

**Inspection Checklist for Toxin Laboratories (42 CFR 73; BMBL 6th Edition)**

**Entity Name:**

**Inspection Date:**

**Building/Rooms:**

**Inspectors:**

**When information is entered in this form, the form is to be considered "Sensitive Select Agent Information."**

Section	Regulation Text	Observation	Status	Comments
12(a)	An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	Sufficient biosafety and containment procedures developed and implemented for select toxin use.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Sufficient biosafety and containment procedures developed and implemented for select toxin use.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Each laboratory worker must be trained in the theory and practice of the toxins to be used, with special emphasis on the nature of the practical hazards associated with laboratory operations. These include risks associated with transfers of solubilized toxins; manipulation of waste solutions, contamination of materials and equipment; and decontamination after routine operations and spills. Workers must be well-trained and sufficiently adept at all laboratory procedures and safety practices before participating in toxin operations.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If toxins and infectious agents are used together, then both must be considered in the risk assessment when selecting containment equipment, developing safety procedures, and choosing decontamination and disposal methods. Early endpoints need to be designed to balance experimental objectives with safe and ethical application of toxins to animals.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Laboratory work with toxins should be done only in designated rooms with controlled access and at pre-determined bench areas. When toxins are in use, the room should have clearly posted signage stating, for example, "Toxins in Use—Authorized Personnel Only". Signage should provide a knowledgeable point of contact and delineate minimum requirements for PPE.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Routine operations with dilute toxin solutions are conducted under BSL-2 conditions with the aid of PPE and a well-maintained BSC, chemical fume hood, or comparable engineering controls. Engineering controls should be selected according to the risk assessment for each specific toxin operation.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	A certified BSC or chemical fume hood will suffice for routine operations with most solubilized protein toxins. Work involving toxin powders, volatile chemicals, or radionuclides combined with toxin solutions may require additional safeguards or barriers based on the risks associated with each toxin preparation.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Handling of solubilized toxins should be conducted within the operationally effective zone of a BSC or chemical fume hood. Before initiating work, each user should verify the hood or BSC is properly working according to manufacturer guidelines. When using a BSC or hood, workers should wear suitable laboratory PPE to protect the hands, arms, and eyes, such as laboratory coats with knit or elastic cuffs, smocks or coveralls, disposable gloves, and safety glasses. When working with toxins that pose direct percutaneous hazards, special care must be taken to select gloves that are impervious to the toxin and the diluents or solvents employed. When conducting large volume liquid transfers and other operations that pose a potential splash or droplet hazard in an open-front hood or BSC, workers should wear a disposable facemask or face shield.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	The interior of the hood or BSC should be decontaminated periodically; for example, at the end of the day or after a spill. Until thoroughly decontaminated, the hood or BSC should remain posted to indicate that toxins are present, and access should be restricted to staff trained in toxin use and decontamination.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Selected operations with toxins may require modified BSL-3 practices and procedures. The determination to use BSL-3 is made in consultation with available safety staff and is based upon a risk assessment that considers the variables of each specific laboratory operation, especially the toxin under study, the physical state of the toxin (solution or dry form), the total amount of toxin used relative to the estimated human lethal dose, the volume of the material manipulated, the methodology, and any human or equipment performance limitations.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	



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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Only workers trained and experienced in handling animals and toxin operations should be permitted to conduct operations with animals, especially injection of toxin solutions using hollow-bore needles. Discarded needles/syringes and other sharps should never be recapped; instead, they should be placed directly into properly labeled, puncture-resistant sharps containers, and decontaminated.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	In specialized laboratories, the intentional, controlled generation of aerosols from toxin solutions may be undertaken to test antidotes or vaccines in experimental animals. These are extremely hazardous operations that should only be conducted after extensive validation of equipment and personnel, using non-toxic simulants.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Aerosol exposure of animals should be done in a certified Class III BSC or hoodline. While removing exposed animals from the hoodline, and for required animal handling during the first 24 h after exposure, workers should take additional precautions, including wearing protective clothing (e.g., disposable Tyvek suit) and appropriate respiratory protection. To minimize the risk of dry toxin generating a secondary aerosol, areas of animal skin or fur exposed to aerosols should be gently wiped with a damp cloth containing water or buffered cleaning solution before the animals are returned to holding areas.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Depending upon the toxin, contaminated materials and toxin waste solutions can be inactivated by incineration or extensive autoclaving, or by soaking in suitable decontamination solutions (refer to BMBL Appendix I Tables 1 and 2).	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	All disposable contaminated solid material should be placed in secondary containers and then autoclaved and/or disposed of as hazardous waste for incineration. Contaminated or potentially contaminated protective clothing and equipment that is to be re-used should be decontaminated using suitable chemical methods or should be autoclaved after use, if the toxin is heat labile, and before it is re-used or removed from the laboratory for cleaning or repair.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	In the event of a liquid spill, avoid splashes or generating aerosols during cleanup by covering the spill with dry paper towels or other disposable, absorbent material. Ensure that appropriate PPE (at a minimum to include mask, gloves, safety glasses or goggles, and laboratory coat) is worn during the cleanup. Apply an appropriate decontamination solution to the spill, beginning at the perimeter and working towards the center. Allow sufficient contact time for the decontamination solution to completely inactivate the toxin (refer to BMBL Appendix I Table 2).	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	