Inspection Checklist for NIH BL2-N Laboratories (7 CFR 331; 9 CFR 121; 42 CFR 73; NIH Guidelines)

Inspection Date:

Entity Name:

Responsible Official:

SAP Inspector(s):

Principal Investigator (P.I.):

Laboratory Location - Street Address:

Building:

Room number(s):

Agent(s)/Toxin(s):

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

Reference	Statement	Response			Comments
		Yes	No	N/A	
NIH BL2-N (rDNA) REQUIREMENTS					
CFR: Section 12(a)	An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use.				
CFR: Section 12(a)	The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures.				
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)(3)	In developing a biosafety plan, an individual or entity should consider: The "NIH Guidelines for Research Involving Recombinant DNA Molecules," (NIH Guidelines). Copies may be obtained from the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia, 30333 or from the CDC web site at http://www.cdc.gov/. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia.				
CFR: Section 12(d)	The plan must be reviewed annually and revised as necessary.				
CFR: Section 12(d)	Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan.				
CFR: Section 12(d)	The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.				
NIH: Q-I: B-1	When an animal containing recombinant DNA or a recombinant DNA-derived organism is euthanized or dies, the carcass shall be disposed of to avoid its use as food for human beings or animals unless food use is specifically authorized by an appropriate Federal agency.				
NIH: Q-I: B-2	A permanent record shall be maintained of the experimental use and disposal of each animal or group of animals.				

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		Yes	No	N/A	
NIH: Q-II: B-1-a-(1)	The containment area shall be locked.				
NIH: Q-II: B-1-a-(2)	The containment area shall be patrolled or monitored at frequent intervals.				
NIH: Q-II: B-1-a-(3)	The containment building shall be controlled and have a locking access.				
NIH: Q-II: B-1-a-(4)	The Animal Facility Director shall establish policies and procedures whereby only persons who have been advised of the potential hazard and who meet any specific entry requirements (e.g., vaccination) may enter the laboratory or animal rooms.				
NIH: Q-II: B-1-a-(5)	Animals of the same or different species, which are not involved in the work being performed, shall not be permitted in the animal area.				
NIH: Q-II: B-1-b-(1)	Contaminated materials that are decontaminated at a site away from the laboratory shall be placed in a closed durable leak-proof container prior to removal from the laboratory.				
NIH: Q-II: B-1-b-(2)	Needles and syringes shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.				
NIH: Q-II: B-1-c-(1)	When the animal research requires special provisions for entry (e.g., vaccination), a warning sign incorporating the universal biosafety symbol shall be posted on all access doors to the animal work area. The sign shall indicate: (i) the agent, (ii) the animal species, (iii) the name and telephone number of the Animal Facility Director or other responsible individual, and (iv) any special requirements for entering the laboratory.				
NIH: Q-II: B-1-d-(1)	Laboratory coats, gowns, smocks, or uniforms shall be worn while in the animal area or attached laboratory. Before entering non-laboratory areas (e.g., cafeteria, library, administrative offices), protective clothing shall be removed and kept in the work entrance area.				
NIH: Q-II: B-1-d-(2)	Special care shall be taken to avoid skin contamination with microorganisms containing recombinant DNA. Impervious and/or protective gloves shall be worn when handling experimental animals and when skin contact with an infectious agent is unavoidable.				

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NIH: Q-II: B-1-e-(1)	Any incident involving spills and accidents that result in environmental release or exposures of animals or laboratory workers to organisms containing recombinant DNA molecules shall be reported immediately to the Animal Facility Director, Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities (if applicable). 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). Medical evaluation, surveillance, and treatment shall be provided as appropriate and written records maintained. If necessary, the area shall be appropriately decontaminated.				
NIH: Q-II: B-1-e-(2)	When appropriate and giving consideration to the agent handled, baseline serum samples shall be collected and stored for animal care and other at-risk personnel. Additional serum specimens may be collected periodically depending on the agent handled and the function of the animal facility.				
NIH: Q-II: B-1-f-(1)	Biological materials removed from the animal containment area in a viable or intact state shall be transferred to a non-breakable sealed primary container and then enclosed in a non-breakable sealed secondary container. All containers, primary and secondary, shall be disinfected before removal from the animal facility. Advance approval for transfer of material shall be obtained from the Animal Facility Director. Packages containing viable agents may only be opened in a facility having an equivalent or higher level of physical containment unless the agent is biologically inactivated or incapable of reproduction.				
NIH: Q-II: B-1-g-(1)	All genetically engineered neonates shall be permanently marked within 72 hours after birth, if their size permits. If their size does not permit marking, their containers should be marked. In addition, transgenic animals should contain distinct and biochemically assayable DNA sequences that allow identification of transgenic animals from among non-transgenic animals.				
NIH: Q-II: B-1-g-(2)	Needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe needle units (i.e., needle is integral to the syringe) shall be used for the injection or aspiration of fluids containing organisms that contain recombinant DNA. Extreme caution shall be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Following use, needles shall not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe. Needles and syringes shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.				

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NIH: Q-II: B-1-g-(3)	Appropriate steps should be taken to prevent horizontal transmission or exposure of laboratory personnel. If the agent used as a vector is known to be transmitted by a particular route (e.g., arthropods), special attention should be given to preventing spread by that route. In the absence of specific knowledge of a particular route of transmission, all potential means of horizontal transmission (e.g., arthropods, contaminated bedding, or animal waste, etc.) should be prevented.				
NIH: Q-II: B-1-g-(4)	Eating, drinking, smoking, and applying cosmetics shall not be permitted in the work area.				
NIH: Q-II: B-1-g-(5)	Individuals who handle materials and animals containing recombinant DNA molecules shall be required to wash their hands before exiting the containment area.				
NIH: Q-II: B-1-g-(6)	A double barrier shall be provided to separate male and female animals unless reproductive studies are part of the experiment or other measures are taken to avoid reproductive transmission. Reproductive incapacitation may be used.				
NIH: Q-II: B-1-g-(7)	The containment area shall be in accordance with state and Federal laws and animal care requirements.				
NIH: Q-II: B-1-g-(8)	A biosafety manual shall be prepared or adopted. Personnel shall be advised of special hazards and required to read and follow instructions on practices and procedures.				
NIH: Q-II: B-2-a	Animals shall be contained within an enclosed structure (animal room or equivalent) to minimize the possibility of theft or unintentional release and to avoid arthropod access. The special provision to avoid the entry or escape of arthropods from the animal areas may be waived if the agent in use is not known to be transmitted by arthropods.				
NIH: Q-II: B-2-b	Surfaces shall be impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.				
NIH: Q-II: B-2-c	The animal containment area shall be designed so that it can be easily cleaned.				
NIH: Q-II: B-2-d	Windows that open shall be fitted with fly screens.				
NIH: Q-II: B-2-e	An autoclave shall be available for decontamination of laboratory wastes.				
NIH: Q-II: B-2-f	If arthropods are used in the experiment or the agent under study can be transmitted by an arthropod, interior work areas shall be appropriately screened (52 mesh). All perimeter joints and openings shall be sealed and additional arthropod control mechanisms used to minimize arthropod entry and propagation, including appropriate screening of access doors or the equivalent.				

Reference	Statement	Response			Comments
		Yes	No	N/A	
Inspector summary and comments:					
Recommendations:					
Inspector completing checklist:					**Date:**
Other inspectors present:					**Date:**