**DIPTHERIA TOXIN TEMPLATE SOP**

*[Customize to specific procedures and equipment in your laboratory.]*

**Standard Operating Procedures for Work with Diphtheria Toxin and**

**Diphtheria Toxin-treated Animals**

| **TOPIC** | **PROCEDURE** |
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| 1. **Preparation**
 | *If possible do not work with powder form of diphtheria toxin (DT). If necessary, purchase pre-weighed or pre-diluted DT in the least quantity possible to perform work. [Vials of DT will be purchased in pre-weighed powder form and then reconstituted in a [fume hood/glove box/biological safety cabinet (BSC)]. Weighing the toxin is not necessary as reconstitution will occur in the purchased vial and then aliquoted into vials with caps.]*Vaccine is available for diphtheria and must be offered every ten years. If persons working with DT are not current with their immunizations, contact the UW Employee Health Center (EHC) at 206-685-1026. |
| 1. **Chemicals/Hazards**
 | DT can be extremely toxic at very low levels. All contact should be avoided. Symptoms of exposure include skin irritation, respiratory irritation, fever and headache. Do not breathe dust, fume, or vapors of DT powder or solutions. DT may cause death if ingested. |
| 1. **Designated Area**
 | All work with DT must be done in a designated laboratory, work space and [fume hood/glove box/BSC]. Signage must be placed in work spaces and on [fume hood/glove box/BSC] when DT is used. This work will be conducted in Room(s): \_\_\_\_\_\_\_?\_\_\_\_\_\_\_ |
| 1. **Environmental/**

**Ventilation Controls** | Containers with DT must be handled in a [fume hood/glove box/BSC]. Signs will be posted on the room door and [fume hood/glove box/BSC] when toxins are in use stating: “Toxins in Use. Authorized Personnel Only” |
| 1. **Personal Protective Equipment (PPE)**
 | Laboratory coat or gown with long sleevesEye/face protection: safety glasses with side shields or chemical safety goggles, face protection such as a face shield if splash/spatter possible Double gloving with thin nitrile gloves. Change gloves and dispose immediately if contaminated, torn or punctured. |
| 1. **Special Handling Procedures & Storage Requirements**
 | *[Specific cleaning, decontamination agents (and contact times)/equipment and waste disposal procedures must be determined.]***HANDLING**Prep* All preparation of DT will be performed over plastic backed absorbent pads.
* Reconstitution, dilution and administration of the toxin will be performed only in a *[fume hood/glove box/BSC]* while wearing PPE.

Use* Only needle locking (Luer-Lock type) syringes or disposable syringe needle units are used for injection or aspiration of infectious or biohazardous material.
* A sharps container will be in the immediate vicinity for safe sharps disposal*.*
* Hands will be washed upon completion of tasks.

**STORAGE*** Unused DT will be kept in its original container or aliquoted into labeled vials that are tightly closed and stored at -20ºC. The original DT container or vials containing aliquots, will be stored inside a labeled, leak-spill-proof secondary container.
* Store DT in a secure location.

**TRANSPORT*** Transport DT in secondary, sealed, labeled non-breakable containers.
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| 1. **Spill and Accident Procedures**

*[Specific cleaning, decontamination agents (and contact times)/equipment and waste disposal procedures must be determined.]* | If you are not trained or comfortable cleaning up a spill, call 206-543-0467 for the EH&S spill hotline for assistance. If it is an emergency (risk of exposure to others such as an on-going DT release) call 9-1-1.**Liquid spills**: To be cleaned by properly protected and trained personnel. Personnel cleaning up a liquid spill will wear a lab coat/gown, goggles, and two pairs of nitrile gloves. Cover spill with absorbent paper towels and apply 1% sodium hypochlorite (NaOCl) (or10% bleach), starting at the perimeter and working towards the center, allowing 30-min. contact time to deactivate DT before clean up. Clean the spill area with 1% NaOCl (or10% bleach) allowing 30 min. contact time, then soap and water. The decontaminated spill waste will be double bagged and disposed of in regular trash.**Powder spills inside of [*fume hood/glove box/BSC]***: To be cleaned by properly protected and trained personnel. Personnel cleaning up a powder spill will wear a lab coat/gown, goggles, and two pairs of nitrile gloves. Gently cover powder spill with dampened absorbent paper towels to avoid raising dust. Apply 1% NaOCl (or10% bleach), starting at the perimeter and working towards the center, allowing 30-min. contact time to deactivate DT before clean up. Clean the spill area with 1% NaOCl (or10% bleach) allowing 30 min. contact time, then soap and water. The decontaminated spill waste will be double bagged and disposed of in regular trash. Wash hands thoroughly after completing any spill clean up.**Powder spills outside of a *[fume hood/glove box/BSC]***: Remove all personnel from the room and restrict access. A spill cleanup contractor will need to manage the spill since adequate respiratory protection is not available. As soon as possible report the spill by notifying EH&S (during business hours, Monday-Friday 8 a.m. to 5 p.m. call 206-543-0467, outside business hours call 206-685-8973); tell them that a spill has occurred, and you need EH&S to obtain a spill cleanup contractor. Be prepared to provide the following information: * Name and phone number of knowledgeable person that can be contacted:\_\_\_\_\_\_?\_\_\_\_\_\_\_
* Name of chemical, concentration and amount spilled
* Number of injured, if any
* Location of spill

This information can also be used in reporting to the Emergency Department after potential exposure.Any spill incident requires the supervisor to complete and submit the [online accident reporting system (OARS)](https://oars.ehs.washington.edu) form within 24 hours of the incident to EH&S |
| 1. **EXPOSURE PROCEDURES**

**In Case of Emergency** | **First Aid Procedures**: * For oral (mouth) exposure or if DT has been swallowed and if the person is conscious, wash out mouth with water while another worker calls 9-1-1 on campus phone if available (landline phone tracks the person’s location for emergency medical responders.)
* For inhalation exposure, move person to fresh air. If breathing becomes difficult call 9-11.
* For contact exposure to the eye, flush eye with copious amounts of water for at least 15 minutes and call 9-1-1.
* For dermal exposure, rinse area with copious amounts of water for at least 15 minutes, remove any contaminated clothing. Call 9-1-1, or go directly to Emergency Department (ED).

Needlesticks are a medical emergency and all work should be halted, with another person securing things while the injured person washes and obtains treatment. Call 9-1-1, or go directly to ED.**After First Aid Treatment:*** If a non-life-threatening exposure incident occurs, do the first aid as described above, then
* Contact the UW Employee Health Center (206-685-1026). The nurse will advise whether to be seen at EHC or the ED.
* If it has been 5 years or greater since the person received diphtheria vaccine, a booster may be recommended.

**BRING TO THE ED: the DT MSDS and this entire SOP, including the Emergency Dept. information at the end of this document.****Any exposure incident requires the supervisor to complete and submit** [**the online accident reporting system (OARS)**](https://oars.ehs.washington.edu) **form within 24 hours of the incident to EH&S.** |
| 1. **Waste Disposal and Cleaning**
 | Any waste DT will be decontaminated or autoclaved before disposal whenever possible.Work space surfaces must be wiped down with [1% NaOCl, 10% bleach, 1N NaOH or \_\_\_?\_\_\_] daily, during the length of the experiment. To prevent corrosion of metal surfaces rinse with water after using chlorine-based chemicals. Absorbent pads will be replaced daily. The used and contaminated absorbent pads, PPE, etc. will be placed in a biohazard bag and autoclaved. Note that some disinfecting agents may not deactivate DT.If in-lab decontamination/autoclaving is not possible for some DT waste, it should be managed as chemical waste.Request a [chemical waste collection](https://www.ehs.washington.edu/chemical/hazardous-chemical-waste-disposal) on the EH&S website.  |
| 1. **Special Precautions for Use of DT in Animals (if applicable)**
 | *[Give detailed procedures for safely completing tasks.]*Be extremely cautious using needles with DT. Follow the written procedures for safe use of sharps, and practice doing a “dry run” with less hazardous materials as needed. A sharps container must be in the immediate vicinity for safe sharps disposal.DO NOT RECAP needles. Never leave exposed needle tip in work area. Use a syringe holder to secure syringe. Contact EH&S for consultation at 206-221-7770. Perform procedures in a *[fume hood/glove box/BSC]* while wearing double nitrile gloves, lab coat/gown, safety glasses/goggles and face protection such as a face shield if splash/spatter possible. *[Animals will be anesthetized or placed into a restraining apparatus before procedures using DT are performed. Once the animal has been properly fitted into the restraining apparatus, the syringe will be loaded just prior to injection.]*Hands must be washed with soap and water after completion of the injection, and then put on new pair of nitrile gloves. If continuing to inject more animals, remove gloves and wash hands afterwards.After procedures are complete, the restraining apparatus and surrounding work station will be decontaminated using *[1% NaOCl, 10% bleach, 1N NaOH or \_\_\_?\_\_\_]*. All reusable lab equipment will be autoclaved.No special disposal requirements are needed for animals that have received DT. |
| 1. **Training**
 | All staff working with DT must be trained on this SOP prior to starting work. They must also be trained on the DT MSDS and it must be readily available in the laboratory. All training must be documented and maintained by the PI. (training log at end of document) |

**Name:**

**Title:**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date:**

**EMERGENCY DEPARTMENT RESPONSIBILITIES (POST EXPOSURE TO DIPHTHERIA TOXIN)**

1. There have been reports of rapid onset of local pain after percutaneous exposure to diphtheria toxin and such an occurrence would indicate a significant exposure. Onset of symptoms following significant diphtheria toxin exposure would typically have onset delayed by days to weeks and are due to the inhibition of protein synthesis. The Emergency Department (ED) shall assess the severity of the exposure and take appropriate actions to include consultation with the Washington Poison Control System: 800-222-1222. Treatment with Diphtheria Antitoxin (DAT) may be considered in case of an especially severe or large exposure, even in the absence of symptoms.
2. DAT is currently available from the CDC. In the event of problems obtaining a response at any local or state level, the CDC Emergency Operations Center should be contacted at 770-488-7100. Contraindications/Precautions in the use of DAT include a history of prior exposure to horse serum, prior history of serum sickness, or a history of asthma or hay fever, especially when near horses.
3. The ED should draw at least ten milliliters of serum and hold it for possible diphtheria toxin assay. This must be done before any treatment with diphtheria antitoxin.
4. Any patient seen in the ED and released should be given information about the potential for delayed onset of symptoms/toxicity. Any symptoms would be reason for emergent reevaluation. Any exposed individuals should also be referred to the UW Employee Health Center (206-685-1026) for follow-up care.

The Emergency Department will need to complete a Physicians Report of Injury Report L&I form. The ED physician needs to contact the Employee Health Center (206-685-1026) and report that an exposure has occurred.