



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

Operating Policy and Procedure

HSC OP: 73.12, **Possession and Use of Exempt Quantities of CDC Select Agent Toxins**

PURPOSE: The purpose of this Health Sciences Center Operating Policy and Procedure (HSC OP) is to establish 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:

1. Safe laboratory handling, use, and storage procedures for exempt quantity SA Toxins;
2. Effective tracking and security of the regulated toxins; and
3. Compliance with federal, state, and local rules, regulations, and laws.

REVIEW: This HSC OP will be reviewed on June 15 of every odd-numbered year (ONY) by the Director of Safety Services, with recommendations for revisions forwarded to the Senior Vice President for Research and Innovation (SVPRI) by July 30.

POLICY/PROCEDURE

1. **Compliance with federal, state, and local laws.**

TTUHSC adopts and continues the policy that all research involving the utilization of exempt quantities of CDC or APHIS Select Agent Toxins conducted at TTUHSC shall be in accordance with applicable federal, state, and local rules, regulations, and laws, including, but not limited to 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331.

2. **Exempt Quantities of Select Agent Toxins:**

- a. Each Principal Investigator (PI) may possess no more than a specified amount of Select Agent Toxin(s) exempt from CDC/APHIS registration and/or other requirements. Table 1 lists the maximum allowable exempt quantities for certain SA Toxins.
- b. In addition, the following agents or toxins are exempt:
 - (i) 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; or
 - (ii) Non-viable select agent organisms or nonfunctional toxins
- c. **The total aggregate amount of any exempt quantity SA Toxin(s) possessed by any PI must be maintained at or below the Table 1 limits at all times to continue exempt status.**
- d. Procurement, possession, storage, use, transfer, disposal, training, and security of exempt quantities of SA Toxins must meet the requirements of Attachment A (which references Attachments B, C and D), "Operational/Procedural Requirements for Possession and Use of Exempt Quantities of CDC/ APHIS Select Agent Toxins" of this policy.

- e. Failure to maintain total aggregate amounts at or below the Table 1 limits will require CDC/APHIS registration of the SA Toxin(s). Any PI who willfully exceeds the Table 1 limits and does not register with CDC/APHIS may be subject to civil or criminal penalties as prescribed by law (Public Health Security & Preparedness Response Act of 2002, §231(c)).

Table 1
Maximum Allowable SA Toxin per PI for Exemption

SA Toxin	Exempt Quantity	SA Toxin	Exempt Quantity
Abrin	1,000 mg	Saxitoxin (STX)	500 mg
Botulinum neurotoxins (BoNT)	1 mg	Staphylococcal Enterotoxins (SE) (Subtypes A, B, C, D and E)	100 mg
Short, paralytic alpha Conotoxins	100 mg	T-2 Toxin	10,0000 mg
Diacetoxyscirpenol (DAS)	10,0000 mg	Tetrodotoxin (TTX)	500 mg
Ricin	1,000 mg		

3. Possession of Select Agent Toxins above Exempt Quantities:

Prior to possessing select agent toxins above allowable exempt quantities, written approval must be obtained from the TTUHSC President and the TTUHSC Senior Vice President for Research and Innovation, and registration with CDC/APHIS must be obtained by the institution.

4. Audits/Inspections:

- a. Each PI possessing exempt quantities of SA Toxins must perform and document periodic safety/security audits of the SA Toxin program. Attachment B, "Exempt Quantity Select Agent Laboratory Self-Inspection Checklist" may be used as the basis for these audits.
- b. The Department of Safety Services will conduct periodic announced and unannounced laboratory audits to review compliance with institutional requirements on possession of exempt quantities of SA Toxins.

5. Additional Information:

Questions regarding CDC/APHIS Select Agent Toxin possession (exempt or non-exempt quantities) at TTUHSC may be directed to TTUHSC Safety Services, Laboratory Safety Division.