

Inspection Checklist for NIH BL3-LS Laboratories (NIH Guidelines)

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
Note: Appendix K specifies physical containment guidelines for large-scale (greater than 10 liters of culture) research or production involving viable organisms containing recombinant DNA molecules. It shall apply to large-scale research or production activities as specified in Section III-D-6, Experiments Involving More than 10 Liters of Culture.					
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(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 (c)(1)	In developing a biosafety plan, an individual or entity should consider: The CDC/NIH publication, Biosafety in Microbiological and Biomedical Laboratories. This document is available on the National Select Agent Registry website at http://www.selectagents.gov/ .				

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CFR: Section 12 (c)(3)	In developing a biosafety plan, an individual or entity should consider: The "NIH Guidelines for Research Involving Recombinant or Synthetic Molecules," (NIH Guidelines). This document is available on the National Select Agent Registry Web site at http://www.selectagents.gov .				
CFR: Section 12(d)	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.				
CFR: Section 12(e)	Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan.				
CFR: Section 12(e)	The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.				
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.				

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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:				
K-V	Biosafety Level 3 (BL3) - Large Scale				
NIH: K-V-A	Spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities (if applicable). Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax). Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.				
NIH: K-V-B	Cultures of viable organisms containing recombinant or synthetic nucleic acid molecules shall be handled in a closed system (e.g., closed vessels used for the propagation and growth of cultures) or other primary containment equipment (e.g., Class III biological safety cabinet containing a centrifuge used to process culture fluids) which is designed to prevent the escape of viable organisms. Volumes less than 10 liters may be handled outside of a closed system provided all physical containment requirements specified in Appendix G-II-C, Physical Containment Levels --Biosafety Level 3, are met.				
NIH: K-V-C	Culture fluids (except as allowed in Appendix K-V-D) shall not be removed from a closed system or other primary containment equipment unless the viable organisms containing recombinant or synthetic nucleic acid molecules have been inactivated by a validated inactivation procedure. A validated inactivation procedure is one which has been demonstrated to be effective using the organisms that will serve as the host for propagating the recombinant or synthetic nucleic acid molecules. Culture fluids that contain viable organisms or viral vectors intended as final product may be removed from the primary containment equipment by way of closed systems for sample analysis, further processing or final fill.				

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NIH: K-V-D	Sample collection from a closed system, the addition of materials to a closed system, and the transfer of culture fluids from one closed system to another shall be conducted in a manner which prevents the release of aerosols or contamination of exposed surfaces.				
NIH: K-V-E	Exhaust gases removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to high particulate efficiency air/HEPA filters or by other equivalent procedures (e.g., incineration) to prevent the release of viable organisms containing recombinant or synthetic nucleic acid molecules to the environment.				
NIH: K-V-F	A closed system or other primary containment equipment that has contained viable organisms containing recombinant or synthetic nucleic acid molecules shall not be opened for maintenance or other purposes unless it has been sterilized by a validated sterilization procedure except when the culture fluids contain viable organisms or vectors intended as final product as described in Appendix K-V-C above. A validated sterilization procedure is one which has been demonstrated to be effective using the organisms that will serve as the host for propagating the recombinant or synthetic nucleic acid molecules.				
NIH: K-V-G	A closed system used for the propagation and growth of viable organisms containing recombinant or synthetic nucleic acid molecules shall be operated so that the space above the culture level will be maintained at a pressure as low as possible, consistent with equipment design, in order to maintain the integrity of containment features.				
NIH: K-V-H	Rotating seals and other mechanical devices directly associated with a closed system used to contain viable organisms containing recombinant or synthetic nucleic acid molecules shall be designed to prevent leakage or shall be fully enclosed in ventilated housings that are exhausted through filters which have efficiencies equivalent to high efficiency particulate air / HEPA filters or through other equivalent treatment devices.				
NIH: K-V-I	A closed system used for the propagation and growth of viable organisms containing recombinant or synthetic nucleic acid molecules and other primary containment equipment used to contain operations involving viable organisms containing recombinant or synthetic nucleic acid molecules shall include monitoring or sensing devices that monitor the integrity of containment during operations.				

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NIH: K-V-J	A closed system used for the propagation and growth of viable organisms containing recombinant or synthetic nucleic acid molecules shall be tested for integrity of the containment features using the organisms that will serve as the host for propagating the recombinant or synthetic nucleic acid molecules. Testing shall be accomplished prior to the introduction of viable organisms containing recombinant or synthetic nucleic acid molecules and following modification or replacement of essential containment features. Procedures and methods used in the testing shall be appropriate for the equipment design and for recovery and demonstration of the test organism. Records of tests and results shall be maintained on file.				
NIH: K-V-K	A closed system used for the propagation and growth of viable organisms containing recombinant or synthetic nucleic acid molecules shall be permanently identified. This identification shall be used in all records reflecting testing, operation, maintenance, and use of this equipment for research production activities involving viable organisms containing recombinant or synthetic nucleic acid molecules.				
NIH: K-V-L	The universal biosafety sign shall be posted on each closed system and primary containment equipment when used to contain viable organisms containing recombinant or synthetic nucleic acid molecules.				
NIH: K-V-M	Emergency plans required by Sections IV-B-2-b-(6), Institutional Biosafety Committee, and IV-B-3-c-(3), Biological Safety Officer, shall include methods and procedures for handling large losses of culture on an emergency basis. * Section IV-B-2-b-(6): Adopting emergency plans covering accidental spills and personnel contamination resulting from recombinant or synthetic nucleic acid molecule research. * Section IV-B-3-c-(3): Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant or synthetic nucleic acid molecule research.				
NIH: K-V-N	Closed systems and other primary containment equipment used in handling cultures of viable organisms containing recombinant or synthetic nucleic acid molecules shall be located within a controlled area which meets the following requirements:				
NIH: K-V-N-1	The controlled area shall have a separate entry area. The entry area shall be a double-doored space such as an air lock, anteroom, or change room that separates the controlled area from the balance of the facility.				
NIH: K-V-N-2	The surfaces of walls, ceilings, and floors in the controlled area shall be such as to permit ready cleaning and decontamination.				

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NIH: K-V-N-3	Penetrations into the controlled area shall be sealed to permit liquid or vapor phase space decontamination.				
NIH: K-V-N-4	All utilities and service or process piping and wiring entering the controlled area shall be protected against contamination.				
NIH: K-V-N-5	Hand washing facilities equipped with foot, elbow, or automatically operated valves shall be located at each major work area and near each primary exit.				
NIH: K-V-N-6	A shower facility shall be provided. This facility shall be located in close proximity to the controlled area.				
NIH: K-V-N-7	The controlled area shall be designed to preclude release of culture fluids outside the controlled area in the event of an accidental spill or release from the closed systems or other primary containment equipment.				
NIH: K-V-N-8	The controlled area shall have a ventilation system that is capable of controlling air movement. The movement of air shall be from areas of lower contamination potential to areas of higher contamination potential.				
NIH: K-V-N-8	If the ventilation system provides positive pressure supply air, the system shall operate in a manner that prevents the reversal of the direction of air movement or shall be equipped with an alarm that would be actuated in the event that reversal in the direction of air movement were to occur.				
NIH: K-V-N-8	The exhaust air from the controlled area shall not be recirculated to other areas of the facility.				
NIH: K-V-N-8	The exhaust air from the controlled area may not be discharged to the outdoors without being high efficiency particulate air/HEPA filtered, subjected to thermal oxidation, or otherwise treated to prevent the release of viable organisms.				
NIH: K-V-O	The following personnel and operational practices shall be required:				
NIH: K-V-O-1	Personnel entry into the controlled area shall be through the entry area specified in Appendix K-V-N-1.				

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NIH: K-V-O-2	Persons entering the controlled area shall exchange or cover their personal clothing with work garments such as jump suits, laboratory coats, pants and shirts, head cover, and shoes or shoe covers. On exit from the controlled area the work clothing may be stored in a locker separate from that used for personal clothing or discarded for laundering.				
NIH: K-V-O-2	Clothing shall be decontaminated before laundering.				
NIH: K-V-O-3	Entry into the controlled area during periods when work is in progress shall be restricted to those persons required to meet program or support needs.				
NIH: K-V-O-3	Prior to entry, all persons shall be informed of the operating practices, emergency procedures, and the nature of the work conducted.				
NIH: K-V-O-4	Persons under 18 years of age shall not be permitted to enter the controlled area.				
NIH: K-V-O-5	The universal biosafety sign shall be posted on entry doors to the controlled area and all internal doors when any work involving the organism is in progress. This includes periods when decontamination procedures are in progress. The sign posted on the entry doors to the controlled area shall include a statement of agents in use and personnel authorized to enter the controlled area.				
NIH: K-V-O-6	The controlled area shall be kept neat and clean.				
NIH: K-V-O-7	Eating, drinking, smoking, and storage of food are prohibited in the controlled area.				
NIH: K-V-O-8	Animals and plants shall be excluded from the controlled area.				
NIH: K-V-O-9	An effective insect and rodent control program shall be maintained.				

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NIH: K-V-O-10	Access doors to the controlled area shall be kept closed, except as necessary for access, while work is in progress. Service doors leading directly outdoors shall be sealed and locked while work is in progress.				
NIH: K-V-O-11	Persons shall wash their hands when exiting the controlled area.				
NIH: K-V-O-12	Persons working in the controlled area shall be trained in emergency procedures.				
NIH: K-V-O-13	Equipment and materials required for the management of accidents involving viable organisms containing recombinant or synthetic nucleic acid molecules shall be available in the controlled area.				
NIH: K-V-O-14	The controlled area shall be decontaminated in accordance with established procedures following spills or other accidental release of viable organisms containing recombinant or synthetic nucleic acid molecules.				

Comments continued:

Inspector summary and comments:

Lead inspector:

Date:

Other inspectors present:

Date:

Lead inspector signature: _____

Date: _____