Tier 1 Regulation Update – New Select Agent Rules

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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

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

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

Examples of Reportable Behaviors

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

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.

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

• 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

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

Information Technology

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

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?