ie SRA Approval)
- Why?
  - Shared space
  - Person as a barrier

CFR Section 11(f) (4)(iv) (Tier 1)

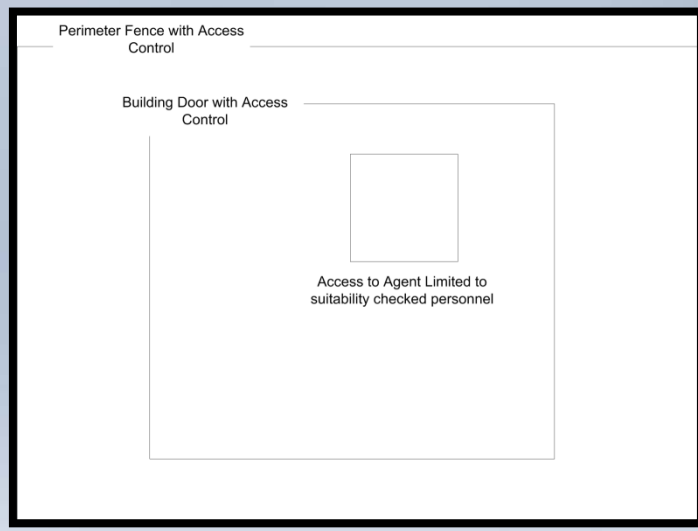
- What's a *security* barrier? A *security* barrier is a physical structure that is designed to prevent entry by unauthorized person.
- Can a person be a barrier? Personnel who are trained to identify and respond to suspicious activities can be a security barrier. They must be present!

CFR Section 11(f) (4)(iv) (Tier 1)

- Are locked freezer doors still a barrier?
  - Yes, the act of opening the door counts as ‘entry’
  - Keep in mind the suitability requirements

CFR Section 11(f) (4)(iv) (Tier 1)

- The *final barrier* must limit access to the select agent or toxin to personnel who are SRA approved.
- The *final barrier. Not ALL barriers.*
- The outer two barriers do NOT have to limit access to SRA approved persons.



3 Barrier Examples (Tier 1)

Barrier 1	Barrier 2	Barrier 3 (linked to access approval)
Guard/Perimeter Fence	Card-Key Access to floor	Key locked freezer with strong key control measures
Building Card Key Access	Limited Room card-key access	Different card-key required for room
Building Card Key Access	Limited Room card-key access	Card-key PIN access room
Building Card Key Access	Limited Room card-key access	Biometric lock system on freezer
Building Card Key Access	Card-key PIN access room	PIN access to freezer
Building Card Key Access	Limited Room card-key access	Restricted card key access to registered space
Floor Card Key Access	Limited Room card-key access	Restricted card key access to registered space

Barriers concerns

- The *final barrier* must limit access to the select agent or toxin to individuals who are approved by the HHS Secretary or Administrator and enrolled in entity's Suitability Assessment Program
- Person as a barrier
  - Must be there all the time the select agent or toxin is present
  - Must be trained (suspicious persons)
- Guards present only during business hours
  - After hours the access point must be secure
- Single guards
  - Must be no disruption of coverage

Shared Space and Barriers

- If they have access to the Tier 1, they must be in the Surety Program
- If they have access to the room but not the agent, they must be approved by the HHS Secretary or Administrator (ie SRA Approved)
- See security guide for examples of
  - Storage only
  - Separated by time

CFR Section 11(f) (4)(ii)

- 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.
- If you have 24 hour access, it's a deliberate decision not a 'default' by the access control system.
- Personnel can't work outside normal business hours without permission

CFR Section 11(f) (4)(iii)

- 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 based on the entity's site-specific risk assessment.
- Have a plan to allow visitor's entry
- Doesn't require you to deny access to visitors

CFR Section 11(f) (4)(v)

- All registered space or areas that reasonably afford access to the registered space must be protected by an intrusion detection system (IDS) unless physically occupied;
- An IDS is a system that uses a sensor(s) to detect an impending or actual security breach and initiate an alarm that notifies a response force.
- Please see the Security guide for examples of sensors.

CFR Section 11(f) (4)(vi)

- Personnel monitoring the IDS must be capable of evaluating and interpreting the alarm and alerting the designated security response force or law enforcement.
  - They should know what to do when an alarm goes off.
  - They know who to call

CFR Section 11(f) (4)(vi)

- For powered access control systems, describe procedures to ensure that security is maintained in the event of the failure of access control systems due to power disruption affecting registered space;
- Locks should fail secure
  - Fail Safe = power off, it's unlocked
  - Fail Secure = power off, it's locked
- Fire Rules

CFR Section 11(f) (4)(viii)

- The entity must:
  - Determine that the response time for security forces or local police will not exceed 15 minutes or
  - Provide security barriers that are sufficient to delay unauthorized access until the response force arrives in order to safeguard the select agents and toxins from theft, intentional release, or unauthorized access.
  - The response time is measured from the time of an intrusion alarm, or report of a security incident, to the arrival of the responders at the first security barrier.

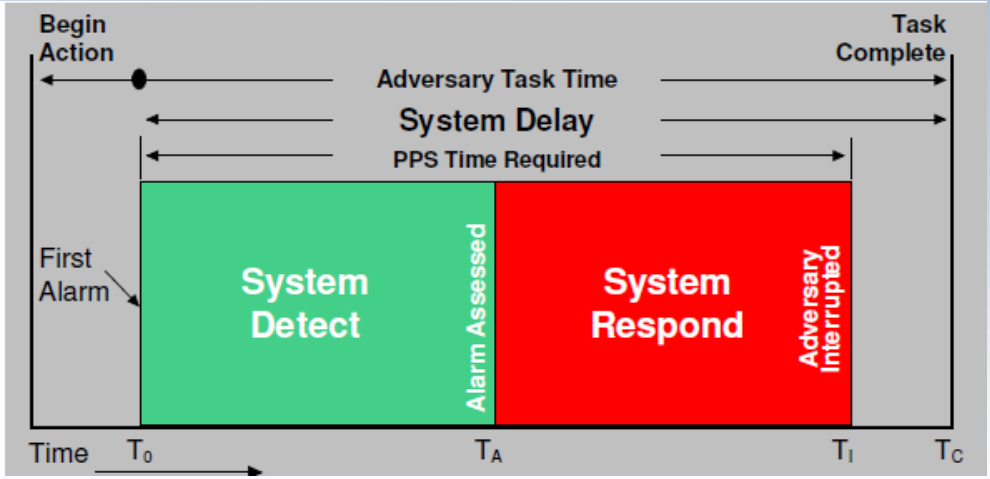
CFR Section 11(f) (4)(viii)

- Police departments are NOT reacting to home security alarms at all!
  - Detroit
  - Las Vegas
  - Indianapolis
  - Orange County CA

- Police do have priority alarms or potentially dangerous alarms
  - Banks
  - Pharmacies
  - Gun shops

CFR Section 11(f) (4)(viii)
Delay Time

- Barriers don't stop anyone, they just slow them down
- Response force stops (interrupts) a threat
- Barriers must slow an adversarial force down long enough for a response force to arrive



CFR Section 11(f) (4)(viii)

- The response force can be:
  - Personnel trained to respond
  - Observe/Report to neutralize
  - Employees who observe

CFR Section 11(g)

- In developing a security plan, an individual or entity should consider the document entitled, “Security guide for select agent or toxin facilities.” The document is available on the Internet at http://www.selectagents.gov.

Autoclaves

- Prior to the cycle:
  - An SRA approved individual should check the autoclave to ensure it is loaded properly and reaches to appropriate temperature and pressure.
  - Once that is complete, the person does not have to remain with the autoclave.
- At the end of the cycle
  - If the cycle was completed within normal parameters the person removing the material does not have to be SRA approved and meet the suitability requirements.
  - If the run was not completed within normal parameters, the personnel security requirements remain. The RO should be notified and the material removed by an SRA approved individual subject to the surety requirements.

Final Thoughts

- Security should always re-enforce other processes.
  - Don’t add a new barrier, add a lock to a current one
  - If you make it hard, no one will do it
- Anonymity is a key deterrence to crime
  - Suspicious Person, Criminal in Nature, IT, IDS and Visitors policies
  - 3 barriers
- “Doubt” is the best way to mitigate insider threat
  - Audits
  - Work hours
  - Access controls
- Barriers won’t stop a threat
  - IDS
  - Response force