

TGA Sciences Quality Assurance Documentation System

<small>TITLE</small> Corrective and Preventative Actions (CAPA)			<small>DOC NUMBER</small> GP-01-06
			<small>VERSION NUMBER</small> T-001
<small>EFFECTIVE DATE</small> March 22, 2007	<small>SUPERSEDES</small> New	<small>LOT NUMBER</small> n/a	<small>PAGE NUMBER</small> 1 of 5

1.0 PURPOSE AND INTRODUCTION

- 1.1 To provide a system with intent of continuous improvement that shall capture issues in order to eliminate potential causes for deviations. This procedure assigns responsibilities for initiating, executing and verifying the effectiveness of corrective and preventive actions.

2.0 REFERENCED DOCUMENTS

- 2.1 21 CFR 211
 2.2 21 CFR 58

3.0 RESPONSIBILITIES AND PRECAUTIONS

- 3.1 It is the responsibility of all laboratory personnel to understand and comply with this procedure. All investigations must be brought to the attention of QA.
- 3.2 It is the responsibility of QA to review the CAPA taken or review the submitted plan for completeness.

4.0 DEFINITIONS

- 4.1 **Corrective Action:** Actions taken to eliminate the cause(s) of an existing non-conformity, defect or other undesirable situation in order to prevent recurrence. Corrective actions are initiated in response to the identification and/or request of deviations relating to testing with quality impact or quality systems. The action may involve changes in order to achieve quality improvement at any stage of the quality loop.
- 4.2 **Corrective action request:** A form that documents an existing or potential non-conformity and subsequent corrective and /or preventative actions.
- 4.3 **Investigation:** A comprehensive review of real or alleged issues related to a deviation.
- 4.4 **Management with executive responsibility:** Senior employees at the testing laboratory who have the authority to establish or make changes to the testing policies and quality systems.
- 4.5 **Deviation:** Non-fulfillment of a specified requirement. The departure or absence of one or more quality characteristics, including dependability characteristics or quality system elements from specified requirements.
- 4.6 **Preventive Action:** Actions taken to eliminate the cause(s) of a potential deviation, defect or other undesirable situation in order to prevent occurrence. Preventive actions are usually initiated in response to trend analysis/reports of key quality indicators or processes.
- 4.7 **Root cause:** A fundamental deficiency that results in a deviation and must be corrected to prevent recurrence of the same or similar deviations.
- 4.8 **Trend:** Evidence that the data is demonstrating a tendency in a certain direction.

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5.0 EQUIPMENT AND MATERIALS

5.1 Not applicable.

6.0 PROCEDURE

6.1 Issue identification and initial failure investigation.

- 6.1.1 Any employee who learns of a deviation or potential deviation related to testing or a quality system shall immediately review the information with his/her manager. The issue shall also be brought to the attention of Quality Assurance (QA).
- 6.1.2 Corrective actions and preventive actions should usually be generated from the following events:
- Customer complaint
 - Process/procedure deviations
 - Out-of-tolerance occurrence
 - Audit observations (supplier, internal, or third party)
 - Other occurrences that do not comply with the documented quality system and/or the regulatory standard and cannot be resolved through standard channels of communication.
- 6.1.3 QA shall review the information with the appropriate personnel and document the initial definition of the problem and determine if any immediate short term corrective action is required.

6.2 Assignment of required action

- 6.2.1 If additional testing or review of information confirms that a deviation exists, QA shall record the failure/issue on the corrective action request (attachment 7.1).
- 6.2.2 QA shall also identify the corrective/preventive action leader that shall investigate the magnitude and root cause for the failure and recommended corrective action.
- 6.2.3 For tracking purpose, QA shall assign a corrective action number.
- 6.2.4 Corrective action request may be entered in a database for trending purposes only.
- 6.2.5 Whenever possible, QA shall target a completion date within 30 calendar days of the finding.
- 6.2.6 The corrective/preventive action shall be marked to indicate whether the action is preventive or corrective.

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6.3 Corrective and Preventive Action

- 6.3.1 The assigned corrective action leader shall review and sign the corrective action request to indicate acknowledgement of the request and the target due date.
- 6.3.2 The individual shall then perform a thorough root cause analysis and identify the recommended action(s). The actions may be short term and/or long term.
- 6.3.3 If appropriate, the individual assigned to the corrective action request should implement the short or long term corrective actions or provide an implementation plan.
- 6.3.4 The individual shall implement the actions. Ensure that all training is adequately documented, and maintain training records.

6.4 Verification Activities

- 6.4.1 QA shall review the actions taken or review the submitted plan for completeness.
- 6.4.2 If further action is necessary, QA shall document the verification activities that were performed on the corrective action request. Objective evidence should be attached.
- 6.4.3 The effectiveness of the implemented actions shall be monitored through elements of the quality system supporting this procedure.

7.0 ATTACHMENTS

NOTICE

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7.1 Corrective/Preventative Action Request

1. Initial Assessment

Corrective or Preventive Action Number _____

Reason for corrective or preventive action _____

Initial definition of problem

Short term corrective/preventive action (required):

Additional Testing or Information

Corrective/preventive action leader assigned: _____

Target Completion Date: _____

Corrective Action

Preventive Action

Corrective/Preventive Action Leader: _____ Date: _____

QA Review: _____ Date: _____

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2. Corrective/Preventive Action Investigation and Recommendation:

Attach investigation and root cause information.

Record short and long term corrective/preventive action:

Implementation Plan:

Corrective/Preventive Action Leader: _____

Date: _____

QA Review: _____

Date: _____

3. Verification Activities

Actions taken or the submitted plan is complete.

Corrective Action

Preventive Action

Attach additional information.

Effectiveness of corrective/preventive action:

Completion Date: _____

QA Review: _____

Date: _____