HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Departmental Policy and Procedure		
Title:	Non Conforming Events Management		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

1.1 To facilitate the establishment and maintenance of an internal nonconforming event (NCE) management program

1.2 To identify and characterize problem-prone processes in a laboratory's path of workflow and within the supporting processes of the Quality Management System (QMS), so Continual Improvement (CI) initiatives can be prioritized, resources allocated, and improvements implemented i.e. using an identification mechanism as a quality improvement tool for early detection and prevention of problems.

2. DEFINITONS:

2.1 Occurrence: An event which is not consistent with routine patient care or with the routine operation of the facility and which adversely affects or threatens the health or life of patient, visitor, employee, student or volunteer which involves loss or damage to personal or organization property. An occurrence also includes any event that might otherwise result in any other adverse situation or a claim against the organization.

2.2 Occurrence Variance Report (OVR): An internal form which is issued to document the details of the occurrence/event and the investigation of an occurrence and the corrective actions taken.

2.3 Adverse Event: It is an unwanted, undesirable and usually unanticipated event. Occurrences such as patient falls are also considered adverse events if there is no permanent effect on the patient.

2.4 Variance: Is the difference in results obtained in measuring the same phenomenon more than once. Excessive variation frequently leads to waste and loss; such as the occurrence of undesirable patient health outcomes and increased cost of health services.

2.5 Near miss: An event or situation that could have resulted in an accident, injury or illness but did not either by chance or through timely intervention. Near-miss has the same root causes as sentinel event that is why they are reported.

2.6 Sentinel event: Any unexpected occurrence involving death, serious physical or psychological injury or the risk thereof, and any event that might cause embarrassment or risk to the organization with potential legal implications and/or media inquiries or coverage. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response.

2.6.1 Sentinel events include, for example;

2.6.1.1 Unexplained or unexpected deaths or permanent loss of limb or function that is not a result of the patient's medical condition.

2.6.1.2 Hemolytic blood transfusion

2.6.1.3 Patient's fall resulting death or severe dysfunction of body part.

2.6.2 Nonconformity: is nonfulfillment of a requirement. It is any occurrence that is not according to rules and/or expectations. Examples are deviation of critical environmental or equipment parameters, accidents, wrongly packed samples, stock outs, etc

2.6.3 Nonconforming event (NCE): an occurrence that does not conform to the laboratory's policies, processes, and/or procedures; does not conform with applicable regulatory or accreditation requirements; or has the potential to affect (or has affected) patient, donor, or employee safety.

2.6.4 Nonconforming work: means current or potential nonconforming, the current nonconforming work needs corrective action and the potential nonconforming work.

2.6.5 A corrective action: is defined as the action taken to correct the cause of a potential nonconformity or any other undesirable potential situation.

A preventive action: is defined as the action taken to prevent recurrence of nonconformity. Preventive action is a proactive process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints (i.e. nonconformities). In addition to review of the operational procedures, preventive action might involve analysis of data, including trend and risk analyses and external quality assessment (proficiency testing).

QMS: quality management system.

Recall: actions taken by a firm or institution to remove a product from the market.

Root cause analysis (RCA): process for identifying the basic or causal factor(s) that underlies variation in performance, including the occurrence or possible occurrence of a nonconforming event.

3. POLICY:

3.1 MCH lab clearly identifies nonconforming event and assess the significance and effect of the nonconformance on reported results, products or services. MCH lab is committed to documentation, correction, and prevention of nonconforming events in all aspects of the QMS.

MCH lab develops policies and procedures to be followed upon the discovery of nonconforming equipment, critical material, blood products and/or services.

Any non-conformity detected shall be reported and investigated and the appropriate corrective and preventive actions taken will be approved

The implemented system covers the following

Definition of a nonconforming event

Assessment of the significance and effect of the nonconformance on reported results, products or services.

Immediate remedial corrective action (identification, retrieval, recall and quarantine).

Conditions for internal and/or external reporting of the nonconformance

Definition of reviewing and approving authorities.

Long-term preventive actions, monitoring and follow-up.

4. PROCEDURE:

4.1 Nonconforming Event Management

4.1.1 An NCE management program is based on principles of quality management, risk management, and patient safety.

4.1.1.1 Representatives from all the laboratory's major sections or functions should promote the program and act as role models in implementation and follow-up activities.

4.1.2 Individual Nonconforming Event Process:

4.1.2.1 Responding to a single NCE is the first connected process in an NCE management program.

4.1.2.2 The NCE Response Process form illustrates the series of activities, including key decision-making steps that can occur from detection to completion or closure of an individual NCE. Use the Non-Conforming Event Report Form to document NCE-management process.

4.1.2.3 Nonconforming Event Detected:

4.1.2.3.1 External Sources: Common external sources from which nonconformance are detected include:

4.1.2.3.1.1 Complaints from patients, donors, visitors, and service or product providers (vendors).

4.1.2.3.1.2 Noncompliance with a requirement uncovered in an external assessment, inspection, or audit.

4.1.2.3.1.3 Proficiency testing (PT) failures

4.1.2.3.1.4 Service alerts, field corrections, hazards, vendor recalls (mandatory or voluntary), and/or withdrawals that are determined as applicable to the organization.

4.1.2.4 Internal Sources can be:

4.1.2.4.1 External Sources: Common external sources from which nonconformance are detected include:

4.1.2.4.1.1 Complaints from patients, donors, visitors, and service or product providers (vendors).

4.1.2.4.1.2 Noncompliance with a requirement uncovered in an external assessment, inspection, or audit.
Proficiency testing (PT) failures.
Service alerts, field corrections, hazards, vendor recalls (mandatory or voluntary), and/or withdrawals that are determined as applicable to the organization.

4.1.2.4.2 Internal Sources can be:

4.1.2.3.2.1 Mistakes and problems in work operations anywhere along the laboratory's path of workflow.

4.1.2.3.2.2 Process or communication failures within the QMS.

4.1.2.3.2.3 NCE detected in an internal audit.

4.1.2.3.2.4 Employee complaints about workplace safety, work environment, and work operations.

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4.1.2.5 Immediate Action Taken: Once an NCE is detected, a sequence of actions and questions commonly occur.

4.1.2.5.1 Respond to the extent possible. This first step means taking immediate action to rectify an NCE.

4.1.2.5.2 What immediate action is needed?

4.1.2.5.2.1 It may be as simple as resending a patient's report or it may include other activities involving more time, resources, and cost.

4.1.2.5.3 Is this event happening elsewhere?

4.1.2.5.3.1 The NCE is a simple isolated event, or whether it is one of a series of similar recurring events that also needs immediate action. Further and deeper investigation is not usually begun at this time.

4.1.2.5.4 Who has the authority to take action?

4.1.2.5.4.1 An employee who identifies or is made aware of an NCE can notify his/her manager and/or other appropriate personnel of the NCE.

4.1.2.5.4.2 The reporting individual may be the one to take immediate action, or the manager or appropriate personnel may take immediate action or assign a task.

4.1.2.5.4.3 It is important to communicate the problem to the right people so immediate action can be taken.

4.1.2.5.5 Document immediate action through reporting

4.1.2.6 Nonconforming Event Investigated:

4.1.2.6.1 Once the NCE and the immediate action have been reported, the supervisor or person responsible for the investigation needs access to the report and needs to complete his/her respective portion in a

timely manner to get an accurate picture of what happened and why it happened.

4.1.2.6.2 Investigation is conducted by evaluating the interactions between the system and the people involved in the system and to determine where the NCE occurred in the laboratory's path of workflow or supporting QMS processes.

4.1.2.7 Course of Action Determined:

4.1.2.7.1 It depends on the severity of the issue and the risk to patients or employees. A risk assessment (based on the probability of occurrence and the severity) helps direct resources and determines what actions are needed.

4.1.2.7.2 The first step in risk assessment is to determine the probability the NCE will occur. Probability can be defined qualitatively and quantitatively.

4.1.2.8 Effectiveness of Action Assessed: Once the corrective action plan (CAP) has been developed and implemented

4.1.2.8.1 Any changes made should be audited and outcomes measured.

4.1.2.8.2 If the plan did not eliminate or reduce recurrence or has caused unintended consequences, then a new plan should be developed and the cycle repeated.

4.1.2.9 Nonconforming Event Closed:

4.1.2.9.1 Completing the final report and communicating the outcomes to laboratory leadership closes the NCE. The process to close a single NCE will vary depending on the course of action taken.

4.1.2.10 Collective Nonconforming Event Data Assessment Process:

4.1.2.10.1 Collective NCE data assessment is the second connected process in an NCE management program. Use the Nonconforming Event Log to track multiple events. Before data collection, a classification system needs to be in place.

4.1.2.10.2 Classification System: (NCEs-grouping based on one or more common elements such as :)

4.1.2.10.3 Severity or risk of NCE, Location in path of workflow or QMS, process and/or procedure in which the event occurred, Root cause, or recurring events.

4.1.2.11 Data Collected and Compiled:

4.1.2.11.1 A review of all NCEs reported needs to occur at regular intervals to look for potential patterns and trends to identify potential problematic areas worthy of additional study to improve organization performance, reduce errors, and improve patient safety.

4.1.2.11.2 Tools are used to show and interpret data and to guide an investigation. Often, simple tools will suffice. Examples are checklists, check sheets and run charts.

4.1.2.12 Data Analyzed: Questions to ask during the analysis include:

4.1.2.12.1 What patterns are seen in the aggregate data (increases and reductions in type, frequency, severity)?

4.1.2.12.2 What trends are seen in the aggregate data as compared to prior time periods?

4.1.2.12.3 What patterns are seen in the aggregate data (increases and reductions in type, frequency, severity)?

4.1.2.12.4 What trends are seen in the aggregate data as compared to prior time periods?

4.1.2.12.5 Which NCEs have been reported multiple times? For them, was an RCA conducted? If an RCA was conducted, does the current pattern or trend indicate improvement as compared to prior time periods?

4.1.2.12.6 Do the aggregate data identify an increasing trend for an NCE that has not been investigated previously?
4.1.2.12.7 What are the processes most frequently involved in reported NCEs?
4.1.2.12.8 What is the effect on customer perception of laboratory services?
4.1.2.12.9 Was there an effect on patient safety?
4.1.2.12.10 Investigation and data reporting tools may include bar graph, fishbone diagram, control chart, flow diagram, histogram, pie chart, scatter diagram, and 5 Whys

4.1.2.13 Report Prepared: It should focus on process changes to:
4.1.2.13.1 Improve performance.
4.1.2.13.2 Ensure the necessary resources are available to support implementation.
4.1.2.13.3 Promote consideration of possible lessons learned that could be applied to other areas to prevent potential future NCEs.

4.1.2.14 Management Review Process:
4.1.12.14.1 Management review is the third connected process in an NCE management program. The management review process.
4.1.12.4.2 It ensures involvement by management in a review of QMS assessments and indicators, and provides management an opportunity to respond to trend analysis of cumulative quality data

4.1.2.15 Continual Improvement (CI) Process:
4.1.2.15.1 In an effective NCE management program, the focus is not on who did what, but on why the system failed and how the process can be changed to eliminate future failures.
4.1.2.15.2 The cycle begins when an error or risk is reported without fear of retribution. CI closes the cycle with a focus on improved patient care and services and on ensuring that improvement is both integrated and sustained over time.
4.1.2.15.3 Laboratory quality efforts are successful when the CI cycle becomes a regular part of laboratory operations

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

4.2.1 Deviation management and corrective and preventive actions:
4.2.1 Refer to "Quality Management System"

4.2.2 Non-Conformance And Recall (General Principles):
4.2.2.1 Blood components deviating from prevalent Good Practices shall be released for transfusion only in exceptional circumstances and with the recorded agreement of the prescribing physician and the blood establishment physician.
4.2.2.2 There should be a defined procedure for the release of non-standard blood and blood components under a planned non-conformance system.
4.2.2.3 The decision for such release should be clearly documented and authorized by a designated person and traceability should be ensured
4.2.3.4 There should be systems in place to ensure that deviations, adverse events, adverse reactions and non-conformances are documented, carefully investigated for causative factors of any defect and, where necessary, followed up by the implementation of corrective actions to prevent recurrence.
4.2.3.4.1 There should be systems in place to ensure that deviations, adverse events, adverse reactions and non-conformances are documented, carefully investigated for causative factors of any defect and, where necessary, followed up by the implementation of corrective actions to prevent recurrence.
4.2.3.4.2 Any errors, accidents or significant deviations that may affect the quality or safety of blood and blood components should be fully recorded and investigated in order to identify systematic problems that require corrective action.

4.2.3.4.3 Investigations relating to serious deficiencies, significant deviations and serious component quality defects should include an assessment of component impact, including a review and evaluation of relevant operational documentation and an assessment of deviations from specified procedures.

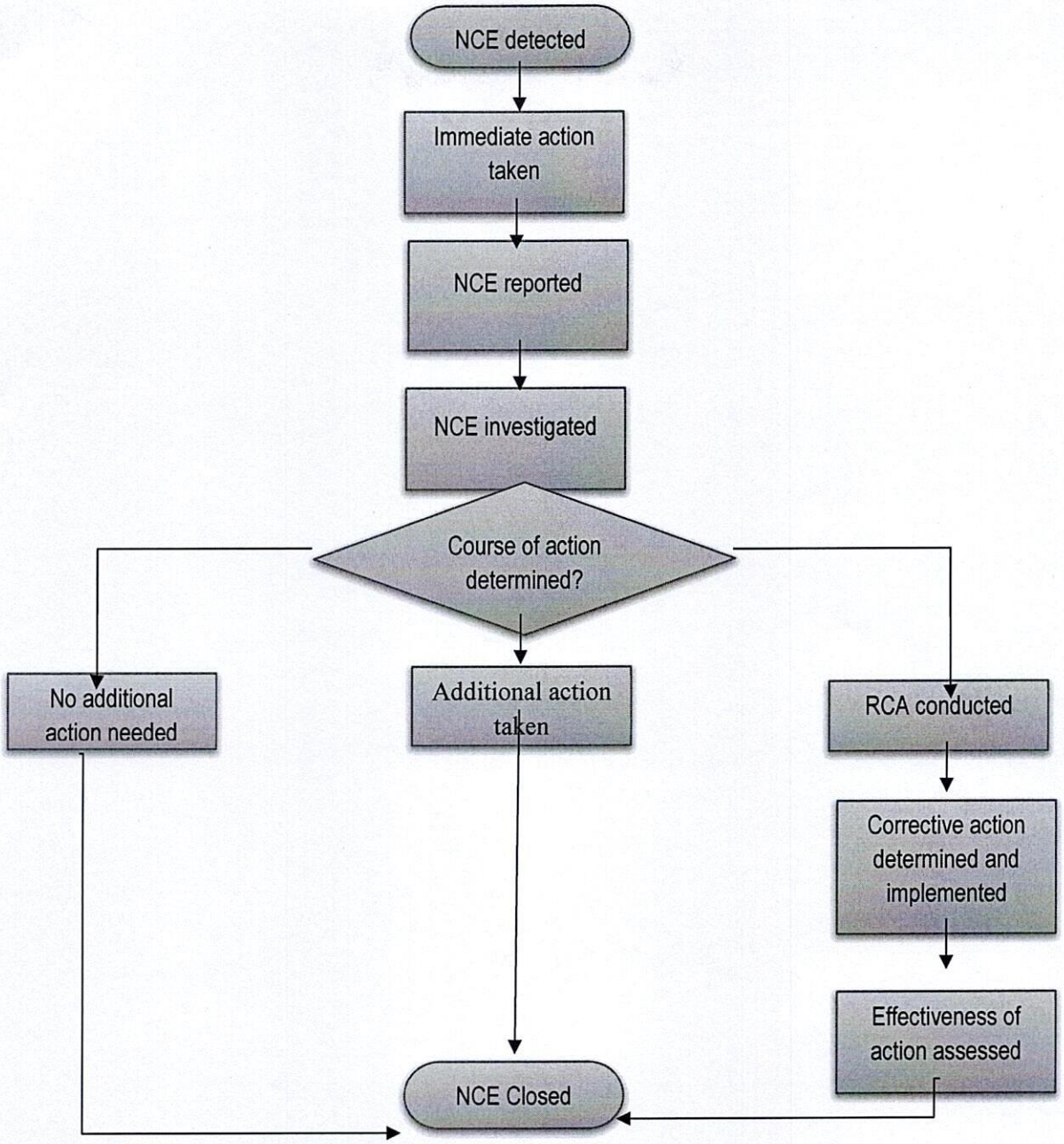
4.2.3.4.4 Appropriate corrective and preventive actions should be defined and implemented.

4.2.3.4.5 The corrective and preventive actions (CAPAs) system should ensure that existing component non-conformity or quality problems are corrected and that recurrence of the problem is prevented.

4.2.3.4.6 There should be procedures for notifying responsible management in a timely manner of deficiencies, deviations or non-compliances with regulatory commitments (e.g. in submissions and responses to regulatory inspections), component or product quality defects, or testing errors and related actions (e.g. quality related complaints, recalls, regulatory actions, etc.).

42.3.4.6.1 Executive management and the Responsible Person should be notified in a timely manner of serious deficiencies, significant deviations and serious component or product quality defects and adequate resource should be made available for their timely resolution.

4.2.3.4.7 A regular review of all significant deviations or non-conformances should be conducted, including their related investigations, to verify the effectiveness of the corrective and preventive actions


NCE detected
Immediate action taken
NCE reported
NCE investigated
Course of action determined?
No additional action needed
Additional action taken
RCA conducted
Corrective action determined and implemented
Effectiveness of action assessed
NCE Closed

5. MATERIALS AND EQUIPMENT:

5.1 Non-Conforming Event Report Form
5.2 Nonconforming Event Log

6. RESPONSIBILITIES:

6.1 All the laboratory's key persons in major department, sections or functions should promote the NCEs program and act as role models in implementation and follow-up activities.
6.2 It is the responsibility of anyone working in a laboratory to detect any non-conformity and report it to laboratory management.
6.3 It is the responsibilities of Laboratory Director or his Deputy to review non-conformities records and assess the effectiveness of corrective/preventive actions taken

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:

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