| theranos redefining healthcare | Quality Operating Procedure | Document Number: CL QOP-00008<br>Revision: A |
|---|---|---|
| | CLIA Laboratory | Effective Date: 06/09/2011 |
| Corrective and Preventative Action | | |

CONTROLLED DOCUMENT

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## 1. PURPOSE

1.1. The purpose of this procedure is to provide procedures for the corrective and preventative action (CAPA) programs in the CLIA Laboratory. More specifically, the procedures provide for a system and instructions, and an assignment of responsibilities for initiating, requesting, implementing, and verifying the effectiveness of corrective and preventative actions.

## 2. SCOPE

2.1. This procedure applies to the following categories:

2.1.1. Nonconforming events

2.1.2. Incidents

2.1.3. Deviations

## 3. DEFINITIONS AND ABBREVIATIONS

3.1

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|---|---|
| Adverse event | Untoward incident or occurrence associated with healthcare services. |
| Corrective action | Action to eliminate the (root) cause of a nonconformity or other undesirable situation. |
| Deviation | Departure from a particular requirement usually for a specified timeframe. |
| DAR | Deviation Action Request- request for authorization to depart from a particular requirement. |
| Error | 1) Mistake (that usually does not rise to level of an incident)<br>2) Part of a mistake classification scheme, such as cognitive error, latent error, noncognitive error. |
| Mistake | Failure to formulate the right intention or execute the right procedure or plan. |
| Incident/Occurrence | Something that happens that does not conform to established policies, processes or procedures. |
| Nonconformance | Nonfulfillment of a requirement. |
| Preventative action | Action taken to eliminate the cause of a potential nonconformity or other undesirable potential situation. |
| Process | Interrelated activities which transform inputs into outputs. |
| Remedial action | Action taken to rectify a recognized nonconformance. |
| Root cause analysis (RCA) | Process for identifying the basic or causal factor(s) that underlies variation in performance, including the possible occurrence of a sentinel event. |
| Sentinel event | Unexpected occurrence causing death or serious injury or risk thereof. |

3.2 Examples of nonconformances and incidents by categories:

3.2.1 Sample Accessioning/Handling: error logging in specimen, aliquot

tube mislabeled.

3.2.2 QC errors: QC not performed correctly, results verified before QC completed.

3.2.3 Testing errors: Tests performed ≠ tests ordered, .testing not performed correctly.

3.2.4 Instrument errors: bubbles in lines, fluctuating power supply.

3.2.5 Reagent problems: Change in lot overlooked, expired lot, improperly prepared reagent.

3.2.6 Calibration problems: wrong calibration values used, calibrator expired.

3.2.7 Data entry or transcription errors, calculation errors, interpretation errors.

3.2.8 Failure to communicate critical values.

3.2.9 Testing delayed.

## 4. RESPONSIBILITIES

4.1. It is the responsibility of all laboratory personnel to bring to the attention of their supervisors or managers any nonconformity, incident or potential need for a deviation.

4.2. It is responsibility of supervisors and managers to investigate (root) causes of nonconformities and incidents and, following review by the Quality Manager, designee or Laboratory Director, implement remedial, corrective and preventative actions.

4.3. It is the responsibility of the Quality Manager, designee or Laboratory Director to uncover nonconformances during internal audits, review RCAs and CAPA proposals and monitor the effectiveness of the latter. It is also the responsibility of the Laboratory Director to review and approve DARs.

## 5. PROCEDURE

5.1. Managing nonconforming events and incidents have many elements in similar:

5.1.1. Identification and reporting

5.1.1.1. Any staff person who recognizes or is made aware of a nonconforming event or incident initiates a report:

5.1.1.1.1. Properly trained staff may come across and recognize such occurrences during the course of their work.

5.1.1.1.2. Results of internal or external audits

5.1.1.1.3. External sources such as vendors or customers.

5.1.1.2. Fill out the Incident Log form CL FRM-00008-F1 if an incident.

5.1.1.3. Fill out page 1 of the Occurrence Report Form CL FRM-00008-F2 as appropriate.

5.1.2. Initial remedial action- Depending on the nature of the occurrence, the reporting staff member or supervisor may take action to resolve the immediate problem and document the action taken.

5.1.3. Investigation and documenting- usually by a supervisor, manager, and/or the Quality Manager or designee with review by the Laboratory Director as appropriate to the severity of the problem. (Refer to CLSI publication GP32-A appendix B for severity classification and appendix E for the formal process of investigation/RCA. Minor quality issues do not require formal investigation and reporting.) In summary:

5.1.3.1. Were processes and procedures adhered to?

5.1.3.2. Were processes and procedures adequate?

5.1.3.3. Review training and competency of stall involved

5.1.3.4. Investigate and conduct interviews to determine

5.1.3.4.1. Who was involved?

5.1.3.4.2. When did it occur, when identified, when reported?

5.1.3.4.3. How the problem was identified?

5.1.3.4.4. How the event happened and why it occurred?

5.1.3.4.5. What behavior, if any, led to the error?

5.1.3.4.6. What was the outcome?

5.1.3.5. Conduct tests to evaluate measure and verify the cause(s) as appropriate

5.1.3.6. . If patient results are released prior to identifying an occurrence, then the laboratory needs to make a decision based on investigation:

5.1.3.6.1. Allow the results to stand (a nonconformance) and justify the results based on the investigation.

5.1.3.6.2. Notify the physician that there is a problem, the results may not be valid and seek permission to retest.

5.1.3.7. Assess potential impact of the event

5.1.3.8. Complete the investigation documentation elements of the above form.

5.1.4. Action plan and follow-up. If an investigation generates a need for corrective action, the staff member to whom it is assigned will take and the recommended corrective action(s) to eliminate the (root) cause(s), document the actions taken and the results, and provide a time frame for following up to verify effectiveness.

5.1.5. Analysis. The data is analyzed by the Quality Manager or designee for trends and patterns. (See CLSI publication GP32-A appendix C.)

5.1.6. Management review. Information about nonconforming events or incidents is presented to the Laboratory Director for review and follow-up. Catastrophic or major nonconforming events or incidents are also presented to executive management for follow-up and formal process improvement initiatives.

5.1.7. Refer to the Quality Assessment Protocol CL QOP-00007 section 10.9 for further procedures regarding the Corrective and Preventative Action Programs.

5.1.8. Closure

5.1.8.1. Have all of the objectives been met?

5.1.8.2. Have all recommended changes been completed and verified?

5.1.8.3. Has training and appropriate communications been implemented to assure that all relevant employees understand the situation and the changes that have been made?

5.1.8.4. Has the investigation demonstrated that that the actions taken have not had any additional adverse effect?"

5.2. Deviations

5.2.1. Deviations are classified qualitatively by their originators in two ways:

5.2.1.1. By severity as critical (i.e., highly significant effect on safety or health), major (significant effect on health or performance), or minor (does not involve factors listed as critical or major). (This may be modified following review by the supervisor, Quality Manager or designee.)

5.2.1.2. As planned or unplanned

5.2.2. Unplanned deviations are usually reported as nonconforming events.

5.2.3. .A Deviation Action Request form (CL FRM-00008-F3) will be completed by a supervisor or manager for consideration of a planned deviation.

5.2.4. Refer to the Quality Assessment Protocol CL QOP-00007 section 10.9.3 for procedures related to monitoring DARS.

## 6. RECORDS

6.1. Records relating to nonconforming events, incidents and deviations will be stored for 3 years per CL QOP-00010 Record and Specimen Retention.

## 7. ATTACHMENTS

7.1. CL FRM-00008-F1 Incident Log

7.2. CL FRM-00008-F2 Occurrence Report

7.3. CL FRM-00008-F3 Deviation Action Request

## 8. REFERENCES

8.1. CL QOP-00010 Record and Specimen Retention

8.2. CL QOP-00007 Quality Assessment Protocol

8.3. Management of Nonconforming Laboratory Events; Approved Guideline. GP32-A, CLSI, 2007.

8.4. Valenstein P, ed. Quality Management in Clinical Laboratories. College of American Pathologists, 2005.

## 9. REVISION HISTORY

| REVISION HISTORY | | | |
|---|---|---|---|
| **Revision Level** | **Effective Date** | **Initiator** | **ECO Number** |
| A | 06/09/2011 | A. Gelb | CL ECO-00001 |
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| **Section Number** | **Description and Justification of Changes** | | |
| **ALL** | Initial Release | | |
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