



ABSAs Biosecurity Position Paper

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Introduction

Since June 2002 Public Law 107-188 and several Codes of Federal Regulation have been codified in the US to promulgate increased biological security and safeguards at facilities working with, storing, or transporting pathogens and biologically derived toxins. Other countries are currently examining their policies and procedures regarding the safeguarding of certain pathogens and biological toxins. The objective of Public Law 107-188, the Public Health Security and Bioterrorism Response Act of 2002, is to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. The intent of the attendant CFRs addresses a subset of PL 107-188 and focuses on preventing individuals from gaining access to certain biological materials and using them for illicit purposes.

Pathogens increasingly traverse countries via innocuous or unknown reservoirs, infected individuals, and vectors. These novel, and in some cases re-emerging diseases, pose a collective risk to international health, stability, and national/international security. Public health initiatives such as the development of networks of international reference laboratories whose goal is to facilitate global recognition, reporting, and response to emerging health threats will become an increasingly vital component of world biological security and health.

ABSAs believes it is important to recognize the importance of balancing programs that promote global public health initiatives with the need to implement biosecurity requirements intended at preventing potential proliferants from gaining access to sensitive biological materials.

Statement of the Problem

Decades ago, governments defined and established programs to address the security of nuclear materials, chemical stockpiles, and associated weapons. The programs were often conducted at facilities that were closed to the general public and relied heavily on the "guards, gates, guns, and two-man rule" approach to security and personnel reliability. This paradigm does not optimally meet the needs of security in biological facilities and may actually cause a false sense of security, while causing significant damage to academia, research, public health, and the biomedical and biotechnology industry. This does not mean there is no need for biosecurity; rather, that a security approach must (1) understand the unique aspects of biological work and material; (2) identify the assets and vulnerabilities associated with biological programs; and (3) develop measures that address and solve the problem.

Why Biological Materials Pose Unique Challenges

Several aspects intrinsic to work with biological materials have been identified as key drivers for biosecurity to be implemented differently than other security programs. First, biological pathogens can replicate, making the theft of even minute quantities significant. Access control and mechanisms for monitoring access may deter the average unauthorized individual from entering an area and gaining possession of pathogens from working cultures, stocks, infected animals or bedding, and laboratory freezers or refrigerators.

However, it does not address the threat of an authorized individual from obtaining pathogens for illicit use. It is vital that individuals working with, or with access to, pathogens be responsible, reliable, well trained, and trustworthy. ABSA believes that personnel reliability is a cornerstone of biosecurity, and identifying appropriate measures directed at vetting individuals with access to these agents is part of the path forward in implementing a viable biosecurity program.

The second aspect is that there are no devices that detect biological pathogens or toxins being taken from a facility, and existing "tag and detection" technology can be defeated in a number of ways. While random searches of personal belongings may deter some individuals, the minute amounts required can be transported in a number of matrices and never be detected. Again, individual integrity is of paramount importance.

Finally, pathogens deemed as those of "high consequence" and toxins can be found in existent clinical laboratories, research universities, private industry, and numerous government R&D programs. These agents often persist endemically and are responsible for natural outbreaks of disease in many countries.

ABSA believes analyses of new or proposed biosecurity rules should be conducted to determine whether they actually provide increased biosecurity or merely foster the perception of increased security. A relevant example brings to question whether in light of the current availability of these materials, developing more restrictive export rules or enacting an export moratorium, will actually facilitate biosecurity, give the perception of securing materials, or substantially deter future legitimate research and public health endeavors.

Approach to Developing a Biosecurity Program

Several components that form the cornerstones in the development of a biosecurity program include: concept of security management; security plan development; security risk analysis; and assessment of proactive and reactive measures. Security manage-

ment is a systematic process designed to develop a rational and cost-effective biosecurity program strategy that will protect critical facility and programmatic assets. Security plan development would optimally be a coordinated effort between major stakeholders (i.e., security, biosafety, scientific director, local law enforcement, others). The risk analysis process develops assessments of assets, threats, vulnerabilities, and risk that will then be reviewed in the context of countermeasure applicability. Countermeasures are plans, actions, technologies, or other measures that are taken to prevent, lessen, or respond to a threat. Countermeasures are broadly based on personnel, technical, and operational considerations and solutions. The biosecurity program should at a minimum address the following elements: physical protection; personnel suitability/reliability; pathogen accountability (onsite and through the transportation process); and biosecurity incident response.

Proactive Measures to Implement a Biosecurity Program

Measures should be chosen to fulfill identified functional requirements with consideration to mission objectives, goals, and other operating constraints. Institutes, their biosecurity requirements, and approaches to meeting those requirements may vary. Some applied requirements identified by a broad range of facilities may include general aspects of managed access to include visitor control, location of biological materials within a facility and access to biological materials, and material accountability. Approaches should include the development of written and documented security procedures and would optimally provide funding for a designated site security administrator (and trained security staff) to ensure compliance and consistency in implementation. As one commonality across facilities is that personnel are key assets, a combined approach of (1) hiring practices that select for honest, well-balanced employees; (2) establishing a personnel reliability/suitability program; (3) establishing an effective Employee Assistance Program; and (4) raising the level of security awareness among employees may be

among the most important factors in developing an effective biosecurity program.

Conclusion

As a discipline, biosecurity has been evolving at institutes and across various agencies and industries in an independent manner. ABSA believes it would be beneficial for member states to develop national guidelines or a set of recommendations for biosecurity in facilities working with, storing, and transporting pathogens. It will be incumbent upon member states to implement and enforce these guidelines. A proponent organization that develops these guidelines will have to intimately understand the intricacies and unique aspects of pathogens and work with

pathogens. ABSA advocates a unified approach by member states in developing international recommendations and standards. ABSA believes BTWC member states should involve experts from professional associations, such as ABSA, to provide comment on technical aspects of evolving text and new requirements.

Respectfully submitted,

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