Exempt Quantities of Select Agents and Toxins

In compliance with the “Public Health Security and Bioterrorism Preparedness Response Act of 2002” (Public Law 107-188) and the Select Agent regulations from the Centers for Disease Control (42 CFR 73) and the U.S. Department of Agriculture (9 CFR 121, 7 CAR 331), any lab at the University of Kentucky possessing any Select Agents or Toxins must contact the Department of Biological Safety. A complete list of all Select Agents and Toxins is available at http://www.selectagents.gov/SelectAgentsandToxinsList.html. The following policy has been developed to assist labs that maintain exempt quantities of listed toxins in complying with federal regulations. This policy ensures that laboratories with listed toxins maintain:

1. Exempt Quantities.
2. Secure Storage.

Exempt Quantities:
A list of exempt quantities of toxins on the Select Agents and Toxins list is available at http://www.selectagents.gov/PermissibleToxinAmounts.html. Toxins in these quantities may be possessed by a laboratory without completion of Select Agent registration. If at any time the exempt amount is exceeded, the laboratory is in violation of Select Agent regulations. Violations of the Select Agent regulations may result in serious monetary and/or criminal penalties.

To prevent violations of the Select Agent regulations, a periodic survey of research labs on campus is conducted.
- A survey form is sent via email from the Responsible Official, Brandy J. Nelson, and returned by the researcher via campus mail or fax. This form requests the names of toxins possessed by the lab, the quantities of the toxins, and the locations of the toxins.
- The Responsible Official and/or Alternate Responsible Official will conduct a visit to the lab to verify the quantity of toxin in the lab and the method of storage of the toxin.

Secure Storage:
To prevent unauthorized usage or theft, access to toxins should be restricted at all times.

Recommendations for secure storage:
- Two levels of security are recommended for safe storage.
  o In a standard lab setting, this would mean locking the main lab door when the lab is unoccupied and locking the freezer or refrigerator where the material is stored. If the storage freezer or refrigerator is not equipped with a lock, a locked box stored within the freezer or refrigerator would be sufficient.
  o In an open lab setting, the main entrance to the lab should be restricted by card access or other means and the freezer or refrigerator needs to be locked. If the freezer or refrigerator is not equipped with a lock, a chain or cable lock can be retrofitted for the freezer or refrigerator.
- The primary container of toxin and any dilutions should be labeled with the toxin symbol. Additionally, if the material is stored in a box or other secondary container, this container
should be labeled. The outside of the freezer or refrigerator does not need to be labeled. Contact the Department of Biological Safety at 859-257-1049 for labels.

- It is important to maintain inventory records for toxins to prevent theft and loss. Inventory records should include the amount of toxin currently on hand, the date the toxin is used, the amount used, and the name of the user.

**Safe Handling Practices:**

- Toxins should be utilized inside a containment device such as a fume hood or biological safety cabinet.
- Many toxins are utilized in minute quantities and can be difficult to weigh. It is recommended that stock solutions of toxins be made by adding diluent directly to the original containers. Dilutions for experimental use can then be prepared from this stock solution.
- Appropriate personal protective equipment should always be utilized when working with toxins. This includes lab coats and gloves.
  - Double gloving is recommended and glove selection may vary based upon the solvent that will be used to dilute the toxin.
  - For aqueous diluents, a nitrile inner glove and latex outer glove would be ideal. This allows for easy visualization of holes or tears in the outer glove.
  - Be careful to remove gloves inside out and always wash hands after removing gloves.
- Proper disposal is crucial for all materials that come in to contact with toxins.
  - Autoclaving is not effective for many toxins; therefore, chemical inactivation is preferred.
  - Bleach is an effective means of chemical inactivation for many toxins.
  - Contact the Department of Biological Safety for recommendations for inactivation of the specific toxin utilized in your laboratory.
  - Undiluted toxins or high concentration stock solutions no longer necessary for research may be ticketed as hazardous waste to be collected by Environmental Management.
SELECT AGENT TOXIN INVENTORY RECORD

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<tr>
<th>PRINCIPAL INVESTIGATOR:</th>
<th>CATALOG &amp; LOT NUMBER:</th>
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<table>
<thead>
<tr>
<th>TOXIN NAME:</th>
<th>STRAIN DESIGNATION:</th>
<th>CHARACTERISTICS:</th>
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<tr>
<th>INITIAL QUANTITY ACQUIRED:</th>
<th>DATE OF ACQUISITION:</th>
<th>SOURCE:</th>
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<thead>
<tr>
<th>STORAGE LOCATION:</th>
<th>BUILDING:</th>
<th>ROOM:</th>
<th>FREEZER:</th>
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INVENTORY OF USAGE

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<th>TIME OF ACCESS</th>
<th>NAME OF APPROVED PERSON ACCESSING TOXIN</th>
<th>PURPOSE</th>
<th>QUANTITY REMOVED</th>
<th>DATE RETURNED TO STORAGE</th>
<th>RETURNED BY</th>
<th>QUANTITY RETURNED</th>
<th>QUANTITY REMAINING</th>
<th>DATE DESTROYED</th>
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COMMENTS:

CONTACT THE DEPARTMENT OF BIOLOGICAL SAFETY IMMEDIATELY IF ANY DISCREPANCY EXISTS IN THE INVENTORY

Reviewed & Verified:

Principal Investigator: _______________________________ Date: _______________

Department of Biological Safety: _______________________________ Date: _______________