Quality Report SQAS96-001

Preparation for a Software Quality Audit

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Software Quality Assurance Subcommittee
of the
Nuclear Weapons Complex Quality Managers

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Abstract

This document will enable a site to prepare for a software quality audit by providing specific guidance. It will also provide guidance to a site that would enable it to perform a software quality audit.

ACKNOWLEDGMENT

This document was prepared for the Department of Energy (DOE) by a Working Group of the Nuclear Weapons Complex (NWC) Quality Managers' Software Quality Assurance Subcommittee (SQAS). The following contributed towards the creation of this document:

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Section 1. Purpose

Software is becoming increasingly important to both production and administration operations within the Department of Energy. Many individuals involved with software are now being audited. The purpose of this document is to help those individuals better understand the software quality auditing process and their roles and responsibilities.

According to the Institute of Electrical and Electronics Engineers (IEEE Std 610.12-1990) a software audit is "An independent examination of a work product or set of work products to assess compliance with specifications, standards, contractual agreements, or other criteria."

The goal of a software audit is to provide an independent determination as to whether the software, its documentation, and/or the development and maintenance processes meet stated requirements.

An audit is usually conducted for one of the following reasons:

- A specific project milestone has been reached and an audit is initiated as planned or as required by the auditing organization's charter.

- External parties or customers request an audit of a specific item, at a specific date, or at a project milestone. This could be part of a contract agreement.

- An internal organization has requested the audit, establishing a clear and specific need.

An audit is not a software assessment. A software assessment appraises software processes and identifies potential areas for improvement. (See SQAS Document SQAS 95-001 Planning For a Software Process Assessment.)

A software quality audit is not much different than any other type of audit. Configuration items of software may sometimes be a little harder to put your finger on, but they are still auditable.

This document describes the mechanics of an audit and what individuals should expect. There are steps that the auditor and the auditee can take that make the results of the audit more positive. Many of the steps are discussed in this document.

Section 2. Software Quality Audit Roles and Processes

2.1 Roles and Responsibilities

A software quality audit involves:

- the client, person or organization which requests the audit,

- the auditor or team who performs the audit, and

- the auditee whose work is being examined.

To achieve a successful audit, the auditor and auditee must understand their roles and responsibilities. The auditor and the auditee can then improve communication, agree on findings, use the audit time more efficiently and make the overall audit more effective.

2.1.1 Client

The client (i.e., person or organization) is responsible for authorizing the audit and for defining the scope and identifying the requirements of the audit. The management of the auditing organization assumes responsibility for the audit and allocates the necessary resources to perform the audit.

2.1.2 Auditor or Audit Team

The audit team performs the audit. The audit team is composed of one or more people. Normally, one individual is designated the lead auditor. It is the lead auditor's responsibility to organize and direct the audit and to coordinate the preparation and issuance of the audit report. The lead auditor is also responsible for:

- determining the team size,

- briefing team members on the audit scope and areas to be audited,

- providing background about the organization being audited,

- assigning the workload of who will audit what areas,

- determining the audit schedule,

- notifying and briefing the audited organization on the scope of the audit and materials that need to be provided,

- ensuring that the audit team is prepared to conduct the audit,

- ensuring that the audit plan or procedures are performed, and

- issuing reports in accordance with the audit plan or procedures.

The audit team should have:

- auditor training, and

- technical expertise in the area being audited.

The audit team assists the lead auditor by helping prepare and review checklists, doing background work, conducting research, fulfilling their assigned part of the audit, and creating the report.

2.1.3 Auditee

The auditee is the party being audited. The auditee is responsible for:

- establishing a professional, positive attitude about the audit among the members of the audited organization,

- participating in the audit,

- providing all relevant materials and resources to the audit team,

- understanding the concerns of the auditors and verifying their factual accuracy,

- providing a response to the audit report, and

- correcting or resolving deficiencies cited by the audit team.

2.1.4 Others

An audit may include interested observers other than the client such as regulatory agencies. However, the role of the observer should be fully understood and agreed upon in the opening meeting.

2.2 Process

An audit should be performed in accordance with documented plans and procedures. An audit consists of four phases: a planning phase, a performance phase, a reporting phase, and a follow-up phase.

2.2.1 Planning Phase

The planning phase should answer these questions:

- What is the audit's scope?

- What should the audit achieve?

- Does the audit cover the entire project? Does it cover the total system or part of the system?

- What is the authority for the audit?

- What background information is needed?

In the planning phase the client requests an audit. The scope and purpose of the audit are agreed upon by the client and auditor. The auditor forms an appropriate team and contacts the auditee. The auditors convey to the audited organizations the audit's purpose, scope, and authority (who or what authorizes the audit). This may be done by phone, letter or personal contact, followed by a written notification of the audit. The auditor will then request preliminary documentation needed for the audit. Typical documentation includes the organization's Quality Assurance Program Plan and organizational charts.

The auditor and auditee agree on the audit schedule, audit procedures or requirements, responsible people, and content of the audit. The auditor reviews the requirements imposed by the client on the auditee, which form the basis of the audit. An audit plan is developed and documented. Meeting rooms and other audit logistics are also discussed.

The auditor then reviews the available information, including previous audits and corrective actions. The auditor should have an understanding of the organization and the areas to be audited before the audit. Adequate familiarization should result in:

- accurate understanding of what the audit assignment really is,

- an effective audit program,

- spending an appropriate amount of time on each activity,

- emphasizing the significant findings and exemplary practices,

- understanding the information being gathered and

- understanding the people in the audited organization and being able to communicate with them.

During the planning phase the auditee prepares for the audit. An audit coordinator, who has a thorough knowledge of the area of the audit, will make arrangements for the audit. People are selected to be principal points of contact for each task to be audited. Escorts are assigned to accompany the auditor during the audit. Both principal contacts and escorts should be prepared to clarify some of the answers of employees or place answers in the appropriate context.

The auditee conducts a self-evaluation to prepare the employees for the audit and to identify any problems that can be fixed before the audit. The auditee locates and reviews procedures and records that the auditor requests to examine. The auditee locates office space and equipment the auditors will use while on-site.

2.2.2 Performance Phase

The performance phase of an audit consists of auditors interviewing, reviewing records, observing operations and collecting information. There are usually daily meetings by the audit team, as well as briefings to the auditee by the auditors to discuss observations. These are informal sessions usually held at the end of each day. Their purpose is to share information such as facts, tentative conclusion, problems, etc. This allows everyone involved in the audit to understand where the audit is headed before the final report. During the performance phase the auditee gives the audit top priority. Questions should be answered promptly, accurately and honestly. The auditee can challenge the auditor if the auditor makes a dubious conclusion. More evidence may be presented or requirements reviewed to substantiate the challenge. If problems are discovered, the auditee should correct them immediately, if possible, and inform the auditors.

The performance phase has three main activities:

- Opening meeting

- Performance of the Audit

- Closing Meeting

2.2.2.1 Opening Meeting

The first day of the on-site part of an audit starts with an opening meeting in which the scope of the audit is reviewed, schedules are determined, auditor and auditee personnel are introduced, and logistics and the time for the closing meeting are determined. The auditor will communicate to the auditee the audit's objectives, areas of concentration as seen by the auditor and a preliminary assessment of the organization. The lead auditor will establish the audit's tone, sense of cooperation, and act as a seeker of information and facts. The audit team will describe the audit process, clarify any administrative matters and solicit the auditee's input.

Audit team members form important judgments during the meeting. Is the auditee relaxed or anxious? Is the auditee open or defensive? What seems to be the style? These general

observations provide valuable understanding of the audited organizations and help guide the remainder of the audit.

2.2.2.2 Performance of the Audit

Guided by their checklists, the auditors check compliance with requirements by reviewing written instructions and procedures, conducting interviews, checking records, and observing work activities. They follow up on questions that arise during these checks and observations, and assemble factual evidence of the auditee's compliance with requirements and effectiveness in achieving the goals of their organization. The audit records include auditors' notes from interviews and observations, and photocopies of examples from the record reviews. The facts noted in the audit are reviewed by the lead auditor and conclusions are drawn as to the existence and extent of deficiencies or good practices.

2.2.2.3 Closing Meeting

The performance phase of an audit ends with the closing meeting or exit interview where the lead auditor reports the audit team's conclusion. This is the last opportunity for the auditee to provide input to the audit.

2.2.3 Reporting Phase

The lead auditor is responsible for generating the audit report that is the product of the audit. The lead auditor should start the report the first day of the audit. Team meeting discussions and the facts collected will help guide the report.

At the closing meeting, the lead auditor will provide a summary of the written report. The summary allows for factual corrections and explanations.

The report usually consists of an introduction, purpose, scope, findings, observations, exemplary practices, and response requirements.

The report is mailed to the client, the auditee and the audit team.

2.2.4 Follow-up Phase

If problems were discovered during the audit, the auditee proposes corrective actions, which may be reviewed by the client or auditor. The resolution of a problem requires three steps that should be outlined in a corrective action plan:

- correction of the specific deficiency found,

- resolution of the root cause of the problem,

- setting a date when corrective action will be in place to prevent a recurrence.

A follow-up audit may be required or requested to verify each finding is resolved by a proposed corrective action, the corrective action has been implemented, and the problem has been resolved. The follow-up activities include: evaluation of the response, re-audit, closing and documentation. The auditor is responsible for requesting a timely response from the auditee. The authority for evaluating the adequacy of the response is normally delegated to the auditor who performed the particular audit. When all the findings have been resolved, the auditee is notified that the audit is closed.

The closing activity is the final acknowledgment that the audit is formally and officially at an end. The documentation activity includes the collection and filing of all the documentation related to the audit. Normally the lead auditor receives all the information for storage.

Section 3. How the Auditor Prepares for the Audit

When a client makes the decision to conduct an audit, a request is made to an auditing organization. The auditing organization then assigns a lead auditor who will work with the client to decide the purpose of the audit, the audit's scope, the standards or documents to be used, the schedule and time frame for the audit, and the commitment of resources necessary to meet the audit's scope and depth.

Once these decisions are made, the lead auditor should make the initial contact, usually informal (for example, a phone call) with the auditee. This is to notify the auditee that an audit is going to be conducted and to establish a date for the audit within the client's time frame.

3.1 Preliminary Review

As a planning basis for the audit, the lead auditor should perform an analysis of the applicable requirements. He should then perform a preliminary review or a "desk audit" of the auditee's procedures, instructions, or recorded descriptions for meeting these requirements. If the lead auditor finds major problems during the preliminary audit then the planning phase should be suspended until these major issues can be resolved.

If no major problems are found, the lead auditor provides the auditee with a formal notification of the audit. This notification should contain the objective and scope of the audit, a preliminary schedule, and a request for the names of the people responsible for each task or area to be audited. Also, at this point the lead auditor assembles an audit team if the scope of the audit warrants.

3.2 Preliminary Audit Plan

The lead auditor is responsible for producing a preliminary audit plan. This plan may change during the performance phase of the audit with the approval of the lead auditor, the client, and the auditee. According to ISO 9000, the preliminary plan should contain the following:

- audit objective and scope,

- identification of the individuals having significant direct responsibilities regarding the objectives and scope,

- identification of reference documents (such as the applicable quality system standard and the auditee's quality manual),

- identification of audit team members,

- the language of the audit,

- the date and place where the audit is to be conducted,

- identification of the organizational units to be audited,

- the expected time and duration for each major audit activity,

- the schedule of meetings to be held with auditee management,

- confidentiality requirements,

- audit report distribution and the expected date of issue.

This plan should be approved by both the client and the auditee and any issues should be resolved before the audit's performance phase begins.

3.3 Additional Documentation

The lead auditor, together with the audit team, should prepare the checklists that will be used to evaluate each audit task or area. Additionally, they should prepare any forms for recording and collecting the necessary information to document their observations throughout the audit.

Section 4. How the Auditee Prepares for an Audit

When an organization receives notice of an audit, it should begin planning for the audit. Preparing for an audit is simplified if the audited organization conducts frequent, routine self-assessments or internal audits to ensure work is being done in compliance with the requirements.

Whether or not these self-assessments or internal audits are in place, the following planning activities will help the audited organization through the planning phase.

4.1 Understand and Communicate the Scope and Objectives of the Audit to Relevant Members of the Organization.

Audits may be routinely scheduled or be prompted by changes in the organization's quality process, product, or as a follow up to a previous audit. An audit is initiated to evaluate an organization's compliance with a set of requirements or standards. It is important for the audited organization to have the knowledge of the requirements or standards at a level equal to or higher than the auditor. This will help eliminate any instances where an auditor imposes a condition that is not a requirement, and facilitate the timely resolution of issues.

4.2 Appoint Responsible Members of the Staff to Interface and Accompany the Auditors.

An audit coordinator should be selected. This should be a person of authority who has a thorough knowledge of the audited area and can answer or obtain the answers to the auditors' questions during the planning phase. The audit coordinator will be meeting with the lead auditor during this phase and making all of the arrangements for the audit's performance phase.

The audit coordinator should assign principal points of contact for each task or area to be audited. These people should be knowledgeable about both the process and the product of their work. They should represent a global view for their work area and be able to put other employees' answers into the proper context.

If the audit is large and conducted by sub-teams of auditors, the audit coordinator should also assign escorts to accompany each sub-team throughout the audit. Escorts should be people who have previous experience with audits and understand both the auditor's and the auditee's terminology. These people should be skilled communicators, as their primary responsibility is to be the communication link between the auditor and the auditee.

4.3 Locate and Review Material as Requested by the Auditors

The auditee is responsible for providing access to all procedures and records that the auditors request to examine. Therefore, the auditee should locate all of the required manuals, records and documentation, and make certain they are available, adequate and up to date.

If time permits, a self assessment or work area review should be performed. This helps prepare the employees for the audit. It also verifies that everyone is working to the correct procedures or requirements and identifies any areas where corrective action can be taken before the start of the audit's performance phase.

4.4 Provide Access to Facilities and Equipment

During the performance phase, the auditor will need office space with access to telephones, meeting rooms, word processors or computers, copy machines, and FAX machines. Arrangements for all of these facilities and equipment should be made during the planning phase so the auditors can begin work immediately upon arrival. Any relevant information (for example, names, phone numbers and locations of the auditee's key people, maps of the site and surrounding area, results of the self assessment performed) should be available for the auditors when they arrive.

Section 5. How the Auditor Acts During an Audit

The audit team should maintain a professional manner, and a positive and friendly attitude at all times during the audit.

5.1 Pre-Audit Meeting

The lead auditor should assume the lead in the pre-audit meeting. He or she sets the tone of the audit and should pay particular attention to providing a non-adversarial relationship with the audited organization. Each audit team member should be introduced with a short description of their expertise as well as their role and responsibility during the audit. The lead auditor should clearly and concisely state the scope, objectives, requirements, and ground rules of the audit. The audit schedule should be discussed and the audited organization should be given the opportunity to request revision to accommodate their schedules. After the logistics of the audit have been resolved the audited organization usually provides a briefing of the areas to be audited. This may or may not include all attendees of the pre-audit meeting.

5.2 Audit

The actual audit is usually conducted through interviews with personnel in the audited organization and through documents and records review. Here are several useful techniques auditors should use when conducting interviews.

- Listen. It is difficult to gather information if you are talking.

- Listen ACTIVELY. Do not formulate new questions while interviewees are responding to previous ones. Don't only listen for the "bottom line."

- Observe the interviewee's body language and monitor your own body language to reflect listening, understanding, and empathy.

- Take notes and explain why you are taking them.

- Question. Start with open-ended questions, e.g., why, when, how, who, what, where, to what extent. Keep questions short and to the point. Move to close-ended questions, answered by yes or no, to start the clarification process.

- Clarify details to make sure the information received is clear and complete. Use follow-up questions for more information. Use paraphrasing and repeating to ensure that you heard correctly, and summarize to validate information.

To ensure the success of an audit it is important for each auditor to:

- establish a rapport with the interviewee,

- avoid nit-picking or judgmental comments about individuals,

- avoid placing blame or fault for problems,

- and always operate ethically.

Remember you are taking up the valuable time of the auditee so minimize intrusions and avoid wasting time. The use of a checklist will help in this process by providing structure to the line of investigation and documenting results. Here is a list of additional tips in conducting a successful audit.

- Rely upon objective evidence and maintain objectivity.

- Use random sampling to get representative results.

- Obtain confirmation or explanation of apparent problems or concerns.

- Revisit if needed.

- Document results and retain notes.

- Get a positive "ID" of persons contacted.

- Report known problems and avoid opinions.

- Avoid surprises: keep your contacts informed.

5.3 Closing Meeting

The closing meeting is the time for the auditors to explicitly state the results of the audit. There should be no surprises. The lead auditor should control the meeting. He or she should define the terms used and clearly state each result. It is important to report excellence as well as problems and major deficiencies. The audited organization should be told when to expect the audit report and when and how they are expected to reply. Always close the meeting by thanking the individuals for their time and cooperation.

Section 6. How the Auditee Acts During an Audit

During the audit, the audited organization personnel must maintain a professional image and interact with the audit team. Audit team members should not be allowed to wander freely and unescorted through the audited organization. Although there will ordinarily be fairly stringent rules limiting the help an employee may be given in answering questions, a knowledgeable person, or supervisor, should accompany auditors at all times. Questions will arise concerning specific terminology and semantic differences between the audited organization and the audit team. A knowledgeable person needs to be present to "interpret" in these instances.

In order to avoid surprises, audit team members and supervisors of the audited organization need to meet as quickly as possible after an apparent major discrepancy has been identified. The sooner communications can be established regarding an apparent major discrepancy, the sooner any misunderstanding about the finding can be clarified.

Potential candidates for interviews with auditors should be briefed and coached before the audit begins as to what to expect and how to react during the audit. Clerical staff should be instructed to keep files as clean and orderly as possible and to be as responsive as possible in retrieving information requested by the audit team.

6.1 Conduct of Opening Meeting

For an audit expecting to take 1-2 weeks, a 1-2 hour in-briefing is usually held on the first day of the audit. Participants in this in-briefing normally include the audit team members and representatives from within the audited organization. The purpose of this in-briefing is to familiarize the audit team with physical layouts, organizational structures, topical material breakdowns, etc. This in-briefing should carry a high priority in the audited organization.

Since the briefing can set the tone for the entire audit period, the auditee and the auditor should strive to project a helpful, professional image during the briefing. While not providing any unnecessary gratuitous information the leader of the audited organization team should attempt to control the in-briefing and provide as much useful information to the audit team as possible.

Basic ground rules of the audit should be established during this briefing. These ground rules should include such things as where the office space for the audit team will be located, what material the audit team will need to perform the audit, and in what form. The audited organization should attempt to establish a daily routine with audit team members including a firm schedule for the following day, daily validation meetings, management briefings, and rapid notification of audit team findings or significant deficiencies.

6.2 Conduct of Closing Meetings

By final closing meeting time, the audited organization should clearly understand the issues that have been identified as findings, deviations, exemplary practices, observations, etc. If there will be a lapse between the time of the closing meeting and the submission of the final audit report, the audited organization should make every attempt to obtain at least a draft of this report. This is to avoid any potential surprises or miscommunications. The audited organization should obtain clarification of what "credit" they will receive for corrective actions taken during the audit to eliminate or mitigate deficiencies observed during the closing meeting. The audit team should be urged to comment on positive, as well as negative, observations.

Section 7. How the Auditor Should Handle Audit Results

Although many audit reports have addressed only negative points, experience clearly shows that the credibility and acceptance of audit reports are substantially improved if they include an assessment of over-all performance. "How well are we doing?" is a fair question, and some statement of the audit team's opinion will go a long way in getting the auditee's management attention. Auditing organizations should identify three types of results during the course of an audit:

1. Exemplary Practice -- A practice, procedure, or instruction that is well above the expected norm of performance.

2. Deviation or Finding –

- Any nonconformance or inadequacy which results in a product nonconformance to a specified requirement,

- or the lack of a system or controls to satisfy a customer or system requirement,

- or any nonconformance to a procedural requirement or inadequate procedure which causes the conformance of product, practices, or activities to be unknown.

3. Observation -- An opinion regarding a condition not covered by a specific requirement; or a procedure, practice, or instruction whose effectiveness could be improved.

Typically observations and exemplary practices do not require a response from the audited organization. The term "exemplary practice" should be reserved for those very few instances where the auditee:

- has established an elegant, effective system,

- has developed an unusually high degree of awareness and cooperation internally,

- or has adopted a practice that is clearly superior to anything you have seen elsewhere.

Deviation(s) are normally recorded on a form such as a Corrective Action Request (CAR) by the auditor who identified the deficiency:

- CARs are completed and numbered consecutively in correlation with each finding by the lead auditor.

- Each CAR has the identity of the auditor who issued the finding.

The lead auditor has the responsibility to:

- Review each deviation noted on the CARs and discuss any ambiguous or conflicting observations with the auditor(s).

- Verify that the deviation is a "condition adverse to quality," or a "statement regarding noncompliance with established policy, procedures, etc."

- Remain aware that one objective of auditing is to induce performance improvement. This requires that deviations, in particular, be stated in terms that will arouse management interest, and as a minimum, convince them that there are significant problems which need to be investigated.

- Ensure that each final deviation is a clear, concise statement of a problem.

- Resolve any possible differences or discrepancies among the audit team.

The lead auditor should use discretion in keeping the audited organization(s) and appropriate manager(s) abreast of the audit in progress:

- A guiding factor would be severity and safety impact of the deviation(s).

- Those conditions which require prompt corrective action should be reported immediately to the audited organization.

The lead auditor usually conducts the closing meeting. The following items are a portion of the closing meeting:

- Verbally report audit findings to the audited organization's representatives.

- Call upon individual auditors for additional input.

- Explain that the deviations are "draft" until the audit report is issued and may not appear on the audit report if found unwarranted. (The CARs are intended to give the audited organization an opportunity to begin corrective action on any deviations issued at the conclusion of the audit, instead of waiting until the audit report is received.)

- A copy of each CAR is left with the audited organization(s) upon conclusion of the close out meeting.

- Usually a CAR is not required when a deficiency noted during the audit has been corrected and verified prior to the close out meeting. (This will be reported as a deviation, which will indicate correction and verification prior to completion of the audit.)

The lead auditor usually prepares an audit report within ten (10) working days of the close out

meeting. Care should be taken to ensure the audit report is specific in content and contains no ambiguities. The audit report includes the following:

(a) Audit Report Cover Sheet,

(b) Audit number,

(c) Audited organization or activity,

(d) Date of audit,

(e) Scope of audit,

(f) Audit team with lead auditor identified,

(g) Executive Summary of audit results,

> The Executive Summary will briefly state whether applicable program elements have been implemented, based upon an evaluation of the audited organization's performance. The number of deviations, observations or exemplary practices should be included.

(h) Exemplary Practices, if applicable

(i) Requirements or Deviations, if applicable

> (1) List the requirement first with the deviation statement next. Include deviation(s) identified, corrected, and verified, prior to the close out meeting, with an explanation of completed corrective action.

> (2) Request corrective action for unresolved deviations.

(j) Observations, if applicable,

(k) Key personnel contacted,

(l) Documents reviewed, and

(m) Applicable signatures.

Unresolved deviations require Corrective Actions or Plans from the audited organization:

- Corrective Actions usually require that a response containing the following, as applicable, is submitted to the auditing organization within 30 days from the date of the published report. Information should include:

  (a) Corrective action to correct the unresolved deviations identified in the written audit report.
  (b) Cause identification.
  (c) Actions to prevent recurrence.
  (d) Lessons learned.
  (e) Actions to be taken for improvement.

- Deviations not corrected within the 30-day response period require a Corrective Action Plan including a milestone schedule for each deviation.

The Auditing organization should:

- Provide guidance for unacceptable corrective action,

- Request review by appropriate management for unacceptable corrective action,

- Provide notification of inability to verify or validate completion of acceptable corrective action, with a copy to their client,

- Determine acceptability of corrective action,

- Evaluate overdue response or corrective action correspondence,

- Approve corrective action, and see it through: Evaluation, Verification and Closure of Corrective Action.

Section 8. How the Auditee Should Handle Audit Results

The audited organization should attempt to maximize its benefit from the audit. Where exemplary practices were noted by the auditors, those practices may be publicized and their use reinforced where applicable. Observations, conveying an auditor's opinion that best management practices were not followed, should be evaluated and may serve to improve beyond simple compliance and help to achieve excellence. Exemplary practices and observations do not require a response to the auditing organization.

Deficiencies normally require response from the auditee to the auditing organization. Maximizing the benefit from deficiencies requires several steps to be taken by the auditee, and is part of the proactive approach provided here. Site procedures must be followed, and generally include these steps:

1. Verify the factual accuracy of each deviation statement. This may require checking with the persons interviewed by the auditor, reading the documents that the auditor read, or observing an activity that was observed by the auditor. Finally, verify that the requirement cited is applicable to the activity and was correctly interpreted by the auditor.

2. Identify the scope of the deficiency. While the auditors may have found one or two instances, there could be more that were not observed by the auditors due to their limited time and resources. Corrective actions are needed for all instances, whether found by the audit or not.

3. Identify the person(s) responsible for corrective actions. Generally, site procedures and organizational charters will guide this step. Deficiencies covering more than one parallel organizational unit are normally addressed by the next higher level of management.

4. Once responsibility has been assigned and accepted, a corrective action plan is made for each deficiency. This plan, with brief action statements and stated or clearly defined deliverables and due dates, can become part of the response to the auditing organization.

5. Each deficiency should be graded for significance. High risk, safety related deficiencies are normally given priority for correction. Some deficiencies have so little consequence that they are noted and no corrective action is taken, where this is agreed to by clients and regulatory authorities.

6. Root cause analysis should be considered for the more significant deficiencies. This may lead to an improved corrective action plan that prevents recurrence.

7.   Where corrective actions cannot be completed for a long time, mitigating actions for the short term should be included in the plan as needed.

8.   Tracking the corrective actions in a management commitment system is done to ensure an orderly completion and to provide a means for changing dates, responsible persons, and details of the action.

9.   Verification of completed actions by assembling evidence files, re-audit, or other means allows closure in the tracking system.

10.   Lessons learned from the audit, root cause analysis, and corrective actions should be written and disseminated to those who can apply them in their activities. Sometimes exemplary practices noted in the audit report are the basis for a positive lesson.

Section 9. References

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