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Quality Systems

Compliance Mgmt.

Profitability

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Corrective Action Process

Resolving findings and deficiencies the first time and eliminating repeat findings

Repeat Findings

- Assessments are a snapshot of the laboratory operation. They are not intended to find everything.
- Re-occurring findings and deficiencies are a big problem.
- Assessors and accrediting authorities do not take kindly to laboratories not taking comprehensive corrective actions.
- The Quality Systems approach to corrective actions requires that findings be fixed in all areas of the operation.

Repeat Findings

- It is management's responsibility to take each finding and make sure that it is not occurring in any other area of the laboratory.
- Corrective action must address the problem in all areas and for all applicable staff.
- For example:
  - Error correction practices found in the microbiology area quite likely are occurring in other areas of the laboratory.
  - Temperature readings of the refrigerator in the metals extraction area are not taken and recorded each day.

Quality System Indicators

- Internal audits are one of the most important tools that management has to determine how the operation is functioning.
- Corrective actions are the best mechanism for
  - Continuous improvement
  - Assuring that you are not fixing the same problems time after time – and re-inventing the wheel
  - Spotting trends and establishing a preventive action process
  - Maintaining accreditation requirements
- Using the CAP is mandatory – it is not optional.

Corrective Action Process

- The problem with most corrective action processes are
  - They only look at the short term – the quick fix.
  - These "solutions" don't last. (Repeat findings)
  - The process is not used for all corrections – lacks a comprehensive approach.
  - It is only used by select management – not a "grass roots" program.
  - It does not address the root cause.
  - All staff are not trained and encouraged to use the process.
  - There is no follow through and monitoring.

Symptoms vs. Root Cause

- Most assessment findings are symptoms of something more basic .
- Findings usually can be linked to a failure of the Quality System.
- Most findings occur in more than one area of the operation.
- Symptoms usually roll up into Quality System deficiencies.
- Finding the root cause can be confusing and complex.

Root Cause Analysis

- Clearly define the deficiency. Refer to the Standard.
- Ask some questions …
  - Why did this occur?
  - What contributed to the event?
  - How did this happen?
  - Has this occurred before?
  - Where did the previous solution fail?
  - Which of the foundation systems is affected?
  - Fix the symptom … fix the system.
  - Document the solution and monitor the change.

Large Group Exercise

- Root Cause Analysis
  - Error corrections are not performed according to the quality manual and the NELAC Standard in the QA department, metals extractions and sample receiving.
  - Two of the four analysts in the volatile organics area do not follow the requirements of the SOP. The analysis does not match the test method requirements.

Large Group Exercise

- Root Cause Analysis
  - The data on the report does not match the data on the bench sheet, and the assessor could not get the same calculation results from the raw data as from the working spreadsheet.
  - The laboratory has failed three of the last PT samples for Silver. No documented corrective actions were provided.

How to Effectively Address Corrective Actions

- Understand the finding
  - Here you have a decision to make….
  - If you think the assessor mis-understood, make your case
- Prioritize the needed corrective action
- Assign responsibility and timing for completion
  (Make it reasonable and practical, but timely)
- Conduct a Root Cause Analysis *(Random vs. Systemic)*
  - Findings are usually symptoms of something deeper
  - Look for patterns
  - Depth and breadth - other testing areas - analysts - global

How to Effectively Address Corrective Actions

- Define and document the corrective action
  - Process or procedure change
  - Documentation change
  - Training or attitude adjustment, or
  - Some combination of all three
- Gain signoff and approvals
- Train all appropriate personnel on changes
  - This is an important step
  - Do not just assume that staff reads SOPs or change documentation
  - Document

How to Effectively Address Corrective Actions

- Implement changes in all areas necessary
- Update appropriate documentation
- Monitor for implementation & effectiveness
  - Assess the operation within 30 days
  - Monitor in the next several months
    - Include in future internal audits
    - Check other areas or analysts

Closing Corrective Actions

Steps to successfully addressing and closing corrective actions

1. **Analyze** – define the root cause. Determine if a random event or a system failure.
2. Make operational **change(s)** (if warranted).
3. **Document** the changes (memo/policy/change order/training notes).
4. **Train** all appropriate staff. Document the training.
5. **Update SOPS** to reflect proper practice.
6. **Verify** that the changes have been implemented and are effective.

Now…it's your turn!

- What do you think of this information?
- What did I miss?
- What types of successful corrective action processes have you seen? What are the key elements?
- What do you think about the "Steps to closing"?
- What other examples or questions do you have?