Overview of Select Agent Regulations

Freeda E. Isaac, DVM
Director
Agriculture Select Agent Program
National Center for Import and Export

Safeguarding Animal Health
Select Agent Regulations and Requirements
(Slides produced by Ms. Marsha Ray, DSAT CDC)

http://www.selectagents.gov/training.htm
Regulations

42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331

Publication date: March 18, 2005
Effective date: April 18, 2005
Implemented the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (signed June 12, 2002)
Entity Requirements

• Register for each select agent or toxin it possesses, uses, or transfers
• Designate a Responsible Official (RO)
• Receive government approval of entity (owners), RO, & individuals who need access to select agents
  – Based on DOJ check of electronic databases (“Security Risk Assessment” = SRA)
• Allow for inspections by APHIS &/or CDC
Entity Requirements

• Maintain records (3 years):
  – Inventories
    • Accurate, current
    • All elements under 42 CFR 73.17, 9 CFR 121.17, 7 CFR 331.17
  – Access to areas where agents are used or stored
  – Transfers
  – Training
  – All records pertaining to select agents and toxins
Entity Requirements

- Ensure the accuracy of records and databases
- Develop safety, security, and incident response plans
- Conduct drills or exercises at least annually to test and evaluate the effectiveness of these plans
- Conduct safety and security training
  - Include risks/hazards
  - SRA-approved individuals and visitors
  - Tailored to needs of individual and work performed
- Immediate notification of theft, loss, or release
Entity Requirements

- Document, at least annually
  - BSL3/ABSL3, or BSL4/ABSL4, verification of the facility design and operational parameters, for respective registered laboratories
  - Biosafety cabinet certification
Entity Requirements

• Request prior approval from CDC/APHIS to perform restricted experiments involving recombinant DNA work that:
  – Introduces antibiotic-resistant genes into select agents
  – Produces select toxins lethal for vertebrates at an LD$_{50}$ <100 ng/kg body weight

• Requests reviewed by an Intragovernmental Select Agent and Toxin Technical Advisory Committee
Biosafety
42 CFR 73.12, 9 CFR 121.12, 7 CFR 331.12

Develop and implement a safety plan:

• For BSL 2-4 select agents:
• For toxins:
  – Appendix I: Guidelines for Work with Toxins of Biological Origin.
• For recombinant select agents:
  – Guidelines for research involving recombinant DNA molecules (NIH Guidelines), April 2002.
Security
42 CFR 73.11, 9 CFR 121.11, 7 CFR 331.11

• Access
  – “An individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin.”

• Restricting access
  – Physical barriers
    • Locks on doors and storage containers
    • Card or key pads
  – Escorted and continually monitored by an authorized and approved person
• **The security plan must:**
  - Be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release
  - Be based upon a site-specific risk assessment
  - Include all elements of regulations

• See Guidance Document:
  www.selectagents.gov/securitydoc.htm
Incident Response
42 CFR 73.14, 9 CFR 121.14, 7 CFR 331.14

The incident response plan must:
- Be coordinated with entity-wide plans, kept in the workplace, and available to employees
- Include all elements of the regulations
- Include planning and coordination with local emergency responders
Requirements to be Performed at Least Annually

Documentation of:

- Drills or exercises
- Review plans (biosafety, security, and incident response)
- Safety and security training
- Inspections - all parts
- Verification of facility design and operational parameters (BSL3/BSL4)
- BSC certification
Types of Select Agents and Toxins

HHS-only Agents: (HHS has sole authority and responsibility to regulate)

- Select agents and toxins that have the potential to pose a severe threat to public health and safety

USDA-only Agents: (USDA has sole authority and responsibility to regulate)

- Select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products

Overlap Agents:

- Select agents and toxins subject to regulation by both agencies
APHIS/CDC Forms

Safeguarding Animal Health
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For More Information

APHIS/CDC Select Agent Program web site: http://www.selectagents.gov