## QMP 9.1 - Audit Procedure

Issue Date: updated with highlight 2020-09-24

**PURPOSE and Scope**

To define the responsibilities and describe the methods and documentation to be used to audit and evaluate internal (organization’s) or external (Supplier’s, Designer’s, Contractor’s, etc) quality programs.

The highlights are emphasizing the main points and are examples of items that could be delivered in a presentation on Auditing.

 [**When presenting a QMP, students are strongly advised to emphasize the general information applicable to the principal you are explaining.** QMPs are not “requirements” in the same way that the 9001 elements are Requirements]

**1. Audit Flow Charts**

 1.1 Audit Preparation Process

Lead Auditor

Prepare Audit Program:

Gather info, assess program

Discuss and confirm purpose, scope, date with Auditee

No

Acceptable ?

Revise Audit Program

Yes

Notification to Auditee

Audit Team

Review Auditee’s quality system

Prepare audit checklists

 **Continued at Flowchart “Day of the Audit”**

 1.2 Day of the Audit

**Continued from Flowchart “Audit Preparation Process”**

Audit Team and

Auditee personnel

Introduction, scope schedule, audit process facilities required, and any special gear such as safety gear.

Conduct opening meeting

Discussion / interviews, audit fact finding and review of records

**Internal Audits:** As both Auditor and Auditee are on the same team, the focus is encouraged to shift from compliance to process improvement.

Audit Team

Prepare draft Audit Report,

Attended by Audit Team and Auditee

Closing meeting and presentation of audit findings (draft report)

Lead Auditor

Issue Final Report and

Audit Follow-up

Auditee proposes Corrective Action

Auditee

Action plan agreement and follow-up

Lead Auditor

**2. REFERENCES**

Quality Manual (QM), ISO 9001, 9.2 [The basis for this QMP]

1. **DEFINITIONS AND ABBREVIATIONS**

3.1 **Audit**: systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

3.2 **Auditee:** Organization that is being audited.

3.3 **Auditor**: person with the competence to conduct an audit.

3.4 **Audit Criteria:** set of policies, procedures, specifications, or requirements used as a reference.

3.5 **Audit Findings**: results of the evaluation of the collected audit evidence against audit criteria. [Note: Audit findings can indicate either conformity or nonconformity, or opportunities for improvement (OFI).]

3.6 **Audit Program:**  a set of one or more audits planned for a specific timeframe and directed towards a specific purpose.

3.7 **Corrective Action**: action to eliminate the cause of a detected nonconformity or other undesirable situation to prevent recurrence.

3.8 **Nonconformity or Nonconformance (NC):** A deficiency of a characteristic or a failure to adhere to documented procedures, which may render the quality of a product or service unacceptable. A physical NC requires Engineer of Record sign-off, as the resolution (“to fix the physical problem”) may not be known.

3.9 **Quality Management Procedure**: a procedure that details the methodology for a particular process related to the Quality Management system (QMS) – such as this audit procedure.

1. **RESPONSIBILITIES**

**[In every QMP, the responsibilities are never carved in stone (they are the choice for the organization that wrote them, so do not spend any time on them, other than as examples.]**

4.1 **Quality Manager**

* Review and approve audit schedule
* Review and issue reports prepared by Audit Team

4.2 **Auditor** (often the Quality Manager)

* Schedule audits
* Notify the Auditee of audits
* Prepare audit checklist
* Execute audits
* Prepare audit report
* Follow up on audit findings
* Support and direct audit team

 4.3 **Auditee**

* Represents the organization being audited
* Responds to the bullet points directly above

**5.0 Procedure**

5.1 **Scheduling of the audit**

The Quality Manager prepares an audit program (schedule of audits typically on an annual or semi-annual basis) that provides for audit of the Project Team, Designers, and Contractors throughout the duration of the project.

The audit program and audit frequency of any given auditee is based upon the following:

1. importance of the activity and the perceived difficulty in achieving the specified quality requirements;
2. results of previous audits;
3. results of trend analyses or inspection results;
4. dates and extent of revisions to applicable documentation;
5. changes in the Auditee’s personnel or management structure.

The audit program is flexible and can be revised to reflect a change of any of the above noted items.

5.2 **Planning of the audit**

5.2.1 **Internal versus external audits**: The audit process is largely the same for internal or external audits and hence we have only one procedure for both. The main difference is that external audits are typically looking for “compliance” while internal audits are encouraged to focus on compliance and on improvement. Internal audits are able to be collaborative efforts between auditor and audited (two players on the same team) focused on improvement.

5.2.2 The Quality Manager assisted by the Lead Auditor determines the processes of primary importance in the Auditee’s quality program to be audited, and requests appropriately qualified and or competent personnel to form an audit team.

5.2.3 The audit team is comprised of one or more persons including specialists who can evaluate technical functions and may include observers.

5.2.4 The auditor(s) prepares detailed audit checklists derived from the Auditee’s QM, quality documents and/or the quality standard applicable to the process being audited.

5.2.5 In addition to the above, detailed questions derived from specific requirements within the contract or project may be included.

5.2.6 External and internal audits will typically take place at the Auditee’s place of business.

5.3 **Audit Notification**

5.3.1 The Lead Auditor notifies the Auditee by phone at least one week, preferably two or more weeksin advance of the planned audit to confirm the audit dates.

* + 1. The Lead Auditor communicates with the Auditee in writing at least one week prior to the audit specifying:
		- the process to be audited,
		- specific scope of the audit (e.g. procedures),
		- the identity of the auditor(s), including the Lead Auditor,
		- the quality program standard against which the audit is to be conducted (e.g. ISO 9001:2015, contract specifications, Auditee’s Procedures);
		- any special or protective equipment required, and
		- schedule of meetings and duration of visit.

5.4 **Pre-Audit Meeting**

The Lead Auditor establishes a pre-audit meeting between the auditor(s) and the Auditee. This meeting is used to introduce the auditor(s) and reiterate the contents of the notification letter.

5.5 **Audit Procedure**

5.5.1 Using the appropriate audit checklists discussed in 5.2.4 above (see *QMP 010C – Audit Checklist Form*) the auditor(s) verifies that the Auditee’s quality plan, procedures, or work methods comply with the Auditee’s quality program and contract requirements and are implemented and adequately controlled. If, during the course of the audit, other areas or problems are observed which are not included on the original checklist, the auditor is free to examine these areas as necessary.

5.5.2 All audit findings and observations are documented and evaluated.

5.5.3 Upon completion of the audit, the audit team meets to discuss all audit findings and observations. A draft audit report identifying the audit findings, nonconformances (NCs), and opportunities for improvement (OFIs) is generated at this time. It is recommended to allow sufficient time (min 1 hour) to type and print out the Audit Report so that the exact findings can be discussed and agreed prior to leaving the audit.

5.6 **Post Audit (Wrap-up) Meeting at Auditee’s Location**

5.6.1 A post audit wrap-up meeting is held among the audit team and the Auditee’s team during which the draft audit findings and observations are presented. Auditee senior management should be encouraged to attend so that they can understand first-hand the audit findings.

5.6.2 The Draft Audit Report prepared by the Lead Auditor must be signed and copied to the Auditee for acknowledgement. (For that to happen, the Auditor must schedule the time to type up the audit report at the end of the audit – recommended, but not always possible.) A deadline for OFI and NCR resolution and Corrective Action proposals must also be set.

5.6.3 At this meeting, observations are expressed and recommendations given about improvement of the quality program.

5.7 **Audit Report**

5.7.1 The Lead Auditor prepares a report detailing the audit results using the following standard template (see *QMP 9.1.4 – Audit Report Form*):

* purpose
* basis of audit (eg ISO 9001, and/or QMP, and/or Contract Agreement, etc )
* summary (including observations and audit findings)
* completed audit checklist
* nonconformances (NCs) or Opportunities for Improvements (OFIs)

5.7.2 Ideally, the Audit Report is printed and delivered to the Auditee at the wrap-up meeting on the day of the Audit in order to minimize misunderstandings. As a minimum, the Audit Report must be issued within ten (10) working days of the audit. The report becomes part of the quality records stored by the Quality Manager and is registered (logged). Copies are also sent to and kept by Document Control.

5.8 **Auditee Input**

5.8.1 **Internal audits:** – Discussion of Internal audit process from 5.2.1 deserves a comment here. Auditee input from the internal audit process has fewer constraints (as Auditor and Auditee are on the same team). Therefore the ability to dialogue with the auditor regarding process improvement is greatly enhanced.

5.8.2 **Internal or External Audits:** The Auditee must sign the Audit Report signifying that the audit report reflects the audit performed. If the Auditee disagrees with an audit finding, he/she is free to express that disagreement. Typically agreement can be arranged between the Auditor and the Auditee once the details are properly expressed. As a minimum, the Auditee must sign the document and if necessary, state any disagreement.

5.8.3 If nonconformances are recorded, the Auditee is required to provide the proposed resolution (disposition) (the fix of the problem), and the proposed corrective action (the fix of the procedure so as to prevent reoccurrence). This step can be taken after the audit is finished but the proposed disposition and proposed corrective actions must be written and returned to the Auditor with a target of one week (or as agreed) following the Audit. .

5.9 **Audit Follow-Up**

5.9.1 When the Auditee has provided the proposed disposition and corrective action(s) to the audit findings, they are submitted to the Lead Auditor or others assigned to verify that the stated action(s) have been implemented and are effective. For external audits, one common option for verification is to wait until the next audit.

5.9.2 As audit findings (NCRs and OFIs) are addressed, their status is tracked and recorded in the NCR & OFI log that is maintained by the QA Manager. (Deficiencies may also be tracked if they are part of the findings.)

5.9.3 Once all resolutions and corrective actions have been satisfactorily completed the nonconformance can be closed, the Lead Auditor provides final sign-off and advises the Auditee by letter or by next audit report.

 5.10 **Quality Records**

5.10.1 The original completed and signed-off Audit Report and all backup documentation (e.g. audit checklists) must be forwarded to the Quality Manager and Document Control for filing in the project records. The Quality Manager should keep copies for reference purposes.

1. **Related Documents**

Quality Manual or Quality Management Plan

**7.0 Attached or Learning Hub Documents**

QMP 9.1.1 – Audit Schedule

QMP 9.1.2 – Audit Agenda

QMP 9.1.3 – Audit Checklist Form

QMP 9.1.4 – Audit Report Form

QMP 9.1.5 – Audit Log

**8.0 Revision History**

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| --- | --- | --- |
| **No.** | **Date** | **Description of (Key) Changes** |
| A | 2014-02-02 | Initial procedure by J Turnham - provided the 5 audit files  |
| 0 | 2020-09-24 | Flow chart to the front |

Originated By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ /\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Quality Auditor Date

Approved By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ /\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Quality Manager Date

Approved By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ /\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Project Manager Date

**See Learning Hub for QMPs**

QMP 9.1.1 – Audit Schedule

QMP 9.1.2 – Audit Agenda

QMP 9.1.3 – Audit Checklist Form

QMP 9.1.4 – Audit Report Form

QMP 9.1.5 – Audit Log

 **[END OF QMP 9.1]**