



Tier 1 Regulation Update – New Select Agent Rules

Wanda Reiter Kintz, Ph.D.

Emergency Preparedness Coordinator

State Hygienic Laboratory at the University of Iowa

wanda-reiterkintz@uiowa.edu

319-335-4463



Webinar Objectives

- At the conclusion of the webinar, participants will be able to:
 - Understand the basics of the new Tier 1 regulations
 - Know which select agents will have Tier 1 status
 - Explain how the select agent regulations will impact the Laboratory Response Network
 - Understand the advantages and disadvantages of becoming an agency with Tier 1 status



New Select Agent Regulations

- Changes to the select agent list
- Enhanced personnel suitability assessments
- Increased physical and cyber-security requirements
- Deadline to meet these new requirements in April 3, 2013



Tier 1 Select Agents and Toxins

- Bacteria – *Francisella tularensis*, *Bacillus anthracis*, *Burkholderia mallei*, and *Burkholderia pseudomallei*
- Viruses – Ebola, Marburg, Variola major, Variola minor, Foot and Mouth disease, and Rinderpest virus
- Toxins – Neurotoxin-producing strains of *Clostridium botulinum*



Tier 1 Regulations

- A laboratory that is not registered as a Tier 1 agency will have to either destroy or transfer their stock of Tier 1 select agents.
- The laboratory will be able to test for select agents, but if a strain is found, then they must destroy or transfer the sample within a seven day period.



Suitability Assessments

- Pre-Access Suitability Assessment
- On-going Suitability Assessment
- Designed to reduce the risk of select agents or toxins through “insider” actions/threats



Examples of “Insider Threats”

- An individual who infiltrates a research facility in order to steal or release select agents or toxins
- An individual with access to select agents or toxins who is coerced or manipulated into providing access or expertise to unauthorized individuals
- An individual whose job duties require legitimate access to select agents or toxins but who may misuse or release select agents or toxins due to a significant life-changing event

Reference: Guidance for Suitability Assessments , 7 CFR Part 331, 9 CFR Part 121, 42 CFR, Part 73, Centers for Disease Control and Prevention



Responsibilities of Individuals

- Monitor their own suitability and the suitability of their colleagues
- Follow institutional policies and procedures for the safe and secure use of Tier 1 select agents and toxins
- Participate in and understand training associated with the suitability assessment program
- Report any situations that may affect safety and/or security

Reference: Guidance for Suitability Assessments , 7 CFR Part 331, 9 CFR Part 121, 42 CFR, Part 73, Centers for Disease Control and Prevention



Responsibilities of Individuals (continued)

- Report any situations that may affect safety and/or security
- Respect the privacy and confidentiality of colleagues
- Support an environment where direct or indirect retribution is not tolerated

Reference: Guidance for Suitability Assessments , 7 CFR Part 331, 9 CFR Part 121, 42 CFR, Part 73, Centers for Disease Control and Prevention



Examples of Reportable Behaviors

- Significant increase in distraction or mistakes
- Sending inappropriate emails
- Unexplained absences
- Stated or implied threats to colleagues
- Signs of alcohol or drug abuse
- Performing unauthorized work during off-hours
- Acts of vandalism or property damage
- Significant changes in behavior, such as unjustified anger

Reference: Security Guidance for Select Agent or Toxin Facilities , 7 CFR Part 331, 9 CFR Part 121, 42 CFR, Part 73, Centers for Disease Control and Prevention



Physical Security Requirements

- A minimum of three security barriers must be in place where each security barrier adds to the delay in reaching areas where select agents or toxins are used or stored.
- A security barrier is a physical structure that is designed to prevent access by unauthorized persons

Reference: Security Guidance for Select Agent or Toxin Facilities , 7 CFR Part 331, 9 CFR Part 121, 42 CFR, Part 73, Centers for Disease Control and Prevention



Physical Security Requirements (continued)

- All areas that reasonably afford access to the registered space must be protected by an intrusion detection system (IDS)
- An intrusion detection system consists of a sensor device which triggers an alarm when a security breach occurs and notifies a response force who is capable of stopping the threat

Reference: Security Guidance for Select Agent or Toxin Facilities , 7 CFR Part 331, 9 CFR Part 121, 42 CFR, Part 73, Centers for Disease Control and Prevention



Physical Security Requirements (continued)

- The response time must be determined and the description of the response force must be described in the security plan.
- The response time is the elapsed time, under normal conditions, from the time of notification to the arrival time of the response force
- Reasonable target = 15 minutes

Reference: Security Guidance for Select Agent or Toxin Facilities , 7 CFR Part 331, 9 CFR Part 121, 42 CFR, Part 73, Centers for Disease Control and Prevention



Information Security

- Information Security – the protection of information and information systems from unauthorized access, use, disclosure, disruption, modification, recording, or destruction of data
- Confidentiality, integrity, and availability

Reference: Information Systems Security Control Guidance Document , 7 CFR Part 331, 9 CFR Part 121, 42 CFR, Part 73, Centers for Disease Control and Prevention



Information Technology

- IT security should focus on three areas:
 - Network security
 - Hardware/data storage
 - Physical security

Reference: Information Systems Security Control Guidance Document , 7 CFR Part 331, 9 CFR Part 121, 42 CFR, Part 73, Centers for Disease Control and Prevention



Rationale for Tier 1 Registration

- Identification, additional characterization, and surveillance of suspected agents of bioterrorism
- Training of response personnel
- Validation and verification of new assays and protocols
- Difficulty in transferring or destroying samples in a large-scale event



Rationale for Tier 1 Registration (continued)

- Possible impacts of future preparedness funding
- Selection for special projects and exercises
- Credibility when advising sentinel laboratories and other partner agencies



The State Hygienic Laboratory's Approach to Tier 1 Registration

- Development of a Select Agent Regulation Team
- Members of the Team Include:
 - Associate Directors
 - Safety Officer
 - Biosecurity Officer
 - Human Resources Director (SHL)
 - Emergency Preparedness Coordinator
 - Information Technology Representative
 - Responsible Official and Alternate Responsible Official (University of Iowa)



State Hygienic Laboratory

- Modifications to the registered space, including intrusion detection systems
- Modifications to the operational and security plans
- Development of a personnel reliability document
- CT/FERN lab move
- IT enhancements – stand-alone server



Biological Laboratory Response Network

Federal Labs: Focus on national/global health

Information on national level

Develop new tests, offer rarely performed tests



Public Health Labs: Focus on community

Information to public health officials

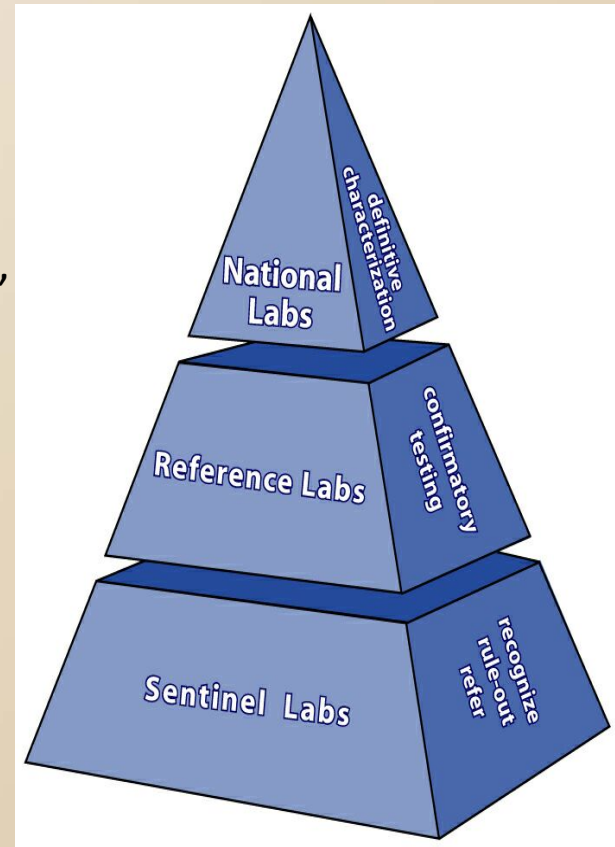
Some diagnostic testing, screening, strain typing, emerging diseases

Environmental testing

Clinical Labs: Focus on the patient

Information to physicians

Specialize in diagnostic testing, offer tests to meet needs of facility





Tier 1 Regulations and the LRN

- Extra requirements are burdensome
- Significant personnel time and cost
- Many LRN reference laboratories will not pursue Tier 1 registration



For More Information:

www.selectagents.gov





Thank You for Your Attention!

Questions?

