HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Departmental Policy and Procedure		
Title:	Internal Assessment And Internal Audit		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

1.1 To actualize the laboratory's commitment to quality, good professional practice, and continual improvement, by identifying problematic processes.

1.2 Regularly scheduled internal audits of the laboratory's Quality Management System (QMS) move a laboratory from a mode of reactive, corrective actions to that of proactive, continual improvements

1.3 Goals for having an audit program and conducting carefully planned internal audits are to:

1.3.1 Improve laboratory service, quality, productivity, and performance.

1.3.2 Identify inconsistencies among policies, processes, and procedures, and their implementation and/or practice.

1.3.3 Serve as effectiveness checks for process improvements

1.3.4 Verify conformance with regulatory and accreditation requirements.

1.3.5 Ensure the QMS is effectively implemented and maintained.

2. DEFINITONS:

2.1 **Assessment:** a systematic process of collecting and analyzing data to determine the current, historical, or projected condition of an organization, process, or activity; (also referred to as inspection and survey). Assessments are systematic examinations to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Assessments can be internal (self) or external. Internal assessments can include internal audit program and quality indicators. External assessments can include proficiency testing/external quality assessment and inspections/accreditation assessments

2.2 **Auditing:** is a "systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which required criteria are fulfilled (ISO9000).

2.3 **Internal audit:**

2.6.1 Internal auditing of work practices is an important QMS tool that helps a laboratory meets regulatory, accreditation, and customer requirements.

2.6.2 Where staff working in one area of the laboratory conduct assessments on another area of the same laboratory. This provides information quickly and easily on how the laboratory is performing and whether it is in compliance with policy requirements

2.4 The Audit Program: arrangements for a set of one or more audits planned for a specific time frame and directed towards a specific purpose (ISO 19011).

2.4.1 Audit Program defines the "who," "what," "when," "where," and "how" of meeting requirements for internal auditing, and the Audit Process describes the details of how to conduct individual laboratory internal audits.

2.4.2 Auditor: person with the competence to conduct an audit (ISO 9000).

2.5 Charter: document or authorization from the organization's leadership that outlines and communicates the principles, scope, rights, and privileges for establishing a project, committee, function, etc.

2.6 QSEs: Quality System Essentials.

3.1 The MATERMITY AND CHILDREN HOSPITAL (MCH) in Hafr Albatin establishes and maintains a process for internal self-assessment. MCH develops policies, processes and a schedule for internal (self) assessment of operations and quality management system. The implemented system covers the following:

3.1.1 Identification of the activities and quality systems to be assessed.

3.1.2 Assessment and data collection tools.

3.1.3 Analysis and reporting of assessment results.

3.1.4 Development of corrective actions (if applicable).

3.1.5 Management review and approval.

3.1.6 Implementation and monitoring of corrective action plan.

3.2 MCH LAB shall have at least annually systematic examinations to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives.

3.3 MCH LAB audits should include the evaluation of steps in the whole laboratory path of workflow. They should be able to detect problems throughout the entire process.

3.4 Results of assessments must be reviewed by the medical director and the organization's executive management to determine the appropriateness and effectiveness of corrective/ preventive actions (if taken).

3.5 As per Saudi FDA's Good Manufacturing Practice for Blood Establishments:

3.5.1 Self-inspection or audit systems must be in place for all elements of operations to verify compliance with the standards set up by the SFDA.

3.5.2 They must be carried out regularly by trained and competent persons, in an independent way, and according to approved procedures.

3.5.3 All results must be documented and appropriate corrective and preventive actions must be taken in a timely and effective manner.

4. PROCEDURE:

4.1 Development of Internal Audit Program:

4.2 Structure of the Internal Audit Program: Fundamentals of an internal audit program include:

4.2.1 Defining roles and responsibilities.

4.2.2 Designing the audit program

4.2.3 Preparing for the audit.

4.2.4 Conducting the audit.

4.2.5 Evaluating the effectiveness of the audit program.

4.3 Defining Roles and Responsibilities:

4.3.1 A clear understanding of the roles and responsibilities of all parties involved in the internal audit program is critical to successful planning for and performance of laboratory audits. Refer to the form LAB-DOC-054 for the functional roles in the internal audit program. An individual may fulfill one or more of these roles.

4.3.2 The commitment of organizational and/or laboratory leadership, the audit program coordinator, and the educator is necessary to ensure a successful audit program.

4.3.3 Some roles and responsibilities apply to both laboratory leadership and staff during the internal audit process, including

4.3.3.1 Obtaining knowledge of the audit process.

4.3.3.2 Identifying stages of the audit process where their input and support are needed.

4.3.3.3 Encouraging all parties to be supportive of and cooperative with the auditor and with implementation of corrective measures, as needed.

4.3.3.4 Making oneself available to provide information as appropriate during the audit.

4.3.3.5 Individually accepting the fact that audits can seem intrusive but also lead to continual improvement.

4.3.3.6 Holding one another to the expectation that cooperation with the process and the auditor will improve operations.

4.4 Organizational and/or Laboratory Leadership Responsibilities:

4.4.1 **Internal (Laboratory) Leadership Staff:**

4.4.1.1 The laboratory director (who may also be the medical director) and laboratory leadership are responsible for ensuring compliance with the organization's audit plan as well as with external expectations such as legal, regulatory, and accreditation requirements. As a result, the scope of internal audits should be developed with these goals in mind. This will help ensure assessment of areas at risk for non conformance as well as confirm conformance with expectations in areas thought compliant.

4.4.1.2 The laboratory director has overall responsibility for laboratory operations, quality, and timely and accurate reporting of results. Because the director is involved in instrument and method selection, verification or validation, and ongoing quality performance, the laboratory director needs to support the entire audit program.

4.4.2 **Ensuring Audit Program Charter Is Appropriate.**

4.4.2.1 Laboratory leadership is responsible for chartering the audit program and ensuring it addresses relevant laboratory expectations, as well as considers aspects of the laboratory's position within the MCH laboratory and blood banks (MCH LAB) in Hafr Albatin region.

4.4.2.2 The MCH LAB has a more global perspective of the laboratory's role in providing services to its customers

4.4.3 **Allocation of Auditor Resources:**

4.4.3.1 Auditors need training; therefore, laboratory leadership needs to commit resources for training staff selected as internal auditors. When additional auditor training is needed, appropriate personnel should be identified and trained.

4.4.3.2 As trained internal auditors are identified and assigned, their availability and the time commitment to complete audits should be reconciled.

4.4.3.3 Auditors must have sufficient scheduled time to perform a complete and thorough assessment, and additional time, when needed, to investigate unexpected findings. Auditors from outside the laboratory or department can be a good resource to perform an audit

4.4.3.4 An exchange program with another department or laboratory can provide auditors with appropriate experience and expertise, or the laboratory can hire an external auditor. When auditors from outside the laboratory are used, there should be an agreement that clearly delineates: scope of the audit, expectations of the auditor and auditees, confidentiality of laboratory information and others as required.

4.4.3.5 The laboratory should expect the external auditor to provide a report that includes the findings, with any noted observations and positive practices.

4.4.4 **Access and Independence of Audit Process:**

4.4.4.1 For the auditors to complete their tasks, they must have access to staff, samples, documents, records, reports, etc. If there is resistance to providing access, laboratory leadership should step in and reassure staff that the audit's goal is to improve operations and ensure compliance with expectations.

4.4.4.2 The auditor is functioning as a member of the laboratory (whether as a laboratory employee or non-laboratory staff) and is granted access to information deemed appropriate to the audit's purpose and scope.

4.4.4.3 It is desirable that the auditor be independent of the practice being audited. It is recommended that the auditor not audit his or her own work.

4.4.5 **Audit Program Coordinator:**

4.4.5.1 The audit program coordinator (could be the quality management director) is responsible for overseeing the internal audit program, which includes ensuring the program stays on schedule, meets milestones, and provides timely reports of audit findings.

4.4.5.2 This individual is responsible for:

4.4.5.2.1 Developing formal audit plans.

4.4.5.2.2 Organizing the audit.

4.4.5.2.3 Initiating the audit.

4.4.5.2.4 Ensuring the audits' timely performance, either independently or in conjunction with the audit sponsor.

4.4.5.2.5 Developing a contingency plan for situations that may arise during the audit that need immediate attention, such as conditions that may present an immediate risk to patient care or employee safety.

4.4.5.2.6 Summarizing audit findings and necessary corrective actions in a report to laboratory leadership.

4.4.6 **Educator:**

4.4.6.1 The educator is responsible for developing the audit process-training program and organizing training for auditors and auditees.

4.4.6.2 Educator responsibilities include ensuring adequate time is provided for initial and ongoing auditor education and training, and appropriate training resources are available. An audit program educator fulfills multiple expectations.

4.4.6.3 The educator trains or facilitates training of new auditors and auditees to help ensure they understand their respective roles in the process before internal audits are performed

4.4.6.4 Individual auditors need to possess the knowledge, skills, and other competencies to fulfill their audit responsibilities. These prerequisites are augmented by the education process

4.4.6.5 Another role of the educator is to assess the auditor competency with respect to the expectations associated with that role, and mitigate identified shortcomings.

4.4.6.6 Education of all involved parties is important to ensure understanding of the nature of an internal audit as an independent, objective, assurance, and consulting activity that has been designed to add value and improve laboratory operations.

4.4.7 **Audit Sponsor:**

4.4.7.1 The audit program sponsor is a member of senior internal laboratory leadership who reviews the overall audit program, ensures resources are requested and provided, regularly receives status reports to forestall problems that are not resolved at the auditor/auditee level, reviews the audit report, and ensures corrective steps are identified and appropriate action taken.

4.4.8 **Auditor:** Depending on the process or system being audited, more than one auditor may be needed.

4.4.8.1 The auditor is selected by the audit program coordinator and performs the internal audit.

4.4.8.2 An auditor's primary role is to verify policies, processes, and procedures are implemented as intended and achieve expected outcomes.

4.4.8.3 In essence, auditors independently verify whether or not staff activities comply with expectations and requirements

4.4.8.4 An auditor performs work in compliance with recognized auditing requirements that include being qualified to perform auditing tasks, collecting objective evidence against defined requirements, and basing every audit conclusion on fact.

4.4.8.5 The auditor can be anyone the laboratory selects, but the individual needs to possess the requisite knowledge, skills, and other competencies to assess the laboratory's operations.

4.4.8.6 The auditor will need access to staff, samples, documents (both paper and electronic), test results, and other records.

4.4.8.7 The auditor's role is not necessarily limited to a specific phase of the laboratory workflow processes (e.g., examination) but instead extends across the entire path of workflow, and includes activities within the quality system essentials (QSEs) as well, such as whether all necessary records for an individual staff member or piece of equipment are present and complete.

4.4.9 **Auditee:**

4.4.9.1 The auditee is the individual working in or with the function or process being audited

4.4.9.2 Auditees participate in the audit by:

4.4.9.2.1 Answering questions truthfully

4.4.9.2.2 Providing as requested: Information, Documents, Records, and others, as needed.

4.4.9.2.3 Showing or describing, when asked, how something is done.

4.4.9.3 Based on findings as the audit progresses, staff working in different parts of the laboratory may be involved in the audit regardless of the original scope of the internal audit. Therefore, all staff members should be aware of the audit program schedule, timelines, their role when asked for information, and the legitimacy of the process

4.4.10 **Designing the Audit Program.**

4.4.10.1 Types of Audits:

4.4.10.1.1 The type of audit is determined by the scope and objectives of the audit. There are three main types of internal audits, a system audit, a process audit, and a product or service audit.

4.4.10.1.1.1 System Audit

4.4.10.1.1.2 Process Audit

4.4.10.1.1.3 Product/Service /Audit.

4.4.10.2 How the audit is conducted is further divided into retrospective and prospective types. A retrospective audit captures information on outcomes that have occurred in the past, whereas a prospective audit captures information in real time. Retrospective audits require reviews of selected records, whereas prospective audits use direct observation

4.4.10.3 System Audits: determines whether the multiple processes in a system meet requirements.

4.4.10.3.1 A system audit is designed with a global view and involves multiple processes. It assesses whether system requirements are met.

4.4.10.3.2 System audits include auditing processes and the products that are the output of the processes being audited. These processes are interrelated and should achieve the objectives of quality, safety, etc.

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4.4.10.3.4 Process Audits: determines whether the inputs, actions, and outputs of a single process occur as intended.

4.4.10.3.5 Process audits should follow the process from beginning to end. It can trace a selected process either forward or backward.

4.4.10.3.6 A process audit determines whether process requirements are met.

4.4.10.3.7 The process audit verifies whether the defined inputs, actions, and outputs are occurring as intended.

4.4.10.3.8 Process auditing is an ideal tool to identify inefficiencies and opportunities for process optimization.

4.4.10.3.9 Auditors, whether they are experienced in the process or new to the process, should always ask "why" a process is happening and whether the activity is "value added" or "waste."

4.4.10.3.10 Process audits include auditing the products that are the output of the process being audited.

4.4.10.3.11 Process audits relate directly to the laboratory's quality management and path of workflow processes.

4.4.10.4 **Product or Service Audits:** determines whether a product or service meets specifications.

4.4.10.4.1 The predefined specifications of the product or service are verified at audit to detect nonconforming practices that may affect the quality of those products or services.

4.4.10.4.2 Product or service audits are also known as focused audits because of their narrow scope. User survey is often the audit tool used when services are audited.

4.4.10.5 **Audit Program Planning:**

4.4.10.5.1 Topics and/or Areas Audited:

4.4.10.5.1.1 Before determining which audits to conduct, the laboratory should review information for ideas about where audits are needed.

4.4.10.5.1.2 In addition, the processes meant to be improved by previous corrective actions could be re-audited to determine the effectiveness of the corrective actions

4.4.10.5.1.3 The laboratory may also want to conduct audits of processes to determine a baseline status before upcoming changes are made.

4.4.10.5.1.4 Input should also be sought from management and leadership on the audits to be conducted.

4.4.10.5.1.5 The topics or areas to include in an audit are determined before planning the details of any audit.

4.4.10.5.1.6 The audit may focus on QSEs, laboratory processes, or reported nonconforming events

4.4.10.5.2 It may be restricted to a single topic or area, may cross over laboratory sections or functions, or may involve areas outside the laboratory.

4.4.10.5.3 The first areas audited could also be chosen because they have had technical or customer service problems in the past, or have been involved in organization-wide problems

4.4.10.5.4 Once the topics/areas are determined, scheduling is established.

4.4.10.6 **Annual Schedule:**

4.4.10.6.1 To ensure the laboratory's QMS is functioning effectively, each QSE should be audited at least annually.

4.4.10.6.2 The frequency of audits may be increased based on, for example, previous audit outcomes or failed effectiveness checks.

4.4.10.6.3 A simple audit schedule can be prepared as a table or spreadsheet.

4.4.10.6.4 The audit program coordinator (could be the quality management director) is responsible for preparing the audit schedule and laboratory leadership is responsible for approval of the audit schedule.

4.4.10.6.5 Details regarding the elements audited, documents for review, staffs who participate, etc., become part of the audit plan, which is discussed later.

4.4.10.7 **Unscheduled Audits**:

4.4.10.7.1 Whereas many external assessments are unannounced, laboratory internal audits are usually scheduled in advance as part of an annual audit plan.

4.4.10.7.2 In general, audits performed in the laboratory's internal audit program should be scheduled, to reduce stress and elicit laboratory

staff cooperation. However, the audit schedule should allow for unplanned audits

4.4.10.7.2.1 In response to an observed or reported serious patient safety or general safety issue.

4.4.10.7.2.2 To determine the existing process when the laboratory has been cited as noncompliant with a regulatory or accreditation requirement.

4.4.10.7.3 **Structure of the Internal Audit Process:**

4.4.10.7.3.1 **The Auditing Process:**

4.4.10.7.3.1.1 Procedures for performing audits should be specific to the type of activity audited, i.e., system, process, or product or service.

4.4.10.7.3.1.2 Audit procedures include details about how the audit is performed, the tools for use during the audit, the expected outcome(s), and the format of the final audit report.

4.4.10.7.4 **Preparing for the Audit:**

4.4.10.7.4.1 The audit program coordinator (could be the quality management director) is responsible for initiating the audit. Outlines the items to prepare and plan before the auditors perform the audit.

4.4.10.7.5 **Scope and Type of Audit**:

4.4.10.7.5.1 The audit scope statement specifies which parts of the system, process, or service will be included in the audit, and any relevant exclusion.

4.4.10.7.5.2 The audit program coordinator (could be quality management director), and audit team, where appropriate, select the type of audit to perform—that is, system, process, or product or service.

4.4.10.7.5.3 Audit types should be rotated to obtain a comprehensive picture of laboratory leadership and operations.

4.4.10.7.6 **Audit Preparation**

4.4.10.7.6.1 It is important that both the auditor and the auditee are prepared for the audit.

4.4.10.7.6.2 Auditor preparation includes desk assessment or document review and preparation of the audit tools.

4.4.10.7.6.3 Both the auditor and auditee need to communicate about the audit.

4.4.10.7.7 **Sampling Plans:**

4.4.10.7.7.1 A sampling plan is used to determine how many and what types of documents, records, or materials the auditor will review.

4.4.10.7.7.2 When applicable, there should be an indication of how many audit samples will be initially evaluated (eg, how many reports, maintenance sheets, and order forms will be assessed for compliance).

4.4.10.7.7.3 Where there are numerous audit samples, a representative sample size should be determined. Samples should be random and representative unless the specified objectives require otherwise.

4.4.10.7.7.4 The auditor should select the samples or provide parameters within which to select, e.g., the first 10 records on a specific date. This provides objectivity and prevents the auditee from skewing the samples in his or her favor.

4.4.10.7.7.5 The auditor should be prepared to examine more than the original sampling plan when problems are identified with the initial sample.

4.4.10.7.8 **Communication and Notification for Scheduled Audits:**

4.4.10.7.8.1 The auditor should provide advance notification of an audit to laboratory leadership.

4.4.10.7.8.2 An outline for a written notice of an upcoming audit has the following elements:

4.4.10.7.8.2.1 Recipient, subject of audit, date(s) of the audit, time(s) of the audit, location, audit scope and purpose, documents to be reviewed.

4.4.10.7.8.2.2 Personnel needed, and estimates of their time commitment during the audit, Expected duration.

4.4.10.7.8.2.3 Auditor workspace needs (dependent on whether documents are paper or electronic), audit scheduler's name and contact information.

4.4.10.7.8.3 It is the auditor's responsibility to collaboratively communicate to laboratory leadership the goals and objectives of the audit, and to notify the appropriate auditee of the details of the audit.

4.4.10.7.8.4 The auditor and the auditee should agree to a communication plan that includes the defined audience and frequency of updates. Refer to the Laboratory Internal Audit Plan form LAB-DOC-054

4.4.10.7.9 **Auditors and Auditee Resources:**

4.4.10.7.9.1 Based on the complexity of the audit, the audit program coordinator (could be the quality management director) in conjunction with the lead auditor will identify how many auditors are needed for each identified topic.

4.4.10.7.9.2 Topics audited monthly or quarterly may need only one or two auditors.

4.4.10.7.9.3 Highly complex topics might need several auditors, and one auditor might be a subject matter expert (SME).

4.4.10.7.9.4 The audit program coordinator (could be the quality management director) should identify laboratory leadership and staff who are available to assist in announced audits.

4.4.10.7.9.5 The audit plan should include a suggested timetable to ensure availability of laboratory leadership and staff.

4.4.10.7.10 **Document Review:**

4.4.10.7.10.1 The auditor(s) should review documents that are within the scope of the audit. Auditors review various documents to determine what is done and examine policy documents to determine where rules exist. Policy documents should describe what is done and why, process documents should describe how it happens, and procedures should contain the instructions for performing a given activity. Auditors review policy documents to determine the laboratory's intent and rules, and process and procedure documents to determine how it happens and how it's done.

4.4.10.7.10.2 Audit staff may not be experts in the particular processes under review, but should be able to create a draft flow chart as they review documents in preparation for an audit. Alternately, the auditee can create a flow chart of the process under review at the request of the auditor. The flow chart provides a road map of the sequential process activities.

4.4.10.7.10.3 Using the audit purpose statement and scope as a guide, draft flow charts for audit purposes should have the following characteristics:

4.4.10.7.10.3.1 The "Start" and "Stop" of the process are identified and included.

4.4.10.7.10.3.2 The sequential activities included between the "Start" and "Stop" of the process are identified and included.

4.4.10.7.10.3.3 The activities are listed as simply and reasonably as possible to facilitate understanding.

4.4.10.7.11 **Audit Tools:**

4.4.10.7.11.1 The auditors should select an audit tool(s) designed to meet the scope of the audit. Questions are prepared based on the requirements for the function(s) being audited and that demonstrate the status of the laboratory's compliance. Most often the questions follow the flow of the process or procedure being audited.

4.4.10.7.11.2 In preparing for the audit, tools are prepared to provide the auditor with a standardized approach for collecting audit evidence. All audit documents should be subject to the laboratory's document control processes. If the audit tools are controlled documents, the auditor can use or modify already existing tools.

4.4.10.7.11.3 The following tools might be used during an audit: audit tool, direct observation forms and surveys.

4.4.10.7.11.3.1 Audit tools can be created as questions or statements -ideally as open-ended "who," "what," "where," "Why," or "how" questions that elicit more than a Yes/No response. Each requirement should be traceable to the specific item being audited. Interview questions, record review items, and/or observed items can be prepared in a checklist form. Checklists provided by inspection, certification, or accreditation organizations can also be used.

4.4.10.7.11.3.2 A direct observation form lists the activities in the process or steps in a procedure in the order in which they are performed. To use this form, the auditor follows the auditee through the process or procedure and records observed actions listed on the form. During a direct observation audit, questions about the process or procedure can be asked of the auditee. This dialogue is a key piece of the communication of the audit process.

4.4.10.7.11.3.3 Internal client or customer-targeted surveys can be used to gather information about a system or process. Questions or statements on the survey need careful construction to prevent

bias or misunderstanding. Survey statements are written to ensure conformance or non conformance information is gathered. Ideally, a contact name should be provided to answer any follow-up questions or concerns.

4.4.10.7.11.3.4 Audit tools are useful for auditors to gather and document information. They must be specific to the audit. An audit tool needs to reflect the requirements of the audit; that is, the specific process, procedure, regulatory, or accreditation requirement(s) that serve as the source of comparison for compliance.

4.4.10.7.12 **Conducting the Audit:**

4.4.10.7.12.1 Once preparation is complete, the audit can begin. Auditors collect evidence and determine success (i.e. compliance) or failure (i.e. noncompliance) in meeting the established requirements or internal customer satisfaction criteria.

4.4.10.7.13 **Opening Meeting:**

4.4.10.7.13.1 Internal audits do not require a formal meeting but in all cases communication should establish the official linkage of the auditee and the auditor.

4.4.10.7.13.2 The communication should verify the audit objectives and plan, and allow for questions and issues to arise before initiation of the audit.

4.4.10.7.13.3 Depending on the scope and type of audit, additional information such as sampling or collection plans (e.g., records for review, direct observations, and/or interview schedules) and the reporting process are reviewed.

4.4.10.7.13.4 Attendance at the opening meeting should be documented.

4.4.10.7.14 **Gathering Objective Evidence:**

4.4.10.7.14.1 Objective evidence is gathered from a number of sources including review of documents and records, physical examination, observing activities, and interviewing. During the audit, the auditor uses assessment tools to verify that activities meet the requirements. Activities are verified by using techniques including record review, interviewing, and direct observation. By asking closed and open-ended questions, using

active listening, and paraphrasing to verify understanding of communicated information, an auditor can determine whether requirements are being met. Making the auditee feel at ease by reassurance that the audit is not a test but a real-time view of actual practice will help the auditor gain information about systems, work processes, or products

4.4.10.7.14.2 Objective evidence is gathered from several sources including: Sensory inputs from physical examination, Reviews of selected records, Comparison of documents reviewed in desk assessment with actual practice, Observation of staff performing process and/or related procedures as well as Staff interviews with corroboration of answers.

4.4.10.7.14.3 Physical Examination: Auditors should use multiple sensory inputs (e.g., auditory, olfactory, visual) and good communication skills to obtain evidence. Physical examination of surroundings will show compliance or noncompliance with safety requirements in work areas. Sights, smells, and sounds should be used as indicators of lighting, noise, interruption, chemical interference, and ventilation. If appropriate and discussed before the audit, taking pictures can provide accurate and undeniable evidence of conformance or nonconformance.

4.4.10.7.14.4 Records: Records are completed forms that specify what was done and the results achieved when performing laboratory processes and procedures. Record review provides a high level of evidence of compliance. When non-conformances are found, it may be necessary to determine the extent by recording the number of records showing non-conformances

4.4.10.7.14.4.1 Additional sampling of records may be needed to verify the percentage of the nonconforming records. It is important to distinguish between an incidental omission in an observation or record or answer to a question and a real flaw in the system, process, or procedure.

4.4.10.7.14.5 Documents: Many documents are reviewed in the desk assessment and used for assessment tool preparation. During the audit, the auditor's duty is to compare documents with actual practice and verify that audit requirements are being met through direct observation, interview, or record review.

4.4.10.7.14.6 Direct Observation: Auditors observe performance of process and procedure activities during the audit. When noncompliance or unethical activities are recognized, the auditor should observe, verify, record, and report the activity. Good judgment and auditor discussions with other auditors (or the lead auditor) are needed when the observation is deemed a patient or employee safety issue.

4.4.10.7.14.7 Interviews: Interviewing an auditee is the most challenging part of the audit. Auditors should make it clear they are there for fact finding and not to find fault with an auditee or to "catch people." One-on-one interviews are usually better received than group interviews. Conflicts are avoided by using good communication skills and asking questions firmly without aggression. When information gathered shows non conformance, it can be corroborated by getting the same answer from another person, another auditor hearing or seeing the same thing, or verification from a document or record.

4.4.10.7.15 Assessing Information Gathered:

4.4.10.7.15.1 Auditing is performed to verify that system or process outputs meet system or process requirements as defined by the organization (i.e., the audit criteria). Audit criteria may also be derived from external agencies. That is, an internal audit can be performed against regulatory or accreditation requirements to ensure policies, processes, and procedures meet the external requirements.

4.4.10.7.15.2 Any unresolved audit issues, questions, or unknowns need resolution before the end of the audit. Where an audit issue cannot be resolved, the problem and reason why are recorded in the audit report.

4.4.10.7.15.3 During the audit, observations beyond the scope of the audit may be made that need investigation. When non-conformances are found that are outside the scope of the audit, they should only be probed if it will interfere with completion of the audit as scheduled, or the non conformance presents a significant threat to patient care.

4.4.10.7.15.4 What was found needs to be included in the audit report, and when unable to probe, a recommendation is made that another audit related to this non conformance should be held at a later time.

4.4.10.7.15.5 When a situation is encountered that the auditor feels will harm a patient or employee, the auditor should bring this to the attention of the lead auditor and/or supervisor of the area immediately. It is important to keep the auditee

informed throughout the audit of any significant problem areas so there are no surprises at the end of the audit.

4.4.10.7.15.6 There should be evidence to verify conformance or nonconformance to the requirements and to fulfill the purpose and scope of the audit. When there is not sufficient evidence, the auditor should continue to audit or report on any limitation or contingencies.

4.4.10.7.15.7 Depending on the type of audit, sorting and classifying objective evidence may be necessary. Sorting data based on risk to the laboratory, consequences to patient safety, or by QSE requirement helps the auditor draw conclusions from the evidence and communicate more clearly to the auditee about the non conformance. Data or evidence may apply to more than one non conformance

4.4.10.7.16 Drawing Conclusions Based on the Evidence:

4.4.10.7.16.1 Conformance or non conformance needs to be verifiable and traceable. To verify conformance, the auditor should ask him- or herself the following questions:

4.4.10.7.16.1.1 Have the audit criteria been achieved?

4.4.10.7.16.1.2 Is implementation complete?

4.4.10.7.16.1.3 Are actions documented as required?

4.4.10.7.16.1.4 Are results traceable to requirements?

4.4.10.7.16.1.5 Is there a common understanding of the term, concept, or requirement among auditees?

4.4.10.7.16.2 When the answer is "yes" to these questions, then the conclusion that compliance is verified may be considered. When the determination is still unclear, the auditor conducts further investigation and asks additional questions.

4.4.10.7.16.3 Recommendations to improve the wording in documents can be made in the final report. When recommendations are provided, they should not be explicit and, when possible, should provide several options; however, the action taken should be left to the discretion of laboratory leadership. Auditors are cautioned to use recommendations judiciously because the auditor is seeing the laboratory for a limited period of time, and is not as knowledgeable about the processes being audited as those who perform them.

4.4.10.7.17 Observations Needing Further Investigation or Immediate Action:

4.4.10.7.17.1 When the auditor identifies a situation that, in his or her judgment, places patient, visitor, or employee safety at risk, the auditor should immediately assemble the objective evidence supporting this conclusion and discuss it with the area supervisor and/or manager.

4.4.10.7.17.2 Together the auditor, auditee, and laboratory leadership, if applicable, should perform the following actions

4.4.10.7.17.2.1 Review the findings.

4.4.10.7.17.2.2 Determine whether findings truly indicate patient, visitor, or employee safety is at risk.

4.4.10.7.17.2.3 Initiate timely actions to mitigate the impact on patient, visitor, or employee safety

4.4.10.7.17.2.4 Investigate whether previous patients, patient results, visitors, or employees were affected.

4.4.10.7.17.2.5 Record reviews or additional interviewing may be needed to determine whether there is a systematic problem or if this is a first-time event.

4.4.10.7.15.3 The auditor should use this unexpected situation as an opportunity to participate in quality improvement, where applicable, and ensure the affected staff is made to feel part of the solution.

4.4.10.7.17.4 The auditor should communicate to the staff that the findings will be reviewed at the closing meeting as part of a preliminary report of findings

4.4.10.7.17.5 **Preparing Preliminary Audit Findings:**

4.4.10.7.17.5.1 Single facts uncovered by an auditor during the audit are not separate audit findings; the single facts merely comprise the objective evidence that a process is or is not working as intended.

4.4.10.7.17.5.2 The single facts need to be combined in a manner that points to a problem(s) in the process or system being audited. Only then is the problem represented by the facts written as audit findings.

4.4.10.7.17.5.3 The following provides a short procedure for how to

write a valid audit finding from collected facts and objective evidence.

4.4.10.7.17.5.3.1 During the audit, write each fact as a statement of what was observed or discovered. NOTE: Ensure each fact is clearly stated and can be traced back to a specific place, person, document, or record.

4.4.10.7.17.5.3.2 Review all the facts and look for underlying common elements or themes. NOTE: It is very useful to group facts by QSE, or processes within a given QSE.

4.4.10.7.17.5.3.3 Group facts into the common themes discovered.

4.4.10.7.17.5.3.4 For each grouping of facts, identify the requirement(s) that has not been satisfied. NOTE: The requirements include clauses or items specified in regulations,accreditation requirements,and the laboratory's own policies, processes, and procedures.

4.4.10.7.17.5.3.5 Write a finding that identifies the condition that is having an adverse effect on the quality of the process or product being audited.

4.4.10.7.17.5.3.6 The auditors should convene to review findings that will be presented at the closing meeting. Preliminary findings should include the following headings and content

4.4.10.7.17.5.3.6.1 Strengths:

4.4.10.7.17.5.3.6.2 Noted while performing the audit. These may include employee leadership, well controlled processes, inno vation, space use, etc. Strengths noted should

	remain within the scope of the audit.
4.4.10.7.17.5.3.6.3	Non-conformances: Found during the audit, including any situation needing immediate actions. These should be presented with documented evidence of noncompliance
4.4.10.7.17.5.3.6.4	Opportunities:For improvement/recommendations. These are areas that could be improved, even though there is no nonconformance. Ideas for efficiency or effectiveness, based on the auditor's knowledge and experience with the process or audit area, can be shared if the auditee is in agreement.
4.4.10.7.17.5.3.7	Once preliminary findings are compiled, the lead auditor should review these items with the auditor before the closing meeting to ensure all areas of concern, comment, and strengths are covered. Preliminary findings may be presented verbally or in writing at the closing meeting.
4.4.10.7.17.5.4	Closing Meeting:
4.4.10.7.17.5.4.1	For an internal audit, closing meetings are usually short and informal.
4.4.10.7.17.5.4.2	Attendance at the meeting should be documented.
4.4.10.7.17.5.4.3	The closing meeting is conducted in an organized and professional manner, led by the lead auditor.
4.4.10.7.17.5.5	The closing meeting should start with thanking all participants, and confirming the "no surprise" nature of the upcoming audit findings. Best practices, commendable

observations, and other strengths should be reported first. These are observations of activities that are outstanding and may be worthwhile to share with other sections or departments.

4.4.10.7.17.5.5.1 The activities in a closing meeting are conducted in the following order: Thanking the audit participants, Reporting of best practices and any other strengths, Presentation of audit findings and non-conformances as well as Time for questions from meeting participants

4.4.10.7.17.5.6 Audit findings/non-conformances should be presented briefly and should represent the key issues of importance related to the audit purpose and objectives. Solutions should not be discussed. It is laboratory leadership's responsibility to correct the non-conformances identified; however, an action plan for laboratory leadership's follow-up may be made. Serious noncomplying items should have a timeline for resolution and completion.

4.4.10.7.17.5.7 Usually, the meeting ends with time for questions from the auditees or laboratory leadership in attendance. Any objections to findings should be documented and noted for further investigation in the final report.

4.4.10.7.18 **Preparing the Final Audit Report of Findings:**

4.4.10.7.18.1 The audit report communicates the results of the audit to laboratory leadership and laboratory staff. It aids the laboratory leadership in determining the effectiveness of quality improvement projects, identifying opportunities

for improvements, and providing information for quality planning.

4.4.10.7.18.2 The audit report may vary in length depending upon the complexity of the audit.

4.4.10.7.18.3 The report should include a brief introduction, summary, list of findings/non-conformances, and a request for corrective action.

4.4.10.7.18.3.1 Introduction – This section states the purpose of the audit and identifies the auditor(s), date of the audit, type of audit, and areas audited.

4.4.10.7.18.3.2 Summary – A synopsis of the audit including recognition of good practices and improvements.

4.4.10.7.18.3.3 List of findings – This may be the actual item, standard, regulation, or a summary statement with objective evidence listed. It is important to note in the report whether any of the findings are repeated from a previous internal or external audit.

4.4.10.7.18.3.4 Request for corrective action – A plan for corrective action and implementation date.

4.4.10.7.18.3.5 Description of any positive practices identified – A suggestion that the positive practice could be replicated in other laboratory areas, as appropriate.

4.4.10.7.19 Interpretation of Findings:

4.4.10.7.19.1 During preparation of the final report, the findings should be reviewed to identify common themes and repeat findings from previous audits.

4.4.10.7.19.2 The review process should include: Classification of all non-conformances, Analyses of repeat findings and Prioritization of repeat findings.

4.4.10.7.19.3 Classification of non-conformances is important when auditing across several laboratory sections to identify common themes. One finding can be written with each of the nonconforming sections listed as objective evidence

4.4.10.7.20 Non conformance Prioritization and Risk Assessment:

4.4.10.7.20.1 It may be beneficial to note in the audit report those findings that are areas of risk to patient or employee safety.

4.4.10.7.20.2 Risk is assessed by several methods, from formal risk assessment tools to recognizing that the laboratory was previously cited by an external inspection agency. It is often helpful to list findings in the order of significance to assist laboratory leadership in prioritizing corrective action.

4.4.10.7.20.3 Another means to prioritize may be to categorize the findings using a key, e.g., 1, 2, and 3, with number 1 being the most significant finding or greatest risk. Still another approach to categorize findings is to organize them by QSE.

4.4.10.7.21 **Issue of Final Report**:

4.4.10.7.21.1 Before issue, the audit report is reviewed and approved according to the laboratory's internal audit program processes and procedures. In complex programs, formal approval may be made by the audit program coordinator, compliance officer, or quality manager. In smaller programs, formal approval may not be needed before issue.

4.4.10.7.21.2 Confidentiality of the report should be maintained following the laboratory requirements for confidentiality and policies regarding the release and sharing of audit reports should be developed.

4.4.10.7.21.3 Once the final report is approved, it is delivered to the laboratory's leadership and the section audited.

4.4.10.7.21.4 Documented acknowledgment of the receipt of the report is recommended

4.4.10.7.21.5 The final report should include a due date for response to the audit findings. The due date is not necessarily the date for completed corrective action but the date that responses are due to the auditor. However, for findings that indicate risks—such as those to patients, visitors, employees, or the laboratory's ability to continue operating—a specified time frame for resolution may be needed, along with a repeat audit.

4.4.10.7.21.6 Laboratory leadership is responsible for meeting due dates included in audit reports.

4.4.10.7.21.7 When there are findings that affect areas outside of the laboratory, the report should be provided to the responsible parties and the laboratory should work with the outside area to ensure findings are resolved.

4.4.10.7.21.8 Based on the internal audit report, laboratory leadership is responsible for:

4.4.10.7.21.8.1 Reviewing the findings.

4.4.10.7.21.8.2 Determining actions necessary to rectify non-conformances.

4.4.10.7.21.8.3 Verifying that corrective actions have been taken.

4.4.10.7.21.8.4 Establishing what, if any, ongoing monitoring is needed to ensure continued compliance with expectations.

4.4.10.7.21.8.5 Assessing risk and determining whether periodic audits may be needed to confirm that the proper process is being followed and that quality improvement activities are effective in achieving stated goals

4.4.10.7.21.8.6 Ensuring adequate resources are assigned for timely implementation and verification of the effectiveness of all corrective actions resulting from internal audits.

4.4.10.7.21.8.7 Determining whether the frequency of initial or follow-up audits is achievable within the context of laboratory operations.

4.4.10.7.21.9 **Follow-up Activities**:

4.4.10.7.21.9.1 Closing the Audit:

4.4.10.7.21.9.1.1 It includes a review of the auditee's corrective action plan for each finding. Laboratory leadership accepts the corrective action plan, rejects it, or asks for clarifying information.

4.4.10.7.21.9.1.2 A **follow-up audit** may be performed to verify corrective action, or the auditor may ask for documentation supporting the corrective.

4.4.10.7.21.9.1.3 The audit is formally closed when corrective action is implemented on all findings. The auditor should notify the auditee,

either verbally or in writing, that the audit is closed.

4.4.10.7.21.9.2 **Evaluation of the Audit Process:**

4.4.10.7.21.9.2.1 The auditee should have an opportunity to evaluate the audit process.

4.4.10.7.21.9.2.2 A survey, which includes elements listed below, is an example of a tool for evaluating the audit process

4.4.10.7.21.9.2.3 Scope of the audit

4.4.10.7.21.9.2.4 Overall satisfaction

4.4.10.7.21.9.2.5 Auditors' conduct and technique

4.4.10.7.21.9.2.6 Time management

4.4.10.7.21.9.2.7 Thoroughness of the audit

4.4.10.7.21.9.2.8 Competence of audit personnel

4.4.10.7.21.9.2.9 Quality and extent of communications

4.4.10.7.21.9.2.10 Areas for improvement

4.4.10.7.21.9.2.11 Quality of findings

4.4.10.7.21.9.3 Evaluating the the Effectiveness of the Audit Program:

4.4.10.7.21.9.3.1 An "effective audit" cannot be taken for granted, even when performed by trained professionals using proven techniques and in accordance with internationally accepted standards.

4.4.10.7.21.9.3.2 Periodic reviews will provide a measure of effectiveness of the audit program and will identify opportunities for improvement. The review process for the audit program and its inherent processes should include:

4.4.10.7.21.9.3.3 Trending and analysis of information from all audits.

4.4.10.7.21.9.3.4 Feedback from auditees and staff from the audited laboratory or site on the audit process.

4.4.10.7.21.9.3.5 Preparation of a report of audit findings for the report period (e.g., quarterly,

annually) for quality report and management review.

4.4.10.7.21.9.3.6 Leadership/management review and assessment of the effectiveness of the audit program.

4.4.10.7.21.9.4 Trending and Analysis of Information From All Audits:

4.4.10.7.21.9.4.1 When summarizing outcomes of the audits, a table format can help show trends in information.

4.4.10.7.21.9.4.2 Categorizing audit outcomes will assist in determining where systemic laboratory problems exist. This information can then be used as part of a risk management program for determining root cause(s), implementing corrective actions, or developing ongoing educational materials and activities for personnel.

4.4.10.7.21.9.4.3 Trending categories are developed on a broad level and can be categorized by QSEs

4.4.10.7.21.9.4.4 Preparing a Report of Audit Findings for Quality Report and Management Review:

4.4.10.7.21.9.4.5 An important outcome of the audit is the implementation of corrective actions that rectify audit findings and sustain improvement.

4.4.10.7.21.9.4.6 A summary of audit findings and corrective actions implemented, clearly presented in a table or as nominal information, should be prepared for inclusion in the laboratory quality report. In a robust audit program, the table categorizes the findings, the root causes, and the corrective actions

4.4.10.7.21.9.4.7 Systemic problems can be identified from the findings

and the root causes and further corrective action may be needed to remove the root cause of the systemic problem.

4.4.10.7.21.9.4.8 Audit findings and outcomes are presented so that laboratory leadership can understand the impact of the changes on the quality of the laboratory services or products.

4.4.10.7.21.10 The effectiveness of an audit program is measured by the following:

4.4.10.7.21.10.1 The level of compliance with requirements.

4.4.10.7.21.10.2 The implementation of corrective actions that eliminate root causes.

4.4.10.7.21.10.3 External assessment findings showing a downward trend.

4.4.10.7.21.11 Assessment of compliance (that changes are sustained) can ensure that actual practice change has occurred. Recurrence of nonconforming events is evidence that the underlying or root cause was not eliminated and the result is no improvement. Laboratory staffs who work in the affected processes are good sources for identifying value-added activities that will help identify root causes of audit findings to reduce or eliminate further non conformance.

4.4.10.7.21.12 Feedback from all stakeholders of the audit program and its related processes is essential for continual improvement. This can be accomplished by using surveys or other review processes. Elements of audit program feedback may include:

4.4.10.7.21.12.1 Overall satisfaction with the audit program.

4.4.10.7.21.12.2 Competence of audit program coordinator and auditors.

4.4.10.7.21.12.3 QMS development and support to facilities.

4.4.10.7.21.12.4 Quality and extent of communications.

4.4.10.7.21.12.5 Areas for audit program improvement

5. MATERIALS AND EQUIPMENT:

5.1 Blood Bank Internal Audit form DOC-LAB 054

6. RESPONSIBILITIES:

6.1 Laboratory Director

6.1.1 Responsible for setting overall policies for the internal audit program.

6.1.2 Responsibilities will include assigning authority for the program (to the audit program coordinator/the quality management director) and supporting the corrective action measures that are indicated

6.1.3 It is essential that the laboratory director be fully informed about the results of all internal audits

6.2 Quality Management Coordinator

6.2.1 If he is the audit program coordinator, he is responsible for organizing and managing laboratory internal audit program. This includes setting a timeframe for the audits, choosing and training the auditors, and coordinating the process

6.2.2 The follow-up activities will also be the responsibility of the quality management director, and these include managing all corrective action effort.

6.2.3 The quality manager must be sure that laboratory management and the laboratory staff are fully informed about outcomes of the audit

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 CBAHI National Standards For Clinical Laboratories & Blood Banks, First Edition 2015.

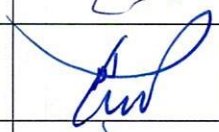
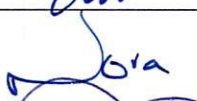
8.2 Good Manufacturing Practice for Blood Establishments, Version 2.0, May 2019, Saudi FDA.

8.3 Management of Nonconforming Laboratory Events; Approved Guideline. QMS11-A. CLSI, 2007.

8.4 Laboratory Quality Control Based on Risk Management; Approved Guideline. EP23-A. CLSI, 2011.

8.5 Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline. EP18-A2. CLSI, 2009.

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Dr. Mohamed Amer	Blood Bank Physician		August 06, 2024
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		August 08, 2024
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		August 11, 2024
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		August 12, 2024
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		August 13, 2024
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		August 20, 2024