Inspection Checklist for NIH BL2-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 or synthetic nucleic acid 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(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 (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/. In developing a biocontainment plan, an individual or entity should consider the following: (1) Containment Facilities and Safeguards for Exotic Plant Pathogens and Pests (Robert P. Kahn and S.B.Mathur eds., 1999); and (2) A Practical Guide to Containment: Greenhouse Research with Transgenic Plants and Microbes (Patricia L. Traynor ed., 2001).	☐	☐	☐	
CFR: Section 12 (c)(3)	In developing a biosafety plan, an individual or entity should consider: The “NIH Guidelines for Research Involving Recombinant DNA Molecules,” (NIH Guidelines). This document is available on the National Select Agent Registry Web site at http://www.selectagents.gov.	☐	☐	☐	

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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.	☐	☐	☐	
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.	☐	☐	☐	
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:	☐	☐	☐	
NIH: K-IV-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).	☐	☐	☐	
NIH: K-IV-A	Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.	☐	☐	☐	
NIH: K-IV-B	Cultures of viable organisms containing recombinant or synthetic nucleic acid molecules shall be handled in a closed system (e.g., closed vessel 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.	☐	☐	☐	
NIH: K-IV-B	Volumes less than 10 liters may be handled outside of a closed system or other primary containment equipment provided all physical containment requirements specified in Appendix G-II-B, Physical Containment Levels--Biosafety Level 2, are met.	☐	☐	☐	
NIH: K-IV-C	Culture fluids (except as allowed in Appendix K-IV-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 organism that will serve as the host for propagating the recombinant or synthetic nucleic acid molecules.	☐	☐	☐	

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NIH: K-IV-C	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.	☐	☐	☐	
NIH: K-IV-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-IV-E	Exhaust gases removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to high efficiency particulate 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-IV-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-IV-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-IV-G	Rotating seals and other mechanical devices directly associated with a closed system used for the propagation and growth of 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-IV-H	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 sensing devices that monitor the integrity of containment during operations.	☐	☐	☐	
NIH: K-IV-I	A closed system used for the propagation and growth of viable organisms containing the recombinant or synthetic nucleic acid molecules shall be tested for integrity of the containment features using the organism that will serve as the host for propagating recombinant or synthetic nucleic acid molecules.	☐	☐	☐	

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NIH: K-IV-I	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.	☐	☐	☐	
NIH: K-IV-I	Procedures and methods used in the testing shall be appropriate for the equipment design and for recovery and demonstration of the test organism.	☐	☐	☐	
NIH: K-IV-I	Records of tests and results shall be maintained on file.	☐	☐	☐	
NIH: K-IV-J	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, and maintenance and in all documentation relating to use of this equipment for research or production activities involving viable organisms containing recombinant or synthetic nucleic acid molecules.	☐	☐	☐	
NIH: K-IV-K	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-IV-L	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.*	☐	☐	☐	

Comments continued:

Inspector summary and comments:

Lead inspector: Date:

Other inspectors present: Date:

Lead inspector signature: _____ Date: _____

Print Form