

Biorisk Management Roles and Responsibilities
Based upon CWA 15793:2008
Adapted by Sandia National Laboratories

A good biorisk management program is critical for maintaining laboratory biosafety and biosecurity. A biorisk program should follow the principles defined in the international “Laboratory biorisk management standard,” CEN Workshop Agreement (CWA) 15793:2008. The objective of this standard is to guide institutes around the world in establishing and implementing a successful system that can manage their biological risks. This standard is based on common biorisk principles and best practices for mitigating biological risks.. The objectives outlined are:

- Establish a biosafety and biosecurity management system to minimize risk to employees, the community and the environment that may be exposed to biological materials as a consequence of its activities;
- Implement, maintain and continually improve biosafety and biosecurity management;
- Assure itself of conformance with its stated biosafety and biosecurity policy;
- Demonstrate such conformance to others;
- Make a self-determination and declaration of conformance;
- Seek internationally recognized third party certification of its biosafety and biosecurity management system.

This standard defines roles, responsibilities and authorities for persons maintaining and managing bioscience facilities. The roles, responsibilities, and authorities as defined in this standard are not exhaustive, but provide a framework for understanding what is needed to ensure a comprehensive biorisk management program. Responsibilities may be shared between multiple roles or assigned to a specific role as determined by top management. The following definitions have been adapted from the standard.

Roles

Top Management is ultimately responsible for the organization’s biorisk management system.

Senior Management is responsible to the oversight of the biorisk management program. The role of senior management is also to review and audit the system to ensure compliance by others in the organization.

The **Biorisk Officer’s** (Biosafety Officer) role is to provide guidance and oversight to the biorisk management program. This person has delegated authority from senior management to audit, review, and, where needed, to stop work in the event the work does not comply with the organizational policies and guidance defined to ensure biosafety and biosecurity.

Scientific Management is responsible for the scientific program within each facility and to ensure that all work is conducted in accordance with the policies and guidelines established by organization to manage biosafety and biosecurity. The details of these responsibilities include: supervising of workers, including ensuring that only competent and authorized persons have laboratory access, and planning and conducting work activities in a manner that complies with the policies and guidance.

Laboratory Manager is responsible to ensure the laboratory is maintained and supplied in accordance with the policies and guidance developed by the organization.

Facility Management is responsible to ensure facilities/ laboratories are operated and maintained in accordance with the policies and guidance developed by the organization.

Security Management is responsible to ensure facilities/ laboratories are operated and maintained in a secure manner in accordance with the policies and guidance developed by the organization.

Occupational Health's role is to ensure access to appropriate health expertise, and, ideally, ensure the facility has an established occupational health program in accordance with the policies and guidance developed by the organization.

Animal Care Management is responsible to ensure facilities/laboratories with animals are operated and maintained in accordance with the policies and guidance developed by the organization.

Biorisk Committee (Institutional Biosafety Committee) should act as an independent review group for biorisk issues. This group should report to the biorisk officer and senior management, and should include a variety of expertise that is appropriate to the nature and scale of the activities for the organization or facility. The committee's role is to approve proposals for new work or to review significant modification to ongoing work that may alter the associated risks. The committee should review and approve risk assessments and risk mitigation measures identified, and also provide guidance on organizational policies and guidance developed to ensure biosafety and biosecurity.

Responsibilities

It is the responsibility of **top management** to review the risk assessment results, and determine if the identified level of risk is acceptable, and if not, support senior management, the biorisk officer, and the scientific management in developing biorisk mitigation strategies to reduce the risk. Further, the responsibilities of **top management** include the defining, documenting, and communicating the roles and responsibilities for the organization as they pertain to biorisk management. They are also responsible to identify the resources required to maintain biosafety and biosecurity, and to define acceptable biosafety and biosecurity risks for the organization.

The responsibilities of **senior management** include the allocation of resources needed to support biosafety and biosecurity, and to report the performance of the biorisk management system to top management.

It is the responsibility of **top** and **senior management** to ensure that a biosafety and biosecurity risk assessment is regularly conducted and reviewed for the institute, its individual laboratories, and all research protocols.

The **biorisk officer** has the primary responsibilities of communicating and educating senior management and scientific management about the institute's policies and guidance for biorisk management, and providing an interface between senior management and scientific management.

It is a joint responsibility of **senior management**, the **biorisk officer**, and **scientific management** to specifically conduct each risk assessment and to interpret the results. Further, it is the responsibility of these individuals to develop organizational, facility and laboratory policies, procedures and guidance documents that accurately describe the biorisk mitigation strategies.

It is the responsibility of the **biorisk committee** to review the risk assessment and the mitigation strategies to determine if the existing and mitigated risks are acceptable.