Incident Management Plan

Purpose

This process describes how the laboratory identifies and resolves activities that produce or have the potential to produce clinically significant consequences and/or negative outcomes that occur as a result of laboratory processes.

Policy

- Staff is trained to recognize potential incidents and how to report them.
- Events/errors are documented on a Nonconforming Event Form or a Quality Investigation Form and submitted to the Laboratory Quality Manager or another manager.
- Events/errors are evaluated to determine whether they constitute an incident; that is, whether they have the potential to result in death or serious injury for patients or laboratory staff.
- Events/errors that are determined to be incidents are documented on Quality Investigation Form.
- Incidents determined to be of sufficient merit are brought to the attention of the Laboratory Director as soon as possible.
- Incidents are investigated, managed, and evaluated to determine the true or root cause, then corrected, reported and communicated to prevent future incidents.
- Documentation of each incident is signed by the Laboratory Director and Manager, indicating approval of the overall process.

Scope

This process includes responsibilities for all laboratory staff, managers, the laboratory operations director and laboratory director.

This process includes incidents that occur as a result of:

- Non-compliance with expected laboratory policies and procedures resulting in a significant negative impact on patient care or the safety of patients or staff;

and

- Errors, accidents, or unexpected events that caused, or have the potential to cause, death or serious injury to patients or staff.

Forms

- Nonconforming Event Form
- Quality Investigation Form

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Special Safety Precautions

Refer to the safety manual for general safety requirements.

Definitions

Causal factors – issues or reasons that lead to the outcome of an event. Causal factors include:

- Equipment problems
- Control problems
- Environmental factors
- Human errors

Incident – an event that results in or has the potential to result in death or serious injury for patients or laboratory staff.

Incident Management Plan – written policies and procedures that describe the actions to be taken in response to an incident. This process is an extension to the overall laboratory quality assurance plan.

Systemic noncompliance – a condition where recurring noncompliance with stated policies and procedures in several phases of related laboratory activities has the potential to seriously impact laboratory testing.

Systems - the processes an organization has in place to ensure patient safety and to encourage personnel to take the appropriate actions and discourage them from taking inappropriate actions.

True Cause Analysis – steps taken to investigate the incident and determine the true or underlying cause of the occurrence. (May also be referred to as Root Cause Analysis.)

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Procedure: Completing the Written Investigation

Step	Action
1.	Laboratory staff documents an event or error that has the potential to become an incident on a Nonconforming Event form. Examples include: • Analytical processes such as incorrect test results that lead to misdiagnosis or improper treatment. • Safety issues such as accidents or improper disposal of contaminated waste causing injury to staff or patients. • Test tracking errors such as reporting a result on the wrong patient or mislabeling of a specimen leading to disastrous results. • Recurring complaints such as patients reporting excessive pain, burning, numbness or tingling from phlebotomy that could indicate an injury from the procedure.
2.	Laboratory staff submits the Nonconforming Event form to a laboratory manager or the quality manager for evaluation as an incident as soon as possible. Any materials that could be involved in the incident are retained for the investigation.
3.	The laboratory manager or quality manager evaluates an event/error determined to be an incident to ascertain whether it has sufficient merit to warrant notification of the laboratory manager and director as soon as possible.

If the incident	**Then** the laboratory manager or quality manager
Has sufficient merit	Notifies the laboratory manager and director as soon as possible
Does not have sufficient merit for notification as soon as possible	Completes the Nonconforming Event form and submits it to the quality manager, who will obtain signatures from the laboratory manager and director

4.	The laboratory manager or quality manager determines if any outside agency reporting requirements apply to the incident. The ordering physician is notified, if appropriate.

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Procedure: Completing the Written Investigation, **continued**

Step	Action
5.	The director or designated manager performs the evaluation and investigation of the incident. • Unlike a routine quality assurance review, the serious nature of the incident makes it important that someone with appropriate technical knowledge and experience evaluates the incident. • The individual must have the authority to recommend changes in policy, procedure, and process to effectively resolve and prevent a recurrence of the incident.
6.	The designated incident investigator analyzes the impact of the incident: • During the time prior to the initial report of the incident • During the investigation of the incident • For future testing **Notes:** • It may be prudent to suspend testing or make other treatment decisions until the true cause has been determined and corrected. • There may be a need to notify affected patients and re-evaluate their medical care.
7.	The incident investigator performs a true (root) cause analysis. (See Procedure: *Completing the Written Investigation*)
8.	The incident investigator • Documents the facts, findings, and conclusion on the Quality Investigation Form and • Gives the report to the laboratory quality manager
9.	The laboratory quality manager • Documents the incident on the Incident Management Tracking Form and • Submits the Investigation Report form to the laboratory manager and director for review and signature.
10.	Based on the findings, the laboratory director or designated manager determines the appropriate corrective actions to prevent a recurrence of the incident. • Establish a timeline for implementation of corrective actions. • Document the date that each corrective action is completed.

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Procedure: Completing the Written Investigation, **continued**

Step	Action
11.	The investigation findings and outcome are communicated to staff. • Complete policy or procedure revisions. • Retrain personnel as appropriate.
12.	The laboratory director or designee performs a follow-up evaluation (within a pre-determined amount of time) of the corrective actions to ensure that they were effective.

Procedure: Completing the True (Root) Cause Analysis

Step	Action
1.	Ask "why" at least five times to dig progressively deeper to reach the true underlying cause of the situation. Many contributing factors may be uncovered while striving to identify the true cause to the incident.
2.	A "true cause analysis" could be performed by mapping or flowcharting the events and circumstances surrounding the event. All steps in the analysis must be thorough and credible.
3.	All causal factors, barriers, and system issues are identified with an indication of how each impacted the incident. Once all the facts of the case are known, the true cause is identified. **Notes:** • True causes are the weaknesses in the system that allows the causal factors to occur. • If the true cause is not addressed, the event is likely to repeat in the future.
4.	A corrective action plan is developed and implemented. The focus should be on the systems and processes, not individual performance, i.e., written procedures and instructions, maintenance and calibration, and standards and policies.
5.	Final step is to follow-up within a pre-determined amount of time to ensure that the corrective action plan is effective.

Incident Management Plan

Non-Controlled Documents

The following non-controlled documents support this policy.

COLA Lab Guide 71: Incident Management: Developing a Plan. COLA 2/10.

Controlled Documents

Process
Procedure
National Sentinel Event Management Policy and Procedure NATL.HQDCDE.001
Quality Management and Improvement Program
Reporting Device-Related Adverse Patient Events
Form
Nonconforming Event Form
Quality Investigation Form

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