



Bioterrorism: Impact and Implications for Biosafety

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Abstract

The biosafety community has traditionally been involved in laboratory safety issues regarding the safe handling of biological agents. We are now seeing biosafety practitioners handling bioterrorism issues that include biosecurity and emergency response to suspicious packages. With growing concern about the possible use of biological agents from laboratories as agents for bioterrorism, the regulatory environment is changing to prevent such misuse of pathogens.

Bioterrorism has impacted biosafety in the areas of biosecurity, laboratory containment facilities, emergency response, and the transportation of biological agents.

1. Biosecurity

In response to questions regarding the adequacy of security at laboratories that work with, store, or transport pathogens and toxins, biosecurity guidelines have been developed to prevent unauthorized entry into laboratory areas and the unauthorized removal of biological agents from laboratories.

The traditional “guards, gates, guns, and two-man rule” is not optimal for securing biological agents. Biological materials pose unique challenges because of their inherent nature (e.g., pathogens can replicate; theft of minute quantities is significant). No devices can detect pathogens being removed from a facility. Laboratories handling these materials (e.g., hospital clinical laboratories, research laboratories in universities) are usually accessible to the pub-

lic, have a continuous workforce turnaround, and a high degree of collaboration and exchange of materials among laboratories.

A biosecurity approach should consider these unique aspects of biological work, and the material should identify all assets and vulnerabilities associated with the biological problems and develop measures that address and solve the problem. A plan to respond to biosecurity incidents should be developed to deal with specific incidents such as breaches of containment, unauthorized access to pathogens, and the unauthorized removal of pathogens from a facility. Measures taken to implement a biosecurity program should include the physical security of the facility. A graded protection system, relative to risk for loss of materials, should be developed with a tiered layer of security features that are incrementally more restrictive (e.g., signage, physical barriers, access controls, intrusion detection systems). An inventory system and procedures to maintain accountability of pathogen collections and experimental and working stocks should also be developed. Records should be kept for the database of stocks and the disposition of materials from the stock collection. The security of stored material, including controlled access to rooms, freezers, refrigerators, with a well maintained log of all entries to these areas, is also an important component of the inventory system.

A comprehensive biosecurity program also addresses the personnel in the facility. This includes factors such as suitability for working in containment facilities with access to pathogens, background checks, and security clearances for all personnel

(including staff, visiting collaborators, maintenance personnel, and students). Periodic reinvestigations should also be instituted.

Biosafety specialists will require security training that outlines physical facility security mechanisms, personnel screening issues, and pathogen inventory systems. Several timely information papers, symposia, and conferences that deal specifically with the issue of biosecurity are now available. The American Biological Safety Association's Biosecurity Task Force has produced a White Paper, *Understanding Biosecurity*, which can be accessed at our web site: at www.absa.org. The web site also provides relevant bioterrorism links and related information. ABSA also cosponsored with the Canadian Centres for Applied Biosafety and SAIC a Biosecurity Conference in April 2003 (<http://www.saic.com/natsec/homeland-security/biosecurity.html>).

2. Laboratory Containment Facilities

Bioterrorism concerns have also led us to change the scope of work carried out in clinical laboratories to include diagnostics for bioterrorism agents. Since many of these agents are classified as Risk Group 3 or higher, there has been a steady increase in the demand for and construction of containment facilities. Research facilities for work with Risk Group 4 pathogens are also on the increase. National and international laboratory response networks to efficiently and effectively manage bioterrorism incidents are being developed.

Laboratories are being asked to collaborate with the first responder community to respond to and analyze anthrax hoax letters and suspicious packages for the presence of biological pathogens of concern. Laboratory workers and biosafety specialists are receiving training in forensic evidence handling (e.g., evidence seals and signatures, recording and photographing evidence, avoiding cross-contamination). Developing precautions for the presence of chemicals in suspicious packages is an important component of such responses. Containment laboratories are not necessarily designed to provide containment of and protection from the presence of dangerous chemicals, and packages must be scanned to rule out the presence of chemicals prior to performing any

biological analysis.

In direct response for rapid diagnosis in the field by the first responder community, we are also seeing the movement of the laboratory to the field. Traditional laboratory techniques are being applied to rapid field devices (e.g., biotickets, real-time PCR). Deployable containment laboratories, personal protective equipment for the field, and medical countermeasures are all being implemented in field responses today.

The increase in containment facilities has, in turn, brought increased demand for biosafety practitioners to oversee these facilities, as well as increased demand for biosafety training for those who design, build, and work in containment facilities (e.g., engineers, architects, contractors, laboratory workers, laboratory supervisors, and maintenance personnel). Associated impacts also include an increase in the basic cost of containment facilities and higher prices for containment equipment.

Stricter regulatory requirements for containment laboratories handling and transferring biological agents are also being considered. These regulations may include restricting access to biological agents, the control (registration and/or certification) of all facilities possessing bioterrorism agents, biosecurity requirements for facilities, personnel screening protocols, reporting of breaches of containment and theft of pathogens, enhancement of penalties for enforcement, coordination with veterinary authorities for the handling of animal pathogens, and the protection of sensitive information from disclosure.

3. Emergency Response

Traditional emergency response plans for biosafety practitioners have included response to spills of infectious materials, laboratory accidents/exposures, and breaches of containment. These plans have been augmented to include plans specifically for bioterrorism incidents. Facilities have developed standard practices and procedures on how to work together with the first responder community (police, fire, emergency medical) to respond to such events. Today, biosecurity breaches, theft of pathogens, and responses to suspicious packages and anthrax hoax letters are all included in our emergency

response plans. For many biosafety specialists, management of these plans has become a familiar, if not routine, part of our work.

In the area of decontamination, bioterrorism concerns have prompted us to take our standard decontamination plans and procedures and modify them for bioterrorism incidents. Biosafety practitioners are familiar with standard decontamination procedures for potentially contaminated laboratories (e.g., after spill of infectious materials, fumigation of containment facilities). These procedures are now being modified for nonlaboratory areas which present unique challenges to ensuring effective decontamination (e.g., mail rooms, office buildings).

4. Transportation

Difficulties in arranging shipment of biological specimens and bioterrorism samples to laboratories are a significant problem for bioterrorism laboratory response networks and biosafety specialists assigned to arrange such shipments. Transporters may be reluctant to ship specific bioterrorism samples and Risk Group 4 materials. The urgency of these shipments necessitates a 24-hour, 7 day/week transportation capacity. Quick diagnostics enable the medical community to provide initial advice to potentially exposed individuals on the need for antibiotic therapy and the first responder community to provide advice on building closure, decontamination, and equipment use.

The UN *Model Regulations on the Transport of Dangerous Goods* outlines packaging, labelling, and ship-

ping requirements to ensure the safe transport of dangerous goods. These regulations are currently undergoing a review and revision to include the agents of bioterrorism in the highly regulated category and to streamline the process to eliminate confusion and difficulties associated with shipping biological pathogens. Proposed changes to the transportation of dangerous goods regulations can be viewed at the UN's web site: www.unece.org.

Changes to ensure adequate measures related to the security of the shipment are also being considered. These include proposals to remove the requirement for inclusion of the technical name on the shipment and proposals for new security provisions for "sensitive dangerous goods" including bioterrorism agents. Shippers and transporters would be required to develop a security plan, to conduct security risk assessments, to implement measures to reduce security risks, to develop contingency plans for security incidents, and to introduce personnel screening and background checks.

Finally, a noteworthy positive impact of bioterrorism on biosafety is the increased collaboration and cooperation at the national and international level among biosafety specialists, first responders (police, fire, medical authorities), laboratory staff and scientists, those who design and construct containment facilities (architects, engineers), and security experts. Adaptation to the bioterrorism crisis has provided an opportunity for biosafety specialists to enhance their knowledge, improve biosafety standards and procedures, and build more effective working relationships.