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

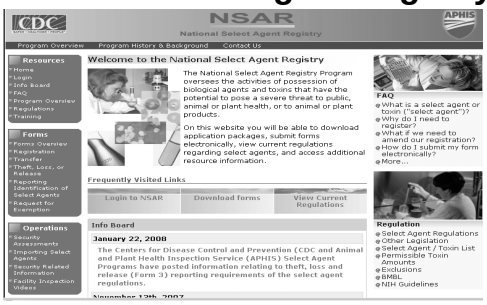
Reporting and Documentation

- 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

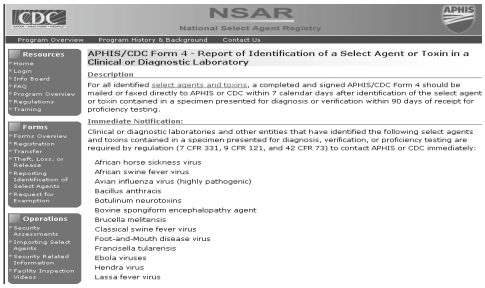
- Handling
- Destroying
- Transporting
- Documentation

National Select Agent Registry



www.selectagents.gov

National Select Agent Registry



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