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Quality Document

F4E-QA-101 - Quality Audit Implementation

This document defines the details and instructions to implement the Quality Audit process, by F4E when performing a quality audit (external or internal).This instruction is applicable to External and Internal quality audits performed by F4E.

Approval Process			
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Change Log			
F4E-QA-101 - Quality Audit Implementation (24XXZF)			
Version	***Latest Status***	***Issue Date***	***Description of Change***
v0.0	In Work	17 December 2015	
v1.0	Signed	17 December 2015	first issue
v1.1	Signed	21 January 2016	Updated title and scope (avoid confusion of second and third party) Changed finding grading to serious and significant to avoid confusion with minor and major NCRs Removed grading from IA (by principle their are serious) Simplified Criteria
v1.2	Approved	29 January 2016	title changed

QUALITY INSTRUCTION

Control Page

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Document title:	F4E-QA-101 - Quality Audit Implementation

Areas and functions	
Document ownership:	Quality Manager
Area(s) concerned:	Quality Audits (operational expenditure or internal processes - Working Procedures)
Function(s) concerned:	Audit Team, Quality Manager, QA Officer, TPO, PTM

Purpose

This document defines the details and instructions to implement the Quality Audit process, by F4E when performing a quality audit (external or internal).

Scope

This instruction is applicable to:

- External quality audits performed by F4E. External audits by F4E are those where F4E performs a quality audit of an external party of the supply chain.
- Internal Quality Audits performed by F4E. Internal Audits by F4E are those where F4E performs a quality audit on a process or activity of F4E.

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Objective of the Audit

- Review of the Methods and Procedures for:
    - External Audit: Quality Plan Implementation (e.g. Documents, Monitoring, Control of configuration changes, Resources, Approval process) throughout the life cycle of the project
    - Internal Quality Audit: process or activity implementation.
- Identify opportunity for improvement
- Assure compliance with the requirements (in particular the management specification for external audits)

Scope of the Audit

Internal Quality Audit	External Quality Audit
• Process or Activity • Working Procedures implementing the Process or Activity • The outputs and document produced by the process or activity	• Quality Plan and its implementation • Control Plan and its follow-up • Documents and Processes mentioned in the Quality Plan and Control Plan

Audit Team

The audit team is composed of auditors that do not have direct responsibility on the entity/section to audit (independent).

> *Auditor* - A person with the demonstrated personal attributes and competence to conduct an audit.

During the audit preparation the auditors shall propose the composition of the audit team for validation by the F4E Quality Manager.

The Audit team is independent from the work performed.

Normally, audit teams are composed of 2 auditors (minimum):

- Lead Auditor: QA expert, supervises the team, organises and directs the audit, coordinates the preparation, and manages the performance of the audit.
- Auditor: QA expert or technical expert.

Further elements can be added to the team (such as additional auditors), with specific expertise if needed.

The Lead Auditor of an F4E Quality Audit must be an F4E staff member.

Witnesses and/ or observers can be further added by the Audit team as required.

In external Quality Audits the presence of the contract technical and QA officers (as witness/ observers) is not required/ essential, but in some cases can be helpful (coordinate audit date with existing progress meeting).

Auditor Qualification

To be able to perform Quality Audits in F4E, the auditors of the F4E Quality Audits system must be qualified by the F4E Quality Manager.

Auditors already included in the Annual Quality Audit plan of the previous years are considered qualified by the Quality Manager.

Qualification Requirements for Quality Auditors in F4E:

1- Must have successfully completed a training course for ISO9001 QMS Internal \ Lead Auditor attested by a training certificate issued by an independent third party.
   - QMS Lead Auditor in the case of Lead Auditor.
   - QMS Internal Auditor in the case of Auditor.

AND

2- Must have the Work and Practical Audit Experience as defined in the table below

	Auditor	Lead Auditor
Work Experience	Number of Years	
Quality related work	2	4
Practical Audit Experience	Number of Audits	
Initial qualification (over a 1-year period)	1	1 as Lead Auditor
Maintenance of Qualification (over a 3-year period)	3 minimum	3 minimum (1 min as Lead Auditor)

Auditor Qualification in F4E is performed through the following steps:

1- Inline manager proposes the Candidate to the Quality Manager.

2- Quality Manager verifies the necessary personal attributes, *Work Experience* and *Training Certification* of the Candidate (as per qualification requirements above).

3- If the Candidate is selected, the necessary *Audit Experience* is required to be qualified.

   a. the on-the-job experience required is defined in the table above;

   b. the audit experience might have been acquired in a previous job;

   c. a practical on-the-job experience can be achieved by participating in an F4E audit as a 'training' Auditor / Lead Auditor under the supervision of a Lead Auditor.

4- Once the required personal attributes, *Work Experience*, *Training Certification* and *Audit Experience* are accepted by the Quality Manager, the Candidate becomes 'qualified'.

Maintenance of the qualification is monitored and renewed yearly by the Quality Manager taking into account:

   a. On-the-job experience (maintenance requirements in table below);

   b. Performance feedback as assessed/received (quality of audit report, feedback of auditee or customer, follow-up of audit until closure, etc);

   c. Need for improvement, such as refresher training or lesson learnt workshop.

Selection of Auditees

The entities to audit are defined in the Quality Audit Annual Plan (QAP) approved by the Director.

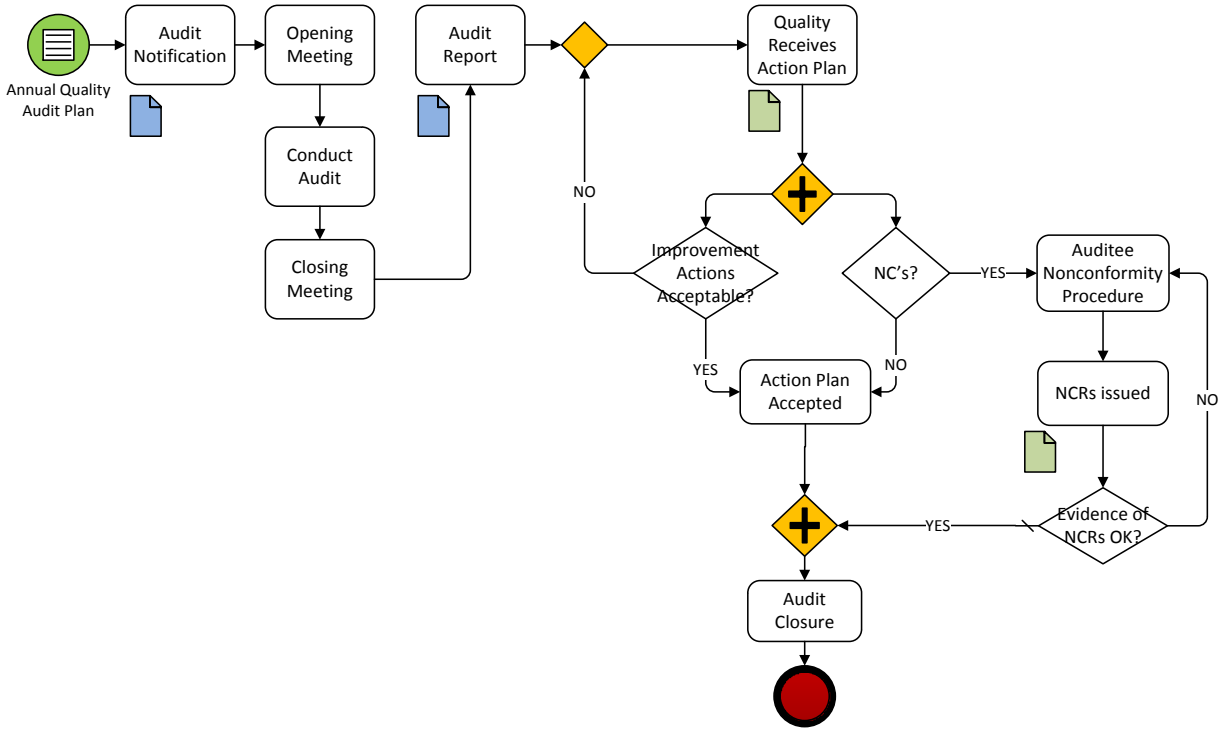
Non-scheduled audits can be defined, if justified, at any moment by the F4E Quality manager following audit outputs or project team's feedback.

In the selection of entities for the annual plan, the following principles are applied:

- The **annual specific criteria** of selection is attached to each annual plan (and approved);
- The **overall eligible population** is prepared from an extract from primavera of November of the current year (N-1) and includes Contracts and Grants signed by the end of November of the current year (N-1) and ongoing in the plan year (N);
- The same contract should **not be audited 2 years in a row** – an exception is made on very high impact/high risk contracts/grants or if the audit is made on a different entity (e.g. Subcontractor);
- At least, between **1 to 3 Internal Quality Audits** are expected annually (internal audits are normally on processes and like this can involve the review of 3 or more contracts/ grants);
- Audits on **Grants (or FPAs)** (~7% of the operational budget) should be limited to 3 per year;
- Audits on **Contracts (or FwC)** (~93% of the operational budget) are the core part of the plan and should be at least five times (5x) the number of audits on grants;
- The selection of the entities, based on the eligible population within the limits defined above, is based on the **impact of the contract (cost or risk assessment** by the Project Teams) as follows:
    - High Impact Cost (HIC) contract or grant, based on the contract/grant total value;
    - High Impact Risk (HIR) contract or grant, based on the assessment made by the project teams and the control mechanisms and recommended for audit;
    - Internal Quality Audit (IQA) process or procedure of high impact in the organisation;
    - If additional samples are needed, they shall be selected based on Monetary Unit Sampling (MUS) from the remaining entities population ordered by WBS.

Audit Procedure

- The Audit Process is described in the F4E process PM-28 Quality Audits (F4E_D_22H84F).
- Brief scheme of the audit process:



- The audit has a minimum duration of 2 days (for R&D 1 and ½ days is acceptable), where:
  - 1 or ½ day for the documentation (includes review of any past audit action plan);
  - 1 or ½ day for the implementation (shop floor/production/reverse findings);
  - ½ day for the audit report drafting and closure meeting.
  - Typical schedule is:

Day	1	2
Morning	Opening Meeting (30 min)	Actions from previous day (30 min)
	Start: Audit - documentation	Audit – implementation
Lunch	--	--
Afternoon	Audit documentation + implementation	Draft the Audit Report
	Resume of the day (30 min)	Closing Meeting (1 hour)

- The Audit is conducted by auditors by means of a checklist prepared for the audit (based on the generic internal checklist based on the provisions/ clauses of the contracts).

Some of the key steps are:

- Opening Meeting:
  - Present the Audit team,
  - Present the objectives and the brief process,
  - Confirmation of the agenda,
  - Expected participation from the Auditee (as a minimum):

Internal Quality Audit	External Quality Audit
• Process Owner • Team Leader of the areas to Audit • Quality Officer of the areas to Audit	• Technical Representative • Quality Representative • Project Manager (Management Representative)

- Conduct Audit:
  - The audit itself consists of collecting and verifying evidence, through appropriate sampling.
  - Only information that is verifiable may be audit evidence (objective evidence that should be recorded).
  - The methods of collecting information include:
    - Interviews,
    - Observation of activities, and
    - Review of documents (processes, procedures, instructions, records, reports, minutes, databases, websites, etc).
  - Audit evidence (normally documents) requested by the audit team to verify information must be provided within 1 hour (unless agreed otherwise in the opening meeting), otherwise it is considered missing/not presented.
  - The verification of compliance and process auditing is done using the audit checklist and the documented quality system (QP).
  - In an External Quality Audit the typical ‘documentation’ part includes review of (not limited to):
    - Supplier Quality Plan,
    - Subcontractors Management,
    - Implementation of the Management Requirements and Risk Plan (for non-R&D contracts) review,
    - Implementation of the Control Plan and Documentation Schedule,
    - Implementation of the Deviation, Nonconformity, Document Flow processes,
    - Management of identification and traceability,
    - Overall documentation traceability (including Incoming Certificates, ADP, parts),
    - If a previous audit exists, the implementation of the Action Plan.
  - In an External Quality Audit the typical ‘implementation’ part includes (not limited to):
    - Control Plan review,
    - Parts identification and traceability,
    - Handling and Storage,
    - Special Processes and operators qualification (including NDT and welding),
    - Calibration and control of measuring and test equipment,
    - Adequate material segregation (non-conform and/or contaminant),

        - Sample reverse traceability audit.
- Closing Meeting:
    - Presentation of the findings,
    - Discussion of the findings,
    - Way to proceed with any nonconformities,
    - Way to proceed with any improvement areas,
    - When to expect the Audit Report,
    - Expected participation from the Auditee is the same as for the opening meeting.
- Audit Report:
    - Based on the result of the audit and the closing meeting the Audit Team issues, the Audit Report, within 7 working days.

Findings

Finding - something that is found or ascertained.

Audit findings are those resulting from the observations during the audit.

The findings are communicated to the Auditee in the following manner:

- During the Audit:
    - Individually, directly to the interlocutor,
    - Summarised, at the end of each day.
- At the end of the Audit:
    - Presented during the Closing Meeting (normally not distributed at the meeting).
    - In the Audit Report and Checklists (after internal review and approval in F4E and then distributed to the auditee).

Findings can be:

- *Strong Area* - positive finding that is performed in a manner that is better than expected or is worth mentioning.
- *Improvement Actions* (IA) - actions on findings that might lead to non-compliances, NOT current non-compliances, of requirements or that would benefit from an improvement to perform better (mitigate the risks).
- Nonconformities (NC) - findings that do not comply with the requirements of the contract and its annexes.

Grading of Nonconformity findings:

- *Significant finding NC* = isolated incident or single observed lapse - minimal risk;
- *Serious finding NC* = repeated incident, a procedural (systemic) error, or an incident that will compromise a deliverable - medium to high risk.

  3 *significant findings* NC (3 NCs) on the same process or area (e.g. Quality Plan section) = 1 *serious finding* NC (due to the process compromise and risk increase).

For each Improvement Area and/ or Nonconformity the audit report will identify:

- Grade of the finding for NCs (identifying serious finding or significant finding),
- Observation/ Fact,
- Requirement or Area of requirement,
- Recommendation or proposal of the path to follow.

(ISO 19011) Audit evidence is verifiable. It is based on samples of the information available, since an audit is conducted during a finite period of time and with finite resources. The appropriate use of sampling is closely related to the confidence that can be placed in the audit conclusions.

In relation to audit findings every attempt should be made to resolve any diverging opinions concerning the audit evidence or finding.

If there are diverging opinions, the auditor can review the supporting evidence and ask for feedback about its accuracy. He or she also can ask for new evidence that would contradict the existing evidence or support a different finding.

Resolving diverging opinions supports an evidence based (let the facts speak for themselves) approach. If the evidence collected is wrong, it should be corrected. If the evidence is accurate, the findings should stand. Any unresolved issues should be recorded.

Any ex-post arbitration of unresolved issues will be performed by the Quality Manager, taking into account the findings reported.

Overall Result

The audit overall result is the assessment of the audit and the observations made during the audit period, not the assessment of the performance of the supplier during the implementation of the contract.

The audit Overall Result must be ascertained as follows:

1 = unsatisfactory	+ Action Plan from previous YEAR(s) not implemented + at least 3 *serious* finding NC + at least 5 finding IA
2 = below criteria	+ Action Plan from previous YEAR(s) not implemented + at least 2 *serious* finding NC + at least 5 finding IA
3 = meets criteria	+ at least 1 strong area + maximum 4 finding IA + maximum 1 *serious* finding NC + Action Plan from previous YEAR(s) implemented (if existing)
4 = above criteria	+ at least 3 strong areas + maximum 4 finding IA + NO *serious* finding NC + Action Plan from previous YEAR(s) implemented (if existing)
5 = outstanding	+ at least 4 strong areas + NO *serious* or significant finding NC + NO finding IA + Action Plan from previous YEAR(s) implemented (if existing)

Any intermedium scenario is left at the discretion of the Lead Auditor to decide between the 2 levels taking into account the audit observations.

Follow-Up

Where the audit report identifies Improvement Areas and/or Nonconformities, the Auditee must:

- Within 15 days of receiving the audit report, present an Action Plan detailing its actions to address the identified findings. This must obtain F4E's quality approval;
- Each nonconformity shall also be the subject of a Nonconformity Report (NCR) to be raised by the Auditee within the required timeframe.

The follow-up of the open NCRs and the implementation of the Action Plan shall be the responsibility of the Auditee under the supervision of the contract/team QA officer.

Closure of the Action Plans (when all actions are implemented) must be followed by the contract/team QA officer.

In the case of External Quality Audits, actions for F4E (either Improvement Actions or Nonconformities) must not be included in the Audit Report. These actions must be the object of a separate Field Observation Report (FOR) (one or several) to be sent to the person responsible for the action.

Resulting FORs must be:

1. Complete (contains all the related facts)
   - why – unmet requirement
   - what – objective evidence
   - where – which work area
   - when – the date
   - who – by title, if relevant
2. Correct (accurately conveys the facts)
3. Concise (fully explained in brief terms)
4. Clear (understood for prompt action)
5. Categorised finding (significant or serious, if used)
6. Confirmable (traceable and verifiable)

Closure

The Audit will be closed when:

- The Audit Report is approved by the F4E Quality Manager;

  AND

- The Action Plan, if requested, is approved by F4E (Quality Manager);

  AND

- All NCRs originated from the audit are raised (initiated).

Confidentiality

The following data is considered to be of limited distribution:

- All the information collected during the audit
- The Audit Checklists
- The Audit Report
- The Action Plan

Limited distribution means that the information access is limited to the following:

- Audit Team members
- F4E Director, F4E Quality Manager and members of the QACB
- From F4E on the:

Internal Quality Audit	External Quality Audit
• Process Owner • Team Leader of the areas to Audit • Quality Officer of the areas to Audit	• Contract/Grant QA Officer • Technical Officer(s) • Project Team manager • Head of Department

F4E representatives (F4E Inspectors, ITER IO, Architect Engineer or Integrator) that will participate in F4E Quality Audits must sign an acknowledgement of confidentiality and non-disclosure undertaking (recommended template: F4E_D_26WVFM).

If the audit report is on a contract that is part of an ITER Procurement Arrangement, the ITER IO might request access to it. In these cases the distribution will be to the requester only after the signature of an acknowledgement of confidentiality and non-disclosure undertaking (recommended template: F4E_D_26WVFM)

If required, F4E staff will sign a *non-disclosure agreement* or *confidentiality agreement* to be agreed in advance.

Documentation SOAP

The audit documentation Sign-Off Authority Policy (SOAP) is defined in the PM-28 Quality Audits (F4E_D_22H84F).

Supplementary documentation sign-off authority is defined as:

Document	Author	Reviewers	Information (on issue)	Approver
Field Observation Report (FOR) As result of Audit	Audit team member	The other(s) member(s) of the Audit Team + Contract/Team QAO	Lead Auditor inline manager External Audits: + Contract TPO + Contract PTM Internal Audits: + Process Owner + Team Leader audited	QM