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QMS PROCEDURES

Corrective Action

CORRECTIVE ACTION PROCEDURE

1.0. Scope

This procedure shall cover all corrective actions that can be done to address a nonconformity which can affect the NLP Quality Management System.

2.0. Definition of Terms

Correction
Action to eliminate a detected nonconformity.

Corrective Action
Action to eliminate the cause of a nonconformity and to prevent recurrence.

Conformity
Fulfillment of a requirement.

Nonconformity (NC)
Failure to comply with a requirement.

Opportunity for Improvement (OFI)
An observed situation which is not a nonconformity but where the results achieved may not be optimal, less than well-organized, or over complicated.

Request for Action (RFA)
Document used to record a nonconformity or an opportunity for improvement; identify the root cause of the nonconformity; and determine correction and corrective action.

Root Cause Analysis
A structured investigation that aims to identify the true cause of a response of a problem and the actions necessary to eliminate it

3.0. Procedure

3.1. Individual product and/or service issues should be written up following the procedures laid down in the Control of Nonconformity. When trends are noticed within nonconforming products, an RFA may be issued to investigate the cause of the trend.

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3.2 The NLP Corrective Action procedure uses two forms:

3.2.1. The RFA, which is used to request for action, or to submit suggestions for improvement.

3.2.2. The Request for Action Log, which is used to track the Requests for Action and provide trend data on the corrective actions for later management review.

3.3. The RFA will be forwarded to the IQA Team, who will begin an entry for the RFA by assigning a control number and entering the information in the Request for Action Log. The information entered should match that on the RFA. The Request for Action Log is maintained by the IQA Team and shall be used to generate trend reports for corrective actions, which will then be reported during the management review.

3.4 A nonconformity that has appeared more than twice in the Request for Action Log shall be subjected to root cause analysis.

3.5. The process owner shall conduct a root cause analysis to determine the cause(s) of the problem. This exercise should be thoughtful and detailed, so as to ensure the actual root causes are identified. Failure to properly conduct root cause analysis may result in the wrong cause being acted upon, and thus the problem not being permanently resolved.

3.5.1. Root cause analysis is mandatory for corrective actions. Root cause analysis may also be conducted for opportunities for improvement.

3.5.2. The process owner will then develop and implement an action plan to address the root cause and eliminate it. By eliminating the root cause, the problem should never occur or recur.

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3.5.3. Once the action is complete and the issue is resolved, the process owner will sign the RFA and indicate a completion date. They shall then return the form to the IQA Team.

3.5.4. The IQA Team will update the log entry for the form, indicating the date that the RFA is closed.

3.6. All RFAs should be responded to immediately. The process owner shall determine the level of priority of a requested action based on the following criteria:

- LOW: Respond as availability allows; may extend deadline with permission of Top Management.
- MEDIUM: Respond as soon as feasible; deadline established, but may be interrupted by higher priority activities.
- HIGH: Respond by established deadline, which may interrupt other staff working low or medium priority activities.

3.7. The QMS Leader will perform independent verification of the actions taken to ensure the actions are effective in resolving the root cause(s). The QMS Leader may also designate any member of the QMS Champions to conduct the verification. In case of RFAs that result from audit findings, the IQA Team shall perform the independent verification.

3.7.1. This verification should examine evidence and take into consideration the following:

- Has the action plan removed the root cause(s)?
- Does the action appear to eliminate the original issue reported?
- Were any related documents updated, as needed?
- Was training conducted, if required?
- Does the action require an update to the internal audit schedule?
- Were all interested parties properly notified of the actions taken?

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3.7.2. The IQA Team will record the results of the verification activity in the Request For Action Log.

3.8. If the issue is satisfactorily addressed, the IQA Team may close the particular request for action by indicating this in the final column on Log. The Request for Action form is then filed.

3.9. If the IQA Team determines the issue is not properly addressed, a new RFA will be filed and its filing indicated in the log.

4. Forms and Records

1.4.1. Request for Action Log
1.4.2. Request for Action Form

5.0. References

5.1. NLP Quality Manual
5.2. NLP Work Instructions
5.3. NLP Maintenance of Documented Information Procedure
5.4. NLP Retention of Documented Information Procedure
5.5. NLP Internal Quality Audit Procedure
5.6. NLP Control of Nonconformity Procedure
5.7. NLP Customer Satisfaction Management Procedure

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6.0. Approval

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