

Summary and Utilization of Select Agent Forms by LRN Sentinel Level Laboratories

LRN Sentinel Level Laboratories are not required to register or be certified with the Select Agent Rule but are required to be compliant under specific conditions. An area of confusion for Sentinel Level Laboratories has been the completion of specific forms related to select agents. The purpose of this document is to provide information on the utilization of Forms 2, 3, and 4A by the Sentinel Level Laboratory, specifically the conditions under which such forms may require completion as directed by the LRN Reference Laboratory or following authorization by the Centers for Disease Control and Prevention (CDC). Additional information regarding the aforementioned forms can be obtained at: <http://www.selectagents.gov>.

Form 2: Request to Transfer Select Agents and Toxins

Sentinel (Diagnostic) Laboratories are not required to be registered with- or certified to handle select agents and, with few exceptions, are exempt from the need to comply with the Select Agent Rule. For example, the Rule Out or Refer responsibility of the Sentinel Level Laboratory applies to specimens or proficiency samples that are suspected of containing a select agent based on the results obtained following the application of the LRN Sentinel Level Testing Protocols. If the isolate cannot be “ruled out” it is then referred to the nearest LRN Reference Laboratory (usually the State Health Department) for confirmatory identification. Unless directed otherwise, within 7 calendar days following notification that the isolate submitted to the LRN Reference is a select agent, the agent/specimen must be destroyed on-site by a recognized sterilization (autoclave) or inactivation process. Completion of Form 2 would not normally be required of Sentinel Level Laboratories however, be advised that the form does contain an option for “nonregistered entities” under Section B, Sender Information. It would be an unusual circumstance for a nonregistered laboratory (Sentinel Laboratory) to request transfer of a select agent but if the Sentinel Laboratory’s autoclave or other form of destruction (chemical inactivation) is nonfunctional, Form 2 would be initiated to facilitate the transfer of the agent. Form 2 can be found and downloaded from <http://www.selectagents.gov/TransferForm.html>. See Paragraph 331.5, Exemptions, for additional information.

Form 3: Report of Theft, Loss, or Release of Select Agents and Toxins

All laboratories must complete Form 3 if there is a theft, loss or release of a select agent or toxin. The CDC Select Agent program considers a release any activity with a select agent outside of the biosafety cabinet. This form is also used to capture any laboratory exposures. Therefore, if a Sentinel Laboratory knowingly has a select agent on site (confirmatory testing conducted by the LRN Reference laboratory), Form 3 must be sent to the CDC within 7 days after the discovery of a theft, loss, or release. For theft or loss, the laboratory must also notify the appropriate local, state, or federal law enforcement agencies. For a release only, the laboratory should notify the local or state health agencies.

Summary: Form 3 is initiated by the laboratory that knowingly harbors a confirmed select agent in the event of a theft, loss or release. For the CAP Laboratory Preparedness Exercise (LPX), the

Sentinel Laboratory **DOES NOT** complete Form 3 because the challenge organisms are **exempt** from the Select Agent Regulations.

Form 3 can be found at <http://www.selectagents.gov/TLRForm.html>.

Form 4: Reporting the Identification of a Select Agent or Toxin from a Clinical/ Diagnostic Specimen.

There are four parts to Form 4. After a select agent has been confirmed by the LRN Reference Laboratory, it is required to complete Parts A and B and send to the CDC. The CDC then calls the Reference laboratory and provides a Case Identification Number for the Sentinel Laboratory to use. The Sentinel Laboratory completes Parts C and D and Form 3 if there was an occupational exposure. For the CAP Laboratory Preparedness Exercise (LPX), the Sentinel Laboratory **DOES NOT** complete Form 4 because the challenge organisms are **exempt** from the Select Agent Regulations.

Summary: The Sentinel Laboratory is required to complete Form 4A **only** if notified by the LRN Reference laboratory following its having been contacted and required by the CDC.

Form 4 can be found here <http://www.selectagents.gov/CDForm.html>.