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Quality Assurance Audit Procedure

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Quality Assurance Audit Procedure

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Quality Assurance Audit Procedure

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Quality Assurance Audit Procedure

1.0 PURPOSE

The purpose of this procedure is to describe the method for scheduling, performing, documenting and closing-out internal quality audits and surveillances performed on Entity operation and maintenance. The purpose of a Quality Audit is to ensure that the Facility minimum Quality requirements have been met and demonstrate that the services/facilities provided conform to the specified requirements. The Audit looks for evidence that management has specified the objectives and policy and established a system of procedures to accomplish them and has assigned duties, delegated authority, and set up suitable testing, inspection, examination and audit programs to verify that the required standards of performance have been achieved.

This procedure applies to the management and control of activities performed during the Operation and Maintenance (O&M) of government facilities across the Kingdom of Saudi Arabia.

2.0 SCOPE

Periodic Quality audit reviews, shall be performed on significant departmental activities and/or processes. The scope of the Quality Audit Reviews may include but are not limited to the following primary areas:

- Quality management system
- Placing inquiries for materials, equipment, services and subcontracts, and performing bid evaluations
- Planning and scheduling of facility activities and deliverables, including the coordination of resources and training and qualification of facility personnel
- Control of documentation and quality records

In addition to conducting internal quality audits, quality surveillances and functional department assessments of internal work processes and products will be used to routinely evaluate compliance to the procedures.

3.0 DEFINITIONS

Definitions	Description
Audit	Quality Audit - A comprehensive review of work execution in a pre-defined area of a project to ensure that quality standards are being maintained.
Deficiency	A general term covering any defect, discrepancy, omission or lack of conformance to requirements.
ECMS	Enterprise Content Management System
Internal Quality Audits	Audits of activities performed by Certified Internal Auditors on the facility organization
Non-conformance	A defect, deficiency or other condition averse to quality. A structure, system, component or product that does not conform to specified requirements. Non-conformances identified during quality assurance audits are recorded as Non-conformance Reports.
Non-Conformance Report (NCR)	Report identifying nonconformities. Can include the approval of remedial works, designer's opinion, inspection of repairs, etc...
O&M	Operation and Maintenance
Observation	Comments, concerns, suggestions and/or recommendations for the benefit of the auditee; such as, opportunities for improvement, including situations with the potential to become non-conformances.
QE	Quality Engineer
QM	Quality Manager
Quality Assurance (QA)	Part of quality management focused on fulfilling quality requirements. Quality assurance is a way of preventing errors and avoiding problems when delivering solutions or services to customers.
Remedial Action	Steps taken to correct a specific instance of deficiency, non-conformance, error or violation of requirements, typically as identified in a NCR.



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Definitions	Description
Surveillance	The act of monitoring, witnessing or observing to verify whether items or activities conform to specified requirements. As used in this procedure, 'surveillance' is an audit of a portion of a contractor's operation. A surveillance examines a smaller number of items than a total system audit.

4.0 REFERENCES

- EOM-EQA-PR-000002 - Non-Conformance and Corrective Action Procedure
- EOM-EQC-PR-000001 - Quality Control Procedure

5.0 RESPONSIBILITIES

5.1 Auditee

The Auditee is responsible for being available to the audit team and providing information that will be necessary to perform a meaningful assessment of the audit scope. The Auditee is responsible for the facility quality approach that conforms to the quality specifications and which ensures that:

- Products and services comply with statutory, regulatory and contract requirements
- Employees implement and continually improve the effectiveness of the FQP
- Facilities establish quality objectives, review them periodically for relevance, and provide adequate resources to ensure they are achieved
- Communicate the quality policy to employees, contractors and stakeholders to ensure that it is understood and followed.

5.2 Audit Team / Auditors

The Audit Team typically consists of people who have sufficient background in the process or area of interest being audited. The Audit team will be comprised of minimum two persons who are independent from the department being audited and must be certified to conduct an internal Audit. The Audit Team members will be called Auditors. The audit team members are selected by the Quality Manager (QM)

5.3 Audit Team Leader

The Audit Team Leader is appointed by the QM and is responsible for the execution of an audit working with the assigned Auditee and Audit Team. After completion of a Quality Audit, the Audit Team Leader or his designee will prepare an audit report.

5.4 Quality Manager

The QM is responsible for determining the audit schedule and scope, assigning an Audit Team members, approving the audit checklist, as applicable, and reviewing the final audit report prior to issuance to the Auditee.

5.5 Quality Engineer

Quality Engineer (QE) is responsible for performing and/or supporting facility audits and surveillances with below items:

- Being a member of Audit and Surveillance team
- Issues Non-Conformance Report (NCR) number to Assessor upon request
- Provides verification that the NCR action items are complete
- Maintains facility NCR Status Report
- Ensures all relevant NCR documentation is stored in the Enterprise Content Management System (ECMS)



6.0 PROCESS

The purpose of an audit is to verify implementation of specific requirements described in documents such as Quality Management System, Contracts, Procedures, Instructions, Specifications and Drawings. The process for conducting both total system audits and surveillances is described within the body of this procedure. A Process Flow Chart describing the Quality Audit process is provided as **Attachment 1**.

6.1 Scheduling of Quality Audits

Audit Schedules shall be prepared at the start of the calendar year by the QM. The Audit Schedule (**Attachment 2**) shall identify all internal audits to be performed during each calendar year. The Audit Schedules shall identify organizations and/or the internal sections/areas to be audited, and the planned dates for conducting the audit. Unscheduled audits may be added at the discretion of the QM. Previously scheduled audits may be rescheduled based on emerging project requirements in which case the schedule shall be updated and revised as necessary. Audit completion status shall be maintained (on the Schedule) by the QM or designee. The current Audit Schedule shall be maintained in the quality records of the ECMS system. The permanent record of audits completed during each calendar year is also maintained for stakeholders to access.

6.2 Audit Report Numbers and Non-Conformance and Corrective Action Reports

6.2.1 Audit Identification and Numbering

The Audit Team Leader should ensure that all Audits shall be identified using the codes given below and numbered sequentially:

- Year audit performed (4-digit, numeric)
- Audit number in sequence (3-digit, numeric)
- Type of Audit (1-character, letter) A = Audit, S = Surveillance

Example: 2017-001S, 2017-002A, 2017-003A (there shall be no hyphens between audit number and type)

6.2.2 Nonconformance and Corrective Action Reports

The Quality Department will be responsible for issuing all associated NCRs and shall manage these notices in accordance with the EOM-EQA-PR-000002 - Non-Conformance and Corrective Action Procedure.

6.3 Audit Notification and Plan

The Audit Team Leader for the Quality Audit shall prepare an Audit Notification and Plan and this plan shall be sent to the organization to be audited. Quality Audit Notifications and Plans shall be distributed to Auditees at least thirty (30) days prior to commencement of the audit. In the case of a Quality Surveillance Audit, the Audit Notification and Plan is not required. Alternatively, for a Quality Surveillance Audit a simple Agenda and Audit Plan is sufficient.

6.4 Quality Audit Scope

The Audit Team members shall utilize a prepared Audit Checklists based upon the scope of the audit and pertinent controlling documents such as contract requirements, drawings, specifications and procedures. Audit Checklists are used to guide Auditors through the verification process. The Auditor shall record results of audit verifications on the Checklist. Completed Audit Checklists shall be reviewed and approved by the QM or designee (e.g. Audit Team Leader)

6.5 Surveillance Audit Scope

A Surveillance Audit is narrower in scope than a total system audit. A Surveillance focuses on a limited number of activities to verify compliance in those areas. The Quality Surveillance Team will select the



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systems, processes, procedures, items etc. to be reviewed at the discretion of the QM or designee. The areas to be considered will be based upon various factors which may include the following:

- Results of previous audit findings
- Identification of performance trends
- Request from senior management.

A formal Audit Checklist and Opening and Closing Meetings are not necessarily required but suggested for Surveillance Audits. However, all findings (including Observations and Positives) shall be recorded in the body of the Quality Surveillance Report (**Attachment 6**).

6.6 Conducting The Audit

6.6.1 Audit Team / Auditors

- Audits will be conducted by interviews and/or examinations of objective evidence using applicable documents which illustrate the application of program requirements being audited.
- Checklist(s) will be used in performing Quality Audits and for recording audit results. Where objective evidence is provided to demonstrate a finding (e.g. digital photo, copy of certificate), it shall be retained and included in the Audit Report as an attachment.
- All Audit Team Meetings should use an Attendance Sheet to document Audit Team participation. **Attachment 4**

6.6.2 Audit Team / Auditee

- Non-conformities identified during all audits will be discussed with the Organization's/ Department's Auditee(s) and where agreed, documented on Nonconformance and Corrective Action Reports (NCRs) within the Audit Report. These require a formal response from the Auditee (see EOM-EQA-PR-000002 - Non-Conformance and Corrective Action Procedure).
- Minor nonconformities are identified as Observations and considered to be opportunities for improvement by the Auditee. They do not require a formal response from the Auditee but are still recorded in Quality Audit and Surveillance Reports.

6.6.3 Post-Audit Meeting

6.6.3.1 Audit Team Leader / Auditee

- A Post-Audit Closing Meeting will be convened by the Audit Team Leader, with the Auditee. All key Auditee participants and relevant members of line management shall be encouraged to attend. Attendees will record their presence on the Attendance Sheet. **Attachment 4**

6.6.3.2 Team Leader / Auditee

At the Post-Audit meeting, the Audit Team Leader will:

- Present an objective summary of the Audit.
- Outline the Audit results providing the Auditee with the opportunity to fully discuss NCRs and Observations such that any misinterpretation or misunderstanding is avoided. Favorable remarks regarding processes, products will also be summarized.
- In conjunction with the Auditee, establish the responsibilities and schedule completion date(s) for close-out of NCRs. Scheduled completion dates shall be established for each NCR with due consideration given to the severity or critical nature of each non-conformance identified.
- Indicate the intended date for issuing the Audit Report and provide details regarding response to audit results, and associated NCRs (when applicable).



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6.6.4 Audit Reports

6.6.4.1 Audit Team Leader

- After completion of a Quality Audit, the Audit Team Leader, or his designee, will prepare an audit report using the Quality Assurance Audit Report (**Attachment 5**). The Audit Report shall contain all the documents identified as Attachments in Section 6.0 of the report template. Audit results shall be summarized using Quality Assurance Audit Results Summary Sheet Template (**Attachment 8**). Original Checklists completed during the audit need not necessarily be attached.
- All Audit Reports will be approved by the Audit Team Leader before transmission to the Auditee.
- At the discretion of the Team Leader, Observations may be included in an Audit Report. Observations are intended to foster process enhancement(s) and/or efficiency improvements. Compliance with the Observations shall not be mandatory.
- In the interests of maintaining a balanced viewpoint, Audit Reports will also identify any favorable points noted during the Audit (e.g. especially effective or efficient implementation activities and/or process improvement opportunities).

6.6.5 Audit Report Distribution

- Audit Reports will be signed and distributed to the Auditee and relevant Functional Management by the Team Leader. A copy of the Audit Report shall be maintained current within the ECMS.

6.6.6 Quality Staff

- The Quality Assurance Audit Status Report (**Attachment 7**) is maintained by the Quality Department and will be updated whenever a new Audit Report is issued and the ECMS updated accordingly.

6.7 Conducting The Surveillance

- A Quality Surveillance differs from an Audit in notification, scope, and formality. However, the actual activities and post audit closeout are identical.
- In the case of a Quality Surveillance, an Audit Notification and Plan is not required (although the Auditor may draw up an Agenda/alternative Plan)
- Formal Pre- and Post-Audit meetings are not required. A brief meeting with the department Manager to provide an overview of the Surveillance process is sufficient.
- A limited number of activities are reviewed in the same manner as a Quality Audit.
- After completion of a Quality Surveillance, the Auditor shall complete a Quality Surveillance Report (**Attachment 6**). Activities monitored during the surveillance shall be documented in the Surveillance Report.

6.8 Corrective Action Verification

The Audit Team Leader shall work with the Auditee to ensure that all NCRs issued during the audit process are addressed by the appropriate departments. After the department has addressed the corrective action, the Auditor shall verify the corrective action has been implemented and is complete. The following two outcomes can occur:

- Where corrective action taken has been completed, the NCR shall be closed out by the QM by signing and dating the NCR as per the EOM-EQA-PR-000002 - Non-Conformance and Corrective Action Procedure.
- If the corrective action has not been completed, the NCR shall remain open pending further action(s) by the Auditee. In either case, the Auditee shall be notified, in writing, by the QM.



6.9 Records

The following records shall be maintained in the ECMS:

- Audit Schedules
- Audit Notifications and Plan
- Audit Site Visit Attendance Sheets
- Quality Audit Reports (including NCRs)
- Quality Surveillance Reports (including NCRs)
- Quality Audit Status Report

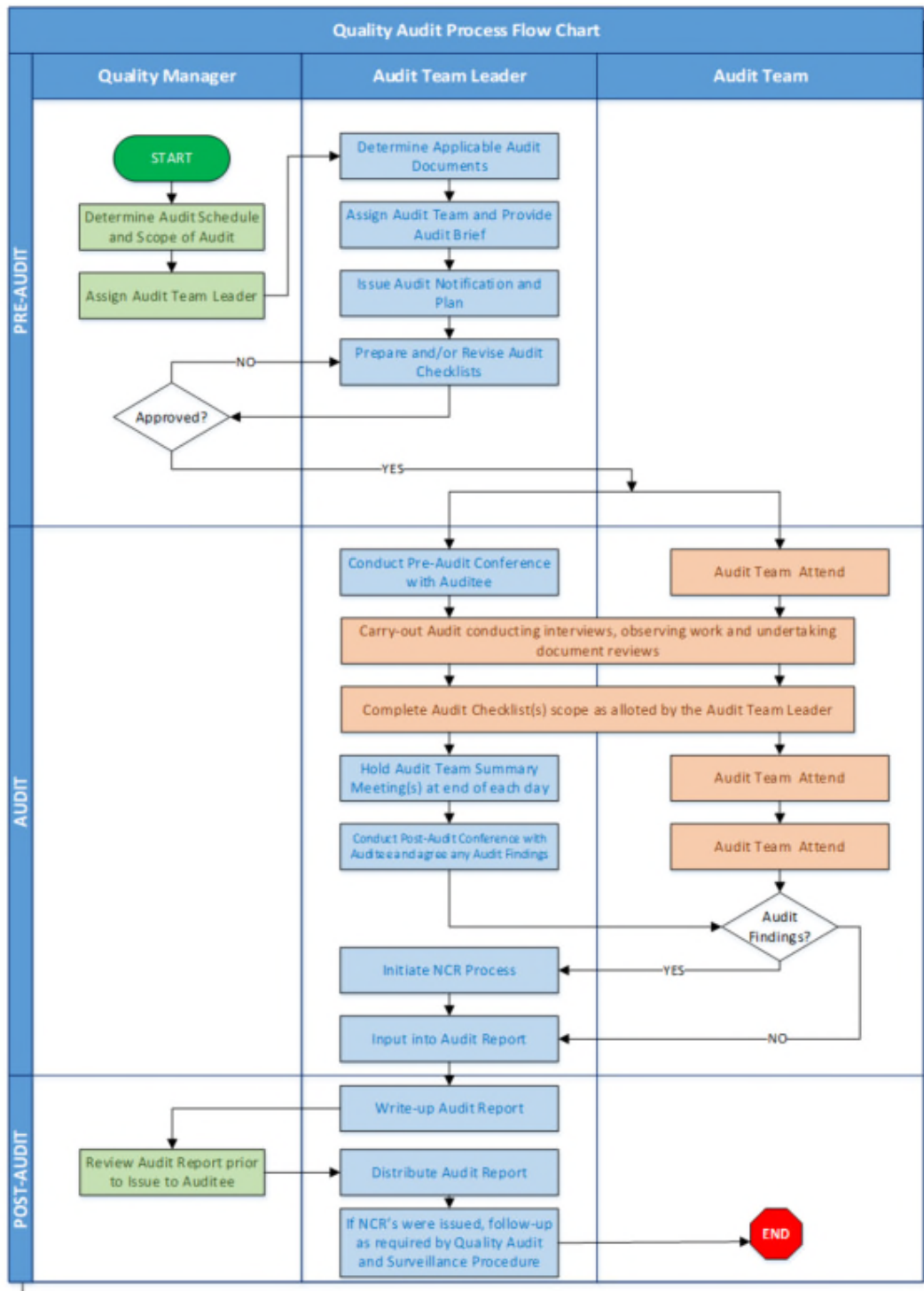
7.0 ATTACHMENTS

1. Quality Audit Process Flow Chart
2. EOM-EQA-TP-000001 - Audit Schedule Template
3. EOM-EQA-TP-000002 - Audit Notification and Plan Template
4. EOM-EQA-TP-000003 - Attendance Sheet Template
5. EOM-EQA-TP-000007 - Quality Assurance Audit Report Template
6. EOM-EQA-TP-000005 - Quality Surveillance Report Template
7. EOM-EQA-TP-000006 - Quality Assurance Audit Status Report Template
8. EOM-EQA-TP-000004 - Quality Assurance Audit Results Summary Sheet Template



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Attachment 1 - Quality Audit Process Flow Chart





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Attachment 2 - EOM-EQA-TP-000001- Audit Schedule Template



Internal Audit Schedule Template

No.	Scheduled Audit Date	Actual Audit Date	Audit Type	Sector	Business Unit	Procedure/Manual	Auditor team

SAMPLE



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Attachment 3 – EOM-EQA-TP-000002- Audit Notification and Plan Template

Audit Notification and Plan Template

Audited:		Lead Auditor:		
Audit Date(S):		Auditor:		
Audit Number:		Auditor:		
AUDIT OBJECTIVES/AUDIT REFERENCE DOCUMENTS				
AUDIT SCHEDULE				
The Schedule shown below may be adjusted according to audit progress and Auditee personnel availability				
No.	Date/Time	Point of Contact	Activity	Location
1.			Pre-Audit Meeting	
2.			Daily Summary Meeting	
3.			Daily Summary Meeting	
4.			Daily Summary Meeting	
5.			Daily Summary Meeting	
6.			Daily Summary Meeting	
7.			Daily Summary Meeting	
8.				
9.				
10.				
11.				
12.				
13.				
14.				
15.				
16.				
17.				
18.				
19.				
20.			Post Audit Meeting	



Attachment 4- EOM-EQA-TP-000003- Attendance Sheet Template

Attendance Sheet Template

Subject : Quality Audit and Surveillance
Purpose : The purpose of a Quality Audit is to ensure that Mashroat Quality plan and requirements have been met
Time :
Date :
Location :

Name	Department	Signature



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Attachment 5 - EOM-EQA-TP-000007- Quality Assurance Audit Report Template

EAUDIT NUMBER:	AUDIT START DATE:	AUDIT END DATE:
TYPE OF AUDIT:		
<input type="checkbox"/> Process Audit	<input type="checkbox"/> Document Audit	<input type="checkbox"/> External Audit
AUDITED:		
<div style="text-align: center;">AUDIT REPORT CONTENTS</div> <div style="text-align: center;"><p>1.0 Executive Summary</p><p>2.0 Statement of Effectiveness</p><p>3.0 Audit Team Members</p><p>4.0 Audit Reference Documents</p><p>5.0 Audit Findings</p><p>Corrective Action Notices</p><p>Observations</p><p>Items of Good Practice</p><p>6.0 Attachments</p><p>6.1 Audit Notification and Plan</p><p>6.2 Audit Stage Attendance Sheet</p><p>6.3 Audit Summary</p><p>6.4 Observations</p><p>6.5 Non-Conformance Reports (NCRs)</p></div>		
<p>This Audit Report was prepared by:</p> <div style="display: flex; justify-content: space-around; margin-top: 20px;"><div>_____</div><div>_____</div></div> <div style="display: flex; justify-content: space-around; margin-top: 5px;"><div>(Name)</div><div>(Date)</div></div>		



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Attachment 6 - EOM-EQA-TP-000005 - Quality Surveillance Report Template

Quality Surveillance Report Template



REPORT NUMBER		DATE
DEPARTMENT:		
REFERENCE DOCUMENT NO.	REV. NO.	REMARKS:
DESCRIPTION OF ACTIVITY BEING MONITORED:		
LOCATION:		
ACTIONS / OBSERVATIONS / COMMENTS:		
Initiated by:		
_____ (Name)		_____ (Date)



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Attachment 8 - EOM-EQA-TP-000004- Quality Assurance Audit Result Summary Sheet Template

Audit Title: _____				
Audit Dates: _____		Audited: _____		
Requirement Document(s), Including Revision: _____				
Checklist Prepared By: _____			Date: _____	
Checklist Approved By (Lead Auditor Signature or Initials) _____			Date: _____	
ITEM NO.	AUDIT ELEMENT STATEMENT (Quote or paraphrase requirement from the applicable Program/Procedure, or state the performance based criteria)	REQUIREMENT DOCUMENT(S) SECTION	SAT/UNSAT (If UNSAT, include NCR/CAN No.)	AUDITOR VERIFICATION STATEMENT (Include objective evidence reviewed during the audit or attach a data sheet/spreadsheet that ties to the Checklist item No.)
Note: Red text provides suggested evaluation criteria guidance and is to be used in conjunction with the scope of work being audited in developing the checklist evaluation items. Checklist preparer is to delete red text after completing checklist.				
1.	Management Responsibility <ul style="list-style-type: none">• Quality Policy<ul style="list-style-type: none">o Verify management with executive responsibility is defined and has documented its policy for quality, including objectives for quality and its commitment to quality.• Organization<ul style="list-style-type: none">o Responsibility and Authority<ul style="list-style-type: none">□ Verify the responsibility, authority, and interrelation of personnel who manage, perform or verify work affecting quality is defined and documented.o Resources<ul style="list-style-type: none">□ Verify identification of resource requirements, adequate resources and assignment of properly trained personnel.o Management Representative<ul style="list-style-type: none">□ Verify executive management appoints a member of management who has independent responsibility to ensure a quality system is established and performance of the quality system is reported to executive management.• Management Review<ul style="list-style-type: none">o Verify management with executive responsibility reviews the quality system at defined intervals to ensure continuing suitability of the stated quality policy and objectives			<u>Discussed with:</u>
2.				<u>Discussed with:</u>
3.				<u>Discussed with:</u>
4.				<u>Discussed with:</u>
5.				<u>Discussed with:</u>
6.				<u>Discussed with:</u>
7.				<u>Discussed with:</u>