

Inspection Checklist for NIH BL4 Laboratories (7 CFR 331; 9 CFR 121; 42 CFR 73; 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
NIH BL4 (rDNA) REQUIREMENTS					
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/ .				
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/ .				

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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.				
42 CFR 73: Section 13 (a) <i>HHS select agent</i>	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) <i>overlap select agent</i>	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) <i>USDA only agent</i>	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:				
Standard Microbiological Practices (BL4)					
NIH: G-II-D-1-a	Work surfaces are decontaminated at least once a day and immediately after any spill of viable material.				
NIH: G-II-D-1-b	Only mechanical pipetting devices are used.				
NIH: G-II-D-1-c	Eating, drinking, smoking, storing food, and applying cosmetics are not permitted in the laboratory.				
NIH: G-II-D-1-d	All procedures are performed carefully to minimize the creation of aerosols.				
Special Practices (BL4)					
NIH: G-II-D-2-a	Biological materials to be removed from the Class III cabinets or from the Biosafety Level 4 (maximum containment) laboratory in a viable or intact state are transferred to a non-breakable, sealed primary container and then enclosed in a non-breakable, sealed secondary container which is removed from the facility through a disinfectant dunk tank, fumigation chamber, or an airlock designed for this purpose.				
NIH: G-II-D-2-b	No materials, except for biological materials that are to remain in a viable or intact state, are removed from the maximum containment laboratory unless they have been autoclaved or decontaminated before exiting the facility.				
NIH: G-II-D-2-b	Equipment or material that might be damaged by high temperatures or steam may be decontaminated by gaseous or vapor methods in an airlock or chamber designed for this purpose.				

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NIH: G-II-D-2-c	Only persons whose presence in the facility or individual laboratory rooms is required for program or support purposes are authorized to enter. The supervisor has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.				
NIH: G-II-D-2-c	Access to the facility is limited by means of secure, locked doors; accessibility is managed by the Principal Investigator, Biological Safety Officer, or other person responsible for the physical security of the facility.				
NIH: G-II-D-2-c	Before entering, persons are advised of the potential biohazards and instructed as to appropriate safeguards for ensuring their safety.				
NIH: G-II-D-2-c	Authorized persons comply with the instructions and all other applicable entry and exit procedures.				
NIH: G-II-D-2-c	A logbook, signed by all personnel, indicates the date and time of each entry and exit.				
NIH: G-II-D-2-c	Practical and effective protocols for emergency situations are established.				
NIH: G-II-D-2-d	Personnel enter and leave the laboratory and/or exit the facility only through the clothing change and shower rooms.				
NIH: G-II-D-2-d	Personnel shower each time they exit the facility.				
NIH: G-II-D-2-d	Personnel use the airlocks to enter or leave the laboratory only in an emergency.				
NIH: G-II-D-2-e	Street clothing is removed in the outer clothing change room and kept there.				
NIH: G-II-D-2-e	Complete laboratory clothing (may be disposable), including undergarments, pants and shirts or jump suits, shoes, and gloves, is provided and used by all personnel entering the facility.				

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NIH: G-II-D-2-e	Head covers are provided for personnel who do not wash their hair during the exit shower.				
NIH: G-II-D-2-e	When exiting the laboratory and before proceeding into the shower area, personnel remove their laboratory clothing and store it in a locker or hamper in the inner change room.				
NIH: G-II-D-2-e	Protective clothing shall be decontaminated prior to laundering or disposal.				
NIH: G-II-D-2-f	When materials that contain organisms containing recombinant or synthetic nucleic acid molecules or experimental animals are present in the laboratory or animal rooms, a hazard warning sign incorporating the universal biosafety symbol is posted on all access doors. The sign identifies the agent, lists the name of the Principal Investigator or other responsible person(s), and indicates any special requirements for entering the area (e.g., the need for immunizations or respirators).				
NIH: G-II-D-2-g	Supplies and materials needed in the facility are brought in by way of the double-doored autoclave, fumigation chamber, or airlock, which is appropriately decontaminated between each use.				
NIH: G-II-D-2-g	After securing the outer doors, personnel within the facility retrieve the materials by opening the interior doors of the autoclave, fumigation chamber, or airlock.				
NIH: G-II-D-2-g	These doors are secured after materials are brought into the facility.				
NIH: G-II-D-2-h	An insect and rodent control program is in effect.				
NIH: G-II-D-2-i	Materials (e.g., plants, animals, and clothing) not related to the experiment being conducted are not permitted in the facility.				
NIH: G-II-D-2-j	Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles.				

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NIH: G-II-D-2-j	Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral part of unit) are used for the injection or aspiration of fluids containing organisms that contain recombinant or synthetic nucleic acid molecules.				
NIH: G-II-D-2-j	Needles should not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe following use.				
NIH: G-II-D-2-j	The needle and syringe should be placed in a puncture-resistant container and decontaminated, preferably by autoclaving before discard or reuse.				
NIH: G-II-D-2-j	Whenever possible, cannulas are used instead of sharp needles (e.g., gavage).				
NIH: G-II-D-2-k	A system is set up for reporting laboratory accidents, exposures, employee absenteeism, and for the medical surveillance of potential laboratory-associated illnesses.				
NIH: G-II-D-2-k	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, and NIH/OBA. Reports to the 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). Written records are prepared and maintained. An essential adjunct to such a reporting-surveillance system is the availability of a facility for quarantine, isolation, and medical care of personnel with potential or known laboratory associated illnesses.				
NIH: G-II-D-2-l	Laboratory animals involved in experiments requiring BL4 level physical containment shall be housed either in cages contained in Class III cabinets or in partial containment caging systems, such as Horsfall units (see Appendix G-III-K, Footnotes and References of Appendix G), open cages placed in ventilated enclosures, or solid-wall and -bottom cages placed on holding racks equipped with ultraviolet irradiation lamps and reflectors that are located in a specially designed area in which all personnel are required to wear one-piece positive pressure suits.				

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Alternative Selection of Containment Equipment (BL4)					
NIH: G-II-D-2-m	Experimental procedures involving a host-vector system that provides a one-step higher level of biological containment than that specified may be conducted in the BL4 facility using containment equipment requirements specified for the BL3 level of physical containment. Alternative combinations of containment safeguards are shown in Appendix G-Table 1, Possible Alternate Combinations of Physical and Biological Containment Safeguards.				
Containment Equipment (BL4)					
NIH: G-II-D-3-a	All procedures within the facility with agents assigned to Biosafety Level 4 are conducted in the Class III biological safety cabinet or in Class I or II biological safety cabinets used in conjunction with one-piece positive pressure personnel suits ventilated by a life-support system.				
Laboratory Facilities (BL4)					
NIH: G-II-D-4-a	The maximum containment facility consists of either a separate building or a clearly demarcated and isolated zone within a building.				
NIH: G-II-D-4-a	Outer and inner change rooms separated by a shower are provided for personnel entering and exiting the facility.				
NIH: G-II-D-4-a	A double-doored autoclave, fumigation chamber, or ventilated airlock is provided for passage of those materials, supplies, or equipment which are not brought into the facility through the change room.				
NIH: G-II-D-4-b	Walls, floors, and ceilings of the facility are constructed to form a sealed internal shell which facilitates fumigation and is animal and insect proof.				
NIH: G-II-D-4-b	The internal surfaces of this shell are resistant to liquids and chemicals, thus facilitating cleaning and decontamination of the area.				
NIH: G-II-D-4-b	All penetrations in these structures and surfaces are sealed.				
NIH: G-II-D-4-b	Any drains in the floors contain traps filled with a chemical disinfectant of demonstrated efficacy against the target agent, and they are connected directly to the liquid waste decontamination system.				

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NIH: G-II-D-4-b	Sewer and other ventilation lines contain high efficiency particulate air/HEPA filters.				
NIH: G-II-D-4-c	Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize the horizontal surface area on which dust can settle.				
NIH: G-II-D-4-d	Bench tops have seamless surfaces which are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.				
NIH: G-II-D-4-e	Laboratory furniture is simple and of sturdy construction; and spaces between benches, cabinets, and equipment are accessible for cleaning.				
NIH: G-II-D-4-f	A foot, elbow, or automatically operated hand washing sink is provided near the door of each laboratory room in the facility.				
NIH: G-II-D-4-g	If there is a central vacuum system, it does not serve areas outside the facility.				
NIH: G-II-D-4-g	In-line high efficiency particulate air/HEPA filters are placed as near as practicable to each use point or service cock.				
NIH: G-II-D-4-g	Filters are installed to permit in-place decontamination and replacement.				
NIH: G-II-D-4-g	Other liquid and gas services to the facility are protected by devices that prevent back-flow.				
NIH: G-II-D-4-h	If water fountains are provided, they are foot operated and are located in the facility corridors outside the laboratory.				
NIH: G-II-D-4-h	The water service to the fountain is not connected to the back-flow protected distribution system supplying water to the laboratory areas.				
NIH: G-II-D-4-i	Access doors to the laboratory are self-closing and lockable.				

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NIH: G-II-D-4-j	Any windows are breakage resistant.				
NIH: G-II-D-4-k	A double-doored autoclave is provided for decontaminating materials passing out of the facility. The autoclave door which opens to the area external to the facility is sealed to the outer wall and automatically controlled so that the outside door can only be opened after the autoclave sterilization cycle has been completed.				
NIH: G-II-D-4-l	A pass-through dunk tank, fumigation chamber, or an equivalent decontamination method is provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the facility.				
NIH: G-II-D-4-m	Liquid effluent from laboratory sinks, biological safety cabinets, floors, and autoclave chambers are decontaminated by heat treatment before being released from the maximum containment facility.				
NIH: G-II-D-4-m	Liquid wastes from shower rooms and toilets may be decontaminated with chemical disinfectants or by heat in the liquid waste decontamination system.				
NIH: G-II-D-4-m	The procedure used for heat decontamination of liquid wastes is evaluated mechanically and biologically by using a recording thermometer and an indicator microorganism with a defined heat susceptibility pattern.				
NIH: G-II-D-4-m	If liquid wastes from the shower room are decontaminated with chemical disinfectants, the chemical used is of demonstrated efficacy against the target or indicator microorganisms.				
NIH: G-II-D-4-n	An individual supply and exhaust air ventilation system is provided. The system maintains pressure differentials and directional airflow as required to assure flows inward from areas outside of the facility toward areas of highest potential risk within the facility.				
NIH: G-II-D-4-n	Manometers are used to sense pressure differentials between adjacent areas maintained at different pressure levels. If a system malfunctions, the manometers sound an alarm.				
NIH: G-II-D-4-n	The supply and exhaust airflow is interlocked to assure inward (or zero) airflow at all times.				

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NIH: G-II-D-4-o	The exhaust air from the facility is filtered through high efficiency particulate air/HEPA filters and discharged to the outside so that it is dispersed away from occupied buildings and air intakes.				
NIH: G-II-D-4-o	Within the facility, the filters are located as near the laboratories as practicable in order to reduce the length of potentially contaminated air ducts.				
NIH: G-II-D-4-o	The filter chambers are designed to allow in situ decontamination before filters are removed and to facilitate certification testing after they are replaced.				
NIH: G-II-D-4-o	Coarse filters and HEPA filters are provided to treat air supplied to the facility in order to increase the lifetime of the exhaust HEPA filters and to protect the supply air system should air pressures become unbalanced in the laboratory.				
NIH: G-II-D-4-p	The treated exhaust air from Class I and II biological safety cabinets may be discharged into the laboratory room environment or the outside through the facility air exhaust system. If exhaust air from Class I or II biological safety cabinets is discharged into the laboratory the cabinets are tested and certified at six-month intervals.				
NIH: G-II-D-4-p	The exhaust air from Class III biological safety cabinets is discharged, without recirculation through two sets of high efficiency particulate air/HEPA filters in series, via the facility exhaust air system. If the treated exhaust air from any of these cabinets is discharged to the outside through the facility exhaust air system, it is connected to this system in a manner (e.g., thimble unit connection (see Appendix G-III-L, Footnotes and References of Appendix G)) that avoids any interference with the air balance of the cabinets or the facility exhaust air system.				
NIH: G-II-D-4-q	A specially designed suit area may be provided in the facility.				
NIH: G-II-D-4-q	Personnel who enter this area shall wear a one-piece positive pressure suit that is ventilated by a life-support system.				
NIH: G-II-D-4-q	The life-support system includes alarms and emergency backup breathing air tanks.				

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NIH: G-II-D-4-q	Entry to this area is through an airlock fitted with airtight doors.				
NIH: G-II-D-4-q	A chemical shower is provided to decontaminate the surface of the suit before the worker exits the area.				
NIH: G-II-D-4-q	The exhaust air from the suit area is filtered by two sets of high efficiency particulate air/HEPA filters installed in series.				
NIH: G-II-D-4-q	A duplicate filtration unit, exhaust fan, and an automatically starting emergency power source are provided.				
NIH: G-II-D-4-q	The air pressure within the suit area is greater than that of any adjacent area. Emergency lighting and communication systems are provided.				
NIH: G-II-D-4-q	All penetrations into the internal shell of the suit are sealed.				
NIH: G-II-D-4-q	A double-doored autoclave is provided for decontaminating waste materials to be removed from the suit areas.				

Comments continued:

Inspector summary and comments:

Lead inspector:

Date:

Other inspectors present:

Date:

Lead inspector signature: _____

Date: _____