

Inspection Checklist for Toxin Laboratories (7 CFR 331; 9 CFR 121; 42 CFR 73; BMBL 5th Edition; 29 CFR:1910.1450)

Entity Name:
 Inspection Date:
 Street Address:
 City, State, Zip:
 RO:
 ARO(s):

 Lead Inspector:
 Other Inspectors:

Building/Room(s):

 PI(s):

 HHS Agents:

 Overlap Agents:

 USDA Agents:

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

Entity Name:		Inspection Date:			
Reference	Statement	Yes	No	N/A	Comments
CFR: Section 12(a)	An individual or entity required to register under this part must develop and implement a written biosafety (biocontainment) plan that is commensurate with the risk of the select agent or toxin, given its intended use.				
CFR: Section 12(a)	The biosafety (biocontainment) 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.				
CFR: Section 12(a)	The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.				
CFR: Section 12(a)(1)	The biosafety plan must include the hazardous characteristics of each agent or toxin listed on the entity's registration and the biosafety risk associated with laboratory procedures related to the select agent or toxin.				

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CFR: Section 12(a)(2)	The biosafety plan must include safeguards in place with associated work practices to protect entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to: personal protective equipment and other safety equipment; containment equipment including, but not limited to, biological safety cabinets, animal caging systems, and centrifuge safety containers; and engineering controls and other facility safeguards.				
CFR: Section 12(a)(3)	The biosafety plan must include written procedures for each validated method used for disinfection, decontamination or destruction, as appropriate, of all contaminated or presumptively contaminated materials including, but not limited to: cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents and toxins, personal protective equipment, animal caging systems and bedding (if applicable), animal carcasses or extracted tissues and fluids (if applicable), laboratory surfaces and equipment, and effluent material.				
CFR: Section 12(a)(4)	The biosafety plan must include procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins to prevent unintentional contamination.				
CFR: Section 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).				
CFR: Section 12(d)	In developing a biosafety plan, an individual or entity: the biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program.				
CFR: Section 12 (e)	The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.				
CFR: Section 12 (e)	Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.				

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42 CFR 73: Section 13 (a)	An individual or entity may not conduct or possess products (i.e., select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, or recombinant and/or synthetic nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight) resulting from, a restricted experiment with a HHS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary.				
42 CFR 73: Section 13 (a)	In addition, an individual or entity may not conduct or possess products (i.e., select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, or recombinant and/or synthetic nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight) resulting from, a restricted experiment with an overlap select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary, after consultation with Administrator.				
9 CFR 121: Section13(a)	An individual or entity may not conduct or possess products (i.e., select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, or recombinant and/or synthetic nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight) resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the Administrator:				
BMBL: Appendix I Training and Laboratory Planning	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. This includes how to handle transfers of liquids containing toxin, where to place waste solutions and contaminated materials or equipment, and how to decontaminate work areas after routine operations, as well as after accidental spills. The worker must be reliable and sufficiently adept at all required manipulations before being provided with toxin.				

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BMBL: Appendix I Training and Laboratory Planning	For complex operations, it is recommended that new workers undergo supervised practice runs in which the exact laboratory procedures to be undertaken are rehearsed without active toxin.				
BMBL: Appendix I Training and Laboratory Planning	If toxins and infectious agents are used together, then both must be considered when containment equipment is selected and safety procedures are developed. Likewise, animal safety practices must be considered for toxin work involving animals.				
BMBL: Appendix I Training and Laboratory Planning	Each laboratory that uses toxins should develop a specific chemical hygiene plan. The National Research Council has provided a review of prudent laboratory practices when handling toxic and highly toxic chemicals, including the development of chemical hygiene plans and guidelines for compliance with regulations governing occupational safety and health, hazard communication, and environmental protection.				
BMBL: Appendix I Training and Laboratory Planning	An inventory control system should be in place to account for toxin use and disposition.				
BMBL: Appendix I Training and Laboratory Planning	If toxins are stored in the laboratory, containers should be sealed, labeled, and secured to ensure restricted access; refrigerators and other storage containers should be clearly labeled and provide contact information for trained, responsible laboratory staff.				
BMBL: Appendix I Training and Laboratory Planning	Laboratory work with toxins should be done only in designated rooms with controlled access and at pre-determined bench areas.				
BMBL: Appendix I Training and Laboratory Planning	When toxins are in use, the room should be clearly posted: "Toxins in Use—Authorized Personnel Only."				
BMBL: Appendix I Training and Laboratory Planning	Unrelated and nonessential work should be restricted from areas where stock solutions of toxin or organisms producing toxin are used.				
BMBL: Appendix I Training and Laboratory Planning	Visitors or other untrained personnel granted laboratory access must be monitored and protected from inadvertently handling laboratory equipment used to manipulate the toxin or organism.				

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BMBL: Appendix I Safety Equipment and Containment	Routine operations with dilute toxin solutions are conducted under BSL-2 conditions with the aid of personal protective equipment and a well-maintained BSC or comparable engineering controls. Engineering controls should be selected according to the risk assessment for each specific toxin operation.				
BMBL: Appendix I Safety Equipment and Containment	A certified BSC or chemical fume hood will suffice for routine operations with most protein toxins.				
BMBL: Appendix I Safety Equipment and Containment	Low molecular weight toxin solutions, or work involving volatile chemicals or radionucleotides combined with toxin solutions, may require the use of a charcoal-based hood filter in addition to HEPA filtration.				
BMBL: Appendix I Safety Equipment and Containment	All work with toxins should be conducted within the operationally effective zone of the hood or BSC, and each user should verify the inward airflow before initiating work.				
BMBL: Appendix I Safety Equipment and Containment	When using an open-fronted fume hood or BSC, workers should wear suitable laboratory PPE to protect the hands and arms, such as laboratory coats, smocks, or coveralls and disposable gloves.				
BMBL: Appendix I Safety Equipment and Containment	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.				
BMBL: Appendix I Safety Equipment and Containment	When conducting liquid transfers and other operations that pose a potential splash or droplet hazard in an open-fronted hood or BSC, safety glasses and disposable facemask, or a face shield, should be worn.				
BMBL: Appendix I Safety Equipment and Containment	Toxin should be removed from the hood or BSC only after the exterior of the closed primary container has been decontaminated and placed in a clean secondary container.				
BMBL: Appendix I Safety Equipment and Containment	Toxin solutions, especially concentrated stock solutions, should be transported in leak/spill-proof secondary containers.				

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BMBL: Appendix I Safety Equipment and Containment	The interior of the hood or BSC should be decontaminated periodically, for example, at the end of a series of related experiments. Until thoroughly decontaminated, the hood or BSC should be posted to indicate that toxins remain in use, and access should remain restricted.				
BMBL: Appendix I Safety Equipment and Containment	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.				
BMBL: Appendix I Inadvertent Toxin Aerosols	Emphasis must be placed on evaluating and modifying experimental procedures to eliminate the possibility of inadvertent generation of toxin aerosols.				
BMBL: Appendix I Inadvertent Toxin Aerosols	Pressurized tubes or other containers holding toxins should be opened in a BSC, chemical fume hood, or other ventilated enclosure.				
BMBL: Appendix I Inadvertent Toxin Aerosols	Operations that expose toxin solutions to vacuum or pressure, for example sterilization of toxin solutions by membrane filtration, should always be handled in this manner, and the operator should also use appropriate respiratory protection.				
BMBL: Appendix I Inadvertent Toxin Aerosols	If vacuum lines are used with toxin, they should be protected with a HEPA filter to prevent entry of toxins into the line.				
BMBL: Appendix I Inadvertent Toxin Aerosols	Centrifugation of cultures or materials potentially containing toxins should only be performed using sealed, thick-walled tubes in safety centrifuge cups or sealed rotors. The outside surfaces of containers and rotors should be routinely cleaned before each use to prevent contamination that may generate an aerosol. After centrifugation, the entire rotor assembly is taken from the centrifuge to a BSC to open it and remove its tubes.				
BMBL: Appendix I Mechanical Injuries	Only workers trained and experienced in handling animals should be permitted to conduct operations involving injection of toxin solutions using hollow-bore needles.				

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BMBL: Appendix I Mechanical Injuries	Discarded needles/syringes and other sharps should be placed directly into properly labeled, puncture-resistant sharps containers, and decontaminated as soon as is practical.				
BMBL: Appendix I Mechanical Injuries	Glassware should be replaced with plastic for handling toxin solutions wherever practical to minimize the risk of cuts or abrasions from contaminated surfaces.				
BMBL: Appendix I Mechanical Injuries	Thin walled glass equipment should be completely avoided. Glass Pasteur pipettes are particularly dangerous for transferring toxin solutions and should be replaced with disposable plastic pipettes. Glass chromatography columns under pressure must be enclosed within a plastic water jacket or other secondary container.				
BMBL: Appendix I Additional Precautions	Experiments should be planned to eliminate or minimize work with dry toxin (e.g. freeze-dried preparations). Unavoidable operations with dry toxin should only be undertaken with appropriate respiratory protection and engineering controls.				
BMBL: Appendix I Additional Precautions	Dry toxin can be manipulated using a Class III BSC, or with the use of secondary containment such as a disposable glove bag or glove box within a hood or Class II BSC.				
BMBL: Appendix I Additional Precautions	“Static-free” disposable gloves should be worn when working with dry forms of toxins that are subject to spread by electrostatic dispersal.				
BMBL: Appendix I Additional Precautions	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.				
BMBL: Appendix I Additional Precautions	Aerosol exposure of animals should be done in a certified Class III BSC or hoodline.				
BMBL: Appendix I Additional Precautions	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.				

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BMBL: Appendix I Additional Precautions	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.				
BMBL: Appendix I Additional Precautions	For high-risk operations involving dry forms of toxins, intentional aerosol formation, or the use of hollow-bore needles in conjunction with amounts of toxin estimated to be lethal for humans, consideration should be given to requiring the presence of at least two knowledgeable individuals at all times in the laboratory.				
BMBL: Appendix I Decontamination and Spills	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 (See Table 2).				
BMBL: Appendix I Decontamination and Spills	All disposable material used for toxin work should be placed in secondary containers, autoclaved and disposed of as toxic waste.				
BMBL: Appendix I Decontamination and Spills	Contaminated or potentially contaminated protective clothing and equipment should be decontaminated using suitable chemical methods or autoclaving before removal from the laboratory for disposal, cleaning or repair. If decontamination is impracticable, materials should be disposed of as toxic waste.				
BMBL: Appendix I Decontamination and Spills	In the event of a spill, avoid splashes or generating aerosols during cleanup by covering the spill with paper towels or other disposable, absorbent material. Apply an appropriate decontamination solution to the spill, beginning at the perimeter and working towards the center, and allow sufficient contact time to completely inactivate the toxin (See Table 2).				

Comments continued:

Inspector summary and comments:

Lead inspector:

Date:

Other inspectors present:

Date:

Lead inspector signature: _____

Date: _____