

Operational/Procedural Requirements for Possession and Use of Exempt Quantities of CDC/APHIS Select Agent Toxins

Each Principal Investigator (PI) shall implement the following institutional requirements for procurement, possession, storage, use, transfer, disposal, training and security of exempt quantities of Centers for Disease Control and Prevention (CDC) and Animal and Plant Health Inspection Service (APHIS) Select Agent (SA) Toxins. These requirements have been established to assure the safe handling, use, and storage of exempt quantity SA Toxins; to effectively track and assure the security of the regulated toxins; and meet or exceed compliance with federal, state, and local rules, regulations, and laws.

While possession and use of exempt quantities of SA Toxins does not require registration with CDC or APHIS, the Texas Tech University Health Sciences Center has established these requirements due to the potentially hazardous nature of the toxins and to protect against the possibility of aggregating dangerous amounts of toxins to do harm to persons or property.

1. Procurement:

- a. All procurement requests for exempt quantity SA Toxins must be made through the TTUHSC TechBuy system.
 - (i) Purchase requisitions must indicate purchase of exempt quantity SA Toxins.
 - (ii) Purchase requisitions shall be routed through Safety Services for electronic approval.
 - (iii) Documentation of current inventory record (Attachment C of this OP) must accompany all procurement requests.
- b. **Procurement card purchasing of exempt quantity SA Toxins is forbidden.**
- c. Institutional Biohazards Committee (IBC) protocol approval and registration of SA Toxins must be obtained prior to purchase.

2. Possession Requirements for Exempt Quantities of Select Agent Toxins:

- a. **Principal Investigator (PI).** The PI is responsible for ensuring the following:
 - (i) **Standard Operating Procedures (SOPs).** The PI must prepare written SOP's for toxin-involved research processes.
 - (ii) **Personnel Training.** The PI must provide initial laboratory-specific safety training to staff on toxin-involved processes, with updates as necessary. Documentation of training shall be maintained for at least one (1) year following completion of the toxin-involved research. Training topics should include, as a minimum:
 - (A) Toxin-associated hazards;
 - (B) Engineering controls used to minimize exposure (i.e., fume hood use);
 - (C) Personal protective equipment (PPE) to be used when handling toxin;
 - (D) Safe handling and storage precautions;
 - (E) Proper decontamination and disposal procedures; and
 - (F) Administrative requirements (recordkeeping, inventory, security).

- (iii) Personal Protective Equipment (PPE): Appropriate personal protective equipment shall be provided (i.e., gloves, safety goggles, lab coat or disposable lab coat).
NOTE: If respirators are necessary, contact Safety Services for necessary respirator training and compliance documentation.
- (iv) Engineering Controls: Proper use of fume hoods, Biosafety cabinets, or glove boxes with toxin-involved procedures.
- (v) Inactivation: Use accepted inactivation procedures specific to the SA Toxin prior to disposal of remaining stock and/or empty containers.
- (vi) Disposal: Following inactivation, dispose of residual wastes (liquids/solids) as follows:
 - (A) Liquids: Collect inactivated materials in a non-leaking container constructed of chemically compatible material, and manage as hazardous waste per TTUHSC Hazardous Waste Management procedures. This information may be found in the TTUHSC Regulated Waste Manual.
 - (B) Stock Vials and other materials: Deface container labeling; collect in non-leaking container and manage as hazardous waste.
- (vii) Storage: All SA Toxins and associated contaminated items must be:
 - (A) Stored with compatible materials within secondary containment; and
 - (B) Provided two layers of physical security (i.e., toxin secured within a locked freezer or secured within a permanently affixed lockbox) within a locked laboratory.
 - (C) May not be stored in common use, shared, or “inner” lab areas.
- (viii) List of PI-Approved Users: A list of PI-approved toxin users (including those having access to toxin materials) shall be maintained. The PI must keep track of who uses the stock, and who has access to the storage area. Before becoming an Approved User, the PI must assure that each person has received training as indicated in section 2.a.(ii) above.
 - (ix) Inventory Maintenance: Inventory of SA Toxins (like other laboratory hazardous materials) must be kept current.
- (x) Documented Security Inspections:
 - (A) Self-Inspections must be performed initially and at least quarterly thereafter. Documentation of inspections must be maintained for at least one (1) year following completion of the toxin-involved research. Inspection criteria should include the following minimum requirements:
 - (1) Review of Approved Users List to verify authorized access to toxins;
 - (2) Verification of appropriate labeling, storage, secondary containment, and security measures; and
 - (3) Comparison of physical inventory with what is accounted for on utilization records.

Attachment B, “Exempt Quantity Select Agent Laboratory Self-Inspection Checklist” may be used as the basis to conduct and document the self-inspection.

- (B) In addition, Safety Services will conduct periodic announced and unannounced laboratory audits to review compliance with institutional requirements on possession of exempt quantities of select agent toxins.

3. Inventory Methodology:

Each PI using SA Toxins shall implement inventory methodology including the following:

- a. Each PI shall designate a person responsible for maintaining a select agent utilization log book and ensuring its accuracy.
- b. The log book should reflect the following for each SA Toxin:
 - (i) Beginning balance;
 - (ii) IBC protocol number;
 - (iii) Date of receipt;
 - (iv) Date container was opened;
 - (v) Expiration date on container (if present); and
 - (iv) Any dispensing, aliquot, and distribution information necessary to allow monitoring of current balances.
- c. Each log book entry should contain the following:
 - (i) Date;
 - (ii) Personnel name
 - (iii) Quantity
 - (iv) Description of utilization (ex: used, transferred, and/or disposed.); and
 - (v) Personnel signature

Attachment C, “Select Agent Inventory Record” may be used as the basis for inventory documentation.
- d. A routine quarterly inventory of all SA Toxins should be conducted to verify the accuracy of log book entries.
- e. Procedures should be established for reporting and investigating inventory discrepancies and reconciling differences.

4. Transfer and Disposal

- a. PI’s shall use appropriate IBC amendment forms to keep IBC records up-to-date.

- b. If SA Toxins are stored in a separate area from the work area, the following transfer guidelines should be observed when moving material from storage areas to work areas, and return:
 - (i) SA Toxins will be transported in a container providing secondary containment with proper labeling;
 - (ii) SA Toxins shall not be transported in personal vehicles;
 - (iii) Only authorized personnel may be involved in the transfer of SA Toxins.
- c. Contaminated or possibly contaminated materials and equipment shall be decontaminated prior to transfer.
- d. PI shall notify the IBC and Safety Services of any transfer of SA Toxins to another PI.
- e. All SA Toxins must be inactivated prior to disposal. Contact Safety Services for assistance.

5. Security:

- a. **All laboratory doors must remain locked when authorized laboratory personnel are not present in the lab.** This includes nights, weekends, holidays, and daytime hours when the lab is empty even for a short time.
- b. Laboratory personnel shall wear visible TTUHSC ID badges bearing their photo, name, and department.
- c. An authorized personnel list shall be posted inside each SA Toxin laboratory.
- d. SA Toxin laboratory doors shall be prominently marked as “Authorized Personnel Only.”
- e. Security background checks shall be completed before personnel are hired or are allowed to work in the SA Toxin laboratory.
- f. All personnel who work with SA Toxins shall be appropriately trained and held accountable for the proper use and storage of SA Toxins.
- g. SA Toxins shall be stored behind at least two layers of security, i.e., locked laboratory doors and a locked refrigerator or permanently affixed lockbox.
- h. SA Toxin containers shall be appropriately labeled.
- i. SA Toxin storage containers shall remain locked when not in direct view of authorized laboratory workers.
- j. Housekeeping and maintenance staff will work in the SA Toxin laboratories only during hours when authorized laboratory personnel are present.
- k. All entries into the SA Toxin laboratory by visitors, maintenance workers, housekeepers, or others needing one-time or occasional entry should be recorded by signature in a log book.
 - (i) Attachment D, “Select Agent Lab Visitor Log” may be used as the basis for visitor documentation.