HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Departmental Policy and Procedure		
Title:	MANAGEMENT REVIEW		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

1.1 To review the effectiveness of the laboratory Quality Management system (QMS), improve the overall quality and efficiency of the laboratory service and assure the accurate, reliable, and prompt reporting of test results.

1.2 To identify opportunities for continual improvement of blood and blood components processes and the QMS (Saudi FDA).

1.3 To describe the procedure of planning, organizing and conducting the regular management review meetings in the laboratory to ensure its continuing adequacy and effectiveness in satisfying the regulatory and accreditation requirements and states policies and objectives

2. DEFINITONS:

2.1 **Review:** an activity undertaken to determine the suitability, adequacy, and effectiveness of the subject matter to achieve established objectives (ISO 9000).

2.2 **Management review:** a process of reviewing key quality inputs to ensure the continuing adequacy, suitability, and effectiveness of the QMS and, ultimately, the laboratory's support of safe care and positive patient outcomes.

2.3 **Continuous Improvement (CI):** recurring activity to increase the ability to fulfill requirements (ISO 9000).

2.4 **Nonconformity:** nonfulfillment of a requirement

2.5 **Opportunity for improvement (OFI):** condition that, if improved, should result in significant enhancement of organizational efficiency, effectiveness, and/or customer satisfaction.

3. POLICY:

3.1 Laboratory leadership is responsible for defining roles and responsibilities to complete management review.

3.1.1 Through management review, laboratory leadership fulfills its responsibility for assessing the effectiveness of the QMS, identifying OFIs, providing oversight to CI initiatives, and facilitating the allocation of resources essential to the provision of high-quality laboratory services

3.2 Management review needs to be conducted at predefined intervals (at a minimum, every 12 months); however, reviews conducted at intervals that are more frequent should be considered, especially when the laboratory's QMS is in the early phases of implementation.

3.3 The laboratory Quality Management Director may opt for more frequent management reviews, e.g., monthly or quarterly, to enhance leadership responsiveness to quality issues and active support of Continuous Improvement (CI).

3.4 As per Saudi FDA's Good Manufacturing Practice (GMP) for Blood Establishments;

3.4.1 Management must review the system at regular intervals to verify its effectiveness and introduce corrective measures if deemed necessary. It should normally be conducted annually and should be documented.

3.4.2 There should be periodic management review and monitoring both of its effectiveness, with the involvement of executive management, and of the operation of the QMS to identify opportunities for continual improvement of blood and blood components processes and the system itself

3.4.3 Product quality reviews should be conducted with the objective of verifying the consistency of the existing process and the appropriateness of current specifications in order to highlight trends and to identify improvements in both component and process.

3.4.3.1 A product quality review may also be considered as an instrument for surveying the overall quality status of a blood component and its manufacturing processes, including the collection.

3.4.4 Management review may include:

3.4.4.1 review of starting materials;

3.4.4.2 review of critical in-process controls;

3.4.4.3 review of results of quality control and quality monitoring;

3.4.4.4 review of all changes;

3.4.4.5 review of the qualification status of equipment;

3.4.4.6 review of technical agreements and contracts;

3.4.4.7 review of all significant deviations, non-conformances, and the corrective actions implemented;

3.4.4.8 review of the findings of internal and external audits and inspections, and the corrective actions implemented;

3.4.4.9 review of complaints and recalls;

3.4.4.10 review of donor acceptance criteria;

3.4.4.11 review of donor deferrals;

3.4.4.12 Review of look-back cases.

4. PROCEDURE:

4.1 The management review process can be conducted in the following sequence: Inputs are gathered, Quality report is created, Meeting agenda is created, Meeting documents are compiled and distributed, Meeting documents are previewed, Management review meeting is conducted, Management review is documented, and finally Outputs are produced.

4.1.1 Preparing for Management Review:

4.1.1.1 Because inputs for management review can be numerous, and are often gathered from a variety of sources, Maternity and children hospital lab should properly prepare and conduct a meaningful and useful management review

4.1.1.2 Typical management review inputs: include

4.1.1.2.1 **Internal assessments** – results of internal audits: Systemic review of internal audit findings, major nonconformance's, and revised audit schedules, including a justification for any missed audits.

4.1.1.2.2 **Internal assessments** – quality indicators or metrics: Summary of key indicators or metrics for the laboratory's contribution to patient care.

4.1.1.2.3 Assessment findings of external agencies (e.g. CBAHI, Saudi FDA and CAP): Results of laboratory surveys and/or inspections

4.1.1.2.4 **Proficiency Testing (PT):** Inter-laboratory comparisons of examination results on samples from an external provider.

4.1.1.2.5 **Evaluation of laboratory suppliers:** Evaluations and audits of supplier and service providers (e.g., referral laboratories, critical suppliers).

4.1.1.2.6 Employee/staff suggestions: Suggestions received and actions taken.

4.1.1.2.7 **Customer/stakeholder satisfaction and complaints:** Customer satisfaction surveys; monitoring and resolution of complaints from patients and clinicians.

4.1.1.2.8 **Corrective actions:** Systemic assessment of corrective actions taken in response to NCEs and assessments.

4.1.1.2.9 **Non conformance Events (NCEs):** Systemic assessment of trends and patterns identified from NCEs.

4.1.1.2.10 **Significant operational changes that may affect the laboratory's QMS and/or service delivery:** A summary of significant changes that may affect QMS and/or service delivery (e.g., test volume, facility, organization, new equipment, processes or procedural changes, new regulatory or accreditation requirements).

4.1.1.2.11 **Continuous Improvement (CI):** Status and results of CI initiatives and preventive actions and recommendations for improvement

4.1.1.2.12 **Action items from previous management review**: Review of action items from previous management review to verify appropriate follow-up and ensure completion.

4.1.1.2.13 **Quality plan**: Status of quality goals and objectives.

4.1.1.3 When lab leaders start preparing for management review, consideration should be given to:

4.1.1.3.1 Compiling data and translating it into actionable information, using graphical representations when appropriate.

4.1.1.3.2 Summarizing information in a clear and concise format for ease and speed of review.

4.1.1.3.3 Organizing the meeting material in a cohesive and logical manner.

4.1.1.4 A Quality Report by Quality System Essential Form can be used to compile the various inputs.

4.1.1.5 An agenda should also be prepared to communicate the topics included in the review and can be used to guide the review itself, keeping discussion on track and ensuring all topics are addressed. Refer to Agenda For Management Review Form

4.1.1.6 To facilitate an efficient meeting, the agenda and quality report may be provided to meeting attendees for review before the management review meeting. As an option, data or information from the quality report could be summarized in presentation form to conduct the management review meeting.

4.1.2 Conducting Management Review:

4.1.2.1 The review of the quality report and related material should allow sufficient time to discuss and agree upon conclusions, make decisions, and/or assign action items, as applicable.

4.1.3 Maintaining Records of Management Review:

4.1.3.1 The quality report should enable a comprehensive review comprising, at least, the following activities:

4.1.3.1.1 Reviewing inputs (as summarized in 4.2.2).

4.1.3.1.2 Verifying that the QMS was implemented as designed.

4.1.3.1.3 Identifying opportunities for improvements (OFI) to the QMS.

4.1.3.1.4 Selecting and prioritizing improvement initiatives, when indicated

4.1.3.1.5 Allocating necessary resources for the recommended follow-up actions to maintain and continually improve the laboratory's QMS.

4.1.3.1.6 Assessing the need to change the quality objectives

4.1.3.1.7 Assessing the effectiveness of the QMS

4.1.3.1.8 Evaluating, to the extent possible, the quality and appropriateness of the laboratory's contribution to patient care.

4.1.3.2 Key findings, decisions, and action items from the management review generally relate to the following outputs:

4.1.3.2.1 Recommended improvements to the laboratory's QMS.

4.1.3.2.2 Recommended improvements of laboratory services for the purpose of enhancing the quality and/or safety of patient care.

4.1.3.2.3 Recommended resources to support the QMS and/or work processes.

4.1.4 Maintaining Records of Management Review:

4.1.4.1 A written record of the management review should clearly demonstrate the presence and active involvement of MCH Laboratory leadership.

4.1.4.2 The record may include all or some of the following:

4.1.4.2.1 A list of attendees.

4.1.4.2.2 Critical discussion items

4.1.4.2.3 Decisions made.

4.1.4.2.4 Recommended action items, including

4.1.4.2.4.1 Referral to CI.

4.1.4.2.4.2 Resources identified, recommended, and/or requested

4.1.4.2.4.3 Approved, rejected, and/or revised plans or proposals

4.1.4.2.4.4 Requests for additional information.

4.1.4.2.4.5 Conclusions of the review, including

4.1.4.2.4.6 Assessment of the effectiveness of the QMS

4.1.4.2.4.7 Evaluation of the quality and appropriateness of the laboratory's contribution to patient care

4.1.4.2.4.8 The management review meeting record should be distributed to all attendees and key stakeholders, as appropriate. The meeting record should be retained in accordance with the record retention period defined in the laboratory's QMS.

4.1.4.3 Taking Action in Response to Management Review:

4.1.4.3.1 Relevant findings and actions arising from management review should be reported to lab staff and other key stakeholders, as appropriate.

4.1.4.3.2 Action items from the management review should specify, in appropriate detail, what outcomes are needed and what steps are necessary to accomplish them.

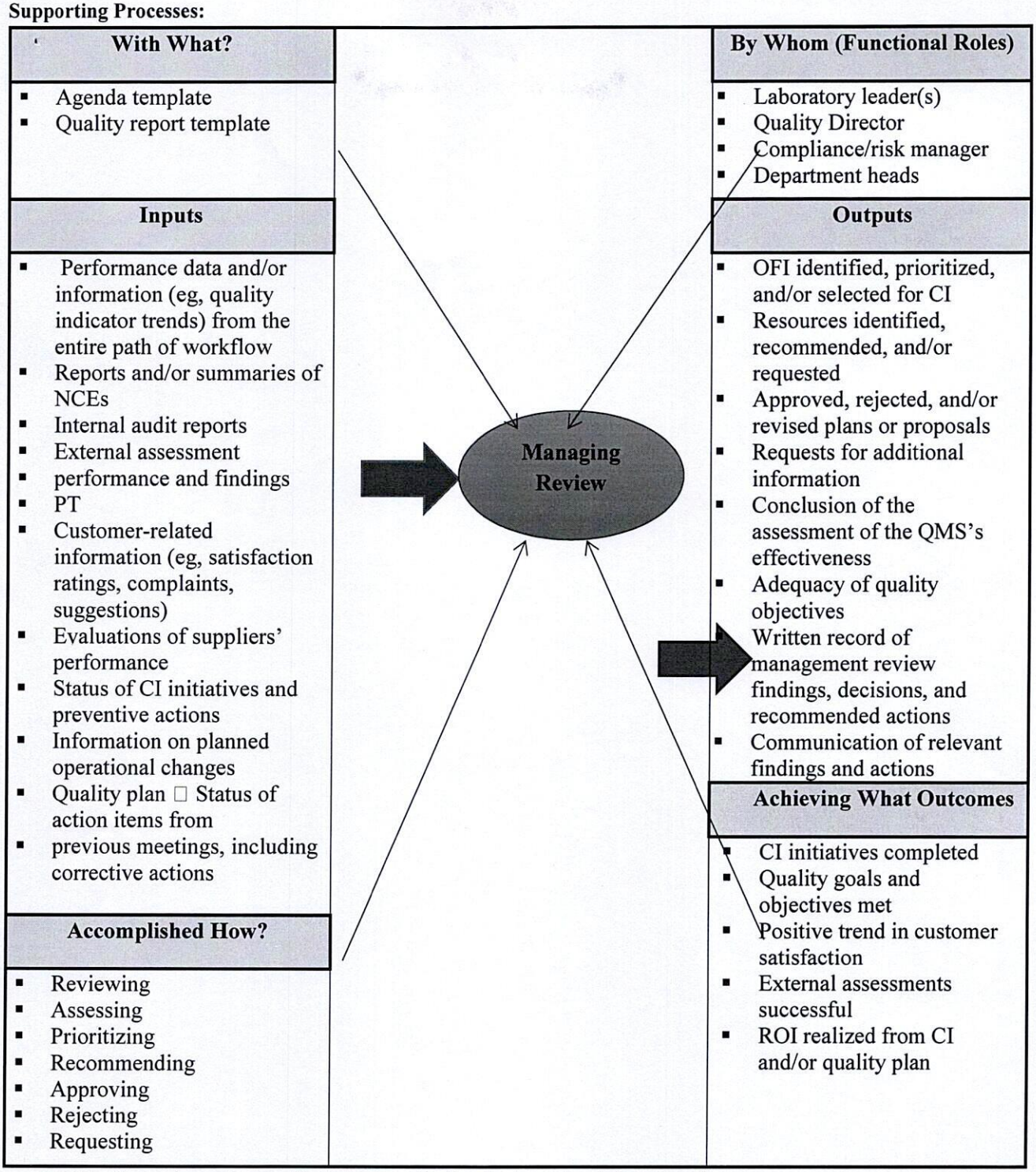
4.1.4.3.3 Action items are assigned to specific responsible staff with an estimated completion date.

4.1.4.3.4 MCH hospital lab leadership are responsible for ensuring that all action items are completed within their specified timeframes

4.1.4.3.5 Recommended improvements to the laboratory's QMS, improvements of laboratory services for the purpose of enhancing the quality and/or safety of patient care, and resources to support the QMS and/or work processes will link to other processes or activities that support management review (Refer to management review- an integrated DOC-LAB-055)

4.1.4.3.6 As such, an action plan is developed and implemented as appropriate for each supporting process or activity.

Supporting Processes:



- Monitoring/reporting quality indicators ▪Performing/reporting internal audit
- Following up on external assessment ▪Monitoring/reporting customer satisfaction
- Managing/reporting NCE ▪Evaluating suppliers and vendors
- Managing process change ▪Planning for quality ▪CI ▪Allocating resources

CI, continuous improvement; NCE, nonconforming event; OFI, opportunity for improvement; PT, proficiency testing; QMS, quality management system; ROI, return on investment.

8. REFERENCES:

8.1 CBAHI Standards, 3rd edition
8.2 College of American Pathologists – General Laboratory Checklist. Revised December 2004
8.3 Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition, 26 October 2010.
8.4 Laboratory Quality Management system, "CLSI Hand Book", WHO, 2011
8.5 Good Manufacturing Practice for Blood Establishments, Version 2.0, May 2019, Saudi FDA.
8.6 Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 2011.

9. APPROVALS:

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