Biorisk Management for Clinical and Public Health Laboratories

Purpose

The Association of Public Health Laboratories, Centers for Disease Control and Prevention, and (Your Public Health Lab) are enhancing support to clinical and local health department laboratories to reduce risk in the areas of laboratory biosafety and biosecurity. As such, new programmatic support has been developed and conversations around biorisk management will be incorporated into ongoing outreach programs. This document provides an overview of a comprehensive, systematic approach to laboratory biorisk management. It includes a list of essential elements laboratories can use to assess their operations and better integrate and enhance programs for biosafety and biosecurity.

Definitions

Key terms used in this document are defined as follows:

- *Biorisk:* combination of the probability of occurrence of harm and the severity of harm where the source of harm is a biological agent or toxin
- *Biosafety:* laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to the biological agents and toxins, or their accidental release
- *Biosecurity*: laboratory biosecurity describes the protection, control and accountability for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release

Introduction

Clinical and public health laboratories should develop and maintain biorisk management systems that address laboratory biosafety and biosecurity tailored to the unique operations and risks of each laboratory. There is no one-size-fits-all biorisk management system. However, each formal, written biorisk management system should:

a) establish the principles that enable the management and staff of laboratories to achieve their biosafety and biosecurity objectives;
b) define the essential components that integrate biosafety and biosecurity processes into the laboratory's overall governance, strategy and planning, management, quality management system, reporting processes, policies, values, and culture; and
c) describe a comprehensive biorisk management process that identifies biorisks (both biosafety and biosecurity risks) and reduces and/or maintains them at acceptable levels.

Biorisk Management System Approach

The biorisk management system should be based on a management system approach, which enables an organization to effectively identify, assess, control, and evaluate the laboratory biosafety and biosecurity risks inherent in its unique activities. The biorisk management system should be built on the concept of continual improvement through a cycle of planning, implementing, reviewing, and improving the processes and actions that an organization undertakes to meet its biosafety and biosecurity goals. This is known as the PDCA (Plan-Do-Check-Act) principle:

a) Plan: Planning, including identification of hazards and risks, and establishing goals,
b) Do: Implementing mitigation controls, including training and exercise along with operational issues,
c) Check: Checking, including monitoring and corrective action, and
d) Act: Reviewing, including process innovation and acting to make needed changes to the management system.

In order to improve biorisk management, the organization should focus on the root causes of non-conformities and undesirable events. Systematic identification and correction of deficiencies will lead to improved performance and control of biorisks.

Implementing a Biorisk Management System

Key factors in establishing and implementing a biorisk management system include:

1. Formal commitment by top management to provide adequate resources, and to prioritize and communicate biosafety and biosecurity policy; to establish performance expectations and integrate biorisk management throughout the organization; and to identify opportunities for improvement and prevention, determining root causes and preventing recurrence.
2. Focus on continual improvement to:
   a) make continual improvement an objective for every individual in the organization;
   b) use periodic assessment against established risk-criteria to identify areas for potential improvement;
   c) continually improve the effectiveness and efficiency of processes;
   d) promote prevention activities;
   e) provide personnel in the organization with appropriate education and training to support biorisk management, including the methods and tools of continual improvement;

f) establish measures and goals for improvement; and
g) recognize improvement.

Essential Elements

A biorisk management system includes the following essential elements. How these elements are implemented should be specific to each facility.

Leadership

1. There is a documented organizational biorisk management policy. This policy articulates the nature of the organization (including its overall mission and goals), and the scope and objectives of the biorisk management system. This policy should reflect top management/leadership commitment to the biorisk management system. This policy commits to:
   a) protecting staff, contractors, visitors, community and environment from biological agents and toxins that are stored or handled within the facility;
   b) reducing the risks to an acceptable level of unintentional release of, or exposure to biological agents and toxins;
   c) reducing the risks to an acceptable level of unauthorized intentional release of hazardous biological materials, including the need to conduct risk assessments and implement the required control measures;
   d) complying with all legal requirements applicable to the biological agents and toxins that will be handled or possessed;
   e) ensuring that the need for effective biorisk management should take precedence over all non "health and safety" operational requirements;
   f) effectively informing all employees and relevant third parties and communicating individual obligations with regard to biorisk to those groups; and
   g) continually improving biorisk management performance.
2. The organization's leadership determines and provides the resources needed for the establishment, implementation, maintenance, and continual improvement of the biorisk management system.
3. A biorisk management committee acts as an independent review group for biorisk issues and reports to senior management. The committee:
   a) has documented terms of reference;
   b) includes a representative cross-section of expertise, appropriate to the nature and scale of the activities undertaken;

c) ensures issues addressed are formally recorded, actions allocated, tracked and closed out effectively;
d) is chaired by an experienced individual;
e) meets at a defined and appropriate frequency, and when otherwise required.

4. A designated competent individual(s) (e.g. biorisk management advisor, biosafety official) provides advice and guidance on biorisk management issues. This individual reports directly to the responsible senior manager and has delegated authority to stop work in the event that it is considered necessary to do so. The functions of this individual(s) include:
   a) verifying, in conjunction with other relevant personnel, that all relevant biorisk considerations have been addressed;
   b) advising or participating in the reporting, investigation and follow-up of accidents / incidents, and where appropriate referring these to management / biorisk management committee;
   c) ensuring that relevant and up-to-date information and advice on biorisk management is made available to scientific and other personnel as necessary;
   d) advising on biorisk management issues within the organization (e.g. management, biorisk management committee, occupational health department, security);
   e) contributing to the development and/or delivery of biorisk training activities;
   f) ensuring that all relevant activities are performed in compliance with existing biosafety and/or biosecurity guidance and/or regulations and that required biorisk authorizations for work are in place.
5. The organization has a communications plan – for both internal and external communications – that explains the goals and strategy of the biorisk management system.

Personnel

6. Management provides clear and regular communication on biosafety and biosecurity expectations to employees. Clear and concise biosafety and biosecurity competencies have been previously published for reference (3,4).
7. Continuing training and education programs are in place to reinforce the priorities of biosafety and biosecurity to employees. Requirements and procedures for biorisk-related training of personnel should be identified, established, and maintained.
8. Programs are in place to ensure the health and well-being of employees (such as occupational health, vaccination, and worker health programs).

9. Procedures are in place to ensure that personnel who have responsibilities and/or perform tasks that impact biorisk management in the workplace are competent to do so.
10. Procedures are in place to ensure that employees are reliable, understand their security responsibilities, and will always act in the best interests of the organization.

Risk Assessment

11. There is a documented policy and process for conducting activity-specific (e.g. scientific protocols, diagnostic tests) risk assessments. Such assessments are inclusive of biological agents, facility design, and laboratory equipment.
    a) This policy articulates the principles of risk assessment, such as hazard identification, risk analysis, and risk prioritization, and how the risk assessments will be documented and communicated to staff.
    b) This policy explains how risk assessments will influence the implementation of control measures and performance management. In other words, risk assessments should be proactive rather than reactive.
    c) The results of risk assessments are reported to senior management for review and be the basis for monitoring and improvement.
12. Risk assessments are conducted or reviewed:
    a) when there is commencement of new work or changes to the program of work including the introduction of new biological agents or alterations to work flow or volume;
    b) when there are modifications to laboratories, equipment or operations; or new construction;
    c) when there is introduction of altered and unplanned staffing arrangements (including contractors, visitors and other non-core personnel);
    d) when there are significant alterations to Standard Operating Procedures (SOPs) or working practices (e.g. disinfection / waste management methodologies, personal protective equipment (PPE) provision / usage entry / exit protocols, etc.);
    e) when unexpected events that may have relevance for the management of biorisks are observed;
    f) when the actual or potential non-conformity with internal / external rules and regulations is identified (e.g. introduction of new legislation or major accident exposure);

g) when considering emergency response and contingency planning requirements, including exercises; and
h) as part of the existing management system review process (e.g. annually or at another appropriate and predetermined frequency).

Risk Mitigation

13. A formal process is in place to identify and manage the risks associated with the safety and well-being of the laboratory workforce.
14. An accurate and up-to-date biological agents and toxin inventory is established and maintained.
15. Documentation is available showing that all personnel handling biological agents and toxins are competent in performing good microbiological techniques and appropriate resources (including time and equipment) are available to ensure such training and practices can be adhered to effectively.
16. PPE needs are identified and suitable equipment is specified, made available, used, and maintained appropriately within the facility.
17. Procedures are established, validated and maintained to ensure that appropriate methods for disinfection, decontamination, and inactivation are chosen and implemented effectively.
18. Appropriate waste management policy and processes are established and maintained for biological materials, biological agents and toxins.
19. Emergency response plans and procedures are established, implemented, practiced, and maintained. Biorisks are taken into account when preparing and implementing emergency plans.
20. Emergency exercises and simulations are conducted at regular intervals based on risk to test the plans, prepare personnel, and learn from any good practices or deficiencies identified.
21. Satisfactory contingency measures are in place to ensure the safety and security of continued operations in the event of an emergency.
22. Facilities, equipment, and processes are designed and operate in a safe and secure way with respect to biorisk management.
23. A formal process is in place for initial commissioning of new or significantly renovated facilities and the final decommissioning of facilities prior to being taken out of service, repurposed or deconstructed.

24. Documented procedures are established and maintained to ensure equipment and elements of the life science facilities physical plant and any ancillary support facilities that may impact biorisk are identified, purchased, maintained, calibrated, certified or validated in a manner consistent with the intent and requirements of the biorisk management program.
25. Procedures for the safe and secure transport of cultures, specimens, samples and contaminated and potentially contaminated materials are established and maintained in accordance with legal requirements for the transport of dangerous goods as specified in Department of Transportation regulations specified in 49 CFR 171-180 and the International Air Transport Association (IATA) standards.
26. The controls for the physical security of cultures, specimens, samples, and potentially contaminated materials or waste determined as part of the risk assessment process are implemented and maintained. Access to certain materials and information should be limited to designated, authorized individuals.
27. Procedures are in place to identify sensitive information; a review and approval process should be used to control access to such information.

Performance and Evaluation

28. The organization evaluates and measures the performance and the effectiveness of the biorisk management system. Documented procedures are established and maintained to report, define, document, analyze, and learn from accidents and incidents involving biological agents and toxins.
29. Internal audits are conducted at planned intervals to provide information on whether the biorisk management system conforms to the organization's own requirements for its biorisk management system, and is effectively implemented and maintained.
30. Top management reviews the organization's biorisk management system, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness.
31. The organization continually improves the suitability, adequacy, and effectiveness of the biorisk management system through the use of the policy, objectives, internal audit results, analysis of data, risk assessment, corrective and preventive actions, and management review.
32. The biorisk management system is formally reviewed by site management at least annually.

References

1. Laboratory biorisk management, CWA 15793:20111, European Committee for Standardization, September 2011.
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3. Centers for Disease Control and Prevention (2011). Guidelines for Biosafety Laboratory Competencies—United States, 2011. MMWR, 60 (Supplemental): 1–23
4. Centers for Disease Control and Prevention (2011). Competency Guidelines for Public Health Laboratory Professionals: CDC and the Association of Public Health Laboratories—United States, 2015. MMWR, 64(1) (Supplemental): 1–95.