

# National Select Agent Workshop: Security

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# Introduction

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- Overview
- Key Components
- Entity Role vs. Government Role
- Site-specific Risk Assessment
- Security Plan Development Aids
- Objectives of Security
- Physical Security vs. Operational Security
- Areas of Interest to Security
- Elements for Security Plan Development
- APHIS/CDC Security Reviews
- Theft, Loss and Release
- Questions



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# Overview

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- In compliance with the Bioterrorism Act of 2002 [The Act], USDA and HHS established regulations to ensure that all entities using or possessing select agents and toxins do so in a safe and secured manner to prevent unauthorized use:
  - “Establish and enforce safeguard and security measures to prevent access to listed agents and toxins for use in domestic or international terrorism or for any other criminal purpose.”
- CFR requires all entities that possess, use and/or transfer select agents and toxins to develop site specific written security plans.



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# Key Components

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- Two key requirements in 7 CFR § 331.11(b), 9 CFR § 121.11(b) and 42 CFR § 73.11(b) must be addressed in order to develop a successful security plan and program:
  - “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.”



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# Entity Role vs. Government Role

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- The entity is required to develop written security; biosafety; and, incident response plans that adequately describes the provisions they have in place to secure and safeguard the select agents and toxins based on a site-specific risk assessment
- The government's role is to review and approve those plans, and
- Determine whether the entity should possess, use, or transfer select agents



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# Site-specific Risk Assessment

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- **Security Formula**
  - Vulnerabilities + Threats + Mitigations = Security Infrastructure
- **Vulnerabilities**
  - “soft” spots inherent in the facility
- **Threats**
  - Internal or external
  - Can be natural



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# Site-specific Risk Assessment

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- **Mitigations**
  - Policies and procedures that off-set vulnerabilities and threats that will maintain an adequate level of security
- **Security Infrastructure**
  - Security that is currently in place at the time risk assessment is performed
- **Graded Protection**
  - Driven by the results of the risk assessment
  - Level of mitigations put into place



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# Security Plan Development Aids

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- **Code of Federal Regulations, March 18, 2005 [7 CFR 331, 9 CFR Part 121 and 42 CFR 73]**
- **Select Agents and Toxins Security Information Document, March 8, 2007**
- **Select Agents and Toxins Security Plan Template, March 8, 2007**
- **APHIS/CDC Security Inspection Checklist, June 5, 2007**
- **<http://www.selectagents.gov>**



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# Objectives of Security

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- **The Code of Federal Regulations implies:**
  - Deterrence
  - Detection
  - Delay



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# Physical Security vs. Operational Security

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- **Physical Security**
  - Physical [fence, locked doors, locked freezers, guards]
  - Technological [electronic, bio-metric]
  - Mechanical [locks and keys]
- **Operational Security**
  - Human aspect
  - Policy and procedures [SOP's]
  - Employee awareness [training]
  - Post orders
  - Key and password management



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# Areas of Interest to Security

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- **Select Agent Activity Area(s)?**
  - Single or multiple buildings
  - Laboratory specific
  - Greenhouses and propagation rooms
  - Growth Chambers
  - Shower facility
  - Anterooms
  - Local or Extended storage areas
  - Airlocks



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# Elements for Security Plan Development

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- **The three security components [§121.11(c); §331.11(c); §73.11(c)]:**
  - **Physical Security**
  - **Information Systems Control**
  - **Inventory Control**



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# Elements for Security Plan Development

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- **Physical Security**
  - Perimeter of facility/site
  - Entry security
  - Interior security
  - Security planning and operation



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# Elements for Security Plan Development

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- Information Systems Control means reviewing procedures for:
  - Non-electronic information storage such as hardcopy records
  - IT infrastructure
    - ★ Firewalls, anti-virus, password protection
  - Hardware asset protection
    - ★ Computer room protection, laboratory/office protection
  - Personnel security
    - ★ Background check for primary IT systems administrators
  - Data protection
    - ★ Data encryption



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# Elements for Security Plan Development

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- **Inventory Control means checking:**
  - **Inventory management**
    - ★ Inventory control manager, training
  - **Inventory data management**
    - ★ Electronic data storage
    - ★ Logbooks for accuracy
  - **Tracking**
    - ★ Chain-of-custody
  - **Transfer records**



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# APHIS/CDC Security Reviews



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# APHIS/CDC Security Reviews

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- **What's involved:**
  - **Review relevant sections of Form 1**
    - ★ Review type of work being done
    - ★ Review the agents and toxins listed
    - ★ Review room(s) that will be used
    - ★ Review room(s) where agents/toxins will be stored
    - ★ How many Principal Investigators are there?



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# APHIS/CDC Security Reviews

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- **What's involved (continued):**
  - **Review Section 5H Form 1**
    - ★ **Physical Security for**
      - Storage units
      - Laboratory
      - Building
      - Facility



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# APHIS/CDC

## Security Reviews

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- **What's involved (continued):**
  - **Review Section 5H Form 1**
    - ★ **What devices/measures are in place?**
      - Guards
      - Locks
      - Card Readers
      - Biometric readers
      - Surveillance cameras
      - Escorts



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# APHIS/CDC

## Security Reviews

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- **What's involved (continued):**
  - **Floor Plans**
    - ★ **Legible?**
      - Show registered rooms?
      - Location of security devices?
      - Location of storage units?
      - Expanded view provided?
      - Interlocking pass through autoclave?



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# APHIS/CDC

## Security Reviews

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- **What's involved (continued):**
  - **Review Section 5K of Form 1**
    - ★ **Restricted access to records**
    - ★ **Restricted access to databases**
    - ★ **Frequency of inventory**
    - ★ **Inventory tracking**



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# APHIS/CDC

## Security Reviews

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### Security....How you can help?

- Complete security sections of Form 1 and continue on an attached sheet of paper if necessary
- Save time upfront by submitting complete floor plans that show locations of security devices such as card readers, cameras, etc.
- Submit floor plans that illustrate how the select agent laboratory fits into the overall facility map.
- If you have a pass through autoclave, tell us if it has an interlock.
- If select agents and toxins are transported down elevators or outside buildings, tell us the safety and security precautions you follow.
- Report all security breaches immediately to your file owner.



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# APHIS/CDC

## Theft, Loss and Release



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# APHIS/CDC

## Theft, Loss and Release

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- **Information Guidance Document**
  - Released on January 18, 2008
  - 20 Scenarios presented
  - Positive feedback received
  - Significant increase in reporting



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# CDC History

## Theft, Loss and Release

Category	2003	2004	2005	2006	2007	2008
Thefts Reported	0	0	0	0	0	0
Losses Reported	4	9	11	6	5	7
Releases Reported	0	10	8	18	55	104
Total	4	19	19	24	60	111



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# Theft, Loss and Release Annual Report to Congress

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- **Historical (APHIS/CDC combined)**
  - 2003-2006: 83 reports
  - 2007: 71 reports
  - 2008: 134 total to date



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# APHIS/CDC

## Theft, Loss and Release

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- **Form 3 Reports**
  - **Problem areas**
    - ★ Incident not reported immediately to RO
    - ★ Incident not reported immediately to CDC
    - ★ Incomplete e-mail addresses
    - ★ Narrative incomplete
      - PPE not described in detail
      - No specifics on medical surveillance



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# APHIS/CDC

## Theft, Loss and Release

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- **Form 3 Reports....How you can help?**
  - **Report Promptly**
    - ★ Notify file owner by phone or e-mail even after hours
    - ★ Follow up with submission of Form 3 within 7 days
  - **On your Form 3 Report, provide specifics**
    - ★ What happened - Root cause?
    - ★ What was done – Response to incident
    - ★ What lessons were learned?
    - ★ What changes have been implemented?
    - ★ What training has been provided?
    - ★ What follow-up is planned?



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# APHIS/CDC

## Theft, Loss and Release

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- **Form 3 Reports....How you can help?**
  - Do not provide copies of biosafety, security or incident response plans unless directed
  - If unsure, report it, let us decide
  - Contact us with your questions



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# Questions?



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