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- Questions and issues raised may be referred to the appropriate TNI committee or decision making body for consideration or action as appropriate.

Assessment Deficiencies: Corrective Actions and Prevention of Repeat Deficiencies

Technical Assistance Committee
Betsy Kent
Part I

Identifying Deficiencies and Implementing Corrective Actions

Identifying Deficiencies

- Select a Team Leader
- Meet with Technical Directors from each Laboratory Section
  - Discuss each deficiency and contact Accreditation Body for clarification(s) if necessary
  - Assign corrective actions
  - Discuss and set firm due dates for each corrective action
Implementing Corrective Actions

- Investigate Root Cause for each deficiencies
  - “Asking why five times”
    - Why didn’t you know the maintenance required documentation? Action – Read the SOP
    - If you didn’t have the SOP, why not?
      Action – Get a copy of the SOP and review
    - If the Technical Director was supposed to write it, why isn’t it complete? Action – Get the Technical Director to write the SOP.

- If the Technical Director was supposed to write it, why isn’t it complete? Action – Get the Technical Director to write the SOP.
- If the Technical Director is too busy, Why is the Technical Director too busy? Action – Get QA staff to help the Technical Director to write the SOP.
Implementing Corrective Actions

- Results of the Root Cause Investigation:
  - Improved training procedures
  - Updated SOPs
  - Evaluation of staffing levels and organization
  - Changes in procedures needed to prevent a repeat deficiency

Implementing Corrective Actions

- Use you Laboratory’s current corrective action documentation procedures, or

- Create a spreadsheet or other document to track progress
  - Deficiency
  - Assigned laboratory section
  - Corrective action
  - Due Date
  - Completion Date
  - Verification Date
  - Comments
### Deficiencies Summary Template

#### Assessment Deficiencies and Corrective Action Tracking Form

<table>
<thead>
<tr>
<th>Deficiency</th>
<th>Lab Section</th>
<th>Corrective Action</th>
<th>Due Date</th>
<th>Completion Date</th>
<th>Verification Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>DO Probe Maintenance Log not current</td>
<td>General Chemistry</td>
<td>Perform maintenance on DO probe and document in log</td>
<td>08/25/07</td>
<td>08/25/07</td>
<td>08/25/07</td>
<td>None</td>
</tr>
<tr>
<td>Quality Manual does not include policy for</td>
<td>Quality</td>
<td>Update Quality Manual to include section for client complaints as specified in</td>
<td>09/15/07</td>
<td>09/30/07</td>
<td>09/30/07</td>
<td>Original Due Date could not be met. A A was contacted and informed of</td>
</tr>
<tr>
<td>dealing with client complaints</td>
<td>Assurance</td>
<td>2005 NELAC Standards</td>
<td></td>
<td></td>
<td></td>
<td>extended due date via email on 0/14/07</td>
</tr>
<tr>
<td>Lot numbers for detergent in use do not</td>
<td>Micro</td>
<td>Replace report for Microbiology Detergent Inhibitory Residue with current</td>
<td>8/25/07</td>
<td>8/25/07</td>
<td>8/25/07</td>
<td>The test had been performed. Documentation could not be located during</td>
</tr>
<tr>
<td>meet lot number on Inhibitory Residue Test</td>
<td></td>
<td>report for detergent lot in use</td>
<td></td>
<td></td>
<td></td>
<td>assessment. The correct report was placed in the Micro QA log</td>
</tr>
<tr>
<td>report</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Proactive

- Include deficiencies as part of your laboratory’s Quality System
  - Include deficiencies as part of your internal audits
- Annual Management Review
  - Address deficiencies from external and internal audits
  - Identify any trends
  - Review laboratory Quality Systems procedures for dealing with deficiencies and corrective actions and revise where necessary.

Consequences of Repeat Deficiencies

- Repeat Deficiencies:
  - Failed Quality System
  - Possibilities of inaccurate results
  - Increased laboratory down time
  - Revocation of certification
  - Loss of revenue
  - Loss of client trust
Conclusions

- The key to preventing repeat deficiencies is on-going verification of corrective actions.

Shared Information

- How does your laboratory prevent repeat deficiencies?