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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.

Implementing Corrective Actions

- 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

Deficiency	Lab Section	Corrective Action	Due Date	Completion Date	Verification Date	Comments
DO Probe Maintenance Log not current	General Chemistry	Perform maintenance on DO probe and document in log	08/25/07	08/25/07	08/25/07	None
Quality Manual does not include policy for dealing with client complaints	Quality Assurance	Update Quality manual to include section for client complaints as specified in 2003 NELAC Standards	09/15/07	09/30/07	09/30/07	Original Due Date could not be met. AA was contacted and informed of extended due date via email on 9/14/07.
Lot numbers for detergent in use do not meet lot number on Inhibitory Residue Test report	Micro	Replace report for Microbiology Detergent Inhibitory Residue with current report for detergent lot in use	8/25/07	8/25/07	8/25/07	The test had been performed. Documentation could not be located during assessment. The correct report was placed in the Micro QA log.

Part II

Preventing Repeat Deficiencies

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?