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# Policy

## Policy

This procedure describes the steps required to report, categorize, investigate, analyze, track and summarize occurrences involving the lab.

## Procedure

### Report occurrences using the Corrective Action Report Form (Quality Manual Attachment 8 Corrective Action Report form).

### **Note.** The Corrective Action report investigation must be initiated immediately upon identification of any occurrence. Timeliness in the investigation and reporting of any occurrence is essential. The investigation should be opened as soon as the non-conformance is discovered should be reported to the Laboratory Director within 24 hours for review.

### **The following 6 steps must be performed in the corrective action**

#### Record how the non-conformity was detected (ie internal audit, External audit, Customer complaint, etc)

#### Describe the nature of the non-conformity and who detected the non-conformity.

##### People involved in committing, compounding, detecting, investigating, resolving the issue

##### Patient identification (Case number)

##### Laboratory where the non-conformance occurred

##### Succinct statement of event, effects, outcome to the patient

#### Perform an investigation and Root Cause analysis of the non-conformity

##### What were the contributing factors

##### Conclusion of why and how the event occurred

##### Lot numbers of reagents if applicable

#### Corrective Action: Describe the action(s) taken to eliminate the cause of the non-conformity

##### Recommended/final actions (corrective/preventive)

##### Implementation dates

#### Categorize the occurrence according to the following classifications:

##### **Class IV** – Major occurrence, immediate harm, life threatening to patient, donor, employee, or potential harm without intervention. I.e. sentinel event.

##### **Class III**– Major Occurrence, potential harm to patient, donor, employee, or big financial impact. i.e. near miss of a sentinel event

##### **Class II** – Medium level occurrence, no serious harm to patient, donor, and employee. Involvement of a non-lab department or customer complaint. I.e. patient complaints, physician office complaints, donor complaints, reporting errors.

##### **Class I** – Internal occurrence, no harm to anyone. I.e. lack of documentation of an event, typographical errors that do not incur above consequences.

#### Verification of the Effectiveness of the Corrective Action

##### Determine if the Corrective action is effective or not effective. If no effective issue new CAR

### Have the report reviewed by the appropriate supervisor(s), Laboratory Manager and Laboratory Director.

### Summarize occurrences quarterly in the Department QA Summary.

## References

### A Quality System Model for Health Care; Approved Guideline, NCCLS GP26-A Vol. 19 No. 20. 1999.

### Quality Systems for the Laboratory. Berte, Lucia and Nevalainen, David. ASCP Press, 2000.

**Revision History**

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| --- | --- | --- | --- |
| Revision Number | Reason for Revision | Author | Effective Date |
| 0 | Change company name and SOP number, reformat Quality System, Add CEO signature Line, clarification of record retention policy. Revise steps needed for corrective action | Sarah Jacobs-Helber | Upon Signatures |

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| --- |
| **Review & Approval History** |
| **Printed Name** | **Signature** | **Date** |
| Sarah Jacobs-Helber, PhD HCLD(ABB), Laboratory Director |  |  |
| William Miller, HTL, MBA Chief Executive Officer |  |  |

**Reviewed by:**

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