

*Insert Facility/Institute Logo Here*

**BIORISK MANAGEMENT SYSTEM**

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| Facility: | |
| SOP Title: BIORISK MANAGEMENT DOCUMENT CONTROL 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.

1. **Introduction**

Documents communicate the laboratory’s quality system and are the essential guidelines for all laboratory operations, including biorisk management. They describe policies, processes, and procedures that are required by standards and accreditors. Document control also applies to texts, articles and books that are part of the documents referenced in a laboratory, as well as documents of external origin (e.g., instrument service manuals, regulations, standards, audit reports). The document control system provides standardized procedures for formatting and maintaining documents, ensuring that the most current version of any document is the one that is in use, documents in use are adequately protected, and that documents are available and suitable for use, where and when needed. Put simply, ‘*Write what you do and do what you write’*. The Document Control Program is reviewed as part of the facility’s regular audit program.

*Describe the results of any institutional assessment/audit if completed that contribute to development of document control plan.*

1. **Purpose**

Document control ensures that all biorisk management (BRM) program documents and procedures are current and were reviewed and approved by approver position. Requirements for document control are established by the position or committee and follow institutional and accreditor requirements.

This document describes the facility BRM Document Control Plan (Plan). The position with oversight oversees the Plan.

The following policies support this plan:

* 1. Facility biorisk management system includes:
     + documented information required by this document, including but not limited to policies, plans, procedures, protocols, and records; and
     + any other documented information determined by the organization as being necessary for the effectiveness of the biorisk management system.
  2. When creating and updating documented information, facility ensures appropriate:
     + identification and description (e.g., a title, date, author, or reference number);
     + format (e.g., language, software version, graphics) and media (e.g., paper, electronic);
     + review and approval for suitability, accuracy, and adequacy;
     + review and approval for suitability for public release; and
     + security and protection of sensitive information.
  3. Documented information required by facility’s biorisk management system and by this document is controlled to ensure:
     + it is available and suitable for use, where and when it is needed;
     + it is adequately protected (e.g., from loss of confidentiality, improper use, or loss of integrity);
     + it reflects the most current policies, plans, procedures, protocols, records, and other information associated with the biorisk management system.
  4. For the control of documented information, facility addresses the following activities:
     + distribution, access, retrieval, and use based on risk;
     + storage and preservation, including preservation of legibility;
     + control of changes (e.g., version control) and status (e.g. draft, interim, final);
     + retention and disposition.
  5. Documented information of external origin determined by facility to be necessary for the planning and operation of the biorisk management system is identified, as appropriate, and controlled.

The following objectives apply to this plan:

1. Notes or procedural changes will not be written on a controlled document. Typographical errors may be corrected by drawing a single line through the error, so the original entry can still be seen, and then initialed and dated by the person making the correction. Correction fluid or tape will not be used to make changes on a controlled document. All other corrections will use the document control revision process.
2. Only controlled copies of documents are used for reference. Uncontrolled documents or printouts from documents located on drives or in personal files will not be used.
3. Photocopies of controlled documents will not be used.
4. Controlled documents will not be discarded except as part of the established process in this document.
5. All controlled and uncontrolled copies of documents are located and turned in to the position prior to receipt of updated versions of the document.
6. Hard copies of all controlled documents are maintained by the position in location. Electronic copies of controlled documents are maintained location.
7. The procedures described in the current version of a controlled document are followed until a revision is authorized and training documentation has been completed for the new version.
8. Approver(s) and authorizer (as applicable) for each document type is described in this document.
9. Additional objectives associated with BRM document control.
10. **Abbreviations & Definitions**

*BRM Biorisk Management*

*IBRMC Institutional Biorisk Management Committee*

*SOP Standard Operating Procedure*

*Ver Document version*

Additional abbreviations

**Authorized**. A document which has been approved for release in the document control system.

**Job Aid.** An auxiliary document which is part of a controlled document but is used by itself. The job aid may be a brief version of the procedure or other useful document related to an SOP.

**Controlled document**. A document in which all changes are tracked and authorized using version control and audit trails in a centralized system. All controlled documents have a unique document number.

**Corrective Action**. An action to eliminate the cause of a detected nonconformity or other undesirable situation. A corrective action report should be completed when an error or out of specification result is detected **prior to the release of test results**, such as when Quality Control (QC) specimens are out of range for a test run.

**Draft**. A document which is under review but not yet authorized.

**Document Number**. The unique document number in the document control system.

**Effective Date**. The date on which a document becomes active for use. Any previous versions of the document must be replaced with the current version on the effective date of the new version.

**History**. All revision, review, notes/comments and print records associated with a document.

**Major Revision.** A major revision involves procedural changes or a significant amount of added material to the document. It also includes changes to specimen/sample types, reagents used, and indications for use of a test or result reporting procedures.

**Marking.** A watermark or other indicator that shows the status, category, or security level of a document.

**Minor Revision.** Minor revisions include the correction of typographical errors or the clarification of existing procedures with no substantive changes to the procedure itself.

**Review**. The approval of documents based on review of content for accuracy.

**Skilled Staff**. Employees trained on procedural documents in the document control system. Training can range from ‘read and understood’ for minor revisions to competency assessments.

**Superseded**. Documents for which a newer version exists.

**Trained Staff**. Designation for staff who have completed a scheduled training course.

**Uncontrolled document**. A document lacking a unique identification number in which changes are not tracked or recorded.

**Version**. The numerical tracking of document revisions. Version numbers begin with 01 and increase by 1 with each new version of the document. A secondary minor revision tracking number can be used following the version (e.g., 02.01 indicating the second major revision with 1 minor revision).

Additional definitions

1. **Scope**

This program applies to all documents in the BRM program. Staff members must understand the use and function of the document control system within the BRM program so that out of date procedures and documents are not used for current work practices.

1. **Responsibilities**

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

**IBRMC (Safety committee)** develops, implements, and reviews the facility document control system 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 and assists in content and performance review of the BRM Document Control system.

**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/Managers**. Responsible for supporting staff adherence to the facility BRM Document Control System Program’s procedures and policies and that staff have documented review of BRM plans, policies, programs, and procedures.

**Facility staff**. Responsible for ensuring that the current, authorized versions of BRM documents are used, requesting changes, and communicating suggestions regarding controlled documents to the position. Staff are also responsible for the completion of document review tasks as assigned in a timely manner.

1. **Program**
   1. Required Documents
      1. Describe what documents are part of the Document Control Plan. Can be table or list as preferred (see Table 1).
      2. List document types.
      3. Indicate location of Master Document List

Table 1. Included Documents *(Example)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| DOCUMENT | OWNER | AUTHORIZER | LOCATION | REVIEW SCHEDULE | Retention Time |
| Standard Operating Procedures | Department Supervisor | Laboratory Director | Laboratory | Annually | Upon revision except for file copy. |
| Job hazard charts | BRM Advisor | Laboratory Director | BRM Advisor Files | Monthly | No destruction |
| Design and commissioning records | BRM Advisor | N/A | BRM Advisor Files | Annually | No destruction |
| Maintenance plans and records | Maintenance Supervisor | BRM Advisor | Maintenance files | As produced | 10 years following equipment removal |
| Incident Reports | BRM Advisor | Laboratory Director | BRM Advisor Files | As produced | 10 years |
| Critical Communications | BRM Advisor | Laboratory Director | BRM Advisor Files | As received | No destruction |
| Audit Reports | BRM Advisor | Laboratory Director | BRM Advisor Files | As received | 10 years |
| BRM Policies | IBRMC | Laboratory Director | Electronic or binders | Annually | No destruction |
| Training records | BRM Advisor | Laboratory Director | BRM Advisor Files |  | 10 years |
| Containment equipment certifications | BRM Advisor | Laboratory Director | BRM Advisor Files | Annually | No destruction |
| Equipment QC records | Department Supervisor | N/A | Department files | Monthly | 10 years after equipment removal |
| Consultation reports | BRM Advisor | Laboratory Director | BRM Advisor Files | As received | No destruction |
| Biosecurity risk assessments | BRM Advisor | Laboratory Director | BRM Advisor Files | As produced | No destruction |
| Safety and Security manuals | BRM Advisor | Laboratory Director | BRM Advisor Files | Annually | Upon revision except for file copy |
| Medical and health surveillance reports | Health provider | BRM Advisor | Medical files | Monthly | 10 years after employee separation |
| Emergency response drills | BRM Advisor | Laboratory Director | BRM Advisor files | Annually | 10 years |
| Job descriptions | Human Resources | Laboratory Director | Human Resource files | Annually | Upon revision except for file copy |
| Security Logs and access requests | Security officer | BRM Advisor | Security files | Monthly | 10 years |

* 1. Document Reference Numbers
     1. Describe the numbering system for documents. BRM-202-SEC-02.00
        + 1. Example. Department indicator:

MB – Molecular Biology, SR – Serology, WC – Water Chemistry, MI – Microbiology, BRM – Biorisk Management Program, etc.

* + - * 1. Document number:

100’s = QA plan, 200’s = procedures, 300’s = equipment, etc.

* + - * 1. Document type

S = SOP, R = report, L = Logbook, Rf = reference text, B = book, Std = standard, QS = quality system document, SEC = security, etc.

* + - * 1. Version

**01**.00 = major revision

01.**01** = minor revision

* + 1. Describe where document numbering starts, zero or one.
    2. Who is responsible for assigning document reference numbers?
  1. Submission of New Documents
     1. Describe how new documents are submitted for review and approval.
  2. Revision of an Existing Document
     1. Describe how an existing document is submitted for review and approval, and how this is process should be documented.
  3. Job Aids
     1. Describe how job aids are produced and updated, with the original document or as a separate document?
  4. Superseded Documents
     1. Describe the handling/filing/destruction of superseded documents.
     2. A paper file with 1 copy of all versions of all documents is stored in a secure location.
  5. Retirement of BRM Documents
     1. Describe how existing documents are retired when no longer needed.
  6. Document Review and Approval
     1. Describe the document review and approval process
        + 1. Is a ‘wet’ signature required (ie signed by pen on physical document), is there a separate form, or is approval conducted in an electronic system?
          2. Describe how all changes are clearly tracked from one version to the next.
     2. Describe who has final approval and how approval is recorded.
     3. Reference Section VI.M for master list of approved documents.
        + 1. This can be addressed in the Master List or Document Type list or cover page of documents. (Section A)
     4. Reference Section VI.L.6 for marking approved documents.
  7. Staff Training
     1. Describe the method to document training on new or revised documents (signature sheet, etc.).
     2. A table can be used if there is a mix of hands-on, seminar, or read-and-understood training methods.
     3. Include how training records are maintained.
  8. Document Retention
     1. Describe the requirements for availability and retention time for documents. This information may be related to certification or related to local or national regulations and laws.
     2. Retention time can be addressed in the Master List or in Table 1.
  9. Document Storage
     1. Describe how documents are kept and stored (electronic, paper documents, etc.).
     2. Storage location for each document can be addressed in the Master List.
  10. Document Security
      1. Program documents and SOPs are available to staff for review during work shifts.
      2. Program documents and SOPs are not shared with other institutions without the prior authorization of the position.
      3. Electronic documents and records are not copied or transferred to other institutions or personnel without prior approval of the position.
      4. Hard-copy records (paper, printouts, test reports, etc.) must be secured when not in use. Methods of securing hard-copy records include (locked file cabinet, locked file room, locked drawer, or other means).
      5. Access to specific documents and records is controlled by the *position* and is assigned based on job duties.
      6. Describe how documents are marked and what markings indicate.
         + 1. Documents may have a watermark or be marked in the header/footer of each page. Marking must be visible on each page.
           2. Markings and indications (examples, Table 2):

Table 2. *Examples:* Document Markings

|  |  |
| --- | --- |
| MARKING | INDICATION |
| Draft | document is in revision and not for use |
| Approved for Use | document has been reviewed and approved by management for use by the laboratory |
| Internal Use Only | document not to be shared outside the facility |
| For Clinical Use | procedures for clinical diagnostic use |
| Research Use Only | procedures only for research use |
| Containment Only | for use by staff with access to containment areas |
| *Additional* |  |

* 1. Document Tracking System
     1. Describe how the document number, version number, title, document changes, and approvals will be indexed and accessible to workforce (master list, cover sheet, software, or any combination of these).
     2. Describe how the numbers of each document in use are tracked and reconciled (e.g., when a new version is distributed and superseded versions collected).
        + 1. The number of copies may be indicated in the Master List along with the location of each copy, or each version copy may be assigned a unique identification number.

1. **Communication** 
   1. Changes to Program
      1. Changes to the Document Control system will be reviewed and approved by the position.
      2. Changes to this document are completed through the procedures described above.
   2. Changes to Documents
      1. Describe how changes to documents are communicated to staff.
2. **Review of Program Performance**
   1. Performance Metrics
      1. An assessment of Program performance is conducted annually by the position.
      2. (Example metric) The percentage of staff successfully completing all required document reviews will be divided by the total number of staff in the facility required to complete BRM document review.
      3. (Example of scoring) A result of 100 – 95% is considered Excellent, 94.9 – 90% Good, 89.9 - 80% Acceptable, and below 80% Needs Improvement.
      4. Additional metrics, such as the number of incidents occurring due to the use of outdated documents or number of outdated documents found during audit may be used as determined by the IBRMC or BRM Advisor.
      5. Performance of the Program is documented and reviewed, and the documents retained.
   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 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. Regular review of documents is conducted as indicated in Table 1.
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. https://biosecuritycentral.org/resource/requirements-and-protocols/cwa-16393/
   3. **Laboratory Quality Management System Handbook**. 2011. World Health Organization. ISBM 978 92.4 154827 4.
4. **Attachments** Attach any forms or documentation relevant to document control here.
   1. Facility Document Master List