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ANALYTICAL LABORATORY QUALITY AUDITS

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Abstract:

Analytical Laboratory Quality Audits

Analytical Laboratory Quality Audits are designed to improve laboratory performance. The success of the audit, as for many activities, is based on adequate preparation, precise performance, well documented and insightful reporting, and productive follow-up.

Adequate preparation starts with definition of the purpose, scope, and authority for the audit and the primary standards against which the laboratory quality program will be tested. The scope and technical processes involved lead to determining the needed audit team resources. Contact is made with the auditee and a formal audit plan is developed, approved and sent to the auditee laboratory management. Review of the auditee's quality manual, key procedures and historical information during preparation leads to better checklist development and more efficient and effective use of the limited time for data gathering during the audit itself.

The audit begins with the opening meeting that sets the stage for the interactions between the audit team and the laboratory staff. Arrangements are worked out for the necessary interviews and examination of processes and records. The information developed during the audit is recorded on the checklists. Laboratory management is kept informed of issues during the audit so there are no surprises at the closing meeting.

The audit report documents whether the management control systems are effective. In addition to findings of nonconformance, positive reinforcement of exemplary practices provides balance and fairness.

Audit closure begins with receipt and evaluation of proposed corrective actions from the nonconformances identified in the audit report. After corrective actions are accepted, their implementation is verified. Upon closure of the corrective actions, the audit is officially closed.

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Analytical Laboratory Quality Audits

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1. Introduction

Management systems are based on the four basic activities of Planning, Performance, Measurement, and Improvement. It is no coincidence that the quality program "pdca" of plan, do, check and act is parallel to the management system. The quality audit is one implementation of the final two activities of "check and act" and is based on the standards from the "plan" phase and the implementation of those standards in the "do" phase.

Arter (1) points out that in order to provide managers the information needed for the "Measuring and Improving" or "check and act" there are five criteria for audits to meet:

a. Auditing is a function of management;
b. Auditors are qualified to perform their tasks;
c. Measurements are taken against defined standards;
d. Conclusions are based on fact; and,
e. Audit reports focus on the control system."

"Modern management audits should be a combination of compliance and effectiveness evaluations. Using defined and agreed to measurement criteria, the audit report will tell the managers the following:

- Whether controls exist and are adequate;
- Whether controls are being implemented;
- Whether controls actually work."

Smith and Russell (2) quote Juran and Gryna (3) as follows: "The usual purpose of quality audits are to provide independent assurance of the following conditions:

- Plans for attaining quality are such that, if followed, the intended quality will, in fact, be attained.
- Products are fit for use and safe for the user.
- Laws and regulations are being followed.
- There is conformance to specifications.
- Procedures are adequate and are being followed.
- The data system provides accurate and adequate information on quality to all concerned.
- Deficiencies are identified and corrective action is taken.
- Opportunities for improvement are identified and the appropriate personnel alerted."

Smith and Russell also quote Mills (4) as follows: "Quality audits are carried out to determine either or both of the following:

1. Suitability of the quality program (documentation) with respect to a predetermined reference standard.
2. Conformity of the operations within the quality system to the documented quality program."

Analytical Laboratory Quality Audits are designed to improve laboratory performance. The success of the audit, as for many activities, is based on adequate preparation, precise performance, well documented and insightful reporting, and productive follow-up.

2. Preparation

As in most endeavors, the quality of preparation is the single most important ingredient of success. Preparation is the foundation upon which the rest of the audit is built.

2.1 Preparation

Arter lists nine steps for preparation:

1. Define the purpose of the audit.
2. Define the scope of the audit.
3. Determine the audit team resources to be used.
4. Identify the authority for the audit.
5. Identify the performance standards to be used.
6. Develop a technical understanding of the processes to be audited.
7. Contact those to be audited.
8. Perform an initial evaluation of lower-tier documents to higher-level requirements.
9. Develop written checklists of the data needs.

The above processes during audit preparation should be guided by keeping in mind the three audiences for the audit: the auditee (audited laboratory); the client (the company audit administrator, the purchasing manager; or the regulatory agency or person requesting registration); and finally the whole organization/agency/corporation. Your effectiveness and efficiency will reflect not only on you but the company/organization you are a part of and the auditing function in general.

2.2 Purpose

According to Arter (1) Quality audits "are performed to analyze the effectiveness and implementation of programs designed to maximize the quality of goods or services delivered to the customer." He goes on to say "Adequate preparation starts with definition of the purpose, scope, and authority for the audit and the primary standards against which the laboratory quality program will be tested. The scope and technical processes involved lead to determining the needed audit team resources. Contact is made with the auditee and a formal audit plan is developed, approved and sent to the auditee laboratory management. Review of the auditee's quality manual, key procedures and historical information during preparation leads to better checklist development and more efficient and effective use of the limited time for data gathering during the audit itself.

2.3 Scope

The scope of the laboratory quality audit is defined as to limits or boundaries. Will the scope be corporate/organization wide; the central laboratory; or a satellite laboratory? Will all analytical methodologies or a specific subset be covered? What impact will the audit scope have on the laboratory personnel and operations.

2.4 Audit Team

Determine what special skills/knowledge are needed among the team members to efficiently and effectively handle the scope of the audit.

2.5 Authority for the audit

The authority for the audit comes from the company/organization quality assurance manual, the contract for the analytical services or the request for the third party audit.

2.6 Performance Standards

The laboratory quality system has as many shapes, pieces and names for the pieces as there are authors. As a result, the audit team must evaluate the auditee's quality system against a standard. This does not mean that all laboratory quality systems are identical or should be. The challenge is to make sure that however the auditee's quality system is named and described that all the necessary functions are covered and implemented.

The audit team will correlate the auditee's system against the auditor's system for equivalency of coverage.

An analogy can be made, especially since we are almost at lunch time, that there are a number of ways to cut a round cake. The important issue is whether there is a whole cake regardless of how it is cut or divided.

One such reference system is the U. S. Department of Energy (DOE) Order (DOE O 414.1A) "Quality Assurance"(5). There are three areas (Management, Performance, and Assessment) with ten parts (Criteria) in this system grouped as follows.

Management

Criterion 1 Program

1. A written Quality Assurance Program (QAP) must be developed, implemented, and maintained.

2.The QAP must describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.

3.The QAP must describe management processes, including planning, scheduling, and resource considerations.

Criterion 2 Personnel Training and Qualification

1. Personnel must be trained and qualified to ensure they are capable of performing their assigned work.

3. Personnel must be provided continuing training to ensure that job proficiency is maintained.

Criterion 3 Quality Improvement

1. Processes to detect and prevent quality problems must be established and implemented.

2. Items, services, and processes that do not meet established requirements must be identified, controlled, and corrected according to the performance of the problem and the work affected.

3. Correction must include identifying the causes of problems and working to prevent recurrence.

4. Item characteristics, process implementation, and other quality-related information must be reviewed and the data analyzed to identify items, services, and processes needing improvement.

Criterion 4 Documents and Records

1. Documents must be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.

2. Records must be specified, prepared, reviewed, approved, and maintained.

Performance

Criterion 5 Work Processes

1. Work must be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means.

2. Items must be identified and controlled to ensure their proper use.

3. Items must be maintained to prevent their damage, loss, or deterioration.

4. Equipment used for process monitoring or data collection must be calibrated and maintained.

Criterion 6 Design

1. Items and processes must be designed using sound engineering/scientific principles and appropriate standards.

2. Design work, including changes, must incorporate applicable requirements and design bases.

3. Design interfaces must be identified and controlled.

4. The adequacy of design products must be verified or validated by individuals or groups other than those who performed the work.

5. Verification and validation work must be completed before approval and implementation of the design.

Criterion 7 Procurement

1. Procured items and services must meet established requirements and perform as specified.

2. Prospective suppliers must be evaluated and selected on the basis of specified criteria.

3. Processes to ensure that approved suppliers continue to provide acceptable items and services must be established and implemented.

Criterion 8 Inspection and Acceptance Testing

1. Inspection and testing of specified items, services, and processes must be conducted using established acceptance and performance criteria.

2. Equipment used for inspections and tests must be calibrated and maintained.

Assessment

Criterion 9 Management Assessment

1. Managers must assess their management processes.

2. Problems that hinder the organization from achieving its objectives must be identified and corrected.

Criterion 10 Independent Assessment

1. Independent assessments must be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.

2. The group performing independent assessments must have sufficient authority and freedom from the line to carry out its responsibilities.

3. Persons conducting independent assessments must be technically qualified and knowledgeable in the areas assessed.

DOE has also published a "Quality Management System Guide" DOE G 414.1-2 (6) of 6-17-99. This guide provides information on principles, requirements, and practices used to establish and implement an effective Quality Assurance Program (QAP or quality management system). The quality requirements described in this Guide are interrelated and include criteria for managing, achieving, and assessing work. Implementing the quality requirements will contribute to improved safety, management, and reliability of DOE products and services. This interrelationship precludes an organization from implementing only selected requirements and ensures the integrated approach. A selective approach to implementing the criteria would create an incomplete system and could lead to quality failure (i.e., a failure to meet customer requirements and mission objectives. Ultimately, the content of the management system must be based on an organization's unique set of overall responsibilities and customer expectations.

2.7 Understanding of Processes to be Audited

The audit team will function more effectively and efficiently if it has a good understanding of the laboratory's quality system. Study of the Quality Manual and implementing procedures and historical information from prior audits (if available) prior to reaching the laboratory provides the mechanism to focus on the "mission critical" issues and develop better checklists.

2.8 Contacting the Auditee

The auditee is informed of the audit by the mechanism appropriate for the situation. The Lead Auditor needs to make sure it is done or do it, as the situation dictates. This initial contact provides the opportunity to establish rapport with the auditee,

to work out the logistics of the audit and to acquire documents necessary for preparation, if not already available.

The formal audit plan is transmitted to the auditee upon its approval.

2.9 Evaluate lower tier documents against the higher level requirements

This process is part of the education of the audit team. The process also provides much of the focus for the actual on-site data gathering efforts.

2.10 Develop written checklists of the data needs

The focus developed in the preceding section is documented in the development of the checklists. Where the audit program is used to cover multiple comparable laboratories, some parts of the checklists generally are generic.

Since the main function of the checklist is to gather data, the specific issues to be examined are listed. The audit question must also be directly linked to the standard that established the requirement. This technique provides protection from the checklist being an auditor's "wish list". Checklists are reviewed or approved (generally by the Lead Auditor).

3. Audit Conduct

The audit begins with the opening meeting that sets the stage for the interactions between the audit team and the laboratory staff. Arrangements are worked out for the necessary interviews and examination of processes and records. The information developed during the audit is recorded on the checklists. Laboratory management is kept informed of issues during the audit so there are no surprises at the closing meeting.

3.1 Opening Meeting

The purpose and scope of the audit is reviewed to achieve a common level of understanding

Introductions may include a review of credentials/experience as appropriate.

The opening meeting provides an opportunity to solicit input from the auditee on audit focus. Accommodation can improve the audit but must not be allowed to detract from the approved audit scope.

A review of the areas of concern developed during the preparation phase alerts the auditee organization to prepare for the rest of the audit.

Audit checklists are presented to the laboratory as tradition dictates.

The critical part of the opening meeting is to set up the schedules for interviews and examination of documentation so the audit can be conducted effectively with a minimum of disruption for the laboratory. The laboratory personnel must continue to function as a productive laboratory during the audit. This is self evident when one remembers some laboratories host about an audit a week.

Audit team logistics should include safety issues as well as the routine logistics of workspace, lunch, etc.

3.2 Data Gathering

Laboratory operations are controlled by procedures covering: personnel training and qualification. sample preparation, analytical separations, instrumentation calibration and operation. data reduction and validation, results reporting, data package development and verification, quality control and quality assurance.

Most, if not all, laboratories participate in external Performance Evaluation Programs (PEPs). These programs may be run by federal governmental agencies such as the USEPA or the USDOE. States may have such programs related to their regulatory responsibilities such as for NPDES. Customers may require the participation of contract laboratories in outside PEPs or their own PEP. That was the case for the Fernald site during the Remedial Investigation/Feasibility Study (RI/FS) phase of site remediation. Since the site is now fully into remediation the Final Remediation Levels (FRLs) are in at least some cases lower than the levels covered by most, if not all, available programs. The value of such programs is that they provide independent testimony as to the quality of the analytical work.

3.3 Status Reports

The auditors keep the area supervisors aware of issues as they work in an area or are finishing an area. The auditors keep the Lead Auditor informed. The Lead Auditor keeps the auditee management informed, generally on a daily basis, of issues. There will be no surprises at the audit closing meeting if the audit team and the auditee management team are doing a good job of communication.

4. Audit Reporting

The audit report documents whether the management control systems are effective or not. In addition to findings of nonconformance, positive reinforcement of exemplary practices provides balance and fairness.

Developing the bases of the report

Arter stresses the importance of preparing pieces of the report from the beginning of the audit. He states:

"The report is being proposed, modified, rejected, and rebuilt by the entire audit team individually and jointly as the audit progresses. You must keep it in the back of your mind constantly. Arter concludes that by starting the report the first day of data gathering has at least four merits.

1. It helps structure the audit by forcing you to develop hypotheses early.

2. The writing of tentative conclusions forces precision in the process.

3. The problem of sorting, understanding, and reviewing a large mass of material before the exit meeting deadline is reduced.

4. Factual errors, perceptual errors, and other distortions are reduced."

4.1 Closing meeting

Based on the work of the auditors, in conjunction with them, the Lead Auditor conducts the Closing meeting with the audited organization. The Lead Auditor presents the audit results as follows:

1. Presents an overall summary of the audit results. The Lead Auditor or the individual auditors present the individual audit results.

2. Discusses each result with sufficient specifics to assure an understanding of the requirements.

3. Covers areas of conformance as well as areas of nonconformance.

4. Makes every effort to clarify misunderstandings prior to the close of the on-site portion of the audit either by reviewing the evidence or by restating the results.

4.2 Audit Report

The audit report is being prepared for management. It should clearly document whether management control systems exist and are adequate, whether the controls are implemented, and whether the controls really work. When the audit information is presented in management terms, management can make changes to improve future performance.

Example Audit Report Format(7)

The audit report conforms to the practices of the auditing organization.

Section 1 Executive Summary

Briefly recap the scope and purpose of the audit, the activities audited, and the applicable standards and/or requirements against which the audit was conducted. Summarize both positive as well as negative results of the audit. This portion is being written to top management.

Section 2 Audit Results

Describe the nonconformances that were identified during the audit. It is common practice to attach a copy of each Nonconformance Form to the report.

Section 3 Corrective Actions During the Audit

Describe items that were identified and corrected during the audit. This section reflects on the early communication of issues to the auditee management and their response to them. It is far more efficient for both the auditors and the auditee to have nonconforming conditions corrected during the audit.

Section 4 Audit Performance

Document the time, scope and attendees for the opening meeting.

Highlight the positive results as "Strengths" as well as the negative results as "Weaknesses".

Summarize the audit checklist(s) content in narrative form. The summary should document the activities of the audit team and support the results. Summarize the issues that resulted in nonconformances as well as the issues that were corrected or resolved during the audit.

Document the time, scope and attendees for the closing meeting.

Section 5 Personnel Contacted During the Audit

List the names and positions of personnel contacted during the audit as well those present for the opening and closing meetings.

Section 6 Identification of Audit Personnel

List the names and titles (positions) of the audit team.

Section 7 Signature Page

The Lead Auditor and the Auditors sign the report. The Audit Manager or equivalent approves the audit report.

5 Audit Closure

Audit closure begins with receipt and evaluation of proposed corrective actions from the nonconformances identified in the audit report. After corrective actions are accepted, their implementation is verified. Upon closure of the corrective actions, the audit is officially closed.

6 Audit Limitations

Laboratory audits are very useful. However, there are limitations. One only has to realize that the Bridgestone/Firestone plant at the center of the investigations was registered to QS-9000 (automotive version of ISO-9001). Arter (8) stated "It is doubtful that any quality audit program could have prevented the recent recall of automobile tires by Bridgestone/Firestone. Auditors don't go around looking for field failures. They often don't even have access to the data. These are design issues for scientists and engineers."

Some of those scientific and engineering issues are summarized in the January 1, 2001 issue of Chemical & Engineering News (9).

Summary

The foundation of the audit is the preparation phase. The audit plan provides the roadmap or building drawings for the execution of the on-site audit. Adherence to the audit plan with reasonable people skills by qualified auditors generally assures a successful on-site audit performance. A clear and concise report documents the entire audit process ("for eternity"). Followup to resolve the identified nonconformances with the institution and verification of effective corrective actions assists management in improving the performance of the laboratory.

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