

SU Requirements for Possession of Exempt Quantities of CDC Select Agent Toxins

A) Purpose of Document:

This document outlines Stanford University's institutional requirements on possession of exempt quantities of Center for Disease Control (CDC) Select Agent (SA) Toxins. (To review the federal legislation on Select Agents (42 CFR Part 73), go to <http://www.cdc.gov/od/sap/docs/42cfr73.pdf>.) These requirements have been established to ensure:

- safe laboratory handling, use, and storage procedures,
- effective tracking and security of the regulated toxins, and
- compliance with federal regulations

B) Exempt Quantities of CDC Select Agent Toxins:

Per the federal regulations each Principle Investigator (PI) may possess a specified amount of toxin without triggering CDC registration and other stringent requirements. Below is the list of SA Toxins and the allowable maximum exempt quantities (per PI).

<u>Toxin</u>	<u>Max. allowable per PI for exemption</u>
Abrin	100 mg
Botulinum neurotoxins	0.5 mg
<i>Clostridium perfringens</i> epsilon toxin	100 mg
Conotoxins	100 mg
Diacetoxyscirpenol	1000 mg
Ricin	100 mg
Saxitoxin	100 mg
Shigatoxin and Shiga-like ribosome inactivating proteins	100 mg
Staphylococcal enterotoxins	5 mg
Tetrodotoxin	100 mg
T- 2 toxin	1000 mg

Additionally, the following toxins are exempt:

1. Any agent or toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
2. Non-viable select agent organisms or nonfunctional toxins

It is important to ensure that the total amount of toxin per PI in a laboratory is maintained below these limits at all times for exemption from registration and the attendant restrictive requirements. Due to the severe penalties associated with non-compliance with the SA rules, it is imperative that each laboratory using and storing toxins maintains current inventory information for these substances. **(Failure to register a Select Agent is now a criminal offense, punishable by up to five years in prison and/or \$500,000 in fines. (Public Health Security & Preparedness Response Act of 2002, s. 231(c)).**

C) SU Requirements for Possession of Exempt Quantities of CDC Select Agent Toxins

The Principle Investigator is responsible for ensuring the following:

- 1) **Standard Operating Procedures (SOPs):** Prepare written SOPs for toxin-involved research processes.
- 2) **Personnel Training:** Provide initial lab-specific safety training to staff on toxin-involved processes, with updates as necessary. Ensure documented training is maintained for at least one year (per Cal-OSHA 8CCR 3203). Training topics should include:
 - toxin-associated hazards
 - engineering controls used to minimize exposure (i.e., fume hood use)
 - personal protective equipment to be used when handling toxin (PPE)
 - safe handling and storage

- proper decontamination and disposal
 - administrative requirements (recordkeeping, inventory, security).
- 3) **Proper PPE:** Appropriate personal protection is to be provided (i.e., gloves, safety goggles, lab coat or disposable lab coat). NOTE: If respirators are necessary, contact EH&S at 725-0448 for necessary respirator use approval and compliance documentation.
 - 4) **Engineering Controls:** Proper use of fume hood, biosafety cabinet or glove box with toxin-associated procedures.
 - 5) **Inactivation:** Use accepted inactivation procedures described on the EH&S Biosafety website ([click here](#)) prior to disposal of remaining stock and/or empty containers.
 - 6) **Disposal:** After inactivation, dispose of residual wastes (liquids/ solids) as follows:
 - **Liquids*:** Collect inactivated materials in a non-leaking container constructed of compatible material, and manage as hazardous waste per Stanford Hazardous Waste Management procedures. ([click here](#)).
 - **Stock Vials and other materials:** Deface container labeling. Collect in non-leaking container and manage as hazardous waste (see above link for proper disposal).

** NOTE: Such inactivated toxin liquid waste shall be managed as hazardous waste unless the material is between 5.5-11.0 pH AND the final NaOCl concentration is less than 1% (wt/wt).*
 - 7) **Storage/Security:** Items must be:
 - Stored with compatible materials within secondary containment; AND
 - Provided one layer of physical security (i.e., toxin secured within a locked freezer, or secured within a permanently fixed lockbox)
 - 8) **List of PI-Approved Users:** A documented list to be maintained of PI-approved toxin users (including those having access to toxin materials). The lab must keep track of who uses the stock (and who has access to the freezer), but it is not necessary to record each use. Before becoming an Approved User, the PI must ensure that each person has received training under section C (2) above.
 - 9) **Inventory Maintenance:** Inventory of toxins (like other laboratory hazardous materials) **must be kept current in the on-line Stanford Chemical Inventory Maintenance System (SCIMS)**. To help PIs ensure inadvertent breaching of exempt quantity levels, inventories are to be promptly updated after every container of CDC toxin is:
 - acquired (by purchase/ intra-campus transfer)
 - depleted (by consumption/ intra-campus transfer); OR
 - inactivated
 - 10) **Documented Security Inspection:**
 - a. Self-Inspections: Are to be conducted using the laboratory safety inspection checklist at:

<http://www.stanford.edu/dept/EHS/prod/training/checklist/labcheck.pdf>

 Inspections must be performed initially and at least quarterly thereafter; documentation of inspections must be kept for one year or the duration of SA possession, whichever is longer. Inspection items include:
 - Review of Approved Users List to verify authorized access to toxins.
 - Verification of appropriate labeling, storage, secondary containment, security measures
 - Comparison of physical inventory with what is accounted for on SCIMS.
 - b. In addition, EH&S will provide periodic laboratory visits to review compliance with institutional requirements on possession of select agent toxins.

D) Possession of Select Agent Toxins Above Exempt Quantities:

- For possession of select agent toxin quantities above exempt quantities, prior approval from the Vice Provost and Dean of Research and Graduate Policy must be obtained and registration by the Centers for Disease Control approved.

For any questions regarding CDC Select Agent possession at Stanford University, contact Environmental Health and Safety- Biosafety Program at 725-1473.