

Overview of Select Agent Regulations

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Safeguarding Animal Health

Select Agent Regulations and Requirements

(Slides produced by Ms. Marsha Ray, DSAT CDC)

<http://www.selectagents.gov/training.htm>



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Regulations

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



Federal Register

Friday,
March 18, 2005

Part III

Department of
Health and Human
Services

42 CFR Parts 72 and 73

Office of Inspector General
42 CFR Part 1003
Possession, Use, and Transfer of Select
Agents and Toxins; Final Rule

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)



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Entity Requirements

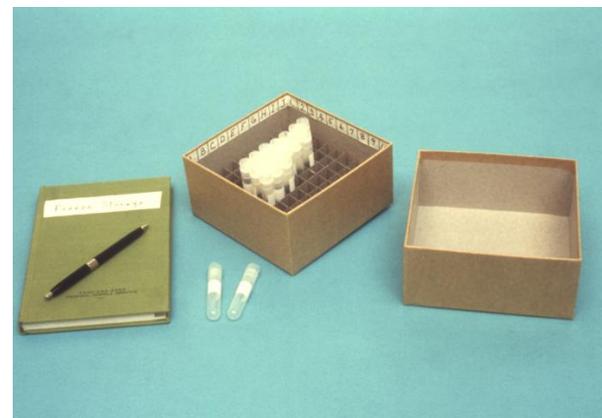
- Register for each select agent or toxin it possesses, uses, or transfers
- Designate a Responsible Official (RO)
- Receive government approval of entity (owners), RO, & individuals who need access to select agents
 - Based on DOJ check of electronic databases (“Security Risk Assessment” = SRA)
- Allow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



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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



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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 LD₅₀ <100 ng/kg body weight
- Requests reviewed by an Intragovernmental Select Agent and Toxin Technical Advisory Committee



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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:
 - Biosafety in Microbiological and Biomedical Laboratories, Fifth edition, February 2007.
- For toxins:
 - 29 CFR 1910.1450 Occupational Exposure to Hazardous Chemicals in Laboratories.
 - 29 CFR 1910.1200 Hazard Communication (for laboratories distributing 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.

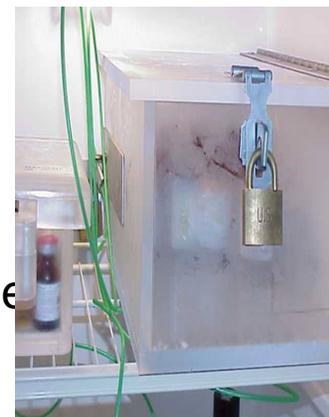


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Security

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



Security

42 CFR 73.11, 9 CFR 121.11, 7 CFR 331.11

- **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



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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



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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)

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



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APHIS/CDC Forms



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APHIS / CDC Forms

APHIS/CDC Form #	Title of Form
1	Application for Laboratory Registration for Possession, Use, and Transfer of Select Agents and Toxins
2	Report of Transfer of Select Agents and Toxins
3	Report of Theft, Loss, or Release of Select Agents and Toxins
4	Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory
5	Request for Exemption of Select Agents and Toxins for Public Health or Agricultural Emergency or Investigational/ Experimental Product



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For More Information

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



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