# Inspection Checklist for NIH BL2-LS Laboratories (NIH Guidelines)

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| **Entity Name:** | 0 | **Insp. Date:** | January 0, 1900 |
| **Street Address:** | , , | | |
| **City, State, Zip:** | , , | **RO:** | 0 |
| **Lead Inspector:** | 0 | **ARO(s):** | |
| **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*."**

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| Reference | Statement | Response | | | Comments |
|---|---|---|---|---|---|
| | | Yes | No | N/A | |
| **NIH Guidelines (LARGE-SCALE) Additional Requirements** | | | | | |
| ***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.** | | | | | |
| **NIH**: K-IV-A | Spills and accidents which result in overt exposures to organisms containing recombinant DNA 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 DNA 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. | | | | |

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| **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 rDNA 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 rDNA molecules. | | | | |
| **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 rDNA molecules to the environment. | | | | |
| **NIH**: K-IV-F | A closed system or other primary containment equipment that has contained viable organisms containing rDNA 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 rDNA 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 rDNA 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 rDNA 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 rDNA molecules shall be tested for integrity of the containment features using the organism that will serve as the host for propagating rDNA molecules. | | | | |

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| | | **Yes** | **No** | **N/A** | |
| **NIH**: K-IV-I | Testing shall be accomplished prior to the introduction of viable organisms containing rDNA 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 rDNA 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 rDNA 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 DNA 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.<br>** Section IV-B-2-b-(6): Adopting emergency plans covering accidental spills and personnel contamination resulting from rDNA research.*<br>** Section IV-B-3-c-(3): Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving rDNA research.* | | | | |

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| | | Yes | No | N/A | |
| **Inspector summary and comments:** | | | | | |
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| **Recommendations:** | | | | | |
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| **Inspector completing checklist:** | | | | | **Date:** |
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| **Other inspectors present:** | | | | | **Date:** |
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