

*Insert Facility/Institute Logo Here*

**BIORISK MANAGEMENT SYSTEM**

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| Facility: | |
| SOP Title: MATERIAL CONTROL AND ACCOUNTABILITY PROGRAM PLAN FOR DIAGNOSTIC LABORATORY SAMPLES | |
| Document Number: | Version Number: *00*  Effective Date: *MM-DD-YYYY* |
| Other documents cross-referenced in this Program (i.e., manuals, SOPs, forms, records):   * Biosecurity Program Plan (*6-01-001)* * External Transport and Shipping Security (*SOP-009-OP*) * Personnel Reliability SOP (*SOP-011-OP*) * Physical Security SOP (*SOP-012-OP)* * Information Security SOP (*SOP-013-OP*) * Material Control and Accountability SOP (*SOP-010C-OP*) * BRM Document Control Plan (xxxxxx) * Material Control and Accountability Log | |

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| Revision Number | Sections Changed | Description of Change | Date | Approved By |
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* ***Red text*** should be considered guidance or examples and must be reviewed and replaced with facility-specific information.

1. **Purpose**

This program specifies that, as a result of a risk-based assessment, there are procedures and practices in place to ensure an accurate, verifiable, and up-to-date record of stored diagnostic laboratory samples. The plan specifies that physical, personnel, and information security associated with these samples is established and maintained to prevent theft, loss, or release of personally identifiable information, and that the performance of the plan is regularly evaluated and improved.

This document describes the facility’s BRM Material Control and Accountability for Diagnostic Laboratory Samples. The Laboratory Director oversees this program.

1. **Program**

The following policies support this plan:

1. *[Insert Institution/Facility Name]* will ensure that an accurate, verifiable, and up-to-date inventory, or itemized record of diagnostic samples including those containing biological agents and toxins specified, is established and maintained based on the organization’s biorisk assessment.
2. *[Insert Institution/Facility Name]* will determine how diagnostic samples including those containing biological agents and toxins are handled and stored, and which of these will be accounted for and controlled through the inventory based on biorisk assessments and other requirements, as applicable.
3. Based on *[Insert Institution/Facility Name]* biorisk assessments, the organization will determine a process for checking, reviewing, updating, and reporting the inventory of diagnostic samples.

Elements of material control and accountability for diagnostic samples are listed below.

* Information
  + inventory (a list of all diagnostic samples being stored by the laboratory) should include:
* the rationale for storing or keeping the diagnostic sample;
* the level of control in a specified location, including the possibility to indicate legible and robust identifiers;
* records of quantities and volumes at an appropriate level and based on risk;
* an inventory of diagnostic samples sent and received, including materials consumed, destroyed, or removed from the facility where appropriate; and
* development of a robust identification system.
* Personnel reliability
  + the name(s) of and contact information for the individual(s) responsible for the material and details of other personnel with access to the materials or immediate area based on the level of the risk and
  + identification of personnel with a demonstrable, legitimate need to access to the information system, inventory list, and/or diagnostic samples.
* Security
  + identification and implementation of effective physical security measures according to risk (e.g., locks, alarms, access controls, etc.) in a specific location.
* Transport and shipping
  + determination of conditions for transportation of diagnostic samples (shipment tracking, verification, responsible personnel)
* Controls are in place to confirm that all the necessary checks and documented assurances are received to ensure that requests for biological agents and toxins originate from legitimate facilities and individuals.
* Diagnostic samples may only be sent elsewhere if authorized by those responsible for the facility and personally identifying information has been removed.
* For materials deemed high risk, more stringent controls including shipment tracking and verification of receipt are important considerations.

1. **Scope**

This plan applies to all personnel in *[Insert Facility Name]* who handle diagnostic samples, including shipping, receipt, testing, information management, and storage.

1. **Responsibilities**

* **Management** will:
  + aid an organization to develop and enforce a biorisk management program: a set of tools, information and associated actions that are overseen, enforced, and continuously improved by an organization’s management. This will ensure that a biorisk management system is properly implemented and maintained.
* The **Biorisk Management Committee** is:
  + an institutional committee created to act as an independent review group for biorisk management issues; it reports to senior management.
  + membership on the biorisk management committee should reflect the different occupational areas of the organization as well as its scientific expertise.
* **Process Leader** ensures that:
  + an SOP is established, implemented, and maintained effectively to align with local, national, and international laws and agreements to provide security for biological materials, dual-use equipment, and other biological-security-relevant items.
  + authorized users are trained on this procedure and are competent prior to reliance on the prescribed security measures.
* **Facility personnel**:
  + follow the procedures outlined in this Program.
  + report any problems to the Process Leader.
* **Laboratory Director***:*
  + determines the items and materials to be secured by material control and accountability processes based on risk assessment and applicable local, national, and international guidelines, standards, and regulations.
  + determines material control and accountability policies and procedures that oversee and ensure the security of diagnostic samples.
  + determines which personnel are given the authority to receive, store, use, transfer or destroy secured items.
  + determines and sets policy on what items to maintain and when to dispose of them.
  + determines resource needs and oversees resource allocation that will be necessary to implement this procedure.
* **Security** *Manager/Officer*:
  + Provides expertise on effective and proportionate biosecurity measures to the team for risk assessment; may support investigations into biosecurity incidents; may provide regular security checks.
  + Ensures security aspects of the material control and accountability plan are followed by all facility personnel.
* **Biorisk Management Advisor**:
  + Provides advice and guidance on biorisk management issues. The role and knowledge of the biorisk advisor is key to develop, maintain and continually improve a biosafety and biosecurity program based on a management system.
* **Members of the Workforce**:
  + All members of the workforce are responsible for the proper implementation of diagnostic sample accountability and control measures.

1. **Abbreviations & Definitions**

*BRM Biorisk Management*

*CoC Chain of Custody*

*IBRMC Institutional Biorisk Management Committee*

*MC&A Material Control and Accountability*

*MTA Material Transfer Agreement*

*SOP Standard Operating Procedure*

*VBM Valuable Biological Materials*

Additional abbreviations

**Chain of Custody.** Document which identifies continuous accountability for a sample through receipt, use, transport, transfer, storage, and destruction.

**De-identify.** Removal of patient information (name, date of birth, contact information, etc.) from primary container or storage labels so that personal identification is not possible.

**Material Transfer Agreement.** Legal document between two organizations – provider and receiver – authorizing the transfer, receipt, and specified use of materials.

**Responsible Staff Member.** Trusted personnel with assigned responsibilities for any part of the material control and accountability program.

**Valuable Biological Materials.** Substances derived from living organisms that possess significant economic, scientific, or medical value, e.g., diagnostic samples, cell lines, biological data, tissues.

1. **Program**
   1. Workflow
      1. Describe Specimen Receiving workflow.  *A flow chart can be used to show an overview of the process as in Table 1.*
      2. Describe Receiving VBM(s) workflow. Table 2.
      3. Describe Shipping of VBM(s) workflow. Table 3.

Table 1. *Example*: Specimen Receiving Workflow

Table 2. *Example*: Receiving VBM(s) Workflow

Table *Example*: Shipping of VBM(s) Workflow

* 1. Inventory
     1. The following diagnostic sample types must be tracked in facility inventory: (follow any regulatory and/or institutional requirements)
        + 1. Add sample types here.
     2. The following information is included on all inventory lists:
        + 1. Unique ID number
          2. Agent name (proper scientific name)
          3. Quantity / volume per container
          4. Location (freezer, shelf, box, location)
          5. Responsible staff member
          6. Contact information (responsible staff member)
          7. Access control level (See Section D, determined by institution)
     3. The Laboratory Director is responsible for determining which organisms are included in the inventory.
     4. The Laboratory Director is responsible for the Master Inventory List and its security.
     5. List who is generally expected to be responsible for specific programs. This can be a list or a table (Table 4).

Table 4: *Example:* Program VBM Inventory Responsibility List

|  |  |  |
| --- | --- | --- |
| Program | Inventoried Materials | Responsible Staff Member  (Contact Phone Number) |
| Microbiology | EHEC: 0157, *Bacillus anthracis, Francisella tularensis,*  *Coxiella burnetii* | *Microbiology Supervisor/Manager* |
| Molecular Biology | Ricin, Abrin, Saxitoxin | *Molecular Biology Supervisor/Manager* |
| Virology | Monkey pox virus, Nipah virus | *Virology Supervisor/Manager* |
| Special Pathogens | Ebola virus, Crimean-Congo hemorrhagic fever virus,  Marburg virus, Rinderpest virus | *Special Pathogens Supervisor/Manager* |
| Toxin Center of Excellence Program | Ricin, Abrin | *Project Lead* |
| Master Facility Inventory | *All inventoried materials* | *Laboratory Director* |

* 1. Accountability and Responsible Individuals
     1. Describe how personnel are added as responsible individuals.
     2. Describe how personnel reliability measures are taken.
     3. Describe the review process of personnel qualifications and determination of the need to access VBM samples or inventory information.
  2. Access Control (Personnel)
     1. Describe levels of access control (including physical security, information security for VBMs, diagnostic samples, and inventory information). Example, Table 5.

Table 5: *Example:* Access Levels

|  |  |
| --- | --- |
| Access Level | Description |
| Visitors | No unescorted access to any area of the facility where VBMs are used or stored. No access to inventory information without prior approval of the Laboratory Director (ex., Inspectors) |
| Level 1 | No access to VBM or VBM storage or waste storage areas. Must be supervised by Responsible Staff Member when in areas where VBM or waste is stored. No access to VBM inventory information. No access to diagnostic samples or protected health information. |
| Level 2 | No access to VBM or VBM storage. Access to waste storage for destruction of material only. No access to VBM inventory information. Access to diagnostic samples and protected health information to perform regular job duties. |
| Level 3 | Access to specific VBM and VBM storage and waste areas to perform specific work tasks. Access to local VBM inventory information related to work tasks only. Access to diagnostic samples and protected health information to perform regular job duties. |
| Level 4 | Access to Department/Program VBM and VBM storage and waste areas to perform inventory control checks. Access to Department/Program VBM inventory information. Access to diagnostic samples and protected health information to perform regular job duties. |
| Master Access | Access to facility-level VBM and VBM storage and waste areas and facility master inventory information. Access to diagnostic samples and protected health information to perform regular job duties. |

* + 1. Access control is granted through the following procedure:
       - 1. All facility personnel are granted Level 1 access to their area of work upon hiring.
         2. Personnel are granted Level 2 access following completion of required training for their area of work and job duties.
         3. Level 3 access is granted following VBM-specific training and approval of the Laboratory Director.
         4. Additional access levels are approved based on job duties, BRM Advisor approval, and approval of the Laboratory Director.
    2. The Access Request form is used to request initial or changes in access level (See Table 5).
  1. Physical Security
     1. Physical security measures are based on the assessed safety and security risks.
     2. The measures employed are adequate to protect the integrity of diagnostic samples and information during transport, use, and storage.
     3. Physical security measures include the following: (list general physical security measures taken at the facility, examples below)
* Keyed or electronic room locks (including storage rooms)
* Locking file cabinets or drawers
* Locking refrigerators and freezers
* Locking incubators
* Key sign-out tracking log
* Password-protected electronic inventory
* Locked master key safe
  1. Forms and Documents
     1. The following forms and documents are used to manage and record diagnostic samples: (list documents and forms used for inventory and tracking of samples)

Table 6. *Example:* Forms & Documents

|  |  |  |  |
| --- | --- | --- | --- |
| Form/Document | Purpose | Location | Responsible Staff |
| Master Key Log | Documents staff in possession of controlled keys | Security Office ‘Master Key Log’ binder | Security Officer/Manager |
| Inventory Control Form | Tracking of inventory | Departmental ‘Inventory’ binders | Department supervisors / managers |
| Access Request Form | Request initial and changes in access level | Security Office ‘Access Request’ binder | Security Officer/Manager |
| Information Access Request Form | Request initial and changes to electronic access. |  |  |
| *Additional forms* |  |  |  |

* 1. Receipt of Diagnostic Samples
     1. Diagnostic samples are received according to procedures stated in the **Sample Receiving SOP** (Reference number).
     2. All samples are stored and transported in a manner which maintains sample integrity.
     3. Receipt of diagnostic samples with suspected VBMs must be handled according to applicable regulations and as described in Table 2 (list any regulations). ~~must~~
  2. Shipping of Diagnostic Samples
     1. Diagnostic samples are prepared and shipped according to procedures stated in the **Transport and Shipping Security SOP** (SOP-009-OP).
     2. *Facility* staff preparing shipments must have up-to-date IATA training and certification (See Table 7).
     3. Shipments of diagnostic samples with confirmed or suspected VBMs must be packaged according to IATA Regulations by staff with current IATA shipping certification.
  3. Staff Training
     1. *Facility* staff are trained on this procedure and all associated SOPs. Required training is listed below:
        + 1. *This can be a table or list. See Table 7.*
     2. Training records are maintained as follows: *(include in Table)*
        + 1. Sign in sheets and quizzes, location, responsible staff.
          2. SOP acknowledgement (sheets, forms, etc.) location, responsible staff.

Table 7. *Example:* MC&A Training Matrix

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Training | Purpose | Type | Schedule | Records Location |
| Basic BRM Biosecurity | Familiarization with biosecurity pillars | Seminar | Annually | *BRM Advisor files* |
| Material Control and Accountability | MC&A Plan requirements and SOP | Seminar | Annually | *BRM Advisor files* |
| IATA Shipping Training | Shipping of Category A and B materials  *\*only for staff shipping specimens* | Hands-on Training | Every 3 years | *BRM Advisor files* |
| Handling Protected Health Information | Information security for PHI, de-identification of samples for shipping. | Seminar | Annually | *QA Coordinator* |
| Waste Handling Procedures | Transport, documentation, and security requirements when handling VBM waste | Hands-on Training | Annually | *BRM Advisor files* |
| SOPs   * Biosecurity Program Plan (*6-01-001)* * Transport and Shipping Security (*SOP-009-OP*) * Personnel Reliability SOP (*SOP-011-OP*) * Physical Security SOP (*SOP-012-OP)* * Information Security SOP (*SOP-013-OP*) * Material Control and Accountability SOP (*SOP-010C-OP*) * BRM Document Control Program (*SOP-xx-OP*) | *Understanding of BRM policies, practices, and procedures for each topic listed.* | Read and understood | initially and at each revision | *QA Coordinator* |

* 1. Records Retention
     1. Program documents are retained according to the BRM Document Control Program (Reference Number).

1. **Communication** 
   1. Changes to Program
      1. Changes to the Program will be reviewed and approved by the *position*.
      2. Changes to this document are completed through Document Control Program procedures.
2. **Review of Program Performance**
   1. Performance Metrics
      1. An assessment of Program performance is conducted *annually* by the *position*.
      2. Program assessment performance metrics include: (Examples below)
         * 1. Percentage of VBM inventory checks with no discrepancies.
           2. Percentage of inventory discrepancies reported within the required reporting window.
           3. Number of staff trained to ship Category A materials. (Target = #)
           4. Number of staff trained to ship Category B materials. (Target = #)
      3. For percentage data, a result of 100% is considered Excellent, 99 – 98% Good, and below 98% Needs Improvement.
      4. For numerical data, a target number has been established and is determined to be *met* or *not met*.
      5. Additional metrics may be used as determined by the IBRMC or BRM Advisor.
   2. Corrective/Preventative Actions
      1. Program performance falling below acceptable levels set by the *position* are subject to the Corrective/Preventative Action process. (Reference Corrective and Preventative Actions SOP)
   3. Review of Documents
      1. The *position or committee* reviews the content of the Program – including training records - annually for relevance and appropriateness of content. For example, documents may be added or removed, or documents may be revised to reflect current or modified procedures.
      2. The responsible staff member(s) as listed in Table 4 review receipt, shipping, and inventory documentation as listed below:
         * 1. Receiving records – review interval
           2. Shipping records – review interval
           3. Inventory - review interval
3. **References** 
   1. **ISO 35001**. **Biorisk management for laboratories and other related organisations**. 2019. International Standards Organization. Geneva, Switzerland.
   2. **CWA 16393**. **Laboratory biorisk management – Guidelines for the implementation of CSA 15793: 2008**. 2012. European Committee for Standardization.
   3. **Laboratory Quality Management System Handbook**. 2011. World Health Organization. ISBM 978 92.4 154827 4.
   4. **Biorisk management: Laboratory biosecurity guidance**. 2006. World Health Organization.
4. **Attachments** *Attach any forms or documentation relevant to diagnostic sample management control and accountability.*