Building a Solid Foundation for Implementing Laboratory Biosafety and Biosecurity

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Abstract
This paper outlines the elements that are required to implement a robust biorisk management program. A sound biorisk management program is critical for infectious disease laboratories and, to be effective, the program must have three key interrelated elements: planning, implementation, and oversight. A biosafety and biosecurity risk assessment should be the principal planning tool that guides management's implementation and oversight of laboratory biosafety and biosecurity, including determination of training needs. The risk assessment process can help management answer some critical questions: How does a laboratory determine which training is required for whom? What level of oversight is appropriate? How are limited resources allocated to address the laboratory biorisks?

Introduction
By the very nature of their missions, infectious disease institutions must manage the risks associated with biological materials in their laboratories. These materials could be the source of accidental and/or deliberate (malicious) infections to the staff or the broader community. A failure in laboratory biosafety or biosecurity may affect the staff and community, and may jeopardize the institution's operations. Laboratory biosafety aims to keep the worker and environment safe from accidental exposure while laboratory biosecurity seeks to keep the valuable biological materials secure from intentional theft or misuse. There are many examples of inadequate program management resulting in safety or security incidents at bioscience facilities. For example, the United Kingdom recently suffered an outbreak of Foot and Mouth Disease virus. This was most likely caused by failures in a laboratory's waste decontamination system due to neglected maintenance and repairs.[1] In the United States, regulators shut down large sections of Texas A&M University's infectious disease research program after it failed to properly report several laboratory incidents.[2] Professor Thomas Butler, a renowned bacteriologist, spent 19 months in jail awaiting trial after 30 vials of *Yesinia pestis* went missing from his laboratory.[3] In 2003 and 2004, there were three separate laboratory-acquired infections of SARS at BSL3 and BSL4 laboratories in Singapore, Taipei, and Beijing; one incident led to multiple infections in the community. A subsequent investigation by a World Health Organization team determined that poor program management was the root cause in all of these cases.[4] To minimize the likelihood of such problems, bioscience facilities must allocate the needed resources, develop guidelines and operating procedures, train their personnel these institutional protocols, and provide adequate oversight of activities. All of these decisions should be influenced by regular risk assessments.

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The nature and scale of these risks at an institution should be the determining factors for the scope of the biorisk management program (laboratory biosafety and biosecurity), but, regardless of size, there are commonalities that stretch across all of these programs: recruiting and retaining qualified individuals, training, laboratory work practices, (e.g. disinfection, waste handling, material control and accountability), personal protective equipment, medical surveillance, maintenance, access controls, self-assessments, documentation, corrective actions, reporting requirements, incident response plans, and so on. To avoid inadequately addressing any of these elements, an institution should ensure they have a cohesive biorisk management program for mitigating their laboratory biorisks; a management system can be a useful framework. One of the primary goals of a management system is to help an organization continually strive for improvement. ISO 9001:2000 (a quality management system), ISO 14001:2004 (an environmental management system), and OHSAS 18001:2007 (an occupational health and safety management system) are all examples of management systems that have been implemented at laboratories, but none of these are specific to managing biorisks. However, a new management system standard should be useful for bioscience facilities seeking to enhance their biorisk management programs: In 2007, biosafety and biosecurity experts developed a voluntary management standard explicitly for managing the biorisks in institutions that handle biological agents and/or toxins, regardless of the type or size of institute or the specific biological materials.[5] A risk-based approach lies at the heart of that standard.

Planning

Planning is the first step of a management system, and risk assessment should be the primary planning and resource allocation tool for managing biorisks. First, the biohazards are identified and characterized. Biological agents are assessed on their properties, such as pathogenicity, virulence, host range, routes of transmission, and environmental stability. Laboratory procedures are evaluated for the potential to cause accidental exposure to the agent (e.g. spill, generation of an aerosol, needle stick) or release from containment. The local threat environment is characterized to help assess the likelihood that the facility will be targeted by those wishing to do harm. Gaps in existing biosafety and biosecurity measures are evaluated for scenarios that pair the potential for accidental or deliberate exposure or release with the potential consequences for the specific biological agent. Once these gaps are identified, management can prioritize efforts on the most significant gaps. Unless the biohazard is eliminated, some level of risk will remain; no biorisk management program can protect against every conceivable adverse scenario. The risk assessment process helps management ensure that the biosafety and biosecurity risk mitigation measures and associated costs are proportional to the risks. Risk assessment provides a foundation for allocating program resources among engineered, administrative, and procedural controls to mitigate the biorisks.

Implementation

Assigning roles and responsibilities is a critical step in building a sustainable biorisk management program. Regardless of program size, the institution should assign

oversight responsibility to a biorisk manager (traditionally the biosafety officer). This individual(s) should be knowledgeable in biosafety and biosecurity; they will oversee the implementation of biorisk mitigation measures; advise and assist with the reporting, investigation, and follow-up of any incidents; oversee the development and implementation of relevant training; and ensure regulatory compliance. The principal investigators or other scientific managers should be directly responsible for managing the biorisks associated with their specific laboratory operations. The biorisk manager and scientific manager should jointly conduct the risk assessments. An institution should establish a biorisk management committee with a cross-section of expertise to act as an independent review group. This committee should be tasked with approving protocols for new work, reviewing incident reports, and developing institutional biorisk policies. Ultimately, top management is responsible for the institution's biorisk management program.

Before individuals begin to work with biohazards, they need training. Training programs can be viewed as a ladder of knowledge and skills. There is basic awareness-raising, knowledge of laboratory biosafety and biosecurity fundamentals, hands-on learning of best practices, advanced training on best practices, facility-specific training, and task-specific training. Typical training programs convey awareness and fundamentals through a series of PowerPoint presentations while the latter topics are learned in an informal mentoring arrangement between a new employee and a more knowledgeable, senior staff member.

Although PowerPoint presentations and informal mentoring can be valuable in the right setting, more interactive, structured training on specific learning objectives is necessary to help individuals climb the ladder of knowledge and skills. There are a range of new training initiatives making this shift. The American Biological Safety Association draws on the depths of their professional expertise to incorporate realistic case studies and lessons learned into a week-long training course on the Principles and Practices of Biosafety.[6] The World Health Organization (WHO), in partnership with the U.S. National Institutes of Health (NIH), piloted a two week training course based on the third edition of the WHO laboratory biosafety manual. This course utilizes lectures, case studies, and hands-on laboratory exercises. NIH also runs a two year Biosafety and Biocontainment Fellowship Program, which trains future biosafety officers through a combination of instruction and a structured mentorship.[7] The International Biological Threat Reduction Program at Sandia National Laboratories has developed a week long training program on Controlling Biorisks.[8] This program focuses on the integration of laboratory biosafety and biosecurity with lectures, case studies, guided discussions, and hands-on laboratory activities.

Two relatively new programs offer excellent training for those individuals seeking instruction on high containment laboratory activities. Emory University conducts a Science and Safety Training Program, which emphasizes knowledge and practice of laboratory activities for BSL3 and BSL4 laboratories.[9] The Canadian Science Centre for Human and Animal Health gives participants the opportunity to work in the special

containment and facility support areas (BSL3 and BSL4) at their annual International High Containment Biosafety Workshop.[10]

The collective impact of these programs and other new training initiatives is still to be determined, but, undoubtedly, they are shifting the paradigm of training for biorisk managers and laboratory personnel. All of these training programs give their students a solid foundation, but they are not sufficient. Laboratory workers still require facility-specific and task-specific training prior to beginning work with biohazards and at regular intervals for retraining. The biorisk manager or other appropriate manager should establish an institutional training program. This program should define the training needs, specify required training, and refresher training requirements, and measure its effectiveness. The risk assessment should be a key tool in developing the institutional biorisk training program.

Oversight

The overarching goal of any biorisk program should be continuous improvement. First, the program must document its current biorisk activities. Documentation will include risk assessments, biorisk manuals, standard operating manuals, organizational charts, maintenance plans, equipment certifications, inventory records, and so forth. Documents should be reviewed and updated at regular intervals and after any incidents. Furthermore, risk assessments need to be reviewed after any changes to the institution's program or threat environment. Oversight of the program should be formalized through regular audits to assess effectiveness and evaluate areas for improvement. The frequency of these audits should be based on the risks. They should consist of both internal self assessments and external third party assessments that provide an independent review. All audit findings should be documented in a report that specifies corrective actions, assigns responsible individuals to each action item, and identifies an expected completion date for each item. Then the biorisk manager needs to follow up and verify the timely completion of the corrective actions. Finally, top management should review the biorisk management program at least annually to explore opportunities for improvement. The end result of such a review should specifically address the suitability of the current risk assessments and appropriateness of the existing resource allocations.

Conclusions

An effective biorisk management program must be based on the specific risks at the institution. The risk assessment then drives allocation of resources, the implementation of the risk mitigation measures, training requirements, level of program management, and degree of oversight. Biorisk management systems can be an effective tool to help institutions create safe and secure laboratories, helping to maintain community confidence in their operations.

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