

Chapter 4 - Laboratory Biosafety Level Criteria

4.1 Introduction

Four biosafety levels (BSLs) are described in BMBL5; each consists of a combination of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically

appropriate for the operations being performed, the documented or suspected routes of transmission of

the infectious agents, and the laboratory function or activity.

The BSLs described in BMBL5 should be differentiated from Risk Groups, as described in the NIH Guidelines and the World Health Organization Laboratory Biosafety Manual. Risk groups are the result

of a classification of microbiological agents based on their association with, and resulting severity of,

disease in humans. The risk group of an agent should be one factor considered in association with mode

of transmission, procedural protocols, experience of staff, and other factors in determining the BSL in

which the work will be conducted.

The recommended biosafety level(s) for the organisms in BMBL5 Section VIII (Agent Summary Statements) represent those conditions under which the agent ordinarily can be safely handled.

Not all

of the organisms capable of causing disease are included in Section VIII; the other resources listed in

Chapter 2 of this manual must be utilized to perform risk assessments for agents not listed in Section VIII. Generally, work with known agents should be conducted at the biosafety level recommended in

Section VIII.

When information is available to suggest that virulence, pathogenicity, antibiotic resistance patterns,

vaccine and treatment availability, or other factors are significantly altered, more (or less) stringent practices may be specified. Often an increased volume or a high concentration of agent may require

additional containment practices.

4.2 Biosafety Level 1

Biosafety level 1 practices, safety equipment, and facility design and construction are appropriate for

undergraduate training and teaching laboratories, and for other laboratories in which work is done with

defined and characterized strains of viable microorganisms not known to consistently cause

disease in healthy adult humans.

Bacillus subtilis, *Nigeria gruberi*, infectious canine hepatitis virus, and exempt organisms under the NIH

Guidelines are representative of microorganisms meeting these criteria. Many agents not ordinarily associated with disease processes in humans are, however, opportunistic pathogens and may cause

infection in the young, the aged, and immunodeficient or immunosuppressed individuals. Vaccine strains that have undergone multiple in vivo passages should not be considered avirulent simply because they are vaccine strains.

BSL-1 represents a basic level of containment that relies on standard microbiological practices with no

special primary or secondary barriers recommended, other than a sink for hand washing.

4.3 Biosafety Level 2

Biosafety level 2 practices, equipment, and facility design and construction are applicable to clinical,

diagnostic, teaching, and other laboratories in which work is done with the broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease

of varying severity. With good microbiological techniques, these agents can be used safely in activities

conducted on the open bench, provided the potential for producing splashes or aerosols is low.

Hepatitis B virus, HIV, *Salmonella*, and *Toxoplasma* are representative of microorganisms assigned to

this containment level. BSL-2 is appropriate when work is done with any human-derived blood, body

fluids, tissues, or primary human cell lines where the presence of an infectious agent may be unknown.

(Laboratory personnel working with human- derived materials should refer to the OSHA Bloodborne Pathogen Standard for specific required precautions).

Primary hazards to personnel working with these agents relate to accidental percutaneous or mucous

membrane exposures, or ingestion of infectious materials. Extreme caution should be taken with contaminated needles or sharp instruments. Even though organisms routinely manipulated at BSL-2 are

not known to be transmissible by the aerosol route, procedures with aerosol or high splash potential

that may increase the risk of such personnel exposure must be conducted in primary containment equipment, or in devices such as a BSC or safety centrifuge cups.

Personal protective equipment should be used as appropriate, such as splash shields, face protection,

gowns, and gloves. Secondary barriers, such as hand washing sinks and waste decontamination facilities,

must be available to reduce potential environmental contamination.

4.4 Biosafety Level 3

Biosafety level 3 practices, safety equipment, and facility design and construction are applicable to

clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potentially lethal infection.

Mycobacterium tuberculosis, St. Louis encephalitis virus, and *Coxiella burnetii* are representative of the microorganisms assigned to this level. Primary hazards to personnel working with these agents relate to autoinoculation, ingestion, and exposure to infectious aerosols.

At BSL-3, more emphasis is placed on primary and secondary barriers to protect personnel in contiguous areas, the community, and the environment from exposure to potentially infectious aerosols. For example, all laboratory manipulations should be performed in a BSC or other enclosed equipment, such as a gas-tight aerosol generation chamber. Secondary barriers for this level include controlled access to the laboratory and ventilation requirements that minimize the release of infectious aerosols from the laboratory.

There are currently no BSL-3 activities occurring at Arkansas State University.

4.5 Biosafety Level 4

Biosafety level 4 is beyond the scope of this manual. There are currently no BSL-4 activities occurring at Arkansas State University.

4.6 Multi-User Research Labs

The advent of large open labs and lab suites creates problems for separation of BSL1 and BSL2 areas and activities. The following NIH Guidelines, which shall apply to all biological activities at Arkansas State, make a multi-PI lab problematic.

For BSL1, Access to the laboratory is limited or restricted at the discretion of the Principal Investigator

when experiments are in progress [Appendix G-II-A-1-a]. For BSL2, Access to the laboratory is limited or

restricted by the Principal Investigator when experiments are in progress [Appendix G-II-B-1-a]. For BSL2, Experiments of lesser biohazard potential can be conducted concurrently in carefully demarcated areas of the same laboratory [Appendix G-II-B-1-h].

Any research group working with agents that are known or potential biohazards shall have an emergency plan that describes the procedures to be followed if an accident contaminates personnel or

the environment. The Principal Investigator shall ensure that everyone in the laboratory is familiar with

both the potential hazards of the work and the emergency plan" [Appendix G-I. Standard Practices and Training].

The Principal Investigator establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific entry requirements (e.g., immunization) may enter the laboratory or animal rooms [Appendix G-II-B-2-c].

For BSL2, Laboratory coats, gowns, smocks, or uniforms are worn while in the laboratory. Before exiting the laboratory for non-laboratory areas (e.g., cafeteria, library, administrative offices), this protective clothing is removed and left in the laboratory or covered with a clean coat not used in the laboratory [Appendix G-II-B-2f].

The BSO shall work with the occupants of each multi-PI lab to determine the most effective way of complying with the cited Guidelines for each lab. The default solution is to designate the entire lab BSL2, with clearly demarcated BSL1 section(s) as required. Note that BSL2 waste must be kept in the BSL2 area until decontaminated. Also, all Risk Group 2 agents must remain secure (under the control of the researcher using the agent only). The highlighted training requirement above will be met by maintaining a notebook containing a Pathogen Safety Data Sheet (PSDS) for each RG2 agent in use.

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