Using Root Cause Analysis and Internal Audits to Optimize Your Laboratory's Accreditation Outcomes

November 16, 2011

Objectives

- Understand the value of applying internal audit and root cause analysis techniques
  - Walk through practical lab examples to verify your system is operating effectively
  - Demonstrate the outcome benefits of investing the time to perform proper root cause analysis
- Understand the relevance to today's healthcare environment

The Team

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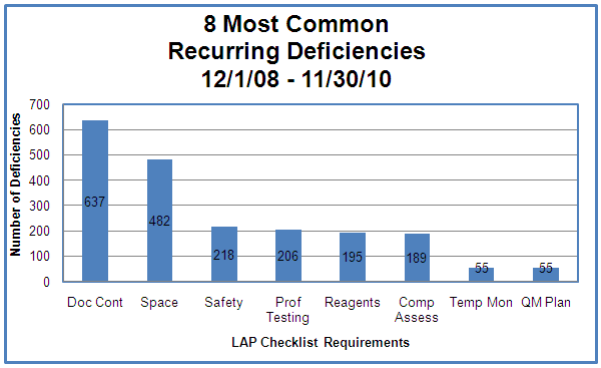
Most Common Recurring Deficiencies



Recurring Deficiencies

- **Would you rather be focused on the future rather than fighting the fires of the past?**
- **Time to reframe our thinking**
- **Bring order to the chaos**

CAP Accreditation & CAP 15189SM Are Complementary

CAP Accreditation

- Exceeds CLIA (required in United States)
- Provides Continuous Compliance
- Focuses on technical procedures and activities for test accuracy and quality improvement
- Monitors laboratory performance against the CAP checklists

CAP15189SM

- Remains voluntary in United States
- Provides Preventive Action
- Focuses on business processes and systems integration for continual improvement and risk mitigation
- Monitors laboratory QMS effectiveness to the ISO15189 standard

From Reactive to Proactive…

Integration of Internal Audits and RCA

- **Reactive**

Proactive

Internal Auditing

What is a true internal audit?

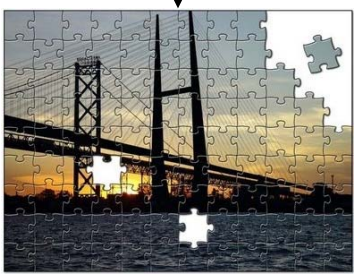
- **A way to evaluate and verify effectiveness of processes, interactions, and associated procedures.**
- **A way to look for areas of potential risk.**
- **A note to keep in mind – a standard defines requirements by category, its up to you to put them into a system.**
- **A good audit is accomplished by evaluating processes and sub processes through the review of procedures and records as well as speaking with and observing people involved in the performance of related activities.**

A good audit is based on 2 ISO principles:

- **Process approach – a desired result is achieved more effectively when activities and related resources are managed as a process.**
- **Systems approach to management – identifying, understanding, and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.**

Processes Are Like Puzzles

We need to put them together into a logical interconnecting flow in order to see the big picture



Is this easy to do?

- **NO!**
- **It takes training, practice, and effort.**
- **Are you up to the challenge?**

Why don't organizations do good internal audits?

- **They don't understand the requirements.**
- **"I don't have time". In this case they do the quickest and shallowest job just to say "I did it", so they can get back to the real work – continually putting out fires because they haven't taken the time to identify and address issues.**

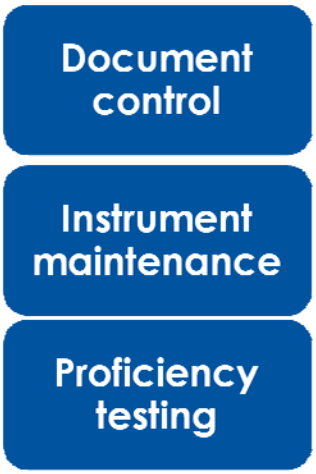
A good auditor is:

- A curious detective following a “scent”.
- A multitasker asking questions, listening to responses, reading procedures and records, thinking of the next question to ask, and taking notes.
- Objective – tries to look at things without bias (difficult to do in your own work environment).

The auditor looks for:

- Procedures where needed and/or required.
- Consistency in following documentation (activities should be somewhat predictable).
- Records to support requirements.
- Effectiveness.
- If something is wrong, the auditor identifies nonconformities or opportunities for improvement.
- Identified issues should focus on the process and system, not individuals. Responses should not focus on retraining the individual or on disciplinary action.

The first internal audit at Lethargy Labs identified major nonconformities in:



Internal Audit Report

ISO 15189 Clause 4.3.2 – Document Control

- **Summary of Clause Description**
- **Procedures shall be adopted to ensure that all documents are:**
  - **Approved by authorized personnel prior to issue**
  - **Available for active use at relevant locations**
  - **Periodically reviewed and revised when necessary**
  - **Promptly removed from all points of use when invalid or obsolete**

Internal Audit Report

Major Non-conformity

Assessor Comment

- **Annual review of blood bank procedures, Specimen Collection manual, and safety policies and procedures has not occurred since 2008.**
- **Handwritten changes in safety policies and procedures made without approval.**
- **No written procedure for the new blood bank computer system that has been in use for over one year.**
- **The specimen collection manual in the Emergency Department is incomplete.**

Internal Audit Report

Corrective Action Responses

- **Procedures reviewed and approved by medical director**
- **Procedure written for blood bank computer system**
- **Specimen Collection manual in Emergency Department has been updated**
- **Documents attached**

Internal Audit Report

ISO 15189 Clause 5.3.2 – Instrument Maintenance

- **Summary of Clause Description**
  - **Equipment shall be shown to be capable of achieving the performance required and shall comply with specifications relevant to the examinations concerned.**
  - **Laboratory management shall establish a program that regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical systems. It shall also have a documented and recorded program of preventive maintenance, which, at a minimum, follows the manufacturer's recommendations.**

Internal Audit Report

Major Non-conformity

Assessor Comment

- **Quarterly maintenance for blood bank instruments was not performed in June 2009.**
- **Reagent and specimen refrigerator temperatures were not recorded many days throughout 2009.**
- **Eyewash stations are not tested regularly.**
- **Chemistry instrument maintenance logs and temperature charts are not reviewed on a monthly basis.**

Internal Audit Report

Corrective Action

- Quarterly maintenance performed in blood bank.
- Email sent out to staff telling them that temperatures must be recorded each day.
- Replace plumbed eyewash stations.
- Monthly evaluation of maintenance logs implemented.
- Evidence presented for each issue.

Internal Audit Report

ISO 15189 Clause 5.6.4 – Proficiency Testing

Summary of Clause Description

- The laboratory shall participate in inter-laboratory comparisons such as those organized by external quality assessment schemes.
- Laboratory management shall monitor the results of external quality assessment and participate in the implementation of corrective actions when control criteria are not fulfilled.

Internal Audit Report

Major Non-conformity

Assessor Comment

- **No corrective action for unacceptable fetal screen and Kleihauer-Betke proficiency testing results on API Survey Event xxxx.**
- **Proficiency testing procedure does not include steps for evaluating ungraded challenges.**

Internal Audit Report

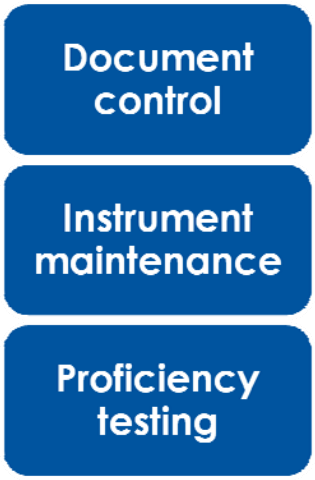
Corrective Action

- **Unacceptable fetal screen and Kleihauer-Betke proficiency test results reviewed and appropriate corrective action taken.**
- **"Proficiency Testing" procedure revised to include evaluation and investigation of ungraded challenges.**
- **Staff educated on revision.**
- **Evidence presented for each issue.**

External Accreditation

- **External accreditation team comes in for an assessment 11 months later.**
- **Guess what area(s) they find problems with?**

-



Document Control – Major Nonconformity

Assessor Comment

- **Annual review of blood bank procedures, Specimen Collection manual, and safety policies and procedures has not occurred since 2008.**
- **Handwritten changes in safety policies and procedures made without approval.**
- **No written procedure for the new blood bank computer system that has been in use for over one year.**
- **The specimen collection manual in the Emergency Department is incomplete.**

Document Control – Major Nonconformity

Immediate Corrective Action

- **Procedures reviewed and approved by medical director.**
- **Procedure written for blood bank computer system.**
- **Specimen Collection manual in Emergency Department has been updated**
- **Procedures submitted.**

Document Control – Major Nonconformity

Root Cause Analysis

- **We assembled a team of individuals from various departments in the laboratory including representatives from pre-analytic, analytic, and post-analytic processes of our quality management system.**
- **After conducting interviews, reviewing the non-conformities and the ISO 15189 requirements the team defined the problem.**

Document Control – Major Nonconformity

1. Problem definition:

- **Document control process does not ensure all documents are approved and reviewed periodically, are available for active use, and invalid or obsolete documents are removed from inadvertent use.**

Document Control – Major Nonconformity

2. Map current process:

- **Our next step was to map the current process. To do this we interviewed staff, reviewed the written document control procedure and audited additional documents to determine the actual process.**
- **Flowchart submitted.**

Document Control – Major Nonconformity

3. Find root cause

- **To determine the root cause or causes of the problem, the team divided the flowchart into smaller sections and treated each step as a possible cause for the problem. We spent time considerable time brainstorming to arrive at the following root causes**

Document Control – Major Nonconformity

Root causes:

- **Document Control procedure does not address all requirements in ISO 15189.**
- **There is no master list of documents that comprise the quality management system to indicate location and number of copies distributed.**
- **The annual review process is left up to each department.**
- **Method Validation checklist does not include "Create/Revise Procedure."**

Document Control – Major Nonconformity

4. Develop solution

- **The team listed all of the ISO 15189 requirements and created a proposed revision to current document control process.**
- **Each team member presented the proposal to staff throughout the laboratory to get feedback on the feasibility of the process.**
- **Some adjustments were made to the new process after all of the ideas and comments were discussed.**
- **Document Control Flowchart submitted.**

Document Control – Major Nonconformity

5. Implement solutions

- Based on findings of a stakeholder analysis we created a change management approach to mitigate risk of implementation failure.
- The team developed an implementation plan that includes the following tasks:
  - Write new document control procedure
  - Create master list of all documents on spreadsheet
  - Utilize Outlook calendars and email for review/approval process
  - Revise Method Validation checklist
- Implementation Plan submitted.

Document Control – Major Nonconformity

6. Assess effectiveness

- To ensure the solutions address the root cause(s) we developed the following validation protocol:
  - Perform focused audit of document control process 6 months after implementation
  - Analyze and summarize audit findings
  - Interview staff and get feedback on new process
  - Identify problems and corresponding changes to be made in process
- Successful corrective action will be indicated by lack of document control-related non-conformities

Instrument Maintenance – Major Nonconformity

Assessor Comment

- **Quarterly maintenance for blood bank instruments was not performed in June 2009.**
- **Reagent and specimen refrigerator temperatures were not recorded many days throughout 2009.**
- **Eyewash stations are not tested regularly.**
- **Chemistry instrument maintenance logs and temperature charts are not reviewed on a monthly basis.**

Instrument Maintenance – Major Nonconformity

Immediate Corrective Action

- **Quarterly maintenance performed in blood bank.**
- **Email sent out to staff telling them that temperatures must be recorded each day.**
- **Eyewash stations checked**
- **Chemistry instrument maintenance logs and temperature charts reviewed .**

Instrument Maintenance – Major Nonconformity

Root Cause Analysis

- **We assembled a team of individuals from various departments in the laboratory including representatives from pre-analytic, analytic, and post-analytic processes of our quality management system.**
- **After conducting interviews, reviewing the non-conformities and the ISO 15189 requirements the team defined the problem.**

Instrument Maintenance – Major Nonconformity

1. **Problem definition:**
   - **The current process for instrument and equipment maintenance does not ensure regular monitoring and demonstration of required performance specifications.**

Instrument Maintenance – Major Nonconformity

2. Map current process:

- **Our next step was to map the current process. To do this we interviewed staff, reviewed the written maintenance procedures and manufacturer's requirements for all analyzers and audited additional maintenance records to determine the actual process.**
- **Flowchart submitted.**

Instrument Maintenance – Major Nonconformity

3. Find root cause

- **To determine the root cause or causes of the problem, the team asked "5 Why's" to look for basic reasons for the problem and to help identify groups of related causes. We documented these steps on a Fault Tree to give us a clear overview of cause and effect by which we uncovered the following root causes**
- **Fault Tree submitted.**

Instrument Maintenance – Major Nonconformity

Root causes:

- **There is no standardized process for instrument and equipment maintenance**
- **Roles are not clearly defined.**
- **There is no standardized process for monthly review.**

Instrument Maintenance – Major Nonconformity

4. Develop solution

- The team created a standardized process in the form a flowchart.
- The new process assigns one person per day to check and record all daily temperatures in one notebook.
- Department supervisors will assign periodic maintenance to specific individuals on a rotating basis. Assignments will be scheduled in Outlook.

Instrument Maintenance – Major Nonconformity

4. Develop solution

- All supervisors will perform monthly reviews no later than the 15 of each month. This task will be scheduled in Outlook.
- Each team member presented the proposal to staff throughout the laboratory to get feedback on the feasibility of the process.
- Some adjustments were made to the new process after all of the ideas and comments were discussed.
- Flowcharts submitted.

Instrument Maintenance – Major Nonconformity

5. Implement solutions

- Based on findings of a stakeholder analysis we created a change management approach to mitigate risk of implementation failure.
- The team developed an implementation plan that includes the following tasks:
  - Write new lab-wide procedure for instrument maintenance
  - Revise quality management plan
  - Create notebook for temperature-dependant equipment
  - Set up schedule for periodic preventive maintenance function checks
  - Set up schedule for supervisory review
- Implementation Plan submitted.

Instrument Maintenance – Major Nonconformity

- **6. Assess effectiveness**
- To ensure the solutions address the root cause(s) we developed the following validation protocol:
  - Perform focused audit of instrument and equipment maintenance 3 months after implementation
  - Analyze and summarize audit findings
  - Interview staff and get feedback on new process
  - Identify problems and corresponding changes to be made in process
- Successful corrective action will be indicated 100% performance of required function checks and preventive maintenance and 100% of supervisory reviews completed by the 15th of each month.

Proficiency Testing – Major Nonconformity

Assessor Comment

- **No corrective action for unacceptable fetal screen and Kleihauer-Betke proficiency testing results on API Survey Event I 2009.**
- **Proficiency testing procedure does not include steps for evaluating ungraded challenges.**

Proficiency Testing – Major Nonconformity

Immediate Corrective Action

- **Unacceptable fetal screen and Kleihauer-Betke proficiency test results have been reviewed and appropriate corrective action taken (see "Response to Unacceptable Survey Results").**
- **Ungraded proficiency testing results have been evaluated**

Proficiency Testing – Major Nonconformity

Root Cause Analysis

- **We assembled a team of individuals representing each of the analytic departments in the laboratory including those delegated to review proficiency testing results.**
- **After conducting interviews, reviewing the non-conformities and the ISO 15189 requirements the team defined the problem.**

Proficiency Testing – Major Nonconformity

1. Problem definition:

- **Proficiency testing results are not consistently evaluated and investigated so that corrective actions can be implemented when failures occur.**

Proficiency Testing – Major Nonconformity

2. Map current process:

- **Next we mapped the current process. To do this, we reviewed the written proficiency testing policy and procedure, interviewed staff, and audited records to determine the actual process.**
- **Flowchart submitted.**

Proficiency Testing – Major Nonconformity

3. Find root cause

- **To encourage the team to look at this problem from different perspectives, we employed a large brainstorming group to encourage creative and unconventional thinking about a topic. The following root causes were uncovered.**

Proficiency Testing – Major Nonconformity

Root causes:

- **There is no standardized process for proficiency testing result review and investigation.**
- **Ungraded educational challenges are not included on the official evaluation form.**
- **Original reports are not always updated with the corrective actions documented on supervisor's copy.**

Proficiency Testing – Major Nonconformity

4. Develop solution

- **The team created a standardized process in the form a flowchart.**
- **All designees reviewed the standardized process**
- **Some adjustments were made to the new process after all of the ideas and comments were discussed.**
- **Proficiency Testing Flowchart submitted.**

Proficiency Testing – Major Nonconformity

5. Implement solutions

- **The team developed an implementation plan that includes the following solutions:**
- **Proficiency testing results will only be available for evaluation electronically.**
- **An electronic Proficiency Testing Evaluation form will be used to document evaluation, investigation and corrective actions.**
- **The Quality Manager will email each proficiency testing report and evaluation form to the appropriate designee and schedule a meeting with that individual within 30 days to discuss the outcome.**
- **Implementation Plan submitted.**

Proficiency Testing – Major Nonconformity

Assess effectiveness

- To ensure the solutions address the root cause(s) we developed the following validation protocol:
  - Perform a focused audit of the proficiency testing process 6 months after implementation
  - Analyze and summarize audit findings
  - Interview staff and get feedback on new process
  - Identify problems and corresponding changes to be made in process
- Successful corrective action will be indicated when 100% of PT reports are completely evaluated within 30 days.

The Problem Starts High -- Varied Moves to Stem Health Care Expenses

The Facts:

- **$2.5T, or $8,000 per individual spent**
- **17.6% of economy, growth of 8 to 9%**
- **8th leading cause of death, 32,000 reported per year**
- **2.4M extra days, $17B cost**
- **40% waste in health care system**

The Problem Starts High -- Varied Moves to Stem Health Care Expenses

The Problem Starts High -- Varied Moves to Stem Health Care Expenses

Payment linked to high-quality care at lower cost

Bonuses to hospitals that improve patient results

Penalties to those that don't make the score

Now, Examine Reform in Light of the Medical Laboratory Environment

- Greater demand for tests
- More complex (and expensive) testing
- Harder to find and keep qualified scientists

Accountable Care Organizations and the Key Role of the Laboratory

- **70% of medical decisions are based on information generated by laboratory tests and the clinical lab is the first to obtain this data.**
- **Clinical data management is a core competency of pathologists and clinical scientists who, as integrative coordinators of clinical laboratory data, can employ pattern recognition, risk factor identification, other clinical judgments and utilization observations including peer comparisons to assist with chronic disease management.**
- **Laboratory's manage the vast amounts of key clinical patient data needed to report on quality measures and improve population management.**

The Problem Starts High -- Varied Moves to Stem Health Care Expenses

Let's Work Together on the Quality Journey for Improved Outcomes and Performance

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