

Accreditation of High Containment Laboratories

American Biological Safety Association

In response to the global threat of emerging infectious diseases as well as the threat of bioterrorism, the number of high containment laboratories (biosafety levels 3 and 4 (BSL-3 and BSL-4) or equivalent) has been increasing to meet research and response needs of various agencies. Recent high profile laboratory-acquired infections and laboratory accidents involving biological hazards have raised the level of concern regarding these laboratories among the public and policy makers.

In light of these events and the resulting public and policy-maker concern, **the American Biological Safety Association (ABSA) believes that independent accreditation of high containment laboratories in the U.S. will be more effective and less costly than government regulation, inspection, and/or permitting of laboratories.** Such an oversight process would assure lab workers and the community that a biocontainment facility has in place the necessary practices, procedures, personnel, and equipment to protect people, animals, plants, and the environment and minimize the potential of lab-acquired infections and lab accidents.

ABSA proposes to lead a process involving all appropriate stakeholders, including representatives from federal agencies and allied professional organizations **to develop an accreditation program** that organizations would seek in order to measure and recognize their competence in management of biological hazards. Similar accreditation programs exist in many fields in the U.S., including hospitals, pathology laboratories, clinical laboratories, and animal research facilities.

ABSA is uniquely positioned and qualified to develop such an accreditation process. ABSA members constitute the country's (and the world's) recognized experts in biological safety, laboratory security, and biocontainment. ABSA was founded in 1984 to promote biosafety as a scientific discipline, to serve the growing needs of biosafety professionals throughout the world, and to provide a forum for the continued and timely exchange of biosafety information. ABSA is committed to expanding biosafety awareness and promoting the development of work practices, equipment and facilities to reduce the potential for occupational illness and adverse environmental impact from the unexpected release of infectious agents or biologically-derived materials.

Key Factors in Accreditation of High Containment Laboratories

Accreditation, conducted by an independent third party, is an objective assessment of the technical competence and quality system of an organization or laboratory as it relates to biohazard management, including personnel training and experience. Accreditation using relevant national and international standards is an effective way of ensuring competence in a comprehensive and uniform manner in laboratories working with biohazards. Typically, accreditation is voluntary.

Key components assessed by an effective accreditation program would include: 1) the biosafety expertise and training of personnel managing and conducting the research; 2) the adequacy and function of the biosafety management structure supporting the research activities; and 3) the adequacy and function of biocontainment measures, including facilities, equipment, practices, and record-keeping systems, in place at the facility that is evaluated. ABSA, either as an organization or through its membership, has had extensive experience in evaluating all three of these components. In addition, ABSA has established alliances with other groups that would provide support of this effort.

Assessment of Expertise: ABSA currently manages programs for certification and registration of biosafety professionals as described below. ABSA's expertise in assessing appropriate experience and competency for biosafety professionals would aid in creating and implementing assessments of expertise for research (and other high-containment support) personnel as part of the accreditation process.

Certified Biological Safety Professional (CBSP): Individuals must provide credentials documenting sufficient education, experience and expertise in biological safety microbiology and, if these credentials are accepted, must then pass a written exam developed by ABSA members and administered by the National Registry of

Microbiologists (NRM). Upon successful completion of the exam, applicants obtain an NRM *Specialist Microbiologist in Biological Safety Microbiology* designation, and can then apply to ABSA for the CBSP designation. This program has been in place at ABSA since 1997. Currently there are 141 biosafety professionals who have earned the CBSP designation, 44 of whom also hold the RBP.

Registered Biosafety Professional (RBP): A Registered Biosafety Professional (RBP) is an individual who can demonstrate examples of work related knowledge, skills and abilities in the field of biosafety. Eligibility requirements include at least 5 years of practical experience in biosafety, or a combination of education and directly relevant work experience. The RBP understands sufficient cell biology, pathogenic microbiology, molecular genetics, immune responses of hosts, and concepts of infection to enable them to apply safeguards to work with biohazardous materials. The ABSA Registration Evaluation Board reviews the applications and approves the RBP designations. This program was established by ABSA in 1992. Currently there are 134 biosafety professionals who have been designated as RBPs, 44 of whom also hold the CBSP.

Biological Safety Management Systems: Beginning in 2006, ABSA partnered with the European Biological Safety Associations (EBSA) to develop an international laboratory biosafety and biosecurity management standard through the CEN (European Standards Organization) Workshop Agreement process. This standard will be published in 2008. A biosafety safety management system is an organized and documented approach to managing biosafety issues within an organization. The aim of such a system is to help employees and other stakeholders effectively and efficiently accomplish the organization's goals and objectives relative to the safe, secure, and legal use of biological materials in research. Additionally, a management system must include appropriate monitoring and review to ensure effective functioning of the program and to identify and implement corrective measures in a timely manner. The accreditation process would use the CEN Workshop Agreement document as a guide for evaluating an organization's management system.

Biocontainment Measures: ABSA members in the U.S. are intimately familiar with existing U.S. biosafety guidelines (*Biosafety in Microbiological and Biomedical Laboratories* (BMBL) and NIH Recombinant DNA Guidelines). ABSA members have made significant contributions to the development of these guidelines since their inception and nearly all U.S. members use these documents as a foundation for the work that they do in the university, government, or industry setting. These documents would likewise serve as key points of reference for the measurement of the adequacy and function of biocontainment at facilities undergoing assessment.

Alliances: ABSA has established alliances and close ties with the agencies that oversee health and safety in U.S. biocontainment laboratories. OSHA and ABSA established an alliance in 2002. This alliance is dedicated to "enhancing workplace health and safety and assisting employers, including small businesses, in developing a preventive focus for biological safety issues." Likewise, ABSA works closely with CDC, USDA, NIH, World Health Organization, and the U.N. to provide training and education to ABSA members and other biosafety practitioners and establishing key resources regarding biosafety. ABSA has also established alliances with several other professional organizations that serve groups that may be affected by any new regulations or accreditation processes (e.g., American Society of Microbiology, American Industrial Hygiene Association, Campus Safety, Health, and Environmental Management Association, Association for the Practitioners of Infection Control, and the American Association for Laboratory Animal Science).

To summarize, ABSA already houses many of the resources necessary to establish an effective accreditation system and is well-positioned to quickly bring together the expertise to develop new resources and procedures.

Definitions

Biological Safety: Biological safety (or biosafety) includes specialized practices, procedures, and proper use of equipment and facilities, in order to assure the safe handling and disposal of infectious organisms or biological material which may harbor infectious organisms. It includes the safe management of recombinant DNA (rDNA) activities. The concept of biosafety has paralleled the development of the science of microbiology and its extension into new and related areas (cell culture, recombinant DNA, animal studies, and biotechnology). The knowledge and skill gained by microbiologists necessary to isolate, manipulate and propagate pathogenic microorganisms required parallel development of containment principles, facility design, and practices and procedures to prevent occupational infections in the biomedical environment or release of organisms into the environment.

Biosecurity: Biosecurity is a growing discipline that leverages and institutes biosafety programs and professionals, and fuses physical security practices and technology to safeguard biohazardous materials such as microorganisms and toxins.

Biocontainment: Biocontainment refers to the practices, techniques, equipment, and facilities needed to contain biohazardous materials such as microorganisms and toxins, thus minimizing worker exposure and preventing their release into the environment.

High containment facility: Laboratories designed and operated at Biosafety Level 3 (BSL3) and Biosafety Level 4 (BSL4) or equivalent containment.