

DPC: Control of Non-Conforming Work

Introduction

This policy addresses those instances when work does not conform to procedures by either

4.9.1

- A departure from procedure
- Non-conforming work that is identified after-the-fact

The goal of the technical problem review process resulting from non-conforming work is to improve the quality of service to the laboratory's customers. To accomplish this, emphasis is placed on identifying and *correcting* problems.

Continued on next page

DPC: Control of Non-Conforming Work, Continued

Departures from procedure

There may occasionally arise unique circumstances on a case-by-case basis where the analyst believes that departure from a documented procedure is warranted. Factors warranting a planned departure from procedure include

4.1.5.a

4.9.1.a

4.9.1.b

4.9.1.c

- amount and condition of the sample
- unique investigative questions

This table gives the procedure for use in departure situations

Step	Action						
1	<p>The analyst completes a <i>Departure from Procedure Request</i> form and submits it to the unit supervisor.</p> <p>NOTE: The supervisor (or DNA Technical Lead for DNA departures) may also initiate this process.</p>						
2	The supervisor (or DNA Technical Lead) reviews the request form. The supervisor will consult peer group members for technical advice as needed.						
3	<table> <tr> <th>If...</th><th>then...</th></tr> <tr> <td>the request is approved</td><td>the supervisor (or DNA Technical Lead) signs the approval line of the form, gives a copy to the Quality Manager, and returns the original to the analyst for insertion into the case file. Now the analyst can perform the departure.</td></tr> <tr> <td>the request is not approved</td><td>the form is returned to the analyst with an explanation for the disapproval. NOTE: Depending on feedback for denial, the analyst may resubmit an alternate request for departure.</td></tr> </table>	If...	then...	the request is approved	the supervisor (or DNA Technical Lead) signs the approval line of the form, gives a copy to the Quality Manager, and returns the original to the analyst for insertion into the case file. Now the analyst can perform the departure.	the request is not approved	the form is returned to the analyst with an explanation for the disapproval. NOTE: Depending on feedback for denial, the analyst may resubmit an alternate request for departure.
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Continued on next page

DPC: Control of Non-Conforming Work, Continued

Identifying non-conforming work

Technical problems resulting from non-conforming work can be identified through

- case record review
 - proficiency tests
 - quality audits
 - supervisor or co-worker observation
 - customer feedback or complaints
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Discrepancies

A course of corrective action often involves evaluating whether the problem is a

- Level 1 (Major nonconformance). Major discrepancies require a root cause analysis in order to determine the underlying reason for the problem and may result in a well-documented investigation, including a “root cause analysis”. Peer groups and management are likely to become involved. See *DPC: Corrective Action* for additional information.
- Level 2 (Minor nonconformance). Minor discrepancies do not affect the overall quality of the analysis. Minor discrepancies are usually straightforward requiring a relatively simple corrective action that may be recorded.

4.9.2

Whenever this evaluation indicates that the non-conforming work could reoccur or there is doubt about the laboratory complying with its own policies and procedures, a corrective action is required.

Continued on next page

DPC: Control of Non-Conforming Work, Continued

Problem investigation

The investigation of technical problems involves

- determining if a problem actually exists
 - determining the severity of the problem
 - determining the impact on other activities within the technical section
 - determining the root cause of the problem
 - developing and reviewing recommended solutions
 - implementing the solutions
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Cause analysis

4.11.2

If it is determined that a significant technical problem exists, then the next step in the development of a correction action plan is to identify the root, or fundamental cause of the problem.

It is understood by management that the root cause of a problem is rarely the fault of any one analyst—although that must be considered during the investigation. In many cases the primary, underlying cause of the problem lies within an unanticipated procedural issue.
