

TITLE:	IBC29- Personnel Access for Biosafety Level 3 Containment Laboratory In the Performance of Research
OVERVIEW:	Individuals requesting access to the BSL-3 containment laboratories on the UNMC campus must undergo a series of biosecurity and biosafety clearance procedures.
APPLIES TO:	All individuals requesting access to the BSL-3 containment laboratories to perform research activities.
DEFINITION(S):	<i>BSL-3 containment (BSL-3)</i> - biosafety level 3 containment is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. For this document, BSL-3 also includes high containment areas housing animals (ABSL-3). Note that all requirements for access to BSL-1 and BSL-2 laboratories also apply.
PROCEDURES:	<p>At BSL-3/ABSL-3 containment, emphasis is placed on primary and secondary barriers to protect personnel working within the laboratory and in contiguous areas to the laboratory, the community, and the environment from exposure to potentially infectious aerosols.</p> <p>Each BSL-3 laboratory suite on the UNMC campus has a Laboratory Director, a Facility Manager, and a Safety and Security Manager.</p> <p>The Laboratory Director is the responsible individual for the facility who gives final approval to work within the laboratory.</p> <p>The Facility Manager coordinates the overall daily operation of the laboratory.</p> <p>The Safety and Security Manager is responsible for clearance and training.</p> <p>The UNMC Biosafety Officer gives general oversight to see that training and facility operational procedures are followed.</p> <p>The UNMC IBC approves Internal Operating policies and procedures as they pertain to the Select Agent Program in general and the operation of BSL-3 containment laboratories in particular.</p> <p>Individuals not from the UNMC campus, in addition to the procedures outlined below, will need to obtain password access to the training program and be registered to obtain a picture ID and keys.</p>

Once a request is made to access the laboratory, the Safety and Security Manager will begin the process to obtain the necessary campus clearance.

All individuals requesting access to the BSL-3 facility must be included on an active IBC protocol. Copies of this protocol must be on file in the BSL-3 facility. (Exceptions to this rule may be for support personnel designated to work in the containment laboratory. This exception will be granted on a case-by-case basis.)

Two phases of access must be considered. The Phase 1 procedures are to be completed and approved by the Laboratory Director before continuing on with Phase 2.

Phase 1 procedures

1. Education and Experience

Minimum requirements for education and experience are described in **Policy # SA24, Education and Experience Requirements**. These requirements can be met during the review process as outlined below.

2. Biosecurity risk assessment

A biosecurity risk assessment is required of all individuals requiring unescorted access to the BSL-3 laboratory. A limited background check by Human Resources or an intensive assessment as required by the U.S. Department of Justice (DOJ) as a part of the Select Agent Program will be done. The Biosafety Officer in consultation with the Safety and Security Manager and the Laboratory Director will determine which individuals require which level of clearance.

If it is determined that DOJ clearance is needed, the Biosafety Officer will process the necessary paperwork and work with the individual through the process. This process may take 10 weeks or longer for final approval.

3. Medical Evaluation

All individuals must have documentation of the following within the last year: (1) TB skin testing, (2) satisfactory respirator fit test, and (3) a medical evaluation by Employee Health.

The Safety and Security Manager will work with the individual through Employee Health to complete this medical evaluation.

Serum banking will be determined on a case-by-case basis according to procedures outlined in policy #IBC37, Serum Banking.

4. Training

	<p>All individuals must show documentation of satisfactory completion of the UNMC/NMC training for chemical safety, radiation safety, blood borne pathogens, General Biosafety, BSL-3 Containment, and Select Agents (when applicable).</p> <p>Additionally, the individual must successfully complete a take-home test pertaining to the following manuals: UNMC/UNO Institutional Biosafety Manual, UNMC/NMC Emergency Preparedness Manual, BSL-3 SOP Manual, BSL-3 Equipment Manual, and the NIH/BMBL/MSDS Manual.</p> <p>All the training is coordinated with the Safety and Security Manager.</p> <p>Phase 2 procedures <i>1. On-site training</i> The Safety and Security Manager will proceed with hands-on training to include BSL-3 SOPs, laboratory equipment usage, security access, biosafety principles and practices, autoclave and decontamination, and research specific practices.</p> <p>Once Phase 2 has been successfully completed, the Safety and Security Manager will submit documentation of completion to the Laboratory Director of the BSL-3/ABSL-3 suite who will give final written permission for laboratory access.</p> <p>Individuals who have been granted permission to use the BSL-3 facility will be given keys and ID access in consultation with the Safety and Security Manager and UNMC Security.</p>
RECORD KEEPING:	<p>The Safety and Security Manager will maintain records of satisfactory completion of the entrance requirements.</p> <p>The Biosafety Officer will maintain all original documentation pertaining to the DOJ security risk assessment as a part of the Select Agent Program.</p>
OTHER INFORMATION:	<p>Maintenance and equipment repair personnel are NOT allowed within the containment area of the BSL-3/ABSL-3 until all work with risk group-3 agents has been stopped. Generally, any instrument or equipment requiring repairs should be decontaminated and removed from the containment area before servicing (Refer also to SA13, Routine Cleaning, Maintenance, and Repair Within the BSL-3)</p> <p>Select agent issues as required by the Select Agent Program must also be considered when unauthorized individuals are requesting access to</p>

	<p>the containment facility (Refer to SA18, Access of Unauthorized Persons into Select Agent Areas).</p> <p>All individuals who are no longer authorized to work in the BSL-3 laboratory must undergo an interview with the Safety and Security Manager and forfeit keys and any other materials pertaining to the containment lab.</p> <p>Individuals who no longer have access include people who have one or more of the following criteria: 1] terminated employment with the University, 2] no longer have an active IBC protocol, 3] do not have active DOJ clearance, 4] do not have records of annual training, or 5] due to any other circumstance.</p>
REFERENCE:	CDC/NIH, Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Service, 5th Edition, 2007, U.S. Government Printing Office, Washington.
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