FUSION FOR ENERGY

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Quality Document

F4E-QA-101 - QMS Audit Implementation

This document defines the details and instructions to implement the QMS Audit process, by F4E when performing a QMS audit (internal QMS process or Project Team and QAO implementation of a Contract). This instruction is applicable to all QMS audits performed by F4E.

Approval Process			
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Change Log			
F4E-QA-101 - QMS 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
v1.3	Approved	18 July 2017	tbd
v1.4	Approved	09 August 2017	Minor format correction

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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 working procedures)
Function(s) concerned:	Audit Team, Quality Manager

Purpose

This document defines the details and instructions to implement the Quality Management System (QMS) Audit and Supplier process (PM-28), by F4E when performing a QMS audit.

Scope

This instruction is applicable to QMS Audits performed by F4E. QMS Audits by F4E are those performed to the implementation of a QMS process(es) or audit performed to the Implementation of the QMS by a Project Team (and its supporting roles) in a specific contract or grant agreement with the Supply Chain

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QMS Audit Manager

- The QMS Audit Manager is the F4E Quality Manager.

Objective of the QMS Audit

- QMS Audit to internal quality/ operational processes:
    - Evaluate the execution of process;
    - Assess the traceability of the process documentation/ records;
    - Assess the compliance with requirements;
    - Identify any risks and improvement opportunities.
- QMS Audit to the Project Team implementing a contract:
    - Assess Project Team's propagation of the quality requirements documents;
    - Assess Project Team's implementation of the quality/ operational processes (Deliverable Acceptance, Deviation control, Nonconformity control, CAR, Quality Surveillance, Documentation control, changes in Subcontracting, follow-up of Control Plans, Export Control, Surveillance Plans, Generic Safety Requirements propagation, etc.);
    - Assess the Contract's Documentation Records;
    - Identify any risks and improvement opportunities.
- Support the assurance of compliance with the internal QMS requirements.

Scope of the QMS Audit

- QMS Audit to internal quality/ operational processes:
    - Process or Activity;
    - Working Procedures implementing the Process or Activity;
    - Outputs and documents produced by the process or activity.
- QMS Audit to the Project Team implementing a contract:
    - F4E Contract and its implementation of the quality and operational processes, including:
        - PM-06 Deviation Control (22CCM4),
        - PM-07 Document Control (22KS43),
        - PM-29 Work-Package Implementation (22DUJM),
        - PM-35 Nonconformity Control (22MDXC),
        - PM-38 Quality Surveillance (22DDMG),
        - PM-42 Corrective Action Request (29KV8Z),
        - PM-43 Contract and GA Modification (Operational Expenditure) (26RCZV),
        - PM-63 Deliverable Acceptance (262PUA),
        - PM-77 Export Control (Dual Use) (23T94X),
        - PM-98 Changes in Subcontracting (24DB5W),
        - QA-013 Propagation of Generic Safety Requirements in the Supply-Chain (23CA9U),
        - QA-016 Surveillance Plans Instructions (23JXHS).
    - All Outputs and documents produced by the contract;

Criteria of the QMS Audit

- QMS Audit to internal quality/ operational processes:
  - QMS, Processes and Working Procedures.
- QMS Audit to the Project Team implementing a contract:
  - QMS, Processes and Working Procedures,
  - F4E Contract and its requirements.

Audit Team

The audit team is composed of auditors who do not have direct responsibility on the entity/ section to audit (independent). The Audit team is independent from the work performed.

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

The preliminary composition of audit team is agreed with potential auditors during the preparation of annual QMS audit programme, and is validated by Audit Manager. In case of changes, they shall be validated by Audit Manager.

Further elements can be added to the team (such as additional auditors), with specific expertise if needed. Witnesses and/ or observers can be further added by the Audit team as required.

Auditor Qualification

To be able to perform QMS Audits in F4E, the auditors must be qualified by the QMS Audit Manager.

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

Qualified for QMS Auditors list: MS Auditor Pool (296MSS).

Qualification Requirements for QMS 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.
   - Minimum of QMS Lead Auditor in the case of Lead Auditor.
   - Minimum of QMS Internal Auditor in the case of Auditor.

AND

2- Must have the Work and Practical Audit Experience as defined in the table below (as a minimum)

	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	3 (1 as Lead Auditor)

QMS Auditor Qualification in F4E is performed through the following steps:

1- The Inline manager proposes the Candidate to the QMS Audit Manager.

2- The Audit 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 Audit Manager, the Candidate becomes 'qualified'.

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

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

   b. Performance feedback as assessed/ received (quality of audit report, feedback of auditee or customer, CAR raised, 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 by the Audit Manager in the QMS Audit Programme (QAP) approved by the Director.

Non-scheduled audits can be defined, if justified, at any moment by the Audit 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 programme (and approved);
- The QMS Audit Programme is a set of audits **aimed at demonstrating conformance** with the QMS (and QA Programme) and **assuring the Director** of the effectiveness of the system implemented;
- The processes and teams to be audited are **selected based on**:

   a) All operational teams need to be audited on implementing the quality/operational processes once every 3 years;

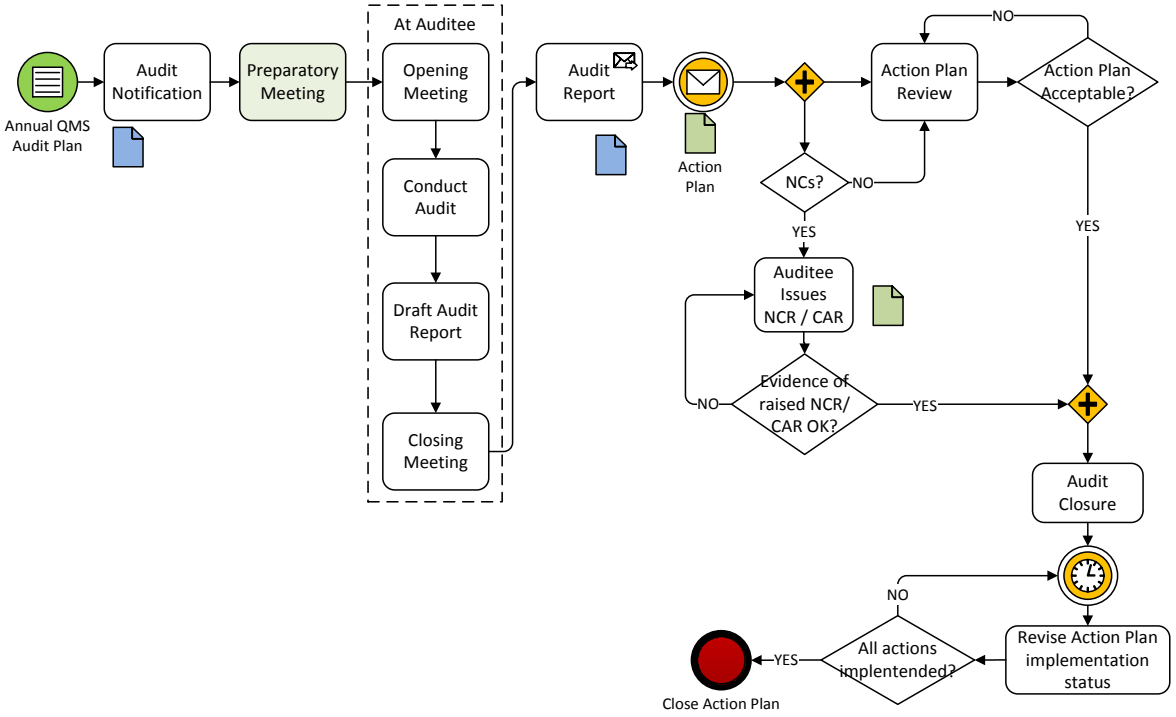
   b) All quality/operational processes or procedures of high impact in the organisation need to be audited once every 3/4 years (those mentioned in ' Scope of the QMS Audit');

   c) Processes that have recently being redesigned of suffered a major update, should be audited the year after, to verify conformance of the implementation;

   d) Overlap with the IAC audits on a 2 year period must be avoided, and consider that a team audited by IAC fulfils the point a) for the next 3 years.

Audit Procedure

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



- The audit has a minimum duration of 2 and ½ days, where:
  - 1 day for the process(es) review and the sampling reverse audit;
  - 1 day for the process(es) implementation with those producing the samples;
  - ½ day for the audit report drafting and closure meeting.
  - Typical schedule is:

Day	1	2	3
Morning	Opening Meeting (30 min)	Actions from previous day (30 min)	Actions from previous day (30 min)
	Start: Audit – review process(es) and samples	Audit – process(es) implementation	Draft the Audit Report
			Closing Meeting (1 hour)
Lunch	--	--	--
Afternoon	Audit – Audit – review process(es) and samples	Audit – process(es) implementation	
	Resume of the day (30 min)	Resume of the day (30 min)	

- 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).
  - F4E-QA-214-2 - QMS Audit Check List (22TWG9)

Some of the key steps are:

- Preparatory Meeting:

- Meeting attendants:

Type Quality/operational processes	Type Project Team implementing a contract
• Audit Team • Process Owner and QAO of Area	• Audit Team • Contract TPO and QAO

- Presentation by the area QAO / Contract QAO of the Audit Documentation,
- Clarification of the Audit plan,
- Review the audit checklist,
- Definition of the specific scope and samples.

- 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):

Type Quality/operational processes	Type Project Team implementing a contract
• Process Owner • Team Leader of the areas to Audit • Quality Officer of the areas to Audit	• Project Team Manager • Contract TPO • Contract QAO

- 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.
  - Audit evidence must not be requested after the closing meeting. What was not requested during the audit, and what was not presented during the audit it is considered not checked or not presented.
  - The verification of compliance and process auditing is done using the audit checklist and the documented quality system.
  - In a QMS Audit the typical process review part includes (not limited to):
    - Requirements/ Criteria: Specified? Documented? Available?

- Plans: Specified? Documented? Available?
- People: Competent? Trained? Aware of objectives?
- Procedures/ Methods of implementing: Documented? Controls? Availability?
- Parts or Inputs: Identified? Preserved? Condition?
- Plan/ Equipment/ Tools: Qualified? Condition/ Maintenance? Capability? ID?
- Results: Correct? Measured? Release control? Authorisations? Feedback?
- Records: Identified? Correct? Accessible?

- Closing Meeting:
  - Presentation of the findings,
  - Discussion of the findings,
  - Way to proceed with any non-compliances,
  - 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.

Audit Numbering

QMS Audits are numbered as follows:
YYYY-QAP-N
Audit Findings are numbered as follows:
YYYY-QAP-N-F
Actions in reply to Audit Findings are numbered as follows:
YYYY-QAP-N-F-A

Where:
YYYY is the year (e.g. 2017)
N = sequential number of the audit in a year
F = sequential number of the finding in an audit
A = sequential number of the finding in a finding

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).

3 *isolated* NC (3 NCs) on the same process or area (e.g. Process implementation) = 1 *systemic* NC (due to the process compromise and risk increase).

For each Improvement Area and/ or Non-Compliances the audit report will identify:

- For NCs the type (identifying *Compromising Deliverable* or *Systemic* or *Isolated*),
- 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 Audit 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 by the Lead Auditor** as follows:

- Action Plan from previous YEAR(s) not implemented = - 10
- Compromise the Deliverable NC = - 5
- Systemic NC = - 3
- Isolated NC = - 1
- Improvement Area = - 1
- Strong Area = + 2

The Audit starts with **10 points** at the opening meeting.

Points at Closure Meeting	Overall Result
< 5	**Below criteria**
5 - 12	**Meets criteria**
>12	**Above criteria**

These scores are indicative and 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

Once the audit report is approved by the Lead Auditor, the Lead auditor distributes the approved audit report to the auditee and the internal stakeholders.

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 to the Audit Team. This must obtain the Lead Auditor approval;

For **Audit Non-Compliances identified**, the auditee must also as a minimum:

Compromising the deliverable	*Systemic* *(no direct impact on deliverable)*	*Isolated incident* *(no direct impact on deliverable)*
Raise an NCR within the stipulated timeframe and identify NCR in action plan. *Define Correction (Remedy) on NCR and perform a Root Cause Analysis and if applicable implement a Corrective Action.*	*Address the Non-Compliance in Auditee system, defining the Correction (Remedy) on Action Plan's first issue and provide evidence of its implementation (on follow-up updates).* *Perform a Root Cause Analysis and if applicable implement a Corrective Action.*	*Address the Non-Compliance in Auditee system, defining the Correction (Remedy) on Action Plan's first issue and provide evidence of its implementation (on follow-up updates).*

For **Findings on F4E**:

- NCR must be raised for non-compliances on the deliverable, using the process PM-35;
- Corrective Action Request (CAR) must be raised to address the Root Cause Analysis and Corrective Actions, using the Corrective Action Request process PM-42.

Examples of Audit Non-Compliance:

- Compromising the deliverable's compliance (on the product/deliverable or on a process whose output directly impacts the capacity of the deliverable to be compliant).
  - Non-compliant deliverable
  - Non-Compliant step of the Control Plan
  - Non-Compliant interim product at a step in the Control Plan
  - Non-Compliant process or measuring device used at deliverable release
- Systemic (procedural) error or repeated incident, not directly impacting the deliverable
  - Documentation archival system non-compliant
  - Persons of supporting process (not on the deliverable, e.g. Calibration Lab) without the adequate training
- Isolated incident or single observed lapse, not compromising the deliverable
  - Correct segregation of tools for Stainless steel, but one carbon steel tool found on the stainless area
  - System is working but an individual lapse is found

The action plan must have the minimum format as displayed below:

Action Plan Reference	**QMS Audit Ref**	**Audit Report Reference**	**Contract ID**
[reference]	[2017-QAP-01]	F4E_D_XXXXXX v1.0	[F4E-OPE-NNNN]

Action Plan in reply to the Audit Report

Action #	**Audit Finding**	**Action to Address Finding**	**Due Date**	**Responsible**	**Ref Doc.**	**Status**
[NN]	[2017-QAP-01-NN] [title]	[title] + [NCR/CAR Ref] [description including *remedy* and for systemic/repetitive the *root cause* and *corrective action*]	[01.Jan.2017]	[Name]	[reference]	[Not started / In Progress / Implemented]

The Action Plan must be uploaded in the IDM Audit report subfolder.

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.

The follow-up of the open CARs is the responsibility of the Quality Manager.

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

Resulting CARs 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. Confirmable (traceable and verifiable)

Closure

The Audit will be closed by the Audit Manager when:

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

  AND

- The Action Plan, if requested, is approved by F4E (Lead Auditor);

  AND

- All Corrective Action Requests originated from the audit are raised (initiated)

Communication on the status of the QMS audits is periodically made in the QCB and monthly Quality Info.

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 QCB
- Process Owner
- Team Leader of the areas to Audit
- Quality Officer of the areas to Audit

F4E representatives (F4E Inspectors, ITER IO, Architect Engineer or Integrator) that will participate in F4E QMS Audits must sign an acknowledgement of confidentiality and non-disclosure undertaking (recommended template: F4E_D_26WVFM). This is ensured by the Lead Auditor.