

The BMBL and Biosafety Levels

Tanya D. Graham*

Biosafety Consulting for Veterinary Medicine, LLC

*Corresponding author: Tanya D. Graham, DVM, DACVP, Biosafety Consulting for Veterinary Medicine, LLC, Estelline, SD 57234, United States; E-mail: tanya.d.graham@gmail.com

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Scientists began developing and publishing a series of best practices to mitigate laboratory risks in the 1970's. These biosafety guidelines are disseminated by the Department of Health and Human Services in the publication *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). Now in its 5th edition, the BMBL publishes guidelines for appropriate laboratory biosafety and biosecurity.

Since the first edition was published, each edition of the BMBL has described primary and secondary barriers to infection as well as standard and special laboratory practices for each biosafety level [1,2]. Primary barriers include equipment such as biosafety cabinets and safety centrifuge cups-each designed to prevent release of aerosols. Secondary barriers refer to the laboratory design itself, and include items such as an on-site autoclave and separation of the laboratory from public areas [1]. The National Research Council's 2009 report-Responsible Research with Biological Select Agents and Toxins-states that the biosafety recommendations in the BMBL are almost universally followed as the standard precautions for both research and diagnostic laboratories [3].

The containment biosafety level (i.e. BSL1 thru BSL4) needed for each submission/patient/case is determined by the combination of laboratory facilities (engineering controls); practices and procedures (administrative controls); and the safety equipment (personnel protective equipment) that will be utilized (Table 1). A typical high school science laboratory where individuals work with agents that are not expected to cause disease in healthy adults is a BSL-1 laboratory. In BSL-1 laboratories standard microbiological processes are followed (no eating or drinking in the lab; no mouth pipetting; everyone must wash hands before leaving the laboratory; etc.) and the facility is required to have a laboratory bench and sink.

BSL-2, -3, and -4 laboratories (Table 1) are designed, constructed, and operated to "...prevent accidental release of infectious or hazardous agents within the laboratory and protect laboratory workers and the environment external to the laboratory, including the community, from exposure to the agents" [4]. These guidelines are based on the combination of the procedures to be performed and the specific transmissibility features of the agent. Thus, "...the correct biosafety level depends on the pathogen, its potential for transmission

and [availability of] treatment, and the research procedure or activity being [performed]" [1]. This means that in some situations, otherwise deadly pathogens can be safely handled at less restrictive biosafety levels, depending on the activities being performed with that pathogen. For example, diagnostic testing to identify the presence of a pathogen may require BSL2 containment while amplifying (i.e. growing more of) the same pathogen in a research or production setting may require BSL3 containment [5].

BSL-1	Organisms are not known to routinely cause diseases in healthy adults.
BSL-2	Pathogens can be associated with human disease. Routes of infection include ingestion, contact with skin or mucous membranes (eyes, nose, and mouth) but NOT AIR-BORNE TRANSMISSION. Confine aerosols created by centrifugation, etc. inside biosafety cabinet if needed.
BSL-3	Agents that may have serious or lethal health implications for humans. Routes of infection MAY INCLUDE AIR BORNE TRANSMISSION. Do all work in containment (i.e. inside a biosafety cabinet). Facility must provide negative airflow and alarms to detect changes in airflow.
BSL-4	Agents that are frequently fatal in humans and for which there are no vaccines or treatments. Route(s) of infection are UNKNOWN or include AEROSOL TRANSMISSION. All work done inside an <i>in-line</i> Class III biosafety cabinet or the investigator must be wearing a positive pressure suit and using a Class II biosafety cabinet.

Table 1: Laboratory Safety Levels

Veterinary diagnostic laboratories typically fall under one or more of the following categories: BSL2, BSL3, or BSL3Ag. Because the risk assessment guidelines for agriculture are somewhat different from human public health standards, risk management is focused on both worker safety and on the potential economic impact associated with most agricultural diseases. Worker safety is important but-with the exception of zoonotic diseases-"greater emphasis is placed on reducing the risk of the agent escaping into the environment" [4]. The 2011 survey-Biosafety & Biosecurity in U.S. Veterinary Diagnostic Laboratories:Results of a National Survey by Laboratory Employees-indicates that most veterinary diagnostic labora-

atories follow the BMBL recommendations and the majority of laboratories operate under BSL2 containment conditions [6].

Biosafety Level-3 Agriculture (BSL3Ag), the newest category, involves performing research and/or diagnosing high consequence pathogens (that may or may not be zoonotic) in large animals such as cattle, pigs, or sheep. Since many agricultural animals (i.e. cows, horses, sheep, pigs, etc.) are too large to fit inside a biosafety cabinet, the sealed necropsy room becomes the equivalent to a biosafety cabinet. The people working in the room must now wear personnel protective equipment because they are, in effect, *inside* the containment area (i.e. the sealed necropsy room) along with the animal. The containment space (i.e. the necropsy room) is guaranteed (e.g. certified) to contain the pathogen in the same way that a certified biosafety cabinet contains a pathogen present in a much smaller sample such as a test tube or a section of lung tissue [4].

Determining when BSL3Ag containment is required involves evaluating 1) the potentially severe detrimental impact on agricultural animal health or animal products; 2) the virulence and transmissibility of the agent; 3) the availability of an effective treatment method(s) for people and/or animals; and 4) the potential impact to the national and/or global economy. Thus, although not necessarily zoonotic, high consequence livestock pathogens require handling using BSL3 or BSL3-Ag containment practices and procedures to prevent accidental or intentional release of the pathogen into the environment [7].

Whether an animal is being evaluated by a diagnostician in the laboratory or a veterinarian in the field, the performance of a risk assessment prior to examining the animal is the same. Knowledge regarding typical clinical signs, host range, basic epidemiology, geographical distribution of diseases, and familiarity with zoonotic and high consequence pathogens is used to determine the safety requirements [7]. Thus from farm to fork, veterinarians truly are instrumental in ensuring that the appropriate safety procedures are followed.

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