SAFETY/PROTECTION GUIDELINES FOR WORK WITH BIOLOGICAL TOXINS

This document is intended as a guide to assist in determining safety/protection requirements for University staff working with Biological Toxins (BT). The document outlines minimum requirements for safe BT work; however, a risk assessment might indicate the need for more stringent requirements. A risk assessment must be conducted for all BT work.

1. Introduction
   a. Biological toxins (BT) are products of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, or protozoa), or infectious substances, or recombinant or synthesized molecules
   b. BTs are serious laboratory hazards that are highly toxic in minute quantities
   c. BT routes of exposure are primarily inhalation ingestion, and absorption (such as ocular, percutaneous, and injection). Skin absorption is also a potential hazard with some BTs.
   d. BTs do not pose a vapor hazard, and do not have short-term exposure limits, ceiling limits or time-weighted average concentrations. They are different from well-characterized chemical toxins and the unknown aspect of their properties must be considered in any risk assessment.
   e. Batches of BTs from the same source can vary widely in activity/toxicity
   f. Risk assessment is key to developing and implementing an effective BT safety strategy
   g. A ‘zero level’ toxin exposure philosophy will be the goal.

2. General Practices
   a. All work with BTs must be done in a Biosafety Cabinet (BSC) that is certified annually, except where prior approval from the biosafety officer is obtained for working outside of a BSC based on a comprehensive risk assessment done by the PI.
   b. Approvals will not be granted for future for toxin work outside of a BSC unless a detailed risk assessment makes a convincing case that the risk will be mitigated through the use of alternative safety procedures when manipulating the toxin. This assessment will include, at a minimum, the amount of toxin to be used, the probability of aerosol generation, the route of exposure, and the toxin LD50.
   c. When conducting high risk operations/procedures with BTs work must be conducted in a BSC and a respirator must be worn. High risk procedures include:
      i. Working with BT powders
      ii. Manipulating BTs in ways that intentionally generate dust or aerosols (Table 1)
   d. SOPs must be prepared and approved by the Institutional Biosafety Committee (IBC) for toxin work
   e. Follow approved IBC protocol/SOPs for toxin work
   f. Comply with Select Agent rules as necessary

3. For assistance: Contact the Biosafety Officer (BSO) or other DEHS Biosafety Specialist at 612 626 6002 for assistance with risk assessment and/or if you have trouble questions with regard to meeting these guidelines.
Table 1: Requirements for high risk biological toxin work

<table>
<thead>
<tr>
<th>Operation/procedures</th>
<th>Two trained individuals</th>
<th>Spills procedures</th>
<th>Respirator¹</th>
<th>Engineering controls¹</th>
<th>Gloves</th>
<th>Eye protection</th>
<th>Lab coat/disposable gown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work with powdered toxins</td>
<td>+</td>
<td>+</td>
<td>Fitted N95 or better with APF² ≥10</td>
<td>Class II or Class III BSC</td>
<td>+</td>
<td>+</td>
<td>+</td>
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<tr>
<td>Toxin manipulated to intentionally generate dust/aerosols</td>
<td>+</td>
<td>+</td>
<td>Fitted N95 or better with APF² ≥10</td>
<td>Class II or Class III BSC</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Work with powdered toxins or toxin manipulated to intentionally generate dust/aerosols while using volatile materials</td>
<td>+</td>
<td>+</td>
<td>Fitted N95 or better with APF² ≥10</td>
<td>Ducted Class II or Class III BSC</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

¹Any respirator usage by U of M community members, either required or voluntary, shall be pre-approved by the Department of Occupational Health and Safety (http://www.ohs.umn.edu/rpp/respirator/home.html). U of M community members shall only wear the specific respirator-type(s) for which they were pre-approved.

²APF = Assigned Protection Factor.