

**Inspection Checklist for NIH BL3-N 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
<b>NIH BL3-N (rDNA) REQUIREMENTS</b>					
<b>Note: Appendix Q specifies containment and confinement practices when research animals are of a size or have growth requirements that preclude the use of containment for laboratory animals. The animals covered in Appendix Q are those species including but not limited to cattle, swine, sheep, goats, horses, and poultry.</b>					
<b>CFR: Section 12(a)</b>	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.				
<b>CFR: Section 12(a)</b>	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.				
<b>CFR: Section 12(b)</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).				
<b>CFR: Section 12 (c)(1)</b>	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 <a href="http://www.selectagents.gov/">http://www.selectagents.gov/</a> .				

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<b>CFR: Section 12 (c)(3)</b>	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 <a href="http://www.selectagents.gov">http://www.selectagents.gov</a> .				
<b>CFR: Section 12(d)</b>	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.				
<b>CFR: Section 12(e)</b>	The plan must be reviewed annually and revised as necessary.				
<b>CFR: Section 12(e)</b>	Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan.				
<b>CFR: Section 12(e)</b>	The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.				
<b>42 CFR 73: Section 13 (a)</b>	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 <sub>50</sub> < 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.				
<b>42 CFR 73: Section 13 (a)</b>	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 <sub>50</sub> < 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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<b>9 CFR 121: Section13(a)</b>	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:				
<b>Q-I-B</b>	<b>Disposal of Animals (BL1-N through BL4-N)</b>				
<b>NIH: Q-I-B-1</b>	When an animal covered by Appendix Q containing recombinant or synthetic nucleic acid molecules or a recombinant or synthetic nucleic acid molecule-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.				
<b>NIH: Q-I-B-2</b>	A permanent record shall be maintained of the experimental use and disposal of each animal or group of animals.				
<b>Q-II-C-1</b>	<b>Standard Practices (BL3-N)</b>				
<b>NIH: Q-II-C-1-a(1)</b>	The containment area shall be locked.				
<b>NIH: Q-II-C-1-a(2)</b>	The containment area shall be patrolled or monitored at frequent intervals.				
<b>NIH: Q-II-C-1-a(3)</b>	The containment building shall be controlled and have a locking access.				
<b>NIH: Q-II-C-1-a(4)</b>	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) shall enter the laboratory or animal rooms.				
<b>NIH: Q-II-C-1-a(5)</b>	Animal room doors, gates, or other closures shall be kept closed when experiments are in progress.				

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<b>NIH: Q-II-C-1-b(1)</b>	The work surfaces of containment equipment shall be decontaminated when work with organisms containing recombinant or synthetic nucleic acid molecules is finished. Where feasible, plastic-backed paper toweling shall be used on nonporous work surfaces to facilitate clean-up.				
<b>NIH: Q-II-C-1-b(2)</b>	All animals shall be euthanized at the end of their experimental usefulness and the carcasses decontaminated before disposal in an approved manner.				
<b>NIH: Q-II-C-1-b(3)</b>	Needles and syringes shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.				
<b>NIH: Q-II-C-1-b(4)</b>	Special safety testing, decontamination procedures, and Institutional Biosafety Committee approval shall be required to transfer agents or tissue/organ specimens from a BL3-N animal facility to a facility with a lower containment classification.				
<b>NIH: Q-II-C-1-b(5)</b>	Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated every 30 days with an indicator organism.				
<b>NIH: Q-II-C-1-c(1)</b>	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.				
<b>NIH: Q-II-C-1-d(1)</b>	Full protective clothing that protects the individual (e.g., scrub suits, coveralls, uniforms) shall be worn in the animal area. Clothing shall not be worn outside the animal containment area and shall be decontaminated before laundering or disposal. Personnel shall be required to shower before exiting the BL3-N area and wearing of personal clothing.				
<b>NIH: Q-II-C-1-d(2)</b>	Special care shall be taken to avoid skin contamination with microorganisms containing recombinant or synthetic nucleic acid molecules. 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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<b>NIH: Q-II-C-1-d-(3)</b>	Appropriate respiratory protection shall be worn in rooms containing experimental animals.				
<b>NIH: Q-II-C-1-e-(1)</b>	Documents regarding experimental animal use and disposal shall be maintained in a permanent record book.				
<b>NIH: Q-II-C-1-e-(2)</b>	Any incident involving spills and accidents that result in environmental release or exposure of animals or laboratory workers to organisms containing recombinant or synthetic nucleic acid molecules shall be reported immediately to the Biological Safety Office, 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.				
<b>NIH: Q-II-C-1-e-(3)</b>	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 or the function of the facility.				
<b>NIH: Q-II-C-1-f-(1)</b>	Biological materials removed from the animal containment laboratory 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 be opened only in a facility having an equivalent or higher level of physical containment unless the agent is biologically inactivated or incapable of reproduction.				
<b>NIH: Q-II-C-1-f-(2)</b>	Special safety testing, decontamination procedures, and Institutional Biosafety Committee approval shall be required to transfer agents or tissue/organ specimens from a BL3-N animal facility to a facility with a lower containment classification.				

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<b>NIH: Q-II-C-1-g-(1)</b>	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.				
<b>NIH: Q-II-C-1-g-(2)</b>	Appropriate steps should be taken to prevent horizontal transmission or exposure of laboratory personnel. If the agent used as the 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) should be prevented.				
<b>NIH: Q-II-C-1-g-(3)</b>	Eating, drinking, smoking, and applying cosmetics shall not be permitted in the work area.				
<b>NIH: Q-II-C-1-g-(4)</b>	Individuals who handle materials and animals containing recombinant or synthetic nucleic acid molecules shall be required to wash their hands before exiting the containment area.				
<b>NIH: Q-II-C-1-g-(5)</b>	Experiments involving other organisms that require containment levels lower than BL3-N may be conducted in the same area concurrently with experiments requiring BL3-N containment provided that they are conducted in accordance with BL3-N practices.				
<b>NIH: Q-II-C-1-g-(6)</b>	Animal holding areas shall be cleaned at least once a day and decontaminated immediately following any spill of viable materials.				
<b>NIH: Q-II-C-1-g-(7)</b>	All procedures shall be performed carefully to minimize the creation of aerosols.				
<b>NIH: Q-II-C-1-g-(8)</b>	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.				
<b>NIH: Q-II-C-1-g-(9)</b>	The containment area shall be in accordance with state and Federal laws and animal care requirements.				

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<b>NIH: Q-II-C-1-g-(10)</b>	All animals shall be euthanized at the end of their experimental usefulness and the carcasses decontaminated before disposal in an approved manner.				
<b>NIH: Q-II-C-1-g-(11)</b>	Personnel shall be required to shower before exiting the BL3-N area and wearing personal clothing.				
<b>NIH: Q-II-C-1-g-(12)</b>	Animals of the same or different species, which are not involved in the work being performed, shall not be permitted in the animal area.				
<b>NIH: Q-II-C-1-g-(13)</b>	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 or synthetic nucleic acid molecules. 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. The needles and syringes shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.				
<b>NIH: Q-II-C-1-g-(14)</b>	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.				
<b>Q-II-C-2</b>	<b>Animal Facilities (BL3N)</b>				
<b>NIH: Q-II-C-2-a</b>	Animals shall be contained within an enclosed structure (animal room or equivalent) to minimize the possibility of theft or unintentional release and 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.				
<b>NIH: Q-II-C-2-b</b>	The interior walls, floors, and ceilings shall be impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat, to facilitate cleaning. Penetrations in these structures and surfaces (e.g., plumbing and utilities) shall be sealed.				
<b>NIH: Q-II-C-2-c</b>	Windows in the animal facility shall be closed, sealed, and breakage resistant (e.g., double-pane tempered glass or equivalent). The need to maintain negative pressure should be considered when constructing or renovating the animal facility.				

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<b>NIH: Q-II-C-2-d</b>	An autoclave, incinerator, or other effective means to decontaminate animals and waste shall be available, preferably within the containment area. If feasible, a double-door autoclave is preferred and should be positioned to allow removal of material from the containment area.				
<b>NIH: Q-II-C-2-e</b>	If arthropods are used in the experiment or the agent under study can be transmitted by an arthropod, the interior work area 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, or the equivalent of access doors.				
<b>NIH: Q-II-C-2-f</b>	Access doors to the containment area shall be self-closing.				
<b>NIH: Q-II-C-2-g</b>	The animal area shall be separated from all other areas. Passage through two sets of doors shall be the basic requirement for entry into the animal area from access corridors or other contiguous areas. The animal containment area shall be physically separated from access corridors and other laboratories or areas by a double-door clothes change room, equipped with integral showers and airlock.				
<b>NIH: Q-II-C-2-h</b>	Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated every 30 days with an indicator organism.				
<b>NIH: Q-II-C-2-i</b>	An exhaust air ventilation system shall be provided. This system shall create directional airflow that draws air into the animal room through the entry area. The building exhaust, or the exhaust from primary containment units, may be used for this purpose if the exhaust air is discharged to the outside and shall be dispersed away from occupied areas and air intakes. Personnel shall verify that the direction of the airflow (into the animal room) is proper.				
<b>NIH: Q-II-C-2-j</b>	If the agent is transmitted by aerosol, then the exhaust air shall pass through a high efficiency particulate air/HEPA filter.				

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<b>NIH: Q-II-C-2-k</b>	Vacuum lines shall be protected with high efficiency particulate air/HEPA filters and liquid disinfectant traps.				
<b>NIH: Q-II-C-2-l</b>	In lieu of open housing in the special animal room, animals held in a BL3-N area may be housed in partial-containment caging systems (e.g., Horsfall units or gnotobiotic systems, or other special containment primary barriers). Prudent judgment must be exercised to implement this ventilation system (e.g., animal species) and its discharge location.				
<b>NIH: Q-II-C-2-m</b>	Each animal area shall contain a foot, elbow, or automatically operated sink for hand washing. The sink shall be located near the exit door.				
<b>NIH: Q-II-C-2-n</b>	Restraining devices for animals may be required to avoid damage to the integrity of the animal containment facility.				

Comments continued:

Inspector summary and comments:

Lead inspector:

Date:

Other inspectors present:

Date:

Lead inspector signature: \_\_\_\_\_

Date: \_\_\_\_\_