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| VERSION NO. 1 | MANUAL TITLE QUALITY MANUAL | DOCUMENT NO. QM 13.4 |
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1.0 OBJECTIVES

- 1.1 To establish and maintain documented information for the implementation of corrective action.
- 1.2 To maintain a system in controlling the root cause of the problem by correcting the cause and taking action to prevent recurrence of the nonconformance in the quality management system.

2.0 SCOPE

This procedure covers activities of the following and the controls necessary to ensure that appropriate corrections and corrective actions are taken and such actions are effective to rectify nonconformances noted:


- System nonconformance identified during Internal Quality Audits
- Customer feedback
- Problems identified by management
- Inefficiencies or weak controls identified by process performers.

3.0 POLICIES

- 3.1 Corrective Action Request (CAR) shall be raised as a result of the following:
 - Noncompliances detected during scheduled and unscheduled audits
 - Customer feedback
- 3.2 All employees as appropriate shall initiate corrections and corrective actions to ensure that changes have been addressed. All corrective actions shall be reported to the QMR and to the persons whose work affects the quality of products/service.
- 3.3 Assessment of the underlying cause of nonconformities noted shall be made by the employees concerned with the assistance as required by the Heads. Such assessment shall be recorded on the CAR form as a result of the following:




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- Audit – The Institution shall conduct an Internal Quality Audit as discussed in QM 13.2 Internal Quality Audit.
- Customer Feedback – Heads and employees shall record any customer feedback and report to management.
- Nonconformity - Heads and employees shall report and document any nonconformities encountered in the performance of the quality management system and procedures.

- 3.4 Reference No. in the CAR shall be: XY-ZZZZ where
- X – A for audit, C for complaint, N for nonconformity
 - Y – number in series for the year
 - ZZZZ – year
- 3.5 The QMSO shall be responsible for maintaining the CAR Status Log and ensuring that all CARs are properly closed.
- 3.6 The CAR shall not be closed out if the action taken has not been effective in correcting the deficiency and/or preventing recurrence.
- 3.7 The institution shall implement and record any changes to the documented information resulting from corrective action.
- 3.8 Results of corrective actions should be reported during the management review.




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4.0 PROCEDURES

| Responsibility | Activity |
|--------------------------------|---|
| IQA/Head Concerned | <ol style="list-style-type: none"> Identifies nonconformities, inefficiencies or weaknesses of the system. Discusses findings with Auditee/personnel concerned and documents said findings on the CAR. |
| Auditee/Personnel Concerned | <ol style="list-style-type: none"> Agrees with Auditor/personnel concerned on the date of completion of correction/corrective action/s and signs CAR. |
| IQA/Head Concerned | <ol style="list-style-type: none"> Provides copies of the CAR to the Head concerned and to the QMR/QMSO. |
| QMR/QMSO | <ol style="list-style-type: none"> Updates the CAR Status Log. |
| Auditee/Personnel Concerned | <ol style="list-style-type: none"> Determines correction/s to control and address the findings and deal with the consequences. Determines the cause/s of the findings and if similar findings exist, or could potentially occur. Implements corrective action/s based on the result of the root cause analysis (e.g. fish bone diagram). |
| IQA/Head Concerned | <ol style="list-style-type: none"> On the scheduled date of completion of correction and corrective action, checks and reviews the effectiveness of any corrective action taken. If action/s taken are deemed to be effective in correcting deficiency and/or preventing recurrence, completes the "Follow-up" portion of the CAR. |



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| Responsibility | Activity |
|----------------------------|---|
| IQA/Head Concerned | 11. If deficiency is not addressed, schedules another follow-up audit with Auditee/personnel concerned. 12. If after three (3) follow-up audits, the deficiency is still not addressed, prepares a new CAR, as necessary, and indicates old CAR number on the new CAR. |
| QMR | 13. Informs Head on status of nonconformity noted. 14. Updates risks and opportunities determined during planning with the Auditee/Personnel concerned, if necessary. |
| QMR/Document Controller | 15. Makes changes to the quality management system, if necessary. 16. Completes the "Close Out" portion of the CAR. |
| QMR/QMSO | 17. Updates the CAR Status Log. 18. Maintains files of all documents that contain data associated with nonconformities. |

5.0 LIST OF FORMS AND REPORTS

5.1 Forms

- 5.1.1 Corrective Action Request Form
- 5.1.2 CAR Status Log

5.2 Reports

None

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