CDC Division of Laboratory Systems

EXCELLENT LABORATORIES, OUTSTANDING HEALTH.

Internal Audit Program Overview for Laboratory Biorisk Management Systems

May 2026

Introduction

The purpose of this document is to support organizations in developing, implementing, and maintaining an internal audit program as part of their laboratory biorisk management system (BRMS). Internal audits provide a structured approach to evaluating operations, verifying compliance, identifying vulnerabilities, and promoting continual improvement, thereby strengthening both biosafety and biosecurity.

This document was developed in consideration of the principles described in ISO 35001:2019 – Biorisk management for laboratories and other related organizations, ISO 19011:2018 – Guidelines for auditing management systems, and the CDC's *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), 6th Edition, among other relevant references.

Scope

This document provides an overview of the structure and operation of an internal audit program within a biorisk management system. It describes the program manual, roles and responsibilities, the internal audit process, and supporting elements.

This overview forms part of a BRMS internal audit toolkit that includes the following resources:

- Internal Audit Plan Template for Laboratory Biorisk Management Systems
- Internal Audit Report Template for Laboratory Biorisk Management Systems
- Corrective Action Plan (CAP) Template for Laboratory Biorisk Management Systems

These tools were developed to support the practical implementation of the concepts described herein and to promote consistency, traceability, and accountability throughout the audit cycle.

This resource is intended for laboratories and related organizations that handle biological materials and manage risks associated with biological hazards.

For questions, please contact DLSBiosafety@cdc.gov.

Revision History:

- May 2026; Version 1; Initial posting.

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Definition of Terms

Term	Definition
Auditee	Organization as a whole or parts thereof being audited.[1]
Auditor	Person who conducts an audit.[1]
Audit Checklist	Structured set of questions or criteria used to assess laboratory processes for compliance with applicable policies, standards, and regulations.
Audit Criteria	Set of requirements used as a reference against which objective evidence is compared.[1]
Audit Scope	Extent and boundaries of an audit.[1]
Audit Team	One or more persons conducting an audit, supported if needed by technical experts.[1]
Biorisk Management System (BRMS)	Management system used to establish biorisk management policies, objectives, and processes to achieve those objectives.[2]
Conformity	Fulfillment of a requirement.[2]
Continual Improvement	Recurring activity to enhance performance.[2]
Corrective Action (CA)	Action to eliminate the cause of a nonconformity and to prevent recurrence.[2]
Corrective Action Plan (CAP)	Documented plan developed in response to an audit nonconformity, specifying root causes, corrective and preventive actions, responsibilities, timelines, and monitoring to ensure sustained improvement.
Document Control	System for ensuring that audit-related documents are approved, current, traceable, and protected from unauthorized modification.
Internal Audit	Systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.[2]
Management Review	Formal, documented review conducted by top management to evaluate audit results, CAPs, and BRMS performance at planned intervals.
Nonconformity	Non-fulfillment of a requirement.[2]
Objective	Result to be achieved. In the context of BRMS, objectives are set by the organization, consistent with the organization's policy, to achieve specific results.[2]
Organization	Person or group of people that has its own functions with responsibilities, authorities, and relationships to achieve its objectives.[2]
Performance Indicator	Measurable value used to assess progress toward a BRMS objective.

Preventive Action (PA)	Action taken to eliminate the cause of a potential nonconformity before it occurs.
Program Manual	Documented foundation of the internal audit program that defines governance, policies, procedures, roles and responsibilities, audit criteria, and oversight requirements to ensure audits are conducted in a systematic, impartial, and traceable manner.
Requirement	Need or expectation that is stated, generally implied or obligatory.[1]
Revision History	Record of changes made to a controlled document, including version, date, description of changes, and authorizer.
Root Cause Analysis (RCA)	Structured process for identifying underlying causes of a nonconformity, used to develop effective corrective actions.
Top Management	Person or group of people who directs and controls an organization at the highest level.[2]

[1]*Source: ISO 19011:2018 – Guidelines for auditing management systems*
[2]*Source: ISO 35001:2019 – Biorisk management for laboratories and other related organizations*

Part I: Framework

Internal Audits in a Biorisk Management System

A biorisk management system (BRMS) is the framework laboratories use to manage biosafety and biosecurity risks. It combines policies (what the organization commits to), objectives (what the organization wants to achieve), and processes (how the work is carried out) into a coordinated system for reducing risks.

The BRMS follows the Plan–Do–Check–Act (PDCA) cycle (Figure 1), which is a continuous improvement model used across management systems[3]:

- **Plan**: Plan a change, establish objectives and processes that align with laboratory policies.
- **Do**: Put plans into action and implement the processes outlined in the planning stage, executing the process.
- **Check**: Assess the results against the policy and objectives set during the planning stage. Gather data, analyze results, and measure performance to understand how well objectives are being achieved and the risks are being controlled.
- **Act**: Continuously review processes to ensure laboratory work is not just maintained but consistently improved to achieve the objectives.

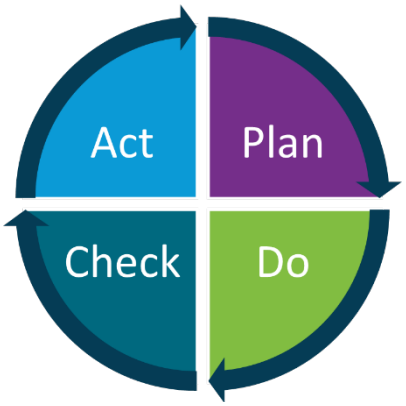

Figure 1: PDCA Cycle Diagram for Continuous Improvement in Risk Management.

Internal audits are a critical element of the Check phase. They allow laboratories to verify that policies and processes are being implemented as intended, confirm progress toward objectives, and ensure that risks are effectively managed. Audits also provide assurance that corrective actions are producing measurable improvements and that the BRMS continues to meet organizational and regulatory expectations.

Objectives are an essential part of the BRMS because they provide measurable targets against which performance can be evaluated. Internal audits are most effective when they are designed to assess progress toward these objectives. However, audits are not limited to objectives alone. For laboratories that have established objectives, audits may use those objectives alongside other audit criteria, such as organizational policies, Standard Operating Procedures (SOPs), and conformity with applicable standards such as ISO 35001:2019 – Biorisk management for laboratories and other related organizations (ISO 35001:2019).

For laboratories that have not yet developed formal objectives in every area, internal audits can still be conducted effectively using policies, procedures, and standard requirements as the audit criteria. This approach ensures that audits provide a comprehensive assessment of BRMS implementation and overall system performance, regardless of the maturity of the objectives framework.

Examples of Biorisk Management Objectives

When objectives are established, they can guide internal audits in specific and measurable ways. Examples include:

- **Personal Protective Equipment (PPE):** Conduct a comprehensive PPE risk assessment for Biosafety Level 2 (BSL-2) laboratory areas by the end of the calendar year and annually thereafter.
- **Emergency Preparedness:** Achieve at least 80% active participation from all laboratory staff in quarterly biosafety emergency response drills within the next six months.
- **Inventory Management:** Implement a centralized electronic inventory management system to achieve 100% accountability and documentation for all biological agents within 12 months.
- **Occupational Health:** Ensure 100% of all new laboratory personnel complete required occupational health screening, vaccinations, and medical surveillance within 30 days of employment start.

For additional information on how to create and refine BRMS objectives, laboratories can refer to CDC's resource: Developing Biorisk Management Objectives

Looking Ahead

This document is designed to assist laboratories in performing audits, by evaluating progress toward established objectives (if in place) and assessing compliance with policies, SOPs, and applicable standards.

The following sections outline the structure of an internal audit program and the steps involved in evaluating elements of a BRMS. Gray callout boxes are included throughout to illustrate how specific concepts (e.g., objectives, checklists, reporting) may appear in practice.

Part II: Program Structure

Internal Audit Program Development

Internal audits should begin with the development of a structured internal audit program. An audit program is not a single audit; rather, it is an organized framework used to plan, schedule, conduct, and follow up on audits as part of the BRMS. Establishing such a program ensures that audits are risk-based, systematic, and support continual improvement.

To be effective, an internal audit program should address the following key actions[2]:

- **Program management:** The program should define audit frequency, methods, responsibilities, planning requirements, and reporting. It should also consider the importance of the processes being audited and the results of previous audits.
- **Criteria and scope:** Each audit should have clearly defined criteria (what it is being measured against) and scope (the boundaries of what is being reviewed).
- **Impartial auditors:** Auditors should be selected in a way that ensures objectivity and avoids conflicts of interest.
- **Planned intervals:** Audits should be conducted on a regular schedule to provide assurance that the BRMS continues to function as intended.
- **Conformance checks:** Audits should verify whether the system meets the organization's own requirements and aligns with recognized standards of best practice.
- **Implementation and maintenance:** Audits should evaluate whether the BRMS is being put into practice effectively and sustained over time.
- **Management reporting:** Audit results should be communicated to relevant parties, including leadership and affected workers.
- **Documented evidence:** The audit program itself, as well as audit plans, reports, and records of corrective actions, should be retained as documented evidence.

These elements form the foundation of the internal audit program and ensure that audits provide meaningful insight into the effectiveness of the BRMS.

To make these elements easier to understand in practice, the audit program can be visualized as three interrelated layers (Figure 2):

1. **Internal Audit Program (outer layer):** The overarching framework through which the organization establishes, manages, and sustains internal audits. It reflects leadership's commitment to biosafety and biosecurity, defines the intent and scope of the program, and ensures that audits are a regular and expected part of the laboratory's BRMS.

2. **Program Manual (middle layer):** The documented foundation of the program. The manual outlines the policies, governance, and requirements that guide internal audits. It ensures consistency, transparency, and accountability across the program.

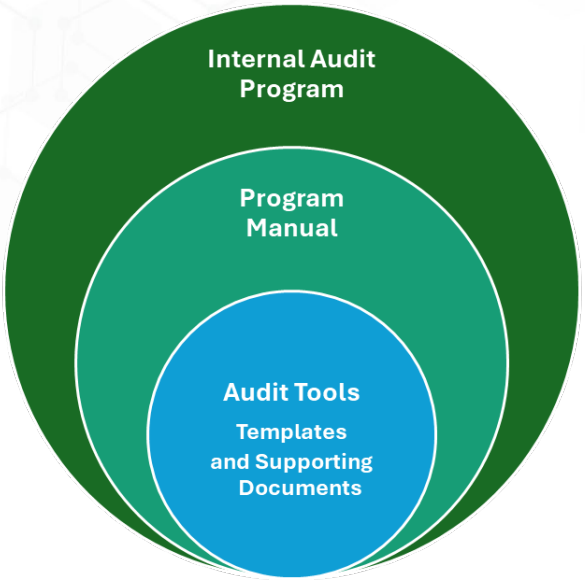

Figure 2. Three Layers of the Internal Audit Program.

3. **Audit Tools (inner layer):** The instruments used to carry out the requirements of the Program Manual. These include structured templates and supporting documents that guide planning, reporting, and corrective actions. Standardized templates—such as the Internal Audit Plan Template, Internal Audit Report Template, and Corrective Action Plan (CAP) Template—are available to support implementation of this layer. These tools translate program requirements into practical documents, enabling traceability across each audit cycle and providing documented evidence that the BRMS is operating effectively.

Together, these three layers operationalize the key actions of the internal audit program. The next section describes the Program Manual, which outlines the policies, procedures, and requirements that guide how audits are planned, conducted, reported, and followed up.

Program Manual

The Program Manual describes how the internal audit program is structured and carried out. Its purpose is to provide consistency, transparency, and accountability, ensuring that audits are carried out in a systematic and traceable way. While each laboratory will tailor its manual to its size, structure, and regulatory environment, the manual should at a minimum cover the following areas:

Audit Policy

The manual should begin with a short, high-level statement of intent that reflects the organization's commitment to impartial, systematic auditing of the BRMS. This policy anchors the program, demonstrates leadership commitment, and establishes the expectation that audits will support both compliance and continual improvement.

> Example statement: "The organization is committed to maintaining an effective internal audit program as part of its biorisk management system. Internal audits will be conducted in a systematic, impartial, and documented manner to verify compliance, identify opportunities for improvement, and ensure the safety and security of laboratory operations."

Governance

Governance refers to the structure and oversight of the internal audit program. The Program Manual should specify who has authority to approve and manage the program, how impartiality is safeguarded, and how results are reported to management. Governance establishes accountability at the leadership level and ensures that the audit program remains aligned with organizational objectives.

Policies and Procedures

The Program Manual should outline the policies and procedures that guide how audits are carried out and documented. These procedures establish consistency and ensure that audits are embedded into daily practice. At a minimum, the manual should include:

- **Audit Planning:** expectations for preparing audit plans that define objectives, criteria, scope, schedules, and team assignments.
- **Conducting Audits:** methods for collecting evidence (e.g., document review, staff interviews, facility walkthroughs).
- **Audit Reporting:** requirements for audit reports, including classification of findings and clear, evidence-based language.
- **Corrective Action:** expectations for developing a CAP for all nonconformities, assigning responsibilities, and setting timelines.
- **Management Review:** requirements for documenting review meetings and leadership decisions, including review of aggregated internal audit results and the status of actions from previous management reviews, as part of ongoing oversight of the BRMS.

- **Records and Documentation**: expectations for retaining and controlling all audit-related records within the organization's document management system.

These policies and procedures provide the framework for audit activities. In Part III: The Audit Cycle, a five-step internal audit process is introduced, which laboratories may adapt when developing their own detailed procedures.

Audit Criteria

Audit criteria are the benchmarks used to judge performance during an internal audit. They provide the standard of comparison for determining whether the BRMS is working as intended.

Audits should use a combination of:

- **Objectives**: Where BRMS objectives have been established in the planning phase of the system, audits should be designed to evaluate progress toward those objectives.
- **Internal requirements**: Organizational policies, SOPs, and laboratory-specific procedures, including actions to address biorisks.
- **External standards**: Recognized frameworks such as ISO 35001:2019, regulatory obligations, and other applicable national or organizational requirements.
- **Organizational context**: The specific characteristics of the laboratory, such as its size, structure, resources, and types of work performed.
- **Interested parties**: The needs and expectations of groups that affect or are affected by the BRMS, such as regulators, organizational leadership, laboratory workers, and external stakeholders.

The program manual sets the expectation that all five sources of criteria will be considered. The specific objectives, policies, standards, and contextual requirements to be applied are defined in each individual audit plan.

Auditor Competence and Independence

The manual should define expectations for auditor competence and impartiality. Auditors should have knowledge of audit principles, familiarity with laboratory operations, and technical expertise in biorisk management. Independence is essential; auditors should not evaluate areas where they have direct responsibilities, ensuring that findings remain objective and credible.

Tools

The manual should reference standardized instruments that make audits consistent and practical in everyday use. These tools turn program requirements into practice and provide structure and traceability across audits. Examples include:

- **Audit plan templates:** The working documents that define objectives, scope, methods, and criteria for each audit. An Audit Plan Template is available to support this documentation.
- **Audit checklists:** Tools that provide structured questions or criteria that address critical biorisk areas such as pathogen inventories, autoclave validation, or Personal Protective Equipment (PPE) use.
- **Interview guides:** Tools that help confirm staff awareness of key procedures, such as spill response or access control.
- **Audit report and corrective action templates:** Documents to ensure consistent documentation of findings, nonconformities, and follow-up actions. An Audit Report Template and a Corrective Action Plan (CAP) Template are available to promote consistency.

Audit Schedules

The manual should also describe how often audits are conducted and how the frequency is determined. Scheduling should be risk-based and flexible enough to adjust to regulatory changes, laboratory modifications, or incidents. Timelines for proposing, reviewing, and approving audits should be included to ensure accountability. Schedules should be communicated to relevant personnel and include follow-up audits when needed. Table 1 provides a risk-based example of determining audit frequency.

Table 1. Audit Frequency Based on Risk

Risk Level	Audit Frequency	Notes
High	Every 6 months	For critical processes, high-hazard activities, or areas with repeated nonconformities.
Medium	Every 12 months	For moderate-risk areas or processes with routine regulatory oversight.
Low	Every 24 months	For stable, low-risk processes with minimal changes or issues.

Note: Audit frequencies should be adapted to the organization's own risk assessments, historical audit results, and incident trends. Higher-risk areas or those with repeated deficiencies may require more frequent or targeted audits, while lower-risk areas may justify extended intervals.

Roles and Responsibilities

Governance, as introduced in the Program Manual section, depends on clearly defined roles and responsibilities. Within a BRMS, every level of the organization, from top management to laboratory staff, contributes to maintaining a safe workplace and reducing biorisks. The following roles carry specific responsibilities within the audit program.

Top Management

The highest level of leadership that directs and controls the organization. Top Management holds ultimate accountability for the BRMS and the internal audit program. They cannot delegate accountability but may delegate authority for tasks and implementation.

Responsibilities:

- Approve the internal audit policy and program manual.
- Ensure that BRMS objectives are established, aligned with laboratory policy, and reviewed through the management review process.
- Ensure adequate resources (personnel, training, financial, and infrastructure) are available to support the audit program.
- Integrate audit results into strategic decision-making and organizational planning.
- Promote compliance, safety, and continual improvement across the organization.

Examples of staff who could serve in this role: Laboratory Director, Chief Executive Officer (CEO), Chief Operating Officer (COO), Hospital Administrator.

Senior Management

The management tier with operational responsibility for implementing the BRMS and ensuring audits are carried out. Senior Management reports to Top Management.

Responsibilities:

- Oversee day-to-day implementation of the internal audit program.
- Translate BRMS objectives into operational priorities and ensure that audits evaluate progress toward them, alongside compliance with policies and standards.
- Designate the audit team and ensure auditor independence.
- Approve audit plans and verify that findings are addressed.
- Report audit status to Top Management.

Examples of staff who could serve in this role: Department Heads, Laboratory Managers, Biosafety Program Managers, Operations Directors.

Biorisk Management Committee
A multidisciplinary committee that supports and advises on BRMS issues. They provide independent oversight and ensure cross-functional representation.

Responsibilities:

- Provide oversight and advice on whether BRMS objectives remain relevant, achievable, and appropriately integrated into audit priorities.
- Support the BRMS in its entirety by reviewing audit findings.
- Maintain independence from the activities under review.
- Establish terms of reference, assign actions, and track their completion.
- Represent expertise across biosafety, security, health, and science.

> Examples of staff who could serve in this role: Institutional Biosafety Committee (IBC) members, Safety Committee members, representatives from facilities, security, occupational health, and scientific units.

Biorisk Management Advisor
A competent individual designated to provide technical advice, guidance, and assurance on biorisk management. The Biorisk Management Advisor is independent of day-to-day laboratory operations and reports directly to Senior Management.

Responsibilities:

- Guide development of audit tools.
- Provide assurance on BRMS compliance.
- Have authority to stop unsafe or insecure work.
- Support auditor training in biosafety and biosecurity.
- Advise management and auditors on how objectives connect to risk assessments, controls, and improvement activities.
- Advise on, participate in, and support reporting investigations and follow-ups.

> Examples of staff who could serve in this role: Biosafety Officer, Biosafety Professional, Biorisk Advisor, Responsible Official (in select agent programs).

Scientific Management
Supervisors or managers responsible for laboratory scientific work, staff, and daily operations. Scientific Management is accountable for applying BRMS requirements into the work environment.

Responsibilities:

- Ensure risk assessments are performed and reviewed for relevant activities.
- Verify that hazard controls are implemented.
- Authorize only competent and trained personnel to work with biological materials.
- Monitor effectiveness of control measures in laboratory operations.

Examples of staff who could serve in this role: Principal Investigators, Laboratory Supervisors, Research Managers, Section Leads.

Auditors

Individuals trained to conduct internal audits independently and objectively. Auditors may be internal staff or external parties, provided impartiality is maintained.

Responsibilities:

- Conduct audits according to approved plans and checklists.
- Use BRMS objectives as part of audit criteria.
- Gather evidence through document review, interviews, and observation.
- Document findings clearly and recommend corrective actions.
- Maintain impartiality and avoid conflicts of interest.

Examples of staff who could serve in this role: Quality Assurance Officers, Trained Internal Auditors, External Consultants (if independence is preserved).

Laboratory Workers / Staff

Personnel who perform laboratory activities under organizational control, including scientists, technicians, and support staff.

Responsibilities:

- Follow BRMS policies, SOPs, and audit requirements.
- Provide information and participate in audits through interviews or demonstrations.
- Report incidents, near misses, or nonconformities.
- Participate in corrective actions following audits.
- Contribute to meeting BRMS objectives by adhering to procedures.

Examples of staff who could serve in this role: Laboratory Technologists, Research Scientists, Clinical Lab Staff, Animal Care Technicians, Custodial/Facilities Staff working in containment areas.

Participation in the Audit Program

Laboratory professionals play a critical role in ensuring that audits reflect actual laboratory practice. Active participation allows auditors to evaluate how procedures are applied in practice and to identify areas for improvement. Engaging staff at all levels supports transparency, accountability, and continual improvement.

Part III: The Audit Cycle

Internal Audit Process

The internal audit process represents the detailed structure that should be captured in the Program Manual and tailored by each organization to meet its needs. Within the BRMS, audits function as part of the "Check" stage of the PDCA cycle. At the same time, each audit also follows its own PDCA rhythm, planning, implementation, evaluation, and corrective action, showing how continual improvement operates at multiple levels.

Internal audits are designed to check progress toward BRMS objectives while verifying compliance with policies, SOPs, and applicable standards such as ISO 35001:2019. Depending on the need, audits may range in size and complexity: from a targeted review of one area, such as training records, to a broad evaluation of the entire BRMS.

This document presents the internal audit process in five key steps (Figure 3). These five steps provide a consistent yet flexible framework for implementing internal audits. For additional guidance on audit principles and practices, laboratories should refer to ISO 19011:2018[1].

1. **Audit Preparation:** Develop the audit plan, including objectives and scope, and allocate resources to ensure readiness.
2. **Conducting the Audit:** Gather evidence through document reviews, personnel interviews, and facility walkthroughs, supported by checklists and other tools.
3. **Audit Reporting:** Summarize findings, identify nonconformities, highlight good practices, and issue the audit report.
4. **Corrective Action Planning:** Develop and implement corrective actions to address findings, assign responsibilities, and monitor progress for effectiveness.
5. **Management Review**: Review audit results and CAP outcomes, record decisions related to corrective actions, and communicate lessons learned and changes to staff.

Figure 3. The Internal Audit Process Cycle.

Step 1: Audit Preparation

Audit preparation begins with developing an audit plan and ensuring that resources and tools are in place. The audit plan is the working document that outlines how a specific internal audit will be conducted. It should be developed with consideration of the importance of the processes being audited and the results of previous audits and risk assessments, so that high-risk areas receive focused attention. A well-prepared plan provides clear expectations for both auditors and auditees.

For each individual audit, the audit plan defines the objectives, criteria, scope, methods, responsibilities, and timing of audit activities.

The key elements of an audit plan include:

Audit Objectives, Criteria, and Scope

- **Audit objectives** describe what the audit aims to achieve. These may include verifying compliance with policies or standards, evaluating the effectiveness of actions implemented to address identified biorisks, or confirming that corrective actions have been implemented.
- **Criteria** are the benchmarks used to judge conformity and performance, such as BRMS objectives, SOPs, documented actions to address biorisks, regulatory requirements, and applicable clauses of ISO 19011:2018, or ISO 35001:2019.
- **Scope** defines the boundaries of the audit, such as the processes, departments, or activities to be examined. The scope can be described in terms of coverage, as described in Table 2, and perspective.

Table 2. Audit Coverage: Horizontal and Vertical Scopes

Scope Type	Description	Example Application
Horizontal	Reviews one process across multiple departments to check consistency and compliance organization-wide.	Auditing biosafety training records across all laboratory units.
Vertical	Examines all aspects of a single procedure or process for depth.	Assessing specimen handling, storage, and disposal practices within a single testing unit.

Example: An audit objective may be to verify that 100% of biological waste handling activities at Facility A comply with approved waste management SOPs and ISO 35001:2019 Clause 8.8 during the past 12 months. The audit criteria include the organization's waste SOPs and ISO 35001:2019 Clause 8.8. The scope is vertical, covering all waste-handling steps within the facility over the past 12 months.

Perspective of the Audit

Beyond coverage, audits can also be defined by their perspective, the lens through which the chosen scope is evaluated. Examples of audit perspectives include:

- **System-based:** Evaluates the overall BRMS for conformity with standards such as ISO 35001:2019.
- **Process-based:** Reviews how a process (e.g., incident reporting) is implemented across units.
- **Product/service-based:** Examines outputs such as laboratory reports or decontamination results.
- **Risk-based:** Focuses on high-hazard activities or areas with previous nonconformities.

Coverage and perspective are not mutually exclusive. In practice, audits often combine both.

Example: A horizontal, process-based audit may review how incident reporting is applied across all laboratories, while a vertical, risk-based audit may examine all practices in one high-containment lab.

Audit Schedule

The audit plan should specify the schedule, including start and end dates, timing of major activities (e.g., document review, staff interviews, facility walkthroughs), and deadlines for report delivery. Communicating the schedule to auditees in advance ensures preparedness and cooperation.

Example: A scheduled audit might reserve day one for reviewing supplier qualification files, day two for on-site observation of equipment maintenance, and day three for interviews with staff.

Audit Team and Competence

The plan should identify audit team members and their qualifications. Auditors should be trained in audit methods, familiar with laboratory operations, and technically competent in biosafety and biosecurity. Auditors should be selected in accordance with program requirements for competence and independence.

Example: An audit team may include one lead auditor with formal training and one subject matter expert with experience in laboratory ventilation systems, particularly when the audit scope includes engineering controls or facility systems that support containment.

Resource Allocation

The audit plan should describe the resources needed to carry out the audit, including time, budget, administrative support, and access to relevant records. Resources may also include standardized templates, document management systems, and logistical support for site visits.

Example: Resources may include checklists for reviewing PPE use in high-containment areas, interview guides for evaluating supplier oversight, and secured access to electronic training databases.

Preparing Audit Tools

Alongside the plan, supporting tools should be developed or customized before the audit begins. These include audit checklists, audit report templates, and CAP templates.

To assist laboratories, templates are provided below. These are intended as references and may be customized to fit organizational needs. Each laboratory should develop and maintain its own approved versions alongside the program manual.

- **Internal Audit Plan Template for Laboratory Biorisk Management Systems**
- **Internal Audit Report Template for Laboratory Biorisk Management Systems**
- **Corrective Action Plan (CAP) Template for Laboratory Biorisk Management Systems**

Step 2: Conducting the Audit

Once the audit plan has been developed and the supporting tools prepared, the next step is to conduct the audit itself. This stage involves gathering evidence and evaluating whether the BRMS is being applied as intended in daily laboratory operations. Evidence should be collected to demonstrate whether safety, security, and risk management requirements are being met in practice.

Evidence is typically collected through three main methods:

Document Review

Auditors thoroughly examine policies, procedures, and records to verify that they align with the laboratory's biorisk management standards. Document reviews may take place during audit preparation or as part of the on-site audit.

Examples of biorisk documents to be reviewed include:

- Risk assessments
- Biosafety and biosecurity SOPs and checklists
- Personnel training records
- Previous audit reports (including findings, corrective actions, and follow-up)
- Calibration and maintenance records for critical laboratory equipment
- Autoclave monitoring records, safety shower, and eyewash logs
- Safety Data Sheets (SDS) and chemical labeling records
- Emergency response plans (e.g., spills, fires, or security breaches)
- Documentation of sample handling, storage, and disposal practices

Personnel Interviews

Interviews allow auditors to assess whether staff understand and follow established procedures. Questions should align with the reviewed documents, confirming that written policies are being implemented in practice. Interviews can also assess the effectiveness of training programs and highlight areas where additional instruction may be needed.

Facilities Walkthroughs

A walkthrough provides auditors with direct observations of laboratory spaces and operations. Walkthroughs confirm that appropriate measures are being followed, facilities are properly maintained, and laboratory conditions support safe and secure practices.

Using Audit Tools

Audit tools such as checklists, interview guides, and observation templates help ensure audits are consistent and objective. These tools should be applied flexibly to reflect the audit's scope, whether the audit is horizontal (e.g., comparing one process across departments) or vertical (e.g., examining all aspects of a single unit).

> Example: A checklist for a vertical audit of a diagnostic unit may include criteria such as proper sample storage, training records, and emergency plan awareness, while a horizontal audit across departments may compare consistency in documentation practices.

Recording Evidence

Auditors should record evidence clearly, distinguishing between conformity, nonconformity, and observations. Notes and supporting documentation should remain objective and provide the foundation for the audit report.

> Example: During a walkthrough of a BSL-2 laboratory, auditors confirmed that spill kits were present and accessible (conformity). However, when staff were asked to describe the spill response procedure, some could not recall all steps (observation). This was recorded in the audit notes and linked to training records for follow-up.

Step 3: Audit Reporting

The evidence collected during the audit is synthesized into the audit report. The report is the primary record of audit results and provides leadership with objective information to guide decision-making. An effective report is clear, factual, and structured, allowing findings to be prioritized and acted upon.

Report Content

An effective audit report should contain both context information and the results of the audit.

- **Context information:** Audit criteria and methodology, key stakeholders, audit team members with their roles and participation dates, and the audit period covered.
- **Audit results:** Objective observations and findings, supported by evidence collected during the audit. These should identify nonconformities, along with noteworthy practices or conformities that demonstrate effective implementation or innovation.

This structure ensures that the report provides a complete record of both the conditions under which the audit was conducted and the outcomes observed.

Categorizing Audit Findings

To help management prioritize corrective actions, auditors should categorize findings based on their nature, severity, and potential impact. Clear categorization ensures findings are addressed proportionally and consistently across audits.

In clinical laboratories, severity classification may also consider potential impact on patient care, diagnostic accuracy, or reportable result integrity.

Table 3 provides examples of common categories, their definitions, and illustrative cases:

Table 3: Categorization of Audit Findings

Category	Definition	Examples
Major Nonconformity	A significant failure to meet a requirement, indicating a serious risk to safety, compliance, or BRMS integrity, or evidence of a systemic breakdown in implementation.	Lack of biosafety cabinet certification; absence of access control in restricted areas.
Minor Nonconformity	A deviation from a requirement that does not indicate a systemic failure; typically, isolated and correctable through routine corrective action.	Missing training records; incomplete chemical labeling.
Observations	A noted condition that is not a nonconformity but may lead to one if not monitored or addressed.	Inconsistent use of PPE in low-risk areas.

Opportunity for Improvement	A suggestion identified during the audit that, while not a nonconformity or risk, could enhance the efficiency, effectiveness, or robustness of the BRMS.	Streamlining documentation to reduce duplication.

Clarity and Objectivity

Findings must be written in precise, neutral language and supported by evidence. Reports should avoid subjective terms or assigning blame.

> Example: Instead of "Staff are careless with PPE," the report should state: "During observation, two staff were not wearing protective eyewear in designated areas, contrary to SOP-BIO-07."

Linking Results to Objectives

Audit results should be aligned with the organization's BRMS objectives, as these objectives define outcomes the system is designed to achieve. When performance indicators have been established for the objectives, auditors should use them to provide measurable evidence of progress.

Examples of BRMS Objectives and How They Link to Audit Results:

- **Objective:** Conduct a comprehensive PPE risk assessment for BSL-2 laboratory areas by the end of the calendar year and annually thereafter.
  - **Performance indicator:** Documentation of completed PPE risk assessment and review date.
  - **Audit report entry:** *Risk assessment was not completed by year-end. Major Nonconformity.*

- **Objective:** Achieve at least 80% active participation from staff in quarterly emergency response drills within six months.
  - **Performance indicator:** Percentage of staff participating in drills.
  - **Audit report entry:** *Participation records showed 72% attendance at the most recent drill. Minor Nonconformity.*

These linked results provide leadership with objective evidence that can be reviewed in Step 5: Management Review, where progress toward objectives is evaluated, and decisions are made about resources, priorities, or adjustments to the BRMS.

Distribution and Storage

Audit reports should be:

- Reviewed and signed or validated by the Lead Auditor, with review or acknowledgement by designated governance roles as defined in the internal audit program.
- Reported to relevant management, including Senior and Top Management, within the agreed timeframe.
- Retained as controlled documented information in accordance with organizational document management procedures as evidence of the audit results.

Step 4: Corrective Action Plan (CAP)

The CAP is the mechanism for addressing nonconformities identified during an audit. Every major and minor nonconformity must have a CAP. A well-prepared CAP ensures that issues are corrected within a defined timeframe, responsibilities are clearly assigned, and improvements are sustained over time.

Core Elements

An effective CAP generally includes:

- **Immediate Actions:** Record any actions to immediately contain or mitigate the nonconformity and minimize its consequences. These actions are implemented prior to completion of root cause analysis to control the issue while longer-term corrective actions are being developed.
- **Root Cause Analysis:** Identify why the nonconformity occurred, including determining whether similar nonconformities have occurred or could potentially occur elsewhere in the organization.
- **Corrective and Preventive Actions:** Define actions to address the root cause of the nonconformity and prevent recurrence. Actions should be written in SMART format (Specific, Measurable, Achievable, Relevant, Time-bound).
- **Responsibilities and Timelines:** Assign responsibility for each action and establish clear deadlines and milestones based on the severity and risk of the nonconformity. CAP responsibilities and timelines should be communicated to relevant personnel to support timely and effective implementation.
- **Verification and Monitoring:** Confirm that corrective actions have been implemented and are effective, with monitoring conducted at defined intervals or through follow-up audits to ensure improvements are sustained.
- **Documentation:** Document the CAP in the laboratory's controlled document system and track progress until closure. Records should capture the nature of the nonconformity, supporting evidence, actions taken, verification results, and closure decision, along with responsible parties, timelines, and status.

Additional Considerations

Corrective actions may, in some cases, extend beyond addressing the immediate nonconformity. Depending on the nature and significance of the finding, follow-up activities may include reassessing relevant risk assessments, evaluating biorisks associated with new or changed hazards, or updating elements of the BRMS to ensure risks are adequately managed and improvements are sustained.

Collaboration and Accountability

CAP development should involve collaboration between auditors, Biorisk Management Advisor, Senior Management, and relevant technical staff to ensure actions are feasible and adequately resourced. Progress toward CAP completion should be reviewed at planned intervals and be communicated to stakeholders to reinforce accountability and support organizational learning.

Step 5: Management Review

Management review is the final step in the internal audit process for a specific audit. It ensures that audit results and associated corrective actions are formally reviewed by management and appropriately integrated into organizational oversight processes. This step reinforces accountability, confirms that audit findings have been addressed, and ensures that lessons learned from the audit inform ongoing management of the BRMS.

Review of Audit Results

Senior and Top Management should review the audit report, CAPs, and evidence of implementation for the individual audit. This review should confirm that nonconformities have been resolved or are being effectively managed, corrective actions address identified root causes, and audit conclusions are understood.

Audit results should be considered in relation to applicable BRMS objectives and performance indicators, where available, to determine whether findings represent localized issues or may warrant broader consideration within the BRMS.

Documentation of Review

The management review of audit results should be documented. Records should include the date of review, participants, audit(s) reviewed, key decisions made, and any required follow-up actions. Documented information should be retained in accordance with organizational document control procedures.

Communication of Management Review Outcomes

Decisions, actions, and lessons learned resulting from the management review of audit results should be communicated to relevant stakeholders through established channels, such as management meetings, staff briefings, newsletters, or other communications, as appropriate.

Effective communication of management review outcomes supports transparency, reinforces accountability, and helps strengthen a culture of biosafety and biosecurity across the organization.

Part IV: Document Control and Revision History

Document control ensures that all elements of the internal audit program are managed within the organization's controlled document system. While documentation has been mentioned throughout this guide, it is emphasized here as a critical supporting element for maintaining the integrity of the BRMS.

Document Control

Procedures should be established for approving, issuing, revising, and archiving all audit-related documents. Controlled access prevents unauthorized modification, while version control ensures that auditors and staff are always working with the most current information. Document control applies to:

- The program manual, including the audit policy, governance, and procedures.
- Audit tools, such as checklists, interview guides, and report templates.
- Audit records, including completed audit plans, reports, and CAPs.
- Management review records, including meeting minutes, decisions, and assigned follow-up actions.

Revision History

Every controlled document should maintain a revision history. At a minimum, this should include:

- Version number
- Date of revision
- Brief description of the change(s)
- Name or role of the individual authorizing the change

Maintaining this record minimizes the risk of confusion, prevents reliance on outdated procedures, and ensures full traceability of the document's evolution.

Integration Across the Audit Program

Document control and revision history are not standalone tasks; they underpin every step of the internal audit process. The program manual must be controlled, audit tools must be updated, audit reports and CAPs must be retained, and management review records must be archived. Strong documentation practices allow laboratories to demonstrate progress over time, prepare for external assessments, and ensure that improvements made through the audit process are sustained well into the future.

Conclusion

An internal audit program is the engine that drives continual improvement within a biorisk management system. By grounding the program in clear policies, recognized standards, and biorisk management objectives, laboratories create a framework that defines both what must be achieved and how success will be measured. Documenting this framework in the Program Manual and maintaining it through robust document control and revision history ensures that the program is stable, traceable, and adaptable over time.

The five-step audit cycle consists of preparation, conducting the audit, reporting, corrective action planning, and management review, and provides a repeatable structure for turning this framework into practice. Each cycle generates new evidence, identifies vulnerabilities, and confirms progress toward objectives. Together, these cycles create a documented record of improvement that can be communicated across the organization and verified by leadership, regulators, and other stakeholders.

When implemented effectively, an internal audit program integrates policies, standards, objectives, and documentation into a coherent system. It enables laboratories to demonstrate accountability, strengthen biosafety and biosecurity, and sustain a culture of learning and improvement.

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