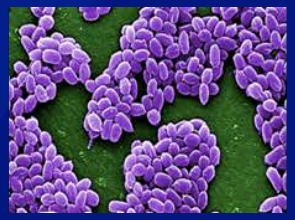


Select Agent Regulations:
Site-Specific Risk Assessments

Federal Select Agent Program

Responsible Official Webinar Series

5 August 2020

USDA

CDC

FSAP Security Specialists

Objectives

- Understand Site-Specific Risk Assessments and Application
- Understand Threats/Hazards, Vulnerabilities, and Consequences
- Assessing Risk, Mitigation or Acceptance
- Countermeasures

Regulatory Requirements

- Section 11 (Security) (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.

- Section 14 (Incident Response) (a) An individual or entity required to register under this part must develop and implement a written incident response plan based upon a site-specific risk assessment (Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations).

Resources

Site-Specific Security Risk Assessment Resources

- BioRam Security Risk Assessment Tool (Sandia National Laboratories) https://www.selectagents.gov/guidance-securityrisk.html
- Interagency Security Committee (ISC)
  - Standards applied to non-military federal facilities in the U.S.
- Local law enforcement, Federal Bureau of Investigation (FBI) Weapons of Mass Destruction (WMD) Coordinator, entity staff, etc.

Importance of Performing Site-Specific Risk Assessment

- Fulfills Requirement of:
  - 7 CFR Part 331 (Agriculture),
  - 9 CFR Part 121 (Animals and Animal Products), and
  - 42 CFR 73 (Public Health)
- Maximizes measures and equipment already in place
- Determines priorities
- Protects assets

Who To Involve?

- Owner/Controller
- Responsible Official/Alternate Responsible Official(s)
- Emergency Responders
  - Local law enforcement or other response forces
  - FBI – Weapons of Mass Destruction (WMD) coordinator
  - Alarm companies
  - Security Staff
- Biosafety Staff
- Human Resources
- Laboratory Management

Identify Assets on Site?

- **Biological Select Agents or Toxins (BSAT) (consider risk of BSAT with assessment)**
- **Information**
  - Classified, Sensitive, Business Information, Patents, Financial Data
- **Equipment**
  - Lab Equipment
- **Facilities**
  - Research and Development, Production, Storage
- **Activities & Operations**
  - Transfers or sensitive movements, sensitive communications

Threats & Hazards?

- **Natural (Think incident response plans)**
  - Hurricane, Tornado, Earthquake, Flooding, Fire, Winter Storms, Power Failure (as a result of)
- **Man-Made**
  - Arson, Assault, Vandalism, Activist Threat, Theft, Diversion, Terrorism, Workplace Violence, Cyber Incidents, vehicle-borne improvised explosive device (VBIED) or Vehicle Ramming, Insider Threats (Unauthorized Access/Changes/Use)

Vulnerabilities (Natural)

- **Natural**
  - Hurricane
  - Tornado
  - Earthquake
  - Flooding
  - Fire
  - Winter storms
  - Power failure

- Building construction
- Flood zone
- Location (easy or hard to get to supplies)
- Maintenance of systems
- Backup systems
- Emergency vs. regular power
- Training of individuals

Vulnerabilities (Man-Made)

- **Man-Made**
  - Arson
  - Assault
  - Vandalism
  - Theft
  - Terrorism
  - Workplace violence
  - Cyber incidents
  - VBIED or vehicle ramming
  - Insider threats (unauthorized access/changes/use)

- Limited or no visibility
- High crime area
- Inadequate key control
- Unprotected network connections
- No segregation of duties or backups
- Poor password management
- No security awareness training
- Soft targets
- Animal research

Assess Vulnerabilities

- Exercise/After Action reviews
- Subject Matter Expert (SME) assessments
- Scenarios (drills) and path development with SME and entity staff
- Modeling & Simulation (natural hazards)
- Actual Events

Notification of Theft, Loss, or Release

- Section 19 (a) Upon discovery of the theft or loss of a select agent or toxin, an individual or entity must immediately notify CDC or APHIS and appropriate Federal, State, or local law enforcement agencies. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.

Notification of Theft, Loss, or Release

- Section 19 (b) Upon discovery of a release of an agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area, an individual or entity must immediately notify CDC or APHIS.

Consequence Assessment

- **What to consider?**
  - Communicability of agent
  - Agent's mortality and morbidity
  - Present availability of known countermeasures to agent/toxin
  - Type of work conducted with select agent or toxin
    - Low Risk
    - Moderate Risk
    - High Risk

Risk Level When Considering Agent/Toxin Use

- **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).

Risk Level When Considering Agent/Toxin Use

- **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).

Consequence Continued

- **Other than Theft, Loss, & Release, what could be considered with consequence?**
  - Population size
  - Contracts
  - Operations and/or mission
  - Facility size

Evaluating Risk

- **Factor in Threats/Hazards, Vulnerability & Consequence to evaluate what the overall risk is**
- **Mitigate risk though various countermeasures**
  - Document mitigation
- **Accept risk not mitigated**
  - Document reasons
    - Budget constrictions
    - Location doesn't allow
    - Legal or zone restrictions

Manage 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

Countermeasures - Physical

- Landscaping (clear areas of concealment)
  - Also use to channel
- Bollards/Barriers
  - Limit vehicle access
  - Provide standoff from building
- Lighting
  - Are areas well lit?
  - Maintenance

Countermeasures – Physical (continued)

- Fencing
  - How often is it checked?
- Parking
  - Away from building
  - Controlled and/or Screening
  - Separate for visitors
- Dumpsters & Trash Locations
- Generator and utility locations
- Separate public and non-public

Countermeasures - Operations/Admin

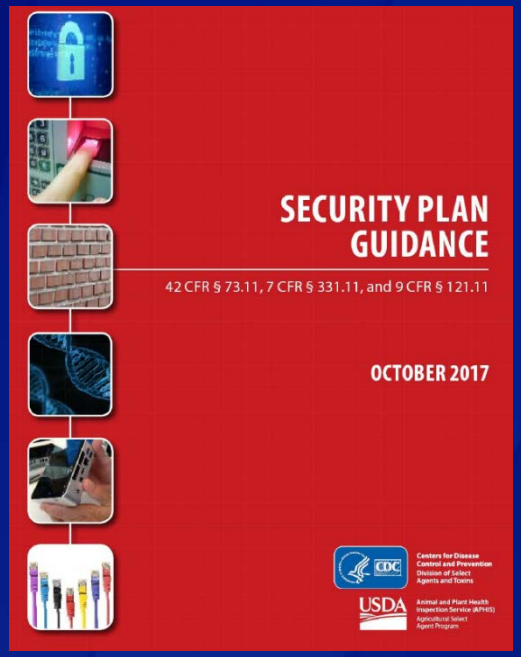
- Security Countermeasures - Administrative
  - Security Patrol Frequency or Fixed
    - Response Procedures
  - Random Measures
  - Security Awareness Training
  - Signage Identifying or Not Identifying
  - After Hours Policy
  - ID/Badge Policy
    - To include temporary identifications
  - Visitor Policy
    - Training
    - Screening

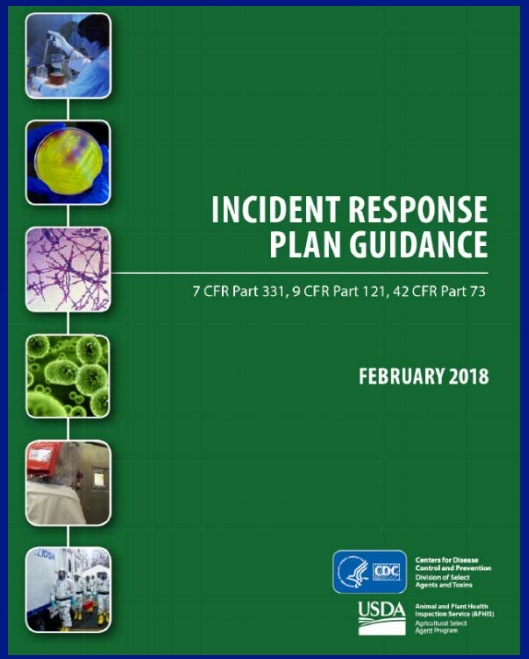
Countermeasures Systems

- **Control Center**
  - Access Control Setup
    - Administration
    - Layers, Card, Card & Pin, Pin, Biometrics
    - Verification of identification
  - Intrusion Detection
    - Zones
    - Arm/Disarm
    - Duress Alarms
    - Motion/Door Forced
  - Camera Systems
    - Monitored
    - Backups
    - Coverage
  - Maintenance Plan
    - System Maintenance
    - Testing

Questions?

Resources





SECURITY RISK ASSESSMENT TOOL

The BioRAM security risk assessment tool (Sandia National Laboratories) is available to assist regulated entities with site-specific security risk assessments. The tool is available at here.

https://www.selectagents.gov/spg-intro.html

https://www.selectagents.gov/irp-intro.html

https://www.selectagents.gov/guidance-securityrisk.html

Discussion

www.selectagents.gov

CDC: lrsat@cdc.gov or 404-718-2000

APHIS: AgSAS@usda.gov or
301-851-3300 option 3 (voice only)