

Clinical Labs and Select Agents

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**The information in this presentation
referring to select agents is for
instructional purposes only.**

**For Specific Questions
And Guidance Please Refer to:**

**CDC Select Agent Program
www.cdc.gov/od/sap**

Federal Regulations 42 CFR Part 73

**Possession, Use, and Transfer of
Select Agents and Toxins, Final Rule**

Prior to Select Agent Regulation

- There were no laws governing movement of human pathogens (except import and export permits)
- First Select Agent regulation (1995) covered only the transfer of agents

42 CFR 73

- **March 18, 2005: Possession, Use, and Transfer of Select Agents and Toxins; Final Rule (HHS)**
- **Covers agents that have the potential to pose severe threat to public health and safety, to animal health, or to animal products**

Select Agents

- **Three government agencies**
 - HHS (CDC)
 - USDA (APHIS)
 - DoJ (FBI)
- **Three regulations**
 - 42 CFR 73 (HHS human pathogens)

Select Agents

- 9 CFR 121 (USDA animal pathogens)
- 7 CFR 331 (USDA plant pathogens)
- **Some agents are on both HHS and USDA lists-Overlap Agents**

42 CFR 73

- Unless exempted under 73.5, 73.6, or 9 CFR 121.6, an individual or entity shall not possess, use, or transfer any HHS or overlap select agent or toxin without a certificate of registration issued by the HHS Secretary

42 CFR 73

- Any laboratory intending to confirm the identity of any SA and/or maintain a stock of viable SA must register with Select Agent Program (SAP) at CDC or USDA

42 CFR 73

- Registration
- Responsible Official
- Restricting access; security risk assessments
- Security
- Biosafety
- Incident response

42 CFR 73

- Training
- Transfers
- Records
- Inspections
- Notification of theft, loss or release
- Civil money penalties

Clinical Laboratories Do Not Need to Register with the Select Agent Program:

- Provided Isolates Are:
 - Suspected isolates of SA are forwarded to a registered LRN lab for confirmatory identification

Clinical Laboratories Do Not Need to Register with the Select Agent Program:

- Patient specimens, isolates and/or stock cultures are not maintained - destroyed or transferred within 7 days after confirmation (90 days for PT)

Select Agents

- Any laboratory identifying SA (presumptive or confirmed) must secure the specimen, isolate or toxin against theft, loss or release from identification to transfer or destruction

Select Agents

- Theft
 - Removal by unauthorized personnel
- Loss
 - Unaccounted absence
- Release
 - Outside of primary containment
- Occupational exposure

Reporting and Documentation

- Form 2: Transfer of SA-prior approval
- Form 3: Theft, loss, or release
 - Includes occupational exposure
 - Report immediately (same day) by phone, fax, email for some agents
 - Notify local law enforcement
 - File form within 7 days

Reporting and Documentation

- Form 4: Confirmed identification of SA
 - In initial receiving lab and/or subsequent reference lab
 - PT isolates
 - Final disposition

Consult with Your State Public Health Laboratory About Select Agent

- Handling
- Destroying
- Transporting
- Documentation

National Select Agent Registry

Resources

- Home
- Login
- Help
- FAQ
- Program Overview
- Regulations
- Training

Frequently Visited Links

- Login to NSAR
- Download forms
- View Current Inquiries

Info Board

January 22, 2008

The Centers for Disease Control and Prevention (CDC) and Animal and Plant Health Inspection Service (APHIS) Select Agent Programs have posted information relating to theft, loss and release (Form 3) reporting requirements of the select agent regulations.

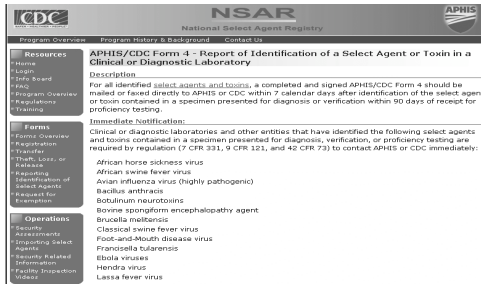
November 1, 2007

Regulation

- Select Agent Regulations
- Other Legislation
- Select Agent / Toxin List
- Normative Town Meetings
- Guidelines
- NPI Guidelines

www.selectagents.gov

National Select Agent Registry



The screenshot shows the 'Resources' section of the National Select Agent Registry website. It includes a navigation menu with links for 'Program Overview', 'Program History & Background', and 'Contact Us'. The main content area is titled 'APHS/CDC Form 4 - Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory'. It contains a 'Description' section with instructions on how to complete and submit the form, and an 'Immediate Notification' section listing select agents and toxins that require immediate reporting to APHIS or CDC. The list includes African horse sickness virus, African swine fever virus, Avian influenza virus (highly pathogenic), Bacillus anthracis, Botulinum neurotoxins, Bovine spongiform encephalopathy agent, Classical swine fever virus, Foot-and-mouth disease virus, Francisella tularensis, Ebola viruses, Hendra virus, and Lassa fever virus.

Resources

APHS/CDC Form 4 - Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory

Description:

For all identified select agents and toxins, a completed and signed APHIS/CDC Form 4 should be mailed or faxed directly to APHIS or CDC within 7 calendar days after identification of the select agent or toxin contained in a specimen presented for diagnosis or verification within 90 days of receipt for proficiency testing.

Immediate Notification:

Clinical or diagnostic laboratories and other entities that have identified the following select agents and toxins contained in a specimen presented for diagnosis, verification, or proficiency testing are required by regulation (7 CFR 331, 9 CFR 121, and 42 CFR 73) to contact APHIS or CDC immediately:

- African horse sickness virus
- African swine fever virus
- Avian influenza virus (highly pathogenic)
- Bacillus anthracis
- Botulinum neurotoxins
- Bovine spongiform encephalopathy agent
- Classical swine fever virus
- Foot-and-mouth disease virus
- Francisella tularensis
- Ebola viruses
- Hendra virus
- Lassa fever virus

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