DPC: Corrective Action

Corrective actions

4.9.2

Laboratories may experience technical or administrative nonconformities. These occurrences can be adverse to the quality of the work product and/or the integrity of evidence. Nonconformities are defined as Level I or II, depending on the impact. The level of nonconformity will be considered in determining the course of corrective action and root cause analysis.

When there is doubt about the laboratory's continued compliance of policies and procedures or that non-conforming work will continue, a corrective action will be initiated.

The purpose of the corrective action is to identify the root cause of a problem and implement the best solution to prevent reoccurrence. The ultimate goal of this process is to preserve and improve the level of service to the customer.

Levels of nonconformity

4.9.1.c
4.9.1.d
4.11.3

Level 1 (Major Discrepancy): Appropriate laboratory management must be notified immediately of the problem in order to start the corrective action process and, if necessary notify the customer and recall the work. The corrective action process begins by first identifying the root cause of the problem. Once the root cause is determined the problem can be corrected and a solution established in order to prevent a reoccurrence. Level 1 nonconformities generally:

- Are unexpected.
- Require an investigation to determine their root cause.
- Require an intensive corrective action with extensive documentation.
- Have compromised the quality of work product and/or the integrity of evidence.

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Levels of nonconformity (continued)

4.9.1.c
4.11.3

Level 2 (Minor Discrepancy): Corrective actions in these situations are routine and may occur during the day-to-day laboratory operations. The cause of the nonconformance does not, to any significant degree affect the fundamental reliability of the work product of the laboratory or the integrity of evidence. Level 2 nonconformities generally:

- Are foreseeable.
- Have a clear immediate cause.
- Can be addressed by a simple action, which can be documented within existing records, case notes, or technical/administrative review forms.
- If addressed properly, will not in any way compromise the quality of work or integrity of the evidence.

Corrective actions for Level 1 non-conformities

Any employee who identifies a potential Level 1 nonconformity shall inform their immediate supervisor as soon as possible. If the nature of the nonconformity is severe enough, it will be necessary to verbally notify the Laboratory Director and Quality Manager as soon as possible.

4.9.1.a
4.9.1.e

If the nonconformity is related to casework or a procedure, the supervisors, the Laboratory Director, and the DNA Technical Lead have the authority to halt (or resume) work, stop the release of reports, issue amended reports, notify customers, request the return of evidence, and implement any necessary short-term response.

See *DPC: Problems with Procedures* and/or *DPC: Problems with Casework* for additional information.

4.9.1.b

Level 1 corrective actions will typically include a supervisor, the Quality Manager, the Laboratory Director, and the DNA Technical Lead (if appropriate) in addition to other personnel involved when investigating the cause.

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Corrective actions for Level 1 non-conformities (continued)

4.11.2

Root Cause of a Level 1 nonconformity: Root cause may identify multiple contributing factors for the nonconformity, but there is typically only one underlying cause. In order to define the problem the following will need to be considered:

- What happened, what equipment, what method?
- When did it occur-date and time?
- Where did it occur and during what process or procedure?
- How much, how often? – How many times did the incident occur? How many cases affected?
- Impact to the laboratory's goals, customer, work product, and performance measures.
- Who was involved?

Disclosure of a Level 1 Non-compliance to ASCLD/LAB-International: The Laboratory Director shall notify the ASCLD/LAB-International Executive Director within 30 calendar days of determining that a Level 1 non-compliance has occurred. The summary report will include a summary of the occurrence(s) and a statement of actions taken or that plan to be taken by the laboratory. The report will also include:

- Root Cause Analysis of the problem
- Who may be impacted by the occurrence
- Information regarding notification of those who are potentially impacted
- Appropriate action to correct or eliminate the cause of the occurrence

Corrective actions for Level 2 non-conformities

Level 2 nonconformities are addressed by staff. These types of nonconformities are minor deviations from protocol or customer requirements. All level of staff members have the responsibility to identify and address this level of corrective action. Once a staff member has identified an issue, they should bring it up to the appropriate Unit Supervisor.

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DPC: Corrective Action

Examples of corrective action situations

Analyst errors or system errors (proficiency/casework/competency) – would likely be Level 1

- Initiated by the Quality Manager - First Signature
- Assigned to the supervisor or the DNA Technical Lead (if appropriate) - Second Signature
- Final Signature by the Laboratory Director

Procedural Errors – can be level 1 or level 2

- Initiated by an analyst, the supervisor, or the Quality Manager – First Signature
- Assigned to the supervisor or the DNA Technical Lead (if appropriate) – Second Signature
- Final Signature by the Laboratory Director

Audit – can be level 1 or level 2

- Initiated by the auditor – First Signature
- Assigned to the unit supervisor or the DNA Technical Lead (if appropriate) – Second Signature
- Final signature by the Laboratory Director

Filling out the corrective action request form

The initiator of the *Corrective Action Request* form (CAR) fills out the *Finding* section of the form.

The initiator and assigned individual investigate the cause analysis. The assigned individual fills out the "Cause Analysis" and "Action Plan" in the *Action Plan* section. The "Action Plan Approved By" and "Action Due By" are filled out by the Quality Manager or DNA Technical Lead (if appropriate).

NOTE: All *Corrective Action Request* forms must be completed within 90 calendar days of the initiation date. The Laboratory Director may extend the due date as necessary and will notify all appropriate parties.

After the corrective action is implemented, the initiator fills out the *Corrective Action* section.

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DPC: Corrective Action

Filling out the corrective action request form (continued)

After the nonconformance has been addressed and measures are put in place to prevent reoccurrence, the initiator will sign followed by the assigned individual.

The Laboratory Director signs the *Corrective Action Request* after all of the steps have been satisfied, the action plan is approved, and the corrective action is complete.

Implementing a course of corrective action

4.11.3

A course of corrective action may involve retraining with emphasis on the correct or improved method to be used by the analyst.

The retraining process may include input from the supervisor, the trainer, the DNA Technical Lead (if appropriate), and the Laboratory Director.

The course of retraining must be broad enough in scope to

- Encompass the problem at hand
- Direct the analyst to acceptable levels of quality casework

A competency test must be successfully completed by the analyst at the completion of retraining (see *AQR: Competency Testing* in the *Quality Manual*).

4.11.4

Following a corrective action and for a period of time determined by the supervisor, the supervisor will closely monitor the casework of the analyst. This may entail

- Observation by the supervisor or a peer analyst
- Re-examination of work by a peer analyst

Continued on next page

DPC: Corrective Action, Continued

Dispute resolution

There may be times when the analyst and peer group do not agree as to the form or extent of the change in procedure required. If this occurs, the supervisor should attempt to facilitate a resolution.

There may be times when those involved in the problem review process do not agree as to the form or extent of the corrective action required.

Disputes that cannot be settled are brought by the supervisor to the Laboratory Director for resolution.

Special audits

4.11.5

A special discipline audit may be warranted when the findings of non-conformity or departures from procedures indicates a significant problem within the discipline. The laboratory will ensure that the scope of the audit is within the appropriate areas of activity.

Special audits will be conducted as described in *Quality Audits,* located in the *Quality Manual*.