HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Departmental Policy and Procedure		
Title:	CHANGE CONTROL (NEW/REVISED PROCESS)		
Applies To:	All Laboratory		
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1. PURPOSE:

1.1 To define how change control is handled and to plan the implementation of the change, so that minimum of disruption is caused

1.2 To ensure that any planned changes or modifications of processes, procedures or policies, which may impact on quality, are communicated to those concerned

1.2.1 All stakeholders have an opportunity to participate in the control of any subsequent changes

1.2.2 All recipients, including personnel within the organization, are made aware of any changes that occur

1.2.3 There is an audit trail which connects a change to a configuration item to the reason for its change, and records the participation and authorization of those people concerned with the change.

2. DEFINITONS:

2.1 Process management includes activities that fulfill applicable requirements for implementing a new - or revising an existing- laboratory processes or others.

2.2 Change can take many forms such as structural, cost-cutting, process, cultural, and strategic changes.

2.3 Process Change includes both introduction of a new process and changing an already present one (i.e. revised process).

2.4 Change Control: is a formal system for managing proposed or actual change in process, equipment or systems. Proper change control requires definition of the

2.4.1 Level of authority required to change each process.

2.4.2 Methods for handling proposals for changing any process.

2.5 Flow chart: a diagram, often using geometric symbols, showing the sequence of activities and decisions

2.6 made in a process; also commonly referred to as "process map."

2.7 Validation: confirmation, through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled (ISO 9000). Examples include validation of the process to use a new diagnostic tool, such as an automated laboratory test system.

2.8 Verification: Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled (ISO 9000).

3. POLICY:

3.1 MCH hospital lab develops a system to implement new processes or procedure or change existing ones.

3.2 As applicable, new or changed processes are validated before implementation.

3.3 Validation protocol of new or changed processes are prepared, reviewed and prospectively approved

3.4 Changes should be documented, validated, reviewed and approved for implementation.

3.5 The implemented change is communicated to all concerned.

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

3.6.1 All modifications, enhancements or additions to validated systems and equipment must be managed through the change control procedure of the blood establishment.

3.6.2 The effect of each change to the system or equipment, as well as its impact on quality and safety must be determined to identify the extent of re-validation required.

3.6.3 Change control procedures should ensure that sufficient supporting data are generated to demonstrate that the revised process results in a blood component of the desired quality, consistent with the approved specifications

3.6.3.1 Supporting data, e.g. copies of documents, should be reviewed to confirm that the impact of the change has been demonstrated prior to final approval.

3.6.4 Written procedures should be in place to describe the actions to be taken if a planned change is proposed for a starting material, blood component specification, process, equipment, environment (or site), product range, method of production or testing or any other change that may affect donor safety, blood component quality or reproducibility of the process.

3.6.5 Changes should be authorized and approved by the responsible persons or relevant functional personnel in accordance with the blood establishment's quality system.

3.6.6 Operational change control, document control and quality control procedures support the maintenance of the validated state.

4. PROCEDURE:

4.1 **In an environment of process management, work processes are:**

4.1.1 Designed to meet applicable regulatory, accreditation, and customer requirements.

4.1.2 Documented.

4.1.3 Monitored to ensure continued acceptable performance.
Changed in a controlled fashion.

4.2 MCH hospital lab has a systematic approach for identifying, planning, and implementing new (and making changes to existing) policies, processes, and procedures.

4.3 The flow chart for process management includes the following steps:

4.3.1 Need for a new or changed process is identified.

4.3.2 New or changed process is identified.

4.3.3 Process is flow-charted.

4.3.4 Implementation plan is developed.

4.3.5 Documents are identified and drafted

4.3.6 Determination of validation or verification is made.

4.3.7 Process and procedure documents are finalized

4.3.8 Internal and external communication plan is developed.

4.3.9 Implementation plan is initiated.

4.3.10 Process is monitored to determine any need for further changes and so on.

4.4 Drivers for new or revised (changed) policies, processes or procedures include

4.4.1 Customer needs and expectations.

4.4.2 Accreditation and regulatory requirements.

4.4.3 Nonconformance and risk assessment.

4.4.4 Current available knowledge (e.g., other successful practices).

4.5 The changes may include:

4.5.1 Document Change: refer to document control/management system policy and procedures.

4.5.2 LIS /Computer Modification or Change: refer to Computer System Modifications and Updates procedures

4.5.3 Test/Services Change: Refer to Scope of laboratory Services policy.

4.5.4 Contract Change: Change control procedures may be included in contracts with suppliers/customers

4.6 Change control policies, processes and procedures must ensure:

4.6.1 Timely development or change of quality and operational policies, processes, and procedures.

4.6.2 Standardized and systematic validation and implementation of new/revised processes.

4.7 Changes should be documented, validated, reviewed and approved for implementation

4.8 Elements of proper process validation must include:

4.8.1 Process Description; including description for all sub-processes and their relationships with other processes. Also, a flowchart describing how the process will be used must be included.

4.8.2 Physical Description; when equipment is part of the process to be validated, the process description should include information about the equipment.

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4.9 Validation Protocols:

4.9.1 Prospective Validation protocol; Defined as validation performed on a new process, when there are significant changes to a process, or when a new system is incorporated into an existing process. The three main elements of the prospective validation are:

4.9.1.1 Installation Qualification (IQ): foundations of IQ are stability, maintenance, and operating procedures.

4.9.1.2 Operational Qualification (OQ): Demonstrates the effectiveness and reproducibility of the process under the worst conditions that are likely to be encountered.

4.9.1.3 Product Performance Qualification (PQ): Includes quantitative and qualitative evidence that the validated process results in an acceptable product by testing product attributes and comparing the results with predefined expectations.

4.9.2 Revalidation Protocol To maintain the process in its validated state through reaffirmation of IQ, OQ and PQ.

4.9.3 Retrospective Validation protocol To be used when the process has been used since before validation was required. Retrospective validation includes

4.9.3.1 Examination of the accumulated test data.

4.9.3.2 Qualification of the test methodology by the IQ, OQ, and PQ.

4.9.3.4 Examination of the operating parameters such as temperature charts, personnel practices and personnel training records.

4.9.4 Procedure: (Refer to CLSI Process Management guideline QMS18 for detailed procedures

4.9.4.1 Need for a new or changed process is identified.

4.9.4.1.1 Internal and external factors can initiate or force changes in laboratories.

4.9.4.1.2 Prioritization to be considered (e.g. Regulatory matters and safety concerns).

4.9.4.1.3 This is done through the change control form. The change control form will be submitted to the Head of total quality management department (or his designee).

4.9.4.1.4 Laboratory Director or deputy may contact the contractor through an email, telephone or by an official letter and discusses with them:

4.9.4.1.4.1 The reasons for change

4.9.4.1.4.2 Configuration items to be changed, costs, timescales, risks, ...etc.

4.9.4.1.4.3 Reviewing change; accept or reject.

4.9.4.2 New or changed process is identified

4.9.4.2.1 The following are included when developing a new or changed process:

4.9.4.2.1.1 Identification of the process' team leader and members and their responsibilities.

4.9.4.2.1.2 Process definition document: Process scope and boundaries (e.g. Goals, objectives, risks, assumptions and constraints, communication plan, dependencies on other processes, etc.). Refer to Process definition document

4.9.4.2.1.3 Process documentation timeline.

4.9.4.2.2 The request must be carried out well in advance of implementing the change. This is important to allow sufficient time for after-relevant actions to be taken and allows quality department to advise the documentation requirements which must be in place for the change to be approved

4.9.4.2.3 The head of total quality management department (or his designee) with relevant managers will decide which other parts of the organization need to be made aware of the change and more specifically which managers/consultants need to give approval. All such managers will receive a copy of the form of the change control and be asked to sign them. The signed forms will be stored in the change control file.

4.9.4.2.4 Each change control request will receive a unique reference number. A file will be opened and this will contain key documentation to support the change. The files will be held for scrutiny when required.

4.9.4.3 Process is flow-charted, implementation plan is developed, documents are identified and drafted as well as determination of validation or verification is made:

4.9.4.3.1 This is done through the head of total quality management department (or his designee) and departmental head/section supervisor related to the concerned process

4.9.4.3.2 Flow chart depicts the sequence of activities between the predefined beginning and end of a selected process.

4.9.4.3.3 Implementation plan provides a guidance for how to implement the new or changed process. Scope, timeline, and budget and resources are the three major components of a process implementation plan.

4.9.4.3.4 After the new or revised process is flow-charted and in preparation for the process validation or verification, the laboratory needs to complete the process documentation by developing procedures, job aids, and forms

4.9.4.3.5 After the laboratory identifies whether the new or changed process needs validation and/or verification, the proper plan should be developed. This plan should identify who will perform the validation/verification, define acceptance criteria, who will approve the results, who will implement the change as well as change monitoring

4.9.4.4 Process and procedure documents are finalized. Changes are documented, validated, reviewed and approved for implementation

4.9.4.4.1 Copies of the completed change control documents will be issued to the relevant personnel.

4.9.4.5 Training and competence assessment is conducted by the concerned department/section

4.9.4.6 Internal and external communication plan is developed. This is to ensure that changes or modifications of processes, procedures or policies are communicated to those concerned (e.g. external and internal customers).

4.9.4.6.1 Potential audiences (affected by the new or changed process) that should receive communications may be internal (e.g. Departmental staff and other concerned departments) or external (e.g. Regulatory and accreditation bodies as well as customers receiving process output).

4.9.4.6.2 Use as many communication formats as are available, including electronic, written, visual, or meetings.

4.9.4.7 Implementation plan is initiated:

4.9.4.7.1 An appropriate departmental head or nominated deputy will be responsible for ensuring that the change control procedure is

initiated. As the implementation continues, staff schedules should be reviewed and adjusted as needed

4.9.4.8 Process is monitored to determine any need for further changes and so on

4.9.4.8.1 Monitoring is to determine how well the new process is working.

4.9.4.8.2 Use quality control (as the primary means) and proficiency testing (as a secondary means of monitoring) as well as related pre existing quality indicators.

5. MATERIALS AND EQUIPMENT:

5.1

6. RESPONSIBILITIES:

6.1 All laboratory Staff
6.2 Department heads/ supervisors
6.3 Quality management head (or his designee):

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 CLSI. Process Management. 1st ed. CLSI guideline QMS18. Wayne, PA: Clinical and Laboratory Standards Institute; 2015.
8.4 Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition. QMS01-A4. Clinical and Laboratory Standards Institute (CLSI), 2011.
8.5 CLSI. Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline. CLSI document GP31-A. Clinical and Laboratory Standards Institute; 2009.

9. APPROVALS:

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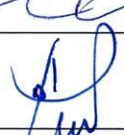
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		August 08, 2024
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