

EMERGENCY PREPAREDNESS BRANCH UPDATE

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Select Agent Program

- New Select Agent Rule went into effect October 2012
- Some agents removed from the list
- Some agents moved to Tier 1 Designation
 - “Cook or Keep”
 - Enhancements
- Compliance by April 2013

Select Agent Program

- **Impact of changes on the LRN Reference and National Laboratories**
 - Wild type strains of *Bacillus anthracis*, *Burkholderia mallei* and *pseudomallei*, *Yersinia pestis*, *Francisella tularensis* and botulinum neurotoxin producing species of *Clostridium* are all included in the Tier 1 designation.
 - Control strains provided by the LRN program office, including *Bacillus anthracis* Pasteur strain, are NOT listed as Tier 1 agents. **Thus, LRN member laboratories are NOT required to be designated as Tier 1 entities.**

LRN Control Strains

QA/QC Strains	Tier 1	Select Agent Status
<i>Bacillus anthracis</i> Pasteur	No	Regulated
<i>Bacillus anthracis</i> Sterne	No	Excluded
<i>Brucella suis</i> 1330 positive control strain	No	Regulated
<i>Brucella melitensis</i> 16 M strain	No	Regulated
<i>Francisella tularensis</i> LVS	No	Excluded
<i>Yersinia pestis</i> A1122	No	Excluded

Designation of Tier 1 agents

Select Agents and Toxins	Overlap Select Agents and Toxins:
1. Ebola virus	1. Bacillus anthracis
2. Francisella tularensis	2. Burkholderia mallei
3. Marburg virus	3. Burkholderia pseudomallei
4. Variola major virus	
5. Variola minor virus	
6. Yersinia pestis	
7. Botulinum neurotoxin	
8. Botulinum neurotoxin producing species of Clostridium	

Select Agent Program

- If your laboratory plans to utilize/store Pasteur strain of *B. anthracis* as well as *Brucella suis* and *B. melitensis* for LRN confirmatory testing, you will need to maintain your Select Agent registration.
- Also, for laboratories that are funded via the CDC Public Health Emergency Preparedness Cooperative Agreement (PHEP), please be aware that there is a requirement to maintain Select Agent registration.
- **LRN Labs will need to maintain SAP status**

Tier 1 Designation

- **LRN member laboratories have the option of being a Tier 1 laboratory if they choose, but this is not a requirement of LRN membership.**
 - For those laboratories which opt to register as a Tier 1 entity, there are additional security requirements including pre-access and ongoing suitability assessments
 - Implementation of a specific occupational health program for individuals with access to Tier 1 agents with the requirement that individuals with access to Tier 1 be enrolled in this program
 - Additional incident response policies
 - Additional annual training on how to identify and report suspicious behavior. More specific information on these requirements for Tier 1 agents is included in the final rule and associated guidance documents provided by the Select Agent Program at <http://www.selectagents.gov/>.

Tier 1 Requirements

- Training
 - Entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings on how to identify and report suspicious behaviors
- Occupational Health Program (OHP)
 - Individuals with access to Tier 1 select agents and toxins must be enrolled in the occupational health program.

Tier 1 Requirements

- An entity with Tier 1 BSAT should consider providing workers with access to Tier 1 BSAT a card that:
 - lists the select agents and toxins that he/she works with,
 - lists emergency phone numbers for
 - personal contacts
 - primary care physicians
 - occupational health physicians
 - preferred or designated hospital
 - the entity's Responsible Official.

Tier 1 Requirements

- Personal reliability program required for labs that handle Tier 1 agents
 - Formal pre-access screening program
 - Ongoing monitoring (Self and peer reporting that is intended to provide reporting avenues for staff members who have concerns about suspicious behavior by other lab workers)
- Increased physical security will also be required for labs working with Tier 1 agents. For example, "A Tier 1 entity needs to have three demonstrable barriers between the public and regulated material."
 - At least one barrier must have an intrusion detection system, something that would tell a security function that an unauthorized person is trying to get in.

Preservation of Stocks

- The laboratories who decide to forgo Tier 1 registration must destroy the Tier 1 Select Agents in their possession by December 4, 2012.
- The CDC Subject Matter Experts (SME) for a subset of these agents, are asking for the transfer of selected isolates into their inventory for the purpose of validation of current and future LRN assays, for documenting strain types naturally present in the US and to advance understanding of the epidemiology of these organisms.
 - *B. anthracis*
 - *Burkholderia mallei* and *pseudomallei*
 - *Y. pestis*
 - *F. tularensis*
 - Botulinum neurotoxin producing species of *C. botulinum*.
- If your laboratory is willing to transfer a subset of your Select Agent inventory, please send a list of the Tier 1 agents in your laboratory's inventory to the LRN Help Desk by November 9, 2012.

DSHS Inventory

Agent	Number of samples
<i>Brucella abortus</i>	3
<i>Brucella melitensis</i>	47
<i>Brucella suis</i>	9
<i>Clostridium botulinum</i> (all types)	44
<i>Francisella tularensis</i>	3
<i>Bacillus anthracis</i>	1
<i>Yersinia pestis</i>	1
<i>Burkholderia pseudomallei</i>	1

Tier 1 Regulatory Impact

- Cost of Background checks may increase 67% due to frequency increase from 5 to 3 years
- Cost of information security may increase approx. \$5500
- Estimated cost for pre-access suitability and occupational health programs: \$9600-15,100 per entity
- Increased amount of time required for monitoring, maintaining, and complying with the regulations...
Priceless

Training Schedule

- Conventional Methods Training
 - January 14-18, 2013
- BSL3 Training + Packaging and Shipping
 - May 20-24, 2013
- TxLRN Conference (Bandera)
 - January 28-Feb 1