

**BIOLOGICAL LABORATORY AND TRANSPORTATION SECURITY AND  
THE BIOLOGICAL WEAPONS CONVENTION**

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## ***Introduction***

The U.S. Government's Concept Paper on "New Ways to Strengthen the International Regime Against Biological Weapons" proposes measures intended to strengthen the Biological Weapons Convention (BWC). One measure recommends implementing "security standards for pathogenic microorganisms." Collections of high-consequence microbial agents and toxins (those that can inflict such grave harm to humans, animals, or plants that their malicious release could represent a threat to national or international security) reside in unprotected biological research laboratories throughout the world – and the numbers of these agents and laboratories increase almost daily. High-consequence microbial agents and toxins are constantly shipped all over the world in an insecure manner. Because an individual without extensive scientific training and expertise can culture and weaponize microorganisms with common, commercially available equipment, inadequately protected high-consequence pathogens represent a significant biological weapons proliferation threat.

Yet guidelines and procedures do not exist for physical protection, access control, personnel reliability, transportation security, pathogen accountability, and information security at international biological research facilities. Moreover, the overwhelming majority of the world's high-containment biological research laboratories lack a work ethos that places a priority on security.

The U.S. is among those States Parties that lack a biological laboratory and transportation security (BLTS) standard to guide those who are responsible for protecting high-consequence microbial agents and toxins. No clear consensus exists within the USG on the nature of the bioterrorist threat or the pathogens that would be most or least likely targeted for theft or diversion. As a result, the limited physical security measures in place at many U.S. biological research facilities, as well as within the system that transports pathogens around the country on a daily basis, are ad hoc, widely variable, and not designed to mitigate the current bioterrorist risk. These facilities will need to look beyond traditional concepts of facility security that generally rely on perimeter fences and armed personnel – often described as "guns, gates, and guards."

There is now a need for BLTS standards analogous to those that already exist for biosafety. Throughout the U.S. biological research community, there is a strong culture and a well-established program for biosafety. The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) have published an extensive manual, entitled *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), on proper biosafety procedures and standards.<sup>1</sup> Now in its fourth edition, the BMBL and its recommended guidelines are accepted as the international "gold standard" for safely conducting microbiological research. Since the BMBL's publication, there has been a significant reduction in the number of reported biosafety incidents in the U.S. The World Health Organisation's *Laboratory Biosafety Manual* (LBM) was derived from the BMBL and thus reinforces the BMBL's fundamental elements of biosafety.<sup>2</sup>

A U.S. BLTS standard could be adopted by the international community and thus could serve as a significant component of the USG's package of alternatives to combat BW proliferation and strengthen the BWC. The Nuclear Non-Proliferation Treaty (NPT) provides an important precedent in this regard. The International Atomic Energy Agency's Information Circular 274 on physical protection of nuclear facilities was adopted directly from the U.S. standards that originally had been developed by the U.S. Department of Energy.

***Unique Problem Requires Unique Solution***

There are several fundamental aspects of high-containment biological research that demonstrate why biological laboratory and transportation security should be differentiated from traditional concepts of high security. First, high-consequence pathogens (with the exception of smallpox) are not unique to any one facility or one country. Many of these organisms are ubiquitous in nature and exist in various quantities in laboratories around the world. This reasoning suggests that a terrorist organization would not likely target any one particular facility – unless it was judged to have especially inadequate security or a particularly virulent or fast growing strain of a pathogen that was not readily available somewhere else.

Second, at an active biomedical research facility, infectious material may be found at any time in a wide variety of places, such as storage freezers, laboratory incubators, living animals, animal excrement, or animal carcasses. Therefore, the absolute amount of any given organism in active biomedical research facilities is not able to be reliably quantified from day to day.

Third, any quantity of a high-consequence pathogen is strategically significant. One viable microorganism can be cultured and weaponized with common, commercially available equipment. This circumstance, combined with the fact that pathogens emit no energy and thus cannot be detected at a distance with currently available technology, reveals how easy it would be for an individual with authorized access to a facility to remove a small amount of pathogenic material without raising suspicion of others. This person could then sell the dangerous pathogens to a would-be bioterrorist or become one himself. In other words, the effectiveness of a security system at a high-containment biological research laboratory will depend – first and foremost – on the integrity of the individuals who have access to the high-consequence pathogens.

Because of the unique nature of biomedical and microbiological research, extensive perimeter and inventory control systems may jeopardize critical research and will not provide adequate protection. High-consequence pathogens will remain at risk of theft or diversion. Precious resources will be wasted unless security guidelines are established that specifically address the unique targets, threats, and risks associated with biomedical research, and recognize the legitimate variation in operating procedures of sites that work with high-consequence microbial agents and toxins.

### *Need for Clear Definitions*

Unique security standards for biomedical research facilities will be impossible to implement without first clearly defining the terms of the discussion. Many individuals and officials construe “biosafety” to include or to be synonymous with “biosecurity.” The United Nations Food and Agriculture Organisation (FAO) defines biosecurity as the management of all biological and environmental risks associated with food and agriculture. In this context, biosecurity consists of ensuring food safety, monitoring the introduction and release of genetically modified organisms and their products, and monitoring the introduction and spread of invasive alien species, alien genotypes, plant pests, animal pests, diseases, and zoonoses.<sup>3</sup>

Yet the FAO’s definition of biosecurity does not include steps to protect high-consequence microbial agents and toxins against theft or diversion from biomedical laboratories and transportation systems. Moreover, the U.S. and international systems for biosafety do not address biological laboratory and transportation security. In fact, the objectives and strategies of biosafety and biosecurity are fundamentally different.

Separating the concept of biosecurity from that of biosafety will help establish a well-understood concept that can address biological weapons nonproliferation issues. This step also would significantly strengthen the U.S. position within the BWC.

This paper will attempt to provide a clear definition of biosecurity in order to build a consensus on how best to secure collections of high-consequence microbial agents and toxins at laboratories and in transit around the world. Such biological laboratory and transportation security standards could be adopted and implemented nationally as a means for strengthening the BWC.

### *Biosafety*

The objective of biosafety is to reduce or eliminate exposure of laboratory workers or other persons and the outside environment to potentially hazardous agents involved in microbiological or biomedical facility research. Achieving biosafety requires the implementation of various degrees of laboratory “containment,” or safe methods of managing infectious materials in a laboratory setting. There are three elements of containment: laboratory practice and technique, safety equipment (primary barriers), and facility design and construction (secondary barriers).

The most crucial element of containment is a firm adherence to sound laboratory practices and techniques. Personnel working with infectious material must be aware of the hazardous nature of their work and properly trained in the procedures for safely handling such material. Labs must provide an operational safety manual, as well as closely monitor the conduct of hazardous work. This oversight requires the most current information about the nature of various infectious agents and close consultation with other professionals in the field. Examples of laboratory practices and techniques include

controlling access during experiments, establishing a sharps disposal policy, following decontamination procedures, and prohibiting food and drink within the laboratory.

Safety equipment, known as a primary barrier, is utilized in conjunction with laboratory procedures and techniques to further ensure containment. Equipment such as biological safety cabinets, safety centrifuge cups, and personal protective covering are frequently employed to prevent exposure to and release of hazardous materials. Primary barriers focus on the protection of the investigator and, by extension, the outside environment.

Lastly, facility design and construction, or secondary barriers, supplement the containment provided by procedures and equipment. Facility containment provides a physical barrier to prevent infectious transmission within and outside the laboratory. Secondary barriers range from simple hand washing facilities to specialized ventilation systems that ensure directional airflow. Design engineers are encouraged to refer to standards found in the *Applications Handbook for Heating, Ventilation, and Air-Conditioning* (HVAC).<sup>4</sup>

The laboratory director is responsible for assessing the degree and combination of containment elements required to achieve biosafety. The BMBL and the LBM outline Biosafety Levels (BSL) for most hazardous agents in order to guide this assessment process. BSL levels range from 1-4. BSL- 1 suggests a low safety risk requiring minimal safety barriers, while BSL- 4 denotes high risks demanding increased containment.

In practice, BSL-1 applies to work that is done with defined and characterized strains of viable microorganisms not known to consistently cause disease in healthy adult humans. BSL-2 denotes work with the broad spectrum of indigenous moderate-risk agents that are present in the community and associated with disease of varying severity, but the organisms are not known to be transmissible by the aerosol route. BSL-3 applies to work with indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potentially lethal infection. BSL-4 is used to define work with dangerous and exotic agents that pose a high individual risk of life-threatening disease, which may be transmitted by the aerosol route and for which there is no available vaccine or therapy.

Despite BMBL suggestions, the lab director or principal investigator ultimately assigns biosafety levels for the work in his/her particular facility. He/she is responsible for using sound judgment in making this decision, considering a variety of issues, such as the nature of the agent, specific parameters for experiments, and the actual function of the laboratory facility. The lab director also should consult other biosafety professionals and the Institutional Biosafety Committee (IBC). The IBC is a localized body that consists of faculty, staff, and community representatives who are responsible for project oversight and approval.

The lab risk assessment and BSL are primarily based upon a qualitative evaluation of the factors that may increase the risk of laboratory-acquired infection. The central risk factor

revolves around the nature of infectious or hazardous agents. However, prescribed algorithms for determining the degree of risk from specific agents prove problematic because living organisms display various characteristics depending on the life cycle stage or the type of manipulation.

Nonetheless, specific agents can be assigned a BSL, which represents the conditions under which the agent can ordinarily be safely handled. Qualitative factors considered when assessing risks and assigning agent BSL include agent pathogenicity, route of transmission, agent stability, infectious dose, concentration, origin, availability of data from animal studies, availability of an effective prophylaxis, type of medical surveillance, and the experience and skill level of at-risk personnel.

### ***Biosecurity***

In contrast to biosafety, the objective of biosecurity is to protect facilities against the theft or diversion of high-consequence microbial agents, which could be used by someone who maliciously intends to conduct bioterrorism or pursue biological weapons proliferation. BLTS standards should be based on substantive assessments of biological targets, threats, and vulnerabilities, and should be achieved through the integration of specifically designed technologies, procedures, and protocols. A comprehensive BLTS system would include many of the following elements:

- Physical protection
- Personnel reliability
- Adequate scientific and commercial program oversight
- Pathogen accountability
- Transportation security
- Information security

Documented BLTS standards must provide guidance to facility directors on each of these elements. The BLTS standards must first identify the primary targets that require protection. High-consequence pathogens (HCP) are those that can inflict such grave harm to humans, animals, and/or plants that their malicious release could represent a threat to national or international security. Thus, they are attractive targets for those intent on pursuing bioterrorism or biological weapons (BW) proliferation. Much like the BMBL agent assessment, a HCP designation must be reached through sound judgment and a qualitative, dynamic risk assessment process.

In addition to HCP, secondary targets such as critical information also require protection. The BLTS standard must define this type of information, which could include any kind of technical knowledge that could be manipulated to create or weaponize a HCP. This could take the form of instructions that outline how to culture agents in large quantities, distill an agent into fine particles, utilize chemicals to reduce the effects of static electricity, etc. Target information also may relate to the creation of new organisms through processes that involve genetic manipulation or recombinant DNA techniques.

Such target information could be scientifically acquired or shared, as was recently demonstrated through the discovery of a virulent mouse pox virus in Australia.

After defining primary and secondary targets, the BLTS standard should describe how to identify and assess security threats and vulnerabilities. A threat may be an insider who takes advantage of his permitted access or an outsider who compromises the facility's physical security. These threats may differ from one country or region of the world to another, but may be similar for most biomedical research facilities. In addition, the BLTS standard should explain how to qualitatively assess facility specific risks based on the established targets and threats. The risk assessment will establish vulnerabilities and determine which BLTS elements, and to what extent, will provide adequate protection of the targeted assets against the calculated threats. The vulnerability assessment should incorporate factors such as the nature of the facility in question, the type of research conducted, and the local environment. The threat and vulnerability assessments also should reflect the collaborative judgments of biomedical experts, law enforcement agencies, physical security experts, and transportation companies.

The final section of the security standards should provide specific recommendations in the six previously identified elements of BLTS: physical protection, personnel reliability, adequate scientific program oversight, pathogen accountability, transportation security, and information security. These recommendations should integrate technologies, policies, and procedures to reduce risk and secure HCP during handling, research, storage, and transport. Finally, the BLTS standards should recognize the unique needs of research, defense, and industry to continue efficiently working with HCP. Measures to restrict access to high-consequence organisms must be balanced with the need for biomedical studies and research on such organisms to continue so that the transmission, infectiousness, pathogenesis and, ultimately, the control of infections from the organisms can continue to be better understood.

In order to create a viable domestic and potentially international BLTS standard, the objectives, strategies, and elements of biological laboratory and transportation security must be consistently delineated from those of biosafety. This goal would best be accomplished by creating a set of biological laboratory and transportation security guidelines analogous to the BMBL and the LBM. A manual for biological laboratory and transportation security could describe those assets that need to be protected by a biological laboratory and transportation security system, discuss methodologies for assessing threats and vulnerabilities to biomedical research, and outline the various but integrated technologies, policies, and protocols for each of the elements of a BLTS system.

### ***Project Description***

This project will include several phases. The first phase will be to develop a campaign to educate the USG, industry, and academia on the differences between biosafety and biosecurity and the need to develop new biological laboratory and transportation security measures. As part of this effort, a course package will be designed and deployed that

focuses on biosecurity issues and generates potential solutions from all relevant stakeholders.

The second phase of the project will be to develop the required legislative framework necessary to regulate and implement BLTS standards in the United States. Developing this framework will require coordination and input from a variety of U.S. agencies as well as industry and academia.

The final phase will be to press for international adoption of U.S. BLTS standards. Unofficial, international meetings will be held to discuss the importance of biosecurity, its differences from biosafety, and the need to establish international standards analogous that exist for biosafety. The precedent, in this case, is IAEA Information Circular 274 on the physical protection of nuclear facilities adopted directly from the U.S. standards. The aim would be for each nation to be responsible for creating a national system for reporting those facilities that store, use, and/or transport high-consequence pathogens, and a national registration system that can verify when BLTS standards have been met by a reported facility.

### ***Potential Benefits to the United States***

The benefits of raising biosecurity issues and developing BLTS standards in the United States and internationally are manifold. Successful implementation of BLTS standards will improve the security of HCP at facilities and in transit in the U.S. and elsewhere. Such security will help protect against the theft or diversion of HCP, which could be used by bioterrorists or BW proliferators. In addition, BLTS standards will help create a national reporting and registration system for facilities that store, use, and/or transport high-consequence pathogens. The USG will then have a mechanism to track where HCP exist and who is working with them – information that does not currently exist. Implementing biosecurity standards clearly supports the requirements under Article IV to fully implement the provisions of the BWC, and it will demonstrate that the U.S. is committed to combating the proliferation of biological weapons.

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<sup>1</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*, Fourth edition, Government Printing Office: May 1999.

<sup>2</sup> World Health Organisation, *Laboratory Biosafety Manual*, Second edition, Geneva, Switzerland: 1993. <http://www.who.int/dsa/cat98/lab8.htm#Laboratory%20Biosafety%20Manual>.

<sup>3</sup> United Nations Food and Agriculture Organisation, Committee on Agriculture, Sixteenth Session, 26-30 March 2001, <http://www.fao.org/DOCREP/MEETING/003/X9181E.HTM>.

<sup>4</sup> American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc., *Heating, Ventilation, and Air-Conditioning Applications*, 1999.