

## Response to Accreditation Comments

The ABSA Accreditation Task Force appreciates all members' comments on the first draft of the accreditation standards that the Task Force has formulated. We received several well thought-out comments from our membership. Following is a response to address those comments.

1. **Scope and focus of the proposed biosafety accreditation program:** The ABSA Accreditation Task force was formed in 2008 primarily to address a need in the United States for oversight of high containment (BSL3) research labs. The initial intent of the ABSA accreditation program is to focus on BSL3 research labs within the United States. The scope is consistent with the U.S. document entitled *Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight*. The proposed accreditation program does not intend to compete or overlap with other laboratory accreditation, regulatory, or certification programs, but to supplement and complement those programs.
2. **U.S. Accreditation Program:** The Accreditation Task Force has benchmarked and intends to model our accreditation program after successful accreditation programs in the United States, such as the College of American Pathologists (CAP), the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), American Association of Veterinary Laboratory Diagnosticians (AAVLD), and others. Because this program is intended to meet specific needs in the U.S., we are modeling the program after similar U.S.-based accreditation programs. Accreditation in the U.S. often differs from accreditation in other parts of the world. In the U.S., an accreditation body sets the standards and then accredits the organization, institution, or system. In some other countries it is common for the accreditation body to accredit a certifying company or body, and the certifying company then accredits the institution, organization, or system.
3. **Structure and Liability:** In addition to having accreditation experts on the Task Force, the Task Force has consulted with other accreditation organizations on structure, liability, and process. Further, the Task Force has consulted, and will continue to consult, with the ABSA attorney regarding liability, process, and structure. The Task Force is aware that the program must be objective, the governing body must be independent, and that the process must be fair, with opportunity for candidates to address grievances. Different organizational models based on other successful accreditation systems are being studied, and the appropriate model is being developed based on the needs of the program.
4. **Standards:** The comments on specific details in the standards within the document are being considered and addressed by the Task Force in formulating the next draft. The committee met in December 2009 and added detail to each section of the standards, ensuring that terms are consistent, reviewed the need for additional laboratory biosecurity detail, and continued to review other standards for inclusion. The intent is that the standards will be dynamic and evolve to meet the needs of the community.
5. **Accreditation Criteria:** A standardized assessment protocol will be developed to ensure consistency and objectivity in the accreditation process. The CWA 15793 and all applicable U.S. regulations and guidelines (e.g., BMBL and *NIH Guidelines for Research Involving Recombinant*

*DNA Molecules*) will be referenced when developing the assessment protocol. The accreditation process will not relate to ISO standards.

6. Laboratory Biosecurity: As the standards are further developed, more specifics will be included. Laboratory biosecurity is considered a part of biosafety. The task force does not intend to address personnel reliability and will look at training rather than prescribed elements of personnel reliability. To address biosecurity, the accreditation program will look at how candidate facilities ensure limited access, secure hazardous agents, and document training for anyone with access to the laboratory.
7. Assessments: The term site visit and site visitor will not be used. Instead we are using the terms assessments and inspections. The assessment will consider whether the entity has embraced an appropriate quality management system to evaluate the effectiveness of components of their biosafety program.

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Laboratory Accreditation Task Force