3. Corrective and Preventive Actions

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ANNUAL REVIEW:

REVIEWED	Sanford N. Bauby, M.D signature/title	July-11-2025 Date
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SUPERSEDES: Procedure titled _____

Purpose

The purpose of this SOP is to establish a systematic approach for identifying, evaluating, and documenting nonconformances and incidents within the clinical laboratory. The SOP outlines the procedures for conducting root cause analysis (RCA) and investigations to minimize or eliminate the recurrence of nonconformances. The SOP also includes the implementation of corrective and preventive actions to ensure the quality and safety of laboratory processes. The overall goal is to create a culture of continuous improvement and proactive risk management, thereby enhancing patient safety and satisfaction.

Scope:

This SOP applies to all laboratory personnel involved in the creation, use, and follow-up of corrective and preventive actions. The scope covers all nonconformities that could potentially impact the quality and safety of laboratory processes and the services provided. This includes but is not limited to, deviations from established procedures, equipment malfunctions, errors in documentation, and incidents related to sample/ instruments handling and processing.

Definitions and abbreviations

PHI-protected health information
QMP-Quality Management Plan
RCA-Root Cause Analysis
SOP- Standard Operating Procedure

Definitions:

Nonconformance – Any deviation from the established requirements or procedures set forth in the Quality Management Plan (QMP) or other SOPs that can affect the quality of service or patient safety. Nonconformities can occur when procedures are not followed correctly, when equipment malfunctions, or when equipment is not maintained to proper standards. Nonconformities may also pose a risk to the confidentiality, integrity, or availability of protected health information (PHI) or they may create unsafe work environments for staff.

Incident – An unexpected event that results in or has ***the potential*** to result in death or serious injury to patients or staff. Incidents can be caused by equipment failure, human error, communication breakdowns, or other factors that compromise patient safety or staff well-being. Incidents should be reported promptly to the appropriate personnel to initiate a formal investigation and corrective action plan.

Near Miss – An event that ***could have resulted in death or serious injury*** to patients or staff but was caught in time to prevent harm. Near misses should be reported, investigated, and documented in a Corrective Action Plan to identify the root cause and implement preventive actions to avoid recurrence.

Recur – Refers to the repeated occurrence of nonconformities, incidents, or near misses. The frequency and severity of recurrences can provide important insights into the underlying causes and potential solutions.

Corrective Action – A plan of action taken to eliminate the root cause of nonconformities, incidents, or near misses. Corrective actions may include changes

to policies or procedures, equipment repair or replacement, staff training, or other measures designed to prevent recurrence.

Preventive Action – A proactive approach to identify and eliminate potential causes of nonconformities and incidents. Preventive actions may include risk assessments, process improvements, staff training, or other measures designed to prevent the occurrence of nonconformities or incidents. The goal of preventive actions is to improve the overall quality and safety of laboratory processes and services.

Policy:

In the event of an incident, suspected incident, near miss, or other nonconformity, all laboratory personnel must immediately report the issue to their supervisor or the Quality Manager. The supervisor or Quality Manager will initiate an investigation to determine the root cause of the issue and to assess its impact on the quality and safety of laboratory processes and services. Based on the findings of the investigation and Appendix A of this SOP, a corrective action report will be filled out to document the nonconformity and the corrective actions taken to prevent recurrence. The plan of correction will be implemented in a timely manner and reviewed periodically to ensure its effectiveness. All personnel are responsible for complying with this policy and for reporting any nonconformities or incidents in a timely and accurate manner.

Procedure:

1. Identification and Investigation of Nonconformity:

Responsibility: All personnel

All laboratory personnel are responsible for identifying and reporting any nonconformities or potential nonconformities to their supervisor or the Quality Manager. Upon receiving a report of a nonconformity, the supervisor or Quality Manager will initiate an investigation to determine the root cause of the error. The investigation will include, but not be limited to, gathering and analyzing relevant data, reviewing relevant procedures and documentation, and interviewing relevant personnel. The investigation will be conducted in a timely and effective manner to minimize the impact of the nonconformity on laboratory processes and services.

If the nonconformity is deemed to be recurring (based on Appendix A of the SOP), the supervisor or Quality Manager will initiate a plan of correction. The plan of correction will include a detailed description of the corrective actions to be taken,

the persons responsible for implementing the actions, and the timeline for completion. All corrective actions will be completed in a timely manner with appropriate follow-up and monitoring to ensure their effectiveness in preventing recurrence.

2. Filling out Corrective Action Report:

Responsibility: Lab Manager/General Supervisor/Quality Personnel, Lab Director.

A. Create a log number for the corrective action report, consisting of the date and a two-digit numerical identifier starting at one (1) for each new date, as shown in the example below:

a. Log number example: 07122022-01 (the first corrective action report form filled out on July 12th, 2022).

B. Answer the following questions in the Corrective Action Report:

a. Was a patient or patients affected? If yes, describe under the Response section:

b. How the physician and/or clinic and/or patient was notified.

c. When they were notified.

C. Record the date and initials of the person being notified.

D. Is the current investigation the result of a complaint (internal or external) that the lab received?

E. Was the incident a "Near Miss"?

F. Circle the area of the lab where the nonconformity occurred under Type of Nonconformity.

G. In the first box of the Corrective Action Report, write the date of the event and all parties involved. Then describe the event FULLY and COMPLETELY, including all relevant details.

a. Feel free to attach additional pages to the form to describe the event if necessary.

H. In the second box of the Corrective Action Report, state the response of the lab personnel to the event (including lab assistants, techs, and management).

I. Conduct a root cause analysis to determine the most likely cause of the nonconformity by a process of elimination.

J. Fill out the table with the corrective actions to be taken, which is a plan of correction taken as a direct result of the root cause analysis.

K. Have all appropriate lab personnel sign the Corrective Action Report and file it with the Lab Manager/Supervisor until a follow-up can be performed. Determine a follow-up time frame at this time.

L. After the determined time period, fill out the Effectiveness Review box to determine if the plan of correction was a success. Whether or not it was successful, close the corrective action after the Effectiveness Review and proceed as follows:

M. If the plan of correction fails and the nonconformity recurs, open a new Corrective Action Report form and begin the process over again from the root cause analysis. Write “Refer to (Previous Report’s Log Number) for details” on the first page to skip the redundant details.

N. Conduct root cause analysis and an effectiveness review until the nonconformity is resolved.

3. Preventive Actions

Responsibility: Lab Management/Quality Personnel/Supervisor

Lab management/Supervisor and quality personnel should periodically review sources of information such as result data, process data, audit results, customer complaints, quality records, and PT results to detect possible causes of nonconformities. When possible nonconforming instances are found in these reviews, they should initiate a preventive action using a corrective action report.

In the first box of the corrective action report form, note that this is a preventive action and the result of data gathering and review, not the result of a specific event. Conduct a root cause analysis and fill out the table with the preventive actions to be taken, based on the findings of the analysis.

All appropriate lab personnel should sign the form and file it with the lab manager/Supervisor until a follow-up can be performed. Determine a follow-up time frame at this point. After the follow-up, fill out the "Effectiveness Review" box to determine if the preventive action was successful. If the preventive action was successful and the nonconformity does not recur, no further action is

necessary. If the preventive action fails and the nonconformity recurs, open a new corrective action report form and begin the process again from the root cause analysis. You can skip the first page by writing "Refer to (previous report's log number) for details." Conduct root cause analysis and an effectiveness review until the nonconformity is resolved.

4. Effectiveness Review

Responsibility: Quality Management/Supervisor Personnel

The purpose of the effectiveness review is to verify the success of corrective or preventive actions. This review will be conducted by Quality Management/Supervisor Personnel by reviewing the appropriate data, providing evidence of conformance, performing audits of processing and testing, and observing operations.

The data reviewed should be appropriate to the nonconformity and the actions taken. Quality Management Personnel should ensure that all corrective or preventive actions have been completed and documented. The effectiveness of the actions taken should be assessed to ensure that the nonconformity has been corrected or prevented.

Based on the results of the effectiveness review, Quality Management/Supervisor Personnel will determine whether any additional actions are necessary. If the actions taken were successful, the corrective or preventive action report should be closed, and the results of the effectiveness review should be documented. If the actions taken were not successful, additional actions should be taken and documented in a new corrective or preventive action report.

Quality Management/Supervisor Personnel should ensure that all corrective and preventive actions are tracked to closure and that the results of all effectiveness reviews are documented.

References:

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CLIA and CAP guidelines

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Appendix A.

Nonconformity	Recurrence to warrant Corrective/Preventive Action
Equipment	Event/error/malfunction that is deemed notable or pervasive by the instrument engineer
Data	Systemic, procedural, or personnel training issue to be address >3 occurrence of a similar nature / individual personnel OR >3 occurrences of similar nature between multiple personnel
Environmental	Unacceptable conditions with QC failure attributed that suspends production for > 24 hours
Analytical	Identifiable trend that lasts for >10 days
Specimen	Identifiable trend with region, sales rep, clinic, client, phlebotomist, etc.
HIPAA	Systemic, procedural, or personnel training issue to be address >1 occurrence of a similar nature / individual personnel OR >1 occurrences of similar nature between multiple personnel
Downtime	Delays in testing/reporting > 24 hours
Incident	Escalate to Corrective Action IMMEDIATELY
FDA Reportable Event	Escalate to Corrective Action IMMEDIATELY