

*Insert Facility/Institute Logo Here*

**BIORISK MANAGEMENT PROGRAM**

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| Facility: | |
| Program Title: BIORISK MANAGEMENT TRAINING AND COMPETENCY ASSESSMENT PROGRAM PLAN | |
| Document Number: | Version Number: *00*  Effective Date: *MM-DD-YYYY* |
| Other documents cross-referenced in this Program (i.e., manuals, SOPs, forms, records): | |

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| Revision Number | Sections Changed | Description of Change | Date | Approved By |
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* **Black text** can be considered generic text which may be appropriate for inclusion in a facility’s biorisk management manual and SOPs.
* ***Red text*** should be considered guidance or examples and must be reviewed and replaced with facility-specific information.

# Introduction

Describe why this program document is necessary as part of the BRM program.

Incidents caused by human error and poor technical skills can be minimized through an effective training and competency program. Personnel who are knowledgeable and well-informed in recognizing and controlling laboratory risks create a safety-conscious culture.

Establishing competency is one of the key components of a BRM program, and has several elements which must be addressed such as the:

* determination of competency levels for the work being performed;
* ensuring of worker competency based on education, training, or experience;
* levels of supervision required for work;
* actions required to attain and evaluate competence; and
* documentation required as evidence of competence.

Training in Biorisk Management is another key component of the BRM program. Specific elements of training are the:

* identification of biorisk training needs;
* provision of programs based on training needs;
* provision of training in line with biorisk management plans;
* determination of effectiveness of biorisk management training;
* provision of consistent refresher training;
* assessment to ensure competency in the material; and
* maintenance of training records.

Training is focused on knowledge, skills, and abilities and uses instructional design models, such as ADDIE (Analyze, Design, Develop, Implement, and Evaluate). Adult learning principles are used in the development, design, and delivery of training to maximize the retention of material.

It is important to note that training does not equal competency. Furthermore, successful completion of a proficiency test alone does not establish competency. Refer to Section III for the definition of each term.

# Purpose

The management of facility recognizes that an established BRM training and competency program (Program) is vital to the maintenance and continuous improvement of the Biorisk Management Program. This plan provides the detailed requirements for safety and security training for all personnel working at or visiting facility.

# Abbreviations and Definitions

*BRM Biorisk Management*

*IBRMC Institutional Biorisk Management Committee (Safety Committee)*

*SOP Standard Operating Procedure*

*additional*

**Competency**. The ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly without direct guidance.

**Instructional design models**. Organizing and visualizing learning theories and principles to guide the learning development process. Structuring teaching strategies, methods, and activities to address specific learning goals and objectives.

**Training**. Hands-on instruction or skill acquisition under the constant and direct guidance of a qualified trainer.

# Scope

This program applies to all staff whose work duties involve the handling of potentially hazardous biological materials, including waste. Staff members whose work duties may inadvertently expose them to hazardous biological materials (administrative staff, maintenance, cleaning staff, contractors, and visitors) must be trained to recognize potential hazards when entering laboratories or other areas with biological hazards. All personnel will be trained in biosecurity as appropriate to their level of responsibilities.

# Responsibilities

*List responsibilities of all positions that require any level of training.*

**IBRMC (Safety Committee)** develops, implements, and reviews the facility training program to ensure a safe working environment and prevent exposure to hazardous biological materials.

**Biorisk Management Advisor** is a recognized expert in the field of biorisk management, assists in content review, and performance review of the training program.

**Deputy BRM Advisor** has the same responsibilities as the BRM Advisor and acts in that capacity in the absence of or in concert with the BRM Advisor.

**Supervisors and Managers** ensures that time is available for staff to attend and complete BRM training activities and provide feedback to the Biorisk Management Advisor when changes in methods or equipment may necessitate additional or modified training. They are also responsible for analyzing staff needs, implementing training, assuring that training is evaluated, and carrying out activities that address both short and long-term institutional goals. Additional responsibilities include training short-term visitors to their departments and submitting training documentation to the Biorisk Management Advisor in a timely manner.

**Facility staff** attend and complete training and competency activities, including any documentation, as required by the Program as well as comply with the Biorisk Management Program.

**Visiting staff** on long-term projects within facility complete all required staff training.

**Contractors** working in areas with hazardous biological materials have documented training by the position name to be aware of specific area hazards.

# Program

## Policies

### Facility will:

* determine the necessary competency of person(s) who work under its control and affect its biorisk management performance;
* ensure that these persons are competent on the basis of appropriate education, training, or experience;
* ensure that all workers are under close supervision until they demonstrate the ability to perform activities in a safe and secure manner;
* where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; and
* retain appropriate documented information as evidence of competence.

### Facility will ensure that requirements and procedures for biorisk management training of workers are identified, established, and maintained.

## Objectives

### Training procedures include, but are not limited to:

### identification of biorisk training needs;

### provision of programmes based on biorisk training needs;

### provision of required biorisk training in line with biorisk management plans;

### determination of effectiveness of biorisk training;

### provision of refresher biorisk training on a consistent basis;

### assessment to ensure that workers are competent to perform assigned tasks; and

### maintenance of biorisk training records.

## BRM training requirements:

### Training Topics

The WHO Laboratory Biosafety Manual (4th Ed.), Table 3.1 can be used for guidance on training and areas to be covered. See Appendix A.

#### Give a general description of each training and the areas to be covered. This can be a table or a list.

* + 1. General familiarization and awareness training
    2. Job-specific training
    3. Safety and security training

#### The *Employee Training Plan* form is used to guide and document the training required in the initial months of employment. The Employee training plan includes all applicable training listed for the position in Table 1.

### *Facility* staff training schedule.

*Example training table but can be in other formats.*

Table 1. *Example:* Required training by position

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Training Name** | **Position** | **Justification** | **Level** | **Schedule (Refresher)** |
| BRM | Research | Direct exposure | Advanced | Annual |
|  | Veterinarians | Direct exposure | Advanced | Annual |
|  | Janitorial | Possible exposure | Basic | Annual |
|  | Administrative | Awareness only | Awareness | Annual |
| Sharps | Research | Direct exposure | Advanced | Annual |
|  | Veterinarians | Direct exposure | Advanced | Annual |
|  | Janitorial | Possible exposure | Basic | Annual |
|  | Administrative | Awareness only | Awareness | Annual |
| Respirator | Research | Required for work | User | Annual |
|  | Veterinarians | Required for work | User | Annual |
| Rabies lab | Veterinarians | Access to rabies lab | User | Annual |

### Training level descriptions

#### Awareness. Information regarding a biorisk to which personnel not working in the laboratory may be exposed, e.g., administrative assistant who enters a laboratory to deliver files. Information is focused on potential hazards.

#### Basic. A standard set of skills or information for staff who do not regularly perform those skills without supervision, e.g., new laboratory personnel. Information is focused on the identification and mitigation of potential hazards and threats directly related to the work performed.

#### Advanced. Staff who have learned the basic skills needed to perform the job but are doing more difficult or higher-risk work, e.g., staff who work in heightened containment or with respiratory pathogens. Information is focused on the identification and mitigation of specific hazards and threats directly related to the work performed.

#### User. Staff whose job duties require use of a piece of personal protective equipment (PPE) that requires certification or access to a restricted area, e.g., fit testing for N95 or powered air-purifying respirator (PAPR), rabies laboratory. Information is focused on the specific requirements of the laboratory area.

#### All training includes information for responding to and reporting incidents and accidents, including safety and security measures.

### Visitor training requirements

#### Visitor training is dependent upon the level of biorisk.

#### The area supervisor or manager is responsible for conducting and documenting training.

#### Training records are submitted to the Biorisk Management Advisor.

#### Long-term visitors (e.g., visiting professors) are trained as facility staff.

### Contractor training requirements

#### Contractor training is dependent upon the level of biorisk.

#### The supervisor responsible for the area of work is responsible for conducting and documenting training.

#### Training records are submitted to the Biorisk Management Advisor.

# Education and certification requirements to perform roles

List any education, certification, or experiential requirements in place for performance of roles. (This may be addressed as a table or in another format and should follow the facility’s human resources practices, job titles, and regulator/accreditor requirements.)

## Technician

* Associate or bachelor’s degree in a laboratory science or certification from an accredited laboratory training organization.
* 0 – 2 Years of laboratory experience.

## Technologist

* Bachelor’s degree in a laboratory science and certification from an accredited laboratory training organization.
* 2-5 Years of laboratory experience.

## Supervisor

* Education
* Laboratory Experience
* Supervisory experience (e.g., demonstrate a high level of understanding of biorisk management requirements, demonstrated leadership capabilities)
* Additional requirements (e.g., demonstrated understanding of documentation requirements, ability to provide completed documents in a timely manner, ability to implement activities as directed to support biorisk management priorities)

## Manager

* + Education
  + Laboratory Experience
  + Managerial experience (e.g., demonstrated high level of understanding and communication of biorisk management requirements, demonstrated leadership and mentoring capabilities)
  + Additional requirements (e.g., demonstrated ability to communicate with multiple levels of the organization, budgeting, ability to implement programs and activities supporting the organization’s biorisk management priorities, willing to serve on the organization’s IBRMC)

## Heightened containment or special pathogens

* + Education
  + Experience (e.g., advanced knowledge of the procedures)
  + Additional requirements (e.g., ability to wear a respirator, ability to pass a competency in containment procedures, no record of safety or security incidents in the past 6 months, demonstrated compliance with established biorisk management procedures)

## Biohazardous waste disposal technician

* + No educational requirements.
  + No previous experience required.
  + Additional requirements (e.g., ability to comply with established biorisk management procedures and practices, can lift 25 Kilos)

## Additional roles

* + Education
  + Experience
  + Additional requirements.

# Training and Competency

## Training

### Any staff member with demonstrated expertise in a procedure may provide training but may not necessarily be qualified to assess competency.

### The timeline of training may include:

#### observation of a properly performed procedure,

#### performance of the procedure under direct and constant guidance using samples with known results, controls, or water blanks as applicable,

#### independent practice of the procedure using written SOPs and samples of known results as applicable, and

#### performance of the procedure while being observed by the trainer who can point out any incorrect procedures to the trainee.

## Competency Assessment

### Competency must be assessed prior to staff independently performing procedures.

### The following positions may assess competency: Describe who may assess competency using regulatory or accrediting body guidance.

### For non-diagnostic procedures, e.g., biosafety or biosecurity response, a written quiz or scenario-based assessment is used to assess and document competency on the ***BRM Competency Assessment Form.***

## Competency Assessment Form

### A ***Competency Assessment Form*** is completed for all procedures prior to staff independently performing the procedure.

### The form identifies the type of assessment, confirms reading and understanding of the procedural SOP, review of the risk assessment, any laboratory information system procedures, pre-analytic, analytic, and post-analytic procedures as applicable, safety procedures, quality control, and security associated with the procedure.

### The form includes a written assessment (quiz) from each topic area and one problem solving situation commonly encountered in the procedure.

### The form includes confirmation that staff was directly observed while performing all procedures as applicable.

### The form includes confirmation that a proficiency test or internal assessment (using samples with known results) was completed as applicable.

### The form includes the specifics of authorities granted to the staff member for performing the procedure.

### Supervisors / managers review the form with the staff member.

## BRM Competency Assessment Form

### The ***BRM Competency Assessment Form*** is used for biosafety and biosecurity-based assessments, e.g., biological spill response, exposure response, etc.

### The form includes documentation of written policy and procedures, performance of response, communication, and the use of any materials (as applicable).

### The form includes a written assessment (quiz) including a problem-solving question.

### The form includes an assessment of the level of understanding of the material by granting authority of competency, trainer, or the ability to assess the competency of others.

## Authorization Form

### The ***Authorization Form*** details the specific procedure, type of competency, and delegates authority from the Laboratory Director to the staff member to perform the work activities.

### The form is used as a coversheet to the competency packet, which includes the:

* competency assessment form,
* proficiency test or independent assessment results, and
* intermediate results and/or instrument printouts

## Documentation specifications

### List location, format, and roles for training and competency (This may be addressed using a table. See Table 2 below for an example.)

Table 2. *Example:* Documentation specifications

|  |  |  |  |
| --- | --- | --- | --- |
| Role | Ensures Training & Competency | Document Name | Document Location |
| Microbiology Technician / Technologist | Microbiology Supervisor | Procedural Competency Assessments | Room ####  File Cabinet A10  Drawer 3 |
| BRM Advisor | BRM Training | Room ####  File Cabinet C02  Drawer 1 |
| BRM Advisor | Security Training | Room ####  File Cabinet C02  Drawer 2 |
| Microbiology Supervisor | Employee Training Plan | Room ####  File Cabinet A10  Drawer 3 |
| Microbiology Supervisor | BRM Advisor | BRM Training | Room ####  File Cabinet C02  Drawer 2 |
| BRM Advisor | Security Training | Room ####  File Cabinet A10  Drawer 3 |

# Communication

## Changes to the Program

### Changes to the Program will be reviewed and approved by the IBRMC.

### Changes to this Program document are completed through established document control procedures. (Reference Document Control Program Plan)

## Training events

### The schedule of training is communicated to staff through email, SMS text messages, newsletter, webpage (web address here), or other methods (specify).

### Add if registration for training is required and any details.

## Top Management

### The IBRMC communicates with the top management of facility (schedule).

### Facility top management receives an annual report of Program performance (list details).

# Review of Program Performance

## Performance Metrics

### An assessment of Program performance is conducted annually by the IBRMC.

### The percentage of staff successfully completing all required training will be divided by the total number of staff in the facility required to complete BRM training.

### A result of 100 – 95% is considered Excellent, 94.9 – 90% Good, 89.9 - 80% Acceptable, and below 80% Needs Improvement.

### Additional performance metrics may be used as determined by the IBRMC.

## Corrective/Preventative Actions

### Program performance falling below acceptable levels set by the IBRMC are subject to the Corrective/Preventative Action process. (Reference Corrective and Preventative Actions SOP)

## Review of Training Program Content

### The IBRMC reviews the content of the Program annually for relevance and appropriateness of content. For example, trainings may be added or removed, staff positions required to attend may be changed, or the mode or schedule of training may be changed as appropriate to the needs of the facility.

# Appendices

## WHO Laboratory biosafety manual, 4th edition. Table 3.1. Training to be implemented for laboratory personnel.

|  |  |
| --- | --- |
| TRAINING | AREAS TO BE COVERED |
| General familiarization and awareness training | Mandatory for ALL personnel, an introduction to:   * Laboratory layout, features and equipment * Laboratory code(s) of practice * Applicable local guidelines * Safety or operations manual(s) * Institutional policies * Local and overarching risk assessments * Legislative obligations * Emergency/incident response procedures |
| Job-specific training | * Training to be determined based on job function; training requirements may vary between personnel of the same job title but performing different functions * All personnel involved in the handling of biological agents must be trained on GMPP * Competency and proficiency assessment must be used to identify any other specific training required, for example, by observation and/or qualification * Proficiency in any procedure must be verified before working independently, which may require a mentorship period * Competencies must be reviewed regularly and refresher training undertaken * Information on new procedures, equipment, technologies and knowledge must be communicated to applicable personnel as and when available |
| Safety and security training | Mandatory for ALL personnel:   * Awareness of hazards present in the laboratory and their associated risks * Safe working procedures * Security measures * Emergency preparedness and response |

GMPP = good microbiological practice and procedure.

# References

1. ISO 35001. Biorisk management for laboratories and other related organizations. 2019-11. The International Organization for Standardization.
2. Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). License: CC BY-NC-SA 3.0 IGO
3. Risk Assessment. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). License: CC BY-NC-SA 3.0 IGO

# Attachments

## Employee Training Plan template

## Competency Assessment template (diagnostic procedures)

## BRM Competency Assessment template

## Authorization Form template