

January 19, 2005

**REQUIREMENTS FOR SUBMITTAL AND APPROVAL OF BIOSAFETY LEVEL-3
(BSL-3) RESEARCH LABORATORY CONSTRUCTION AND RENOVATION**

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy on how to obtain approval for the construction of new Biosafety Level 3 (BSL-3) research laboratories and approval for planning a major renovation of space for a BSL-3 research laboratory, including the renovation of an existing BSL-3 research laboratory. *NOTE: VHA does not permit the construction or operation of Biosafety Level-4 laboratories.*

2. BACKGROUND

a. The concept of laboratory construction that meets different biosafety levels was developed as a secondary means or barrier to ensure that laboratory workers and the environment were protected from exposure to infectious materials. The first line of protection must be practices and equipment used by laboratory workers. The work practices and the equipment are collectively referred to as the primary containment. Specifically, the primary containment consists of good microbiological techniques and the use of appropriate safety equipment. The adherence to good microbiological techniques may not be sufficient to prevent exposure to, or release of, microbiological agents. Therefore, safety equipment such as biological safety cabinets, enclosed containers, engineering controls, and personal protective equipment (e.g., gloves, gowns, respirators, face shields) must also be used. These types of equipment are referred to as primary barriers. *NOTE: Safety equipment is listed as both a “primary containment” and a “primary barrier.”*

b. Biosafety levels as described by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) in the publication “Biosafety in Microbiological and Biomedical Laboratories” (BMBL) (4th edition) consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Four biosafety levels (BSL-1-4) have been identified based on the potential hazard of specific microorganisms to laboratory workers and others. Organisms in BSL-1 laboratories represent the least hazardous, and those in BSL-4 laboratories represent the most hazardous to workers and others. The CDC publishes guidance on the recommended BSL based on the microorganisms that will be used within the laboratory.

c. BSL-3 laboratories are required when work is done with indigenous or exotic agents, vectors, and recombinant DNA with a potential for respiratory transmission that may cause serious or potentially lethal disease or environmental and genetic contamination. The design and construction of the BSL-3, including BSL-3 animal facilities, is crucial in preventing such exposures and safeguarding the well being and safety of the researchers and other building occupants. In addition to all other applicable requirements, the design of BSL-3 laboratories once approved, must include the following requirements:

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- (1) Location of the research laboratory.
- (2) Security in accordance with VA Directive 0730-1 Appendix B and VHA Handbook 1200.6 including:
 - (a) Risk and threat assessment;
 - (b) Access control, e.g., card reader or biometrics;
 - (c) Cyber security, e.g., registering and/or a background check for people with access to data, using select agents;
 - (d) Controlled access to select agent storage; and
 - (e) Transport of agents.
- (3) Furniture construction and materials.
- (4) Special plumbing requirement, e.g., chemical neutralization, tank, liquid effluent treatment system (especially for new construction), deep sealed trap.
- (5) Heating, ventilation, air conditioning (HVAC) systems, including system redundancy. This requires:
 - (a) A HVAC control system with audible or strobic alarms in the facility and signal to a central control station; **NOTE:** *Strobe lights (70,000 foot candles) are preferred to avoid "startle" when working with infectious agents.*
 - (b) A system where exhaust air can not be re-circulated; and
 - (c) A HEPA filtration of exhausted air. **NOTE:** *Scientific protocol may indicate a need for HEPA filtration of supply air as well.*
- (6) Surfaces which must have cleanable and wipeable finishes, e.g., seamless vinyl flooring with integral base, gypsum wall board with epoxy paint, wipeable ceiling, and gas proof light fixtures.
- (7) General construction requirements of:
 - (a) Compliance with CDC-NIH Biosafety in Microbiological and Biomedical Laboratories (BMLB) latest edition,
 - (b) Compliance to life safety and all other applicable codes,
 - (c) Compliance to Americans with Disabilities Act (ADA) requirements,

- (d) Complete and sealed separation of the laboratory from the rest of the facility,
- (e) Laboratory access through anteroom and/or gowning area,
- (f) Shower out capability, and
- (g) All windows are fixed and sealed.
- (8) Back-up and/or redundant utility systems.
- (9) Special electrical, e.g., gas tight sealed light fixture, no surface mounted raceway.
- (10) Communications.
- (11) Laboratory air and gas.
- (12) Vacuum systems.
- (13) Decontamination and fumigation capability, e.g., providing fumigation room for decontamination of equipment autoclaves.
- (14) Comprehensive biosafety evaluation and commissioning for all building components, systems, and laboratory equipment before occupancy and use.
- (15) Annual recertification of the laboratory.

d. In an effort to ensure maximal protections for BSL-3 research laboratory workers, others who may be in the geographic area, and the environment, it is necessary for VHA to ensure that the construction of new BSL-3 research laboratories meets all appropriate standards and that the research laboratories are required to fulfill the research mission of VHA. *NOTE: Only experienced personnel or companies should carry out the design and construction of BSL-3 laboratories.*

3. POLICY: It is VHA policy that permission to begin the project must be obtained from the Under Secretary for Health prior to the initiation of a project that will result in the construction of a new BSL-3 research laboratory or renovation of space for a BSL-3 research laboratory, including the major renovation of an existing BSL-3 research laboratory.

NOTE: This approval is separate from the Minor/Major Construction Approval Process.

4. ACTION

a. **Under Secretary for Health (10).** The Under Secretary for Health provides final project approval and ensures BSL-3 projects incorporate VHA standards for construction, employee safety and environmental protection, compliance with Federal and State regulations and are required to fulfill the research mission of VHA.

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b. Office of Research and Development (12)

(1) The Office of Research and Development (ORD) will initially review the BSL-3 submittal after which ORD coordinates the reviews and comments from the Deputy Under Secretary for Health for Operations and Management (10NB), the Office of Facilities Management (18), and the Office of Research Oversight (10R).

(2) ORD submits the comments and recommendations to the Under Secretary for Health for final approval. ORD coordinates any inquiries from the Under Secretary for Health needed for a final decision and obtains any additional clarification, comment, or documentation from VA Central Office (10NB, 18, and 10R), the Veterans Integrated Services Network (VISN), and the facility during the approval process.

c. Office of Research Oversight (10R). The Office of Research Oversight (ORO), in addition to submitting comments to ORD regarding the submittal, conducts a final assessment of the new or newly renovated BSL-3 research laboratory after construction is completed. Only after receiving approval from ORO may the BSL-3 research laboratory be activated.

d. Veterans Integrated Service Network (VISN) Director

(1) The VISN Director is responsible for reviewing and approving the initial facility request to construct or renovate a BSL-3 research laboratory. The review includes the elements of paragraph 4e(1)(a) through (o), in addition to specific VISN requirements for construction project review.

(2) The VISN Director, or representative, may request additional information from the facility, as necessary. Any additional information used for the basis of BSL-3 research laboratory approval should be documented in the facility submittal and included for review by ORD.

(3) The VISN Director, or representative, sends the request for Under Secretary for Health approval to:

Chief Research and Development Officer (12)
Department of Veterans Affairs
810 Vermont Ave., NW
Washington, DC 20420

(4) The VISN Director, or representative, is responsible for notifying the facility that their request has been either approved or disapproved, and if approved, it has been forwarded to ORD.

e. Facility Director. The Facility Director is responsible for:

(1) Obtaining permission from the VISN Director and Under Secretary for Health to initiate the construction of a new BSL-3 research laboratory or the major renovation of laboratory space

to meet BSL-3 research laboratory specifications, including the major renovation of an existing BSL-3 research laboratory. The request must include the following information:

(a) Justification of need or rationale for the proposed construction including documentation of review of the BSL-3 construction or renovation needs by the facility research biosafety committee and formal approval by the Facility Director, the Subcommittee on Research Safety (SRS) Committee Chair, and the Research and Development Committee Chair.

(b) Type of research that will be conducted in the proposed BSL-3.

(c) Physical location of the BSL-3 research laboratory and the construction site security plan.

(d) Construction and/or renovation engineering goals and a proposed time line for completion.

(e) Coordination of construction and/or renovation effort with the application, registration, and inspection per CDC select agent program (see Title 42 Code of Federal Regulations (CFR) Part 73), when applicable.

(f) The name of the Director of the proposed BSL-3 research laboratory and the qualifications of that person.

(g) The qualifications of the Biosafety Officers (research, facility and/or VISN).

(h) The organizational chart of the BSL-3 research laboratory management including the principal investigators using the BSL-3, and a brief description of the investigators' research and their appointment status (compensated or without compensation).

(i) The plan and process to address public comments and concerns, including a formal environmental impact statement and risk communication plan for new construction and for any increase of current biosafety level in a research facility (any renovation of BSL-1/2 to meet BSL-3).

(j) The select agents or toxins to be used in the BSL-3 research laboratory, if any.

(k) A list of other available BSL-3 laboratories within the facility, or at the university affiliate, and a discussion of why they cannot be used for the research.

(l) Initial estimates for cost of the BSL-3 research laboratory, identification of the funding source(s) for construction and/or renovation, and the long-term maintenance of the BSL-3 research laboratory and equipment.

(m) The name of the architectural and engineering company(ies) designing the BSL-3 research laboratory, including their qualifications and a list of other projects they have completed.

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(n) The name of contractor or VA office responsible for the construction of the BSL-3 research laboratory and their qualifications.

(o) The plans and responsibility for conducting commissioning of the BSL-3, including certification standards, testing and issuance of certificate.

NOTE: All major and minor construction processes still need to be completed in conjunction with the request for approval required by this Directive. Construction funding is dependent upon the funding allocation and the scoring of the project application.

(2) Sending the request to the VISN Director for approval.

5. REFERENCES

a. Biosafety in Microbiological and Biomedical Laboratories (BMLB) 4th Edition CDC-NIH, 1999.

b. NIH Guidelines for Recombinant DNA and Gene Transfer.

c. Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, 2nd Edition, CDC/NIH, September 2000.

d. VHA Handbook 1200.6.

e. VHA Facilities Management Design Guides (<http://vaww.va.gov/facmgt/standard>).

6. FOLLOW-UP RESPONSIBILITY: The Office of Research and Development (12) is responsible for the contents of this VHA Directive. For questions related to this Directive, call (202) 254-0183.

7. RESCISSIONS: None. This VHA Directive expires January 31, 2010.

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Acting Under Secretary for Health

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