FUSION FOR ENERGY

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EXTERNAL REFERENCE

Quality Document

SOP-01.32 Supplier Audit Implementation (F4E-QA-102)

This document describes the system followed in F4E to implement the Supplier Audits through QMS Audits and Supplier Audits process (PM-28), by F4E when performing a Supplier Audit.

Approval Process			
	Name	*Action*	*Affiliation*
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Read Access	**LG: F4E_QAO, AD: IDM_Users, GG: IAS Audit Team, project administrator, RO, LG: QAG, LG: Director, LG: Other auditors from various teams, AD: IDM PI-SE-00-00 PM Systems Engineering, AD: IDM PI-00-00-HD PM Head of Project Management Department, AD: IDM AD-MS-00-QM Quality and Management System**		

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Change Log			
SOP-01.32 Supplier Audit Implementation (F4E-QA-102) (296E7T)			
Version	***Latest Status***	***Issue Date***	***Description of Change***
v0.0	In Work	13 July 2017	
v1.0	Approved	31 July 2017	for review /approval
v2.0	Signed	18 December 2017	"Overall result" section, now consistent with scores from new check-list (Supplier audits)
v2.1	Approved	12 January 2018	Table of Contents: Annex 1 and Annex 2 “available at O:\PM\QA\Supplier Audits” – no hyperlinks anymore. Section Overall Result: “A follow-up audit could be organized.”
v2.2	Signed	11 December 2018	• Proactivity of Supplier after last audit will be also taken into account • Inputs from “Contractor’s assessment” performed by Market Intelligence unit of Commercial department will be taken into account by SAM • approval of PM dpt, instead of DIR • removed “Total work experience” • clarification in Maintenance of auditor qualification "3 (1 as Lead Auditor)", now “3“
v2.3	Approved	17 December 2018	Red text - corrected
v2.4	Signed	17 June 2019	Updates as per changes in ITERD Dpt and Commercial Department (PJM, PGM, PO)
v2.5	Revision Required	27 June 2019	Updated as per 2019 F4E organizational changes (FR, ITRE-D, COM, Glossary)
v2.6	Approved	04 July 2019	Comments from the previous version are implemented.

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QUALITY INSTRUCTION

Control Page

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Document title:	Supplier Audits Implementation (F4E-QA-102) (SOP-01.32)

Areas and functions	
Document ownership:	Supplier Audits Coordinator (C. Brescan)
Process Group and Context:	Corporate Planning Financial Controlling and Reporting; Supplier Audits
Function(s) concerned:	SAC, QA HoU, QAO, PJM, TPO, Audit Team

Purpose

This document describes the system followed in F4E to implement the Supplier Audits through QMS Audits and Supplier Audits process (PM-28), by F4E when performing a Supplier Audit.

Scope

This instruction is applicable to Supplier Audits conducted by F4E. Supplier Audits are those audits performed to a Supplier (or its Supply-Chain) as verification of the implementation of F4E contractual requirements by the Supply-Chain.

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Reference documents

[1] PM-28 QMS Audits and Supplier Audits (22H84F)

Roles/ Definitions

Refer to F4E Acronyms and Definitions and F4E Roles in the Manual for more information

In addition to the "Roles/ Definitions" from PM-28 "QMS Audits and Supplier Audits", new abbreviations are added below:

CAR	Corrective Action Request
HoD/U/G	Head of Department / Unit / Group
IA	Improvement Action
NCR	Nonconformity Report
PgM	Programme Manager - responsible for the management of a Programme. The operational departments HoU (ITERD, ITERP and BA) is equivalent to PgM for financial delegations, its preliminaries and operational activities.
PjM	Project Manager - responsible for managing a Project. The operational departments HoG (ITERD, ITERP and BA) is equivalent to PjM for financial delegations, its preliminaries and operational activities.
QAU	Quality Assurance Unit
SA	Strong Area
SAC	Supplier Audits Coordinator
Supplier Audit Programme	F4E Annual Programme of Supplier' Audits to be performed. Approved in December of Year-1 by the Head of Project Management department
TPO	Technical officer, the task being approved by PJM

Objectives

(a) Assess Supplier compliance with F4E contractual requirements:
  (i) assess the Supplier's implementation of the Contract Quality Plan and Control Plan(s)
  (ii) assess the Contract's Documentation and Records
  (iii) verify processes and working procedures implementing the Process or Activity
  (iv) outputs and documents produced by the process or activity
  (v) support the assurance of compliance with the requirements
  (vi) document the evidences of compliance

(b) Obtain Supplier evidences of capability to perform activities at the required level of quality:
  (i) evaluate the execution of processes
  (ii) examination of activities mentioned in the Control Plan and their follow-up
  (iii) assess the traceability of the process documentation/ records
  (iv) identify any potential risk

(c) Identify improvement opportunities in Supplier organization (and also F4E, if any)

Audit Team Composition

Auditor - A person with the demonstrated personal attributes and competence to conduct an audit. F4E auditor shall be independent – he/ she cannot be involved directly or indirectly into the audited activities/contract.

Witness /Observer - A person who has a professional need to be presented during the course of the audit (e.g. PjM/ TPO/ QAO/ IO TRO/ Engineering integrator/ etc), but this person does not participate in the auditing activity.

(a) The preliminary composition of audit team is defined during the preparation of annual programme, based on the criteria recorded in Annex 1 - Auditor skills matrix. In case of changes (replacement of auditors) at any reason (QAO assignment in a different PT, etc) they shall be validated by SAC. Evidence of the changes shall be kept by SAC.

(b) Composition of the team is based on the type of the contract to audit and available profiles of auditors: R&D, production & manufacturing, follow-up of previous audit, SIC/ PIC implication, buildings, etc.

(c) F4E teams are composed of two* auditors:
  (i) Lead Auditor: QA expert, supervises the team, coordinates the preparation, organises and directs the audit, and manages the performance of the audit.
  (ii) Auditor: QA expert or technical expert, supporting the Lead Auditor (e.g. if specific needs of verification are identified, TPO staff from other technical area with respect to the audited area, could be invited to be part of Audit team).
  (iii) In some cases, one auditor (Lead auditor qualification is mandatory) is assigned to perform alone the audit, but then the duration of audit could be longer (3 days).

(d) Depending on the complexity of the audit, the Audit Team can be supported by additional auditors, external inspectors with specific expertise, TPO/ PPM staff/ ITER Organisation auditors/ etc.

(e) <u>Integrated team F4E – ITER:</u>
  (i) ITER auditors could be part of the team in a Supplier audit from F4E programme, but always the Lead Auditor must be an F4E staff member. Supplier Audits Programme will be circulated to ITER Quality Audit Coordinator, for adding the specific profiles /auditors.

(f) Witnesses:

(i) Witnesses and/ or observers can be further added as required.

(ii) In Supplier audits, the presence of the contract technical and QA officers (as witness/ observers) is not required/ essential. Nevertheless, QAO could be present in special cases (e.g. sensitive contracts, with amendments changing the initial requirements, communication problems with supplier, etc).

Qualification Requirements for F4E Auditor

(a) To be able to perform Supplier Audits for F4E, the staff members must be qualified.

(b) If they already have performed Supplier audits in the previous year's Supplier Audit Programme, the Auditors are considered qualified.

(c) Qualification Requirements for Auditors in F4E

(i) Mandatory training:

(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.

1. QMS Lead Auditor in the case of Lead Auditor
2. (Preferred) NQA-1 Auditor in the case of Lead Auditor for PIC/ PIA contracts
3. QMS Internal Auditor or ISO 9001 Quality Management training in the case of Auditor, AND
4. Minimum Work and Practical Audit Experience as defined in the table below:

	Auditor	**Lead Auditor**
Work Experience	Number of Years	
Quality Assurance related work	3	5
Practical Audit Experience	Number of Audits	
Initial qualification in QAG (over a 1-year period, under supervision of experienced auditor)	1	1
Maintenance of Qualification (over a 3-year period)	3	3

(d) A general "Auditor skills matrix" (Annex 1) is managed and updated by SAC on annual basis during the preparation of the Audit plan for the next year.

(e) Auditor Qualification Process in F4E is performed through the following steps:

(i) The QA HoU/ SAC/ inline manager proposes the Candidate

(ii) The SAC verifies that the qualification of the potential auditor corresponds to the requirements (skills, training certificate(s), and work experience).

(iii) If the Candidate is selected, the necessary *Audit Experience* shall be qualified.

(1) the on-the-job experience required is defined in the table above

(2) the audit experience might have been acquired in a previous job

(3) a practical on-the-job experience can be achieved by participating in an F4E audit as a trainee Auditor/ Lead Auditor

(iv) Once the required personal skills, *Personal Attributes*, *Work Experience*, *Training Certification* and *Audit Experience* are validated, the Candidate becomes 'qualified'.

(f) The Supplier Audit Manager is monitoring the validity of the qualification taking into account:

(i) on-the-job experience (maintenance requirements in table above)

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

(iii) need for improvement, such as refresher training or lessons learnt workshop

Preparation of Supplier Audits Programme

(a) Organisations to be audited during the year are listed in the annual Supplier Audit Programme approved by the Head of Project Management department.

(b) If requested and justified by project teams or QAOs, exceptional audits could be introduced in the yearly Programme.

(c) In the selection of organisations for the annual programme, the following principles and specific criteria of selection are defined, approved and applied:

(i) The **overall eligible population** is prepared by QAOs and SAC from an extract from Primavera / Integrated Reporting System (by project management officer) as at 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) (contracts in 2nd year of execution)

(ii) The first selection of organizations to be audited is made by QAOs in cooperation with the project teams

(iii) The selection of the entities is based also on the **impact of the contract (cost or risk**) as follows:

(1) High Impact Cost (HIC) contract or grant, based on the contract/ grant total value

(2) High Impact Risk (HIR) contract or grant, made by the project teams and the control mechanisms and recommended for audit

(iv) QAOs will rate the contracts from the first selection, as per defined criteria: risk, cost, NCRs, PIC/ PIA, criticality phase of contract, manufacturing stage, and reliability of Supplier. Proactivity of Supplier after last audit will be also taken into account

(v) From the initial list, a classification of contracts to audit will be generated, based on scoring. Head of PM department/ QA HoU /SAC will decide how many contracts will stay in the Annual Programme, based on budget allocation for Auditing activities

(vi) Inputs from "Contractor's assessment" performed by Market Intelligence unit of Commercial department will be taken into account by SAC

(vii) The same contract could be audited 2 years in a row **only if** there is a very high impact/ high risk contracts/ grants or **only if** the audit is made on a different entity (e.g. other part of a consortium or subcontractor)

(d) The approved Supplier Audits Annual Programme includes the information as below.

Nr.	Quality Audit (Contract Reference/ Title/ TPO/ QAO)	Auditee/ Supplier	PT	PBS	Lead Auditor	Auditor	Period/ Date	Location

(e) When the Supplier Audits Programme is approved and distributed to internal stakeholders, QAO of respective PTs shall send emails as below:

(i) To the Project or Project Team (PjM /TPO/ PgM):

The 20xx FSA (F4E Supplier Audits) Programme has been approved recently.

At this stage I would like only to inform you that F4E will perform an audit on XX Auditee XX concerning the quality plan implementation in F4E-TYP-NNN.

The audit is previewed for MONTH of 20xx.

The Audit Team (Lead Auditor: ……(name), Auditor …….. (name)) will provide you with additional details in due time.

(ii) After contacting the TPO - to the Auditee (please keep the Lead auditor and the Contract TPO in cc):

The 20xx F4E Supplier Audits Programme has been approved recently.

At this stage I would like only to inform you that F4E will perform an audit on XX Auditee XX concerning the quality plan implementation in F4E-TYP-NNN.

The audit is previewed for MONTH of 20xx.

The Audit Team (Lead Auditor: …….(name), Auditor …….. (name)) will provide you with additional details in due time.

(iii) Two or three months before the previewed date of the audit, the Lead Auditor shall contact the Auditee to Schedule the exact dates (please keep in copy TPO and QAO of the contract):

As you are already informed, the audit of your organisation is envisaged according to the 20XX FSA (F4E Supplier Audit) Programme.

The audit will be performed by the audit team consisting of Lead auditor ….. and Auditor….

According to the Audit Programme, the audit is envisaged for …. (month). The audit team would kindly ask to confirm, which of the following time-slot is most suitable for your Contract Team.

Proposed dates

Please find attached the preliminary notification of the audit. Please let us know who will be present from your organisation.

After the receipt of your confirmation and proposals, we will update the attached notification.

You are kindly requested to provide us as well with the following data:

Detailed address of your facility (and the gate where we are expected to enter, if relevant)

Are there any formalities to be done at the entrance (or in advance)

A contact person (incl. phone number) to ask for at the gate of the facility,

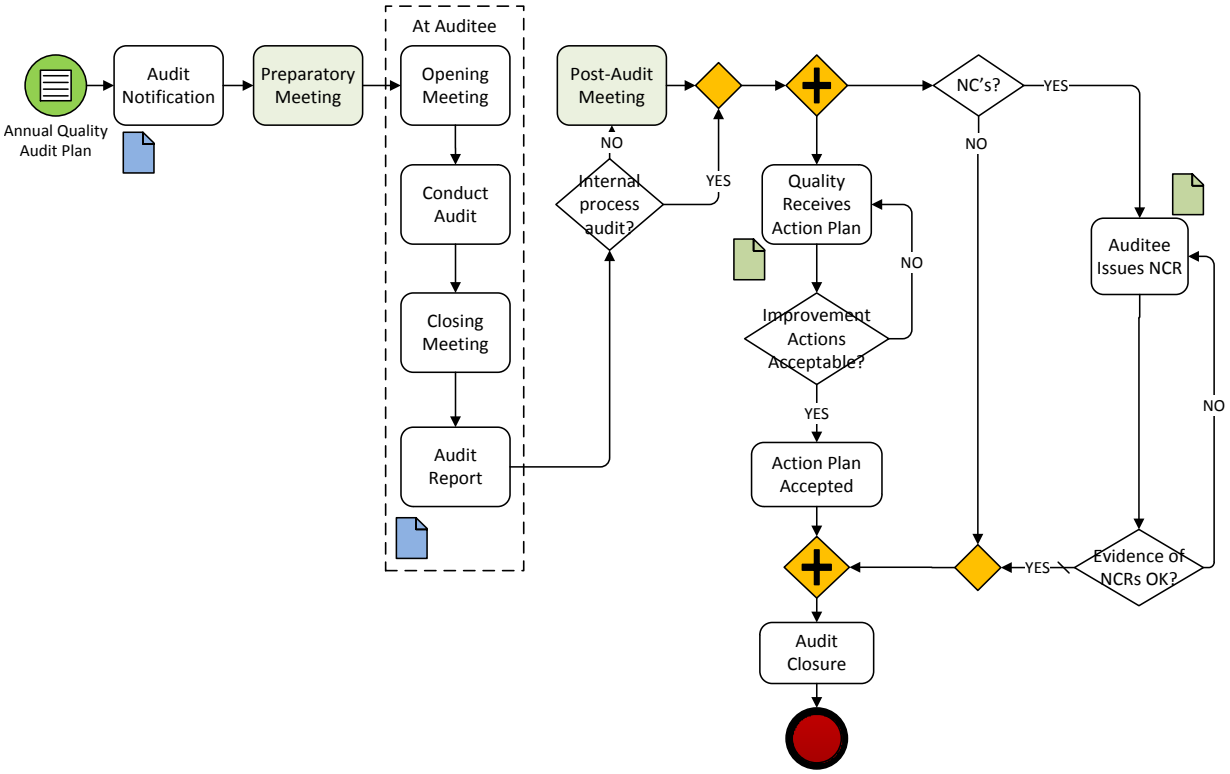
A recommendation for a hotel nearby.

(iv) Further info will be sent by Lead auditor (including detailed Agenda), after Preparatory meeting stage, at least 15 days before the scheduled date (as per PM-28).

Process

(a) The Process is described in the F4E process PM-28 QMS Audits and Supplier Audits (22H84F).

(b) Brief scheme of the process:



(c) Main Responsibilities related to the process:

(i) Lead auditor:

(1) Issues the audit notification
(2) Contacts the TPO/ QAO of the contract and the auditee
(3) Agrees dates of audit, prepares and sends the audit notification
(4) Organises the preparatory meeting
(5) Leads the Audit
(6) Drafts, approves and uploads the Audit report
(7) Distributes the Audit report after its' approval
(8) Approve the Action Plan (audit reply version)
(9) Issue CAR

(d) Auditor:

(i) Support Lead auditor during the audit in any of the above items

(1) Audit manager:
(2) Proposes the audit teams
(3) Approves the Audit Notification
(4) Closes the Audit
(5) Monitors the auditors performance
(6) Monitors the audits programme implementation

(e) QAO:

(1) Participates in audit preparatory meeting
(2) Witnesses the audit, if needed
(3) Follows-up and closes the Supplier Action Plan (subsequent versions)

(4) Follows-up NCRs

(f) Normally the audit lasts 2 days (e.g. for R&D 1 ½ days could be sufficient)

(i) Recommended use of time:

(1) 1 or ½ day for the documentation (includes review of any past audit action plan), site visit

(2) 1 or ½ day for the implementation (shop floor/ production/ reverse audit)

(3) ½ day for the audit report drafting and closure meeting

(4) Typical schedule is shown below:

Day	1	2
Morning	Opening meeting (presentation of Lead auditor)	Pending actions from previous day
	Status of the contract (PowerPoint presentation of Supplier)	Audit – implementation
	Audit – documentation	
Afternoon	Audit documentation + implementation	Clarifications + Draft the Audit Report
	Resume of the day	Closing meeting

(g) In the case where only one auditor (mandatory qualified as Lead auditor) is assigned to perform the audit, the duration could be longer (3 days)

(h) The Audit is conducted by auditors using a checklist prepared for the audit (based on the standard check-list and customized as per provisions/ clauses of the audited contract).

(i) In case of Metrology Inspections/control (metrology staff) or CAD specific matters (by CAD staff), a specific Check-list must be issued by the responsible, uploaded in F4E@idm and referenced in the Audit report.

(j) Some of the key steps are:

(i) Preparatory Meeting

(1) normally organized in F4E; if the supplier is based in Cadarache, this meeting could take place there, one day in advance of the audit):

(2) attendants: Audit Team, contract PgM/ PjM, TPO, QAO, and SAC (if needed).

If the contract to audit is a Framework contract or a Framework Partnership Agreement, Lead auditor shall take care of inviting TPO/ QAO of any task order to audit, as well as TPO/ QAO of Framework contract.

(ii) presentation by the TPO/ QAO of the status of the contract and availability of Audit documentation (minimum documents to be reviewed are Management Specification, Technical Specification, Quality Plan and annexes Control Plan, Documentation Schedule, Risk Plan, Deliverables already submitted, status of NCRs)

(iii) review the audit checklist

(iv) definition of the specific scope and samples

(v) issue the final Audit Notification which will be sent to Auditee at least at least 15 days before the scheduled date.

(k) A preparatory surveillance visit or pre-audit visit by QAO to the Auditee in the previous months is not recommended as it overlaps in scope and objective with the audit, it masks the results, and it's an inadequate use of resources.

(l) **Opening Meeting** (please follow the template of the presentation):

(i) expected participation from the Auditee (as a minimum): Technical Representative, Quality Representative; other staff members should be: Project Manager (Management Representative), process owners part-time (as per Agenda), team leader of the areas to audit

(ii) present the Audit team

(iii) present the scope (e.g. Supplier Quality Plan and its implementation) and criteria of the audit (e.g. Compliance to the F4E contractual requirements)
(iv) present the objectives and the brief process
(v) confidentiality agreement (disclaimer)
(vi) confirmation of the agenda

(m) Conducting an Audit:

(i) the audit itself consists of collecting and verifying evidences, through appropriate sampling
(ii) only information that is verifiable may be audit evidence (objective evidence that should be recorded)
(iii) the methods of collecting information include:
  (1) Interviews
  (2) Observation of activities
  (3) Review of documents (processes, procedures, instructions, records, reports, minutes, databases, etc.)
(iv) audit evidence (normally documents) requested by the audit team must be provided until the closing meeting (unless agreed otherwise in the opening meeting), otherwise it is considered missing/ not presented
(v) audit evidence must not be requested after the closing meeting.
(vi) What was not requested during the audit, and what was not presented during the audit it is considered not checked or not presented
(vii) the verification of compliance and process auditing is done using the audit checklist
(viii) the typical 'documentation' part includes review of (not limited to):
  (1) Supplier Quality Plan
  (2) implementation of the Control Plan and Documentation Schedule
  (3) subcontractors & suppliers management
  (4) implementation of the Deviation, Nonconformity, Document Flow processes
  (5) implementation of the Management Requirements and Risk Plan (for non-R&D contracts) review
  (6) overall documentation traceability (including Incoming Certificates, ADP, parts)
  (7) if a previous audit exists, the implementation of the Action Plan.
(ix) the typical 'implementation' part includes (not limited to):
  (1) Control Plan review
  (2) parts/ raw material identification and traceability
  (3) handling and storage
  (4) Special Processes and operators qualification (including NDT and welding)
  (5) calibration and control of measuring & test equipment
  (6) adequate material segregation (non-conform and/ or contaminant)
  (7) sample reverse audit, to check the full traceability of a component/ process/ maintenance

(n) **Closing Meeting**:

(i) expected participation from the Auditee is the same as for the Opening meeting
(ii) presentation & discussion of the findings
(iii) way to proceed with any non-compliances
(iv) way to proceed with any improvement areas
(v) when to expect the official Audit Report

(o) **Audit Report**:

(i) based on the evidences collected during the audit (as presented in the Closing meeting), the Audit Team issues the Audit Report (see the F4E-QA-214-R - Audit Report Template (22QYBT)) as per PM-28, within 10 working days

(ii) The audit report is uploaded by the Lead Auditor to F4E@idm (ProjectManagement/QualityAssurance/Supplier audits) for internal F4E review/ approval, as per PM-28 QMS Audits and Supplier Audits (22H84F) .

(iii) when the report is finally approved and can be distributed, the Lead auditor sends to the Auditee and to the Project Team the following e-mails.

(1) to the auditee

Please find attached the Audit report following the audit conducted in your premises ….. (date).
Where the Audit Report identifies Improvement Areas and/ or Non-Compliances, the Auditee shall:
Present an Action Plan detailing actions to address the identified findings / Improvement Actions, within 15 working days after the receipt of the Audit Report. This Action Plan shall be approved by F4E.
Non-compliances (NC):

Non-compliances compromising the deliverable shall be the subject of a Nonconformity Report (NCR) to be raised by the Auditee in the NCR Database within the required timeframe (5 working days) and shall be referred in the Action plan

Systemic Non-compliances shall be processed as Internal non-compliance (INC) report according to Supplier NCR processes, included in its QMS and shall be referred in the Action plan

Isolated non-compliances shall not be processed as NCR nor INC but as Improvement Actions in the Action plan

Please use the Action Plan template from Supplier Template Pack at http://fusionforenergy.europa.eu/procurementsgrants/keyreference.aspx (or **see below**) and submit this document to F4E Lead auditor.

Action Plan in reply to the Audit Report

Action Plan Reference	Supplier Audit Ref	Audit Report Reference	Contract ID
[reference]	[YYYY-FSA-NN-F-Nr]	F4E_D_XXXXXX v1.0	[F4E-OPE-NNN]

Action #	Audit Finding	Action to Address Finding	Due Date	Responsible	Ref Doc.	Status/ date of closure
[NN]	[YYYY-FSA-NN-F-Nr] [title]	[title] [description including *remedy* and for systemic/ repetitive the *root cause* and *corrective action*]	[Day.Month.201x]	[Name]	[reference]	[Not started/ In Progress/ Implemented]
		[if NC, just refer NC reference and process it as per NCR procedure]				

(2) to F4E project team and QAO

- The follow-up of the open NCRs, CARs 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.

(p) **Post-Audit Meeting**, if needed, can be conducted by lead auditor at the initiative of PTM /TPO or QAO of the contract

(q) meeting attendants are the same as for the Preparatory Meeting;

(r) presentation of the Audit Report, by the audit team;

(s) discussion about the internal opportunities for improvement or Corrective Action Requests, if any.

Audit Numbering

Supplier Audits are numbered as follows: YYYY-FSA-NN	YYYY = the year (e.g. 2018) FSA = F4E Supplier Audit NN = sequential number of the audit in a year, as per supplier audits programme
Audit Findings are numbered as follows: YYYY-FSA-NN-F-Nr	F = finding in an audit; F could be NC, IA, SA, CAR (if F4E impacted, but shall not appear in the audit report) Nr = sequential number of the finding

Findings

(a) *Finding* - something that is found or ascertained.

(b) Audit findings are those resulting from the observations during the audit.

(c) The findings are communicated to the Auditee in the following manner:

- (i) During the Audit:
  - (1) Individually, directly to the interlocutor
    1. Any identified nonconformity must be highlighted at the time and not saved for the closing meeting
  - (2) Summarised, at the end of each day
- (ii) At the end of the Audit:
  - (1) Presented during the closing meeting
  - (2) In the Audit Report distributed to the auditee (after internal review/ approval in F4E)

(d) Findings can be:

- (i) *Non-Compliances (NC)* - findings that do not comply with the requirements of the audit criteria
- (ii) *Improvement Actions (IA)* - findings that might lead to non-compliances, activities that would benefit from an improvement in order to perform better (mitigate the risks)
  - (1) "Isolated incident or single observed lapse, not compromising the deliverable" shall be treated as IA and monitored in Supplier Action Plan
- (iii) *Strong Area (SA)* - positive finding, work performed in a better manner than expected and is worth mentioning

(e) For each Improvement Area, the audit report will identify:

- (i) Observation/ Fact
- (ii) Requirement/ Area of requirement
- (iii) Recommendation

(f) For each Non-Compliance, the audit report will identify:

(i) Observation/ Fact
(ii) Type of NC (identifying if Compromising the deliverable, Systemic or Isolated incident)
(iii) Requirement/ Area of requirement

(g) Audit Non-Compliance findings can be:
(i) 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, systemic or not).
(ii) Systemic (procedural) error or repeated incident, not directly impacting the deliverable
(iii) Isolated incident or single observed lapse, not compromising the deliverable

(h) (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.

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

(j) If there are diverging opinions between auditor and auditee, the auditor can review the supporting evidence and ask for feedback about its accuracy. He/ she also can ask for new evidence (always within the duration of audit) that would contradict the existing evidence or support a different finding.

(k) Resolving diverging opinions supports evidence based approach ("let the facts speak for themselves"). 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.

(l) Any ex-post arbitration of unresolved issues will be performed by the SAC, taking into account the findings reported.

(m) Corrective Action Request

(n) If actions against F4E (either Improvement Actions or Non-Compliances) are identified during the audit, these must NOT be included/ referenced in the Audit Report. They are formalised through PM-42 Corrective Action Request (29KV8Z) process.

(o) CAR Form (286DJS v1.0) will be sent to the F4E responsible and they are not available for Supplier.

(p) Resulting CARs must be:
(i) Complete (contains all the related facts)
(1) why – unmet requirement
(2) what – objective evidence
(3) where – which work area
(4) when – the date
(5) who – by title, if relevant
(ii) Correct (accurately conveys the facts)
(iii) Concise (fully explained in brief terms)
(iv) Clear (understood for prompt action)
(v) Categorised finding (Compromising the deliverable, Systemic or Isolated, if used)
(vi) Confirmable (traceable and verifiable)

(q) CAR is initiated by Audit Team member, then is followed and closed by the QM.

(r) If FOR against Architect Engineer or Engineer Integrator (e.g. Engage), this supplier could be proposed for an extraordinary audit by the Lead auditor, or for being audited in the next year Programme.

Overall Result

(a) The audit Overall Result is ascertained by the Lead Auditor as per the Check-list score:

%	**Supplier classification according % of score:**
0 - 50	**Bellow standard** Supplier MUST issue an Action Plan and take immediate actions to correct the findings. A follow-up audit could be organized.
51 - 85	**Meet standard** Supplier issue an Action Plan and take mid-terms actions to correct the findings (Improvement, NCR).
86-100	**Above standard** If any finding, an Action Plan is issued.

(b) In case the Overall result is at the border between two scenarios, Audit team should take into consideration also the Strong Areas identified during the audit, if any.

Supplier Action plan management

(a) Where the audit report identifies Improvement Areas and/ or Non-Compliances, the Auditee must:
   (i) 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 F4E's quality approval.
   (ii) The non-compliances compromising the deliverable shall be the subject of Nonconformity Reports (NCR), to be raised by the Auditee within the required timeframe (5 working days as per QA-115) and followed through PM-35.

(b) If the Action Plan is submitted by email, it will uploaded by member of audit team in respective Audit folder (ProjectManagement/QualityAssurance/Supplier audits).

(c) If the Action Plan is uploaded by Supplier in the F4E@idm/ CTS, a shortcut will be added in the respective Audit folder (ProjectManagement/QualityAssurance/Supplier audits).

Closure

(a) The Audit will be closed by the SAC when:
   (i) The Audit Report is approved by the Lead Auditor, AND
   (ii) The Action Plan *, if requested, is approved by Lead auditor, AND
   (iii) All NCRs originated from the audit are raised (initiated).

(b) The follow-up of open NCRs and the implementation of the Action Plan (and its subsequent versions *) shall be the responsibility of the Auditee under the supervision of the contract/ team QA officer.

(c) If any need of clarification about the Action plan proposed by Auditee, the QAO shall contact the auditors.

(d) Closure of the Supplier Action Plans (when all actions are implemented) must be followed by the contract/ team QA officer, who will finally approve the subsequent and last complete versions of this document.

(e) Monitoring the performance of supplier audits

(f) Communication on the status of the audits is periodically made by QAO/ auditors in the QACB. SAC will monitor the implementation of Supplier Audit Annual Programme through Annex 2 "Status of audits", in which following criteria are defined and will be assessed:
  (i) quality of report (e.g. reviewed, recommended, very good)
  (ii) respecting the yearly programme and the expected dates of audits (no impact if justified by Supplier unavailability)
  (iii) timeframe for issuing the report in F4E@idm (less/ more than 10 days)
  (iv) feedback from auditee or customer

(g) Coordination meeting

(h) At the end of yearly Programme, a Coordination meeting will be organized by SAC with all the auditors to present the highlights. Based on this outcome, new objectives and training are defined for next year audits.

(i) Lesson learnt workshops could take place, to further standardise the approach of auditors with respect to type of suppliers, type of audits, etc. Improvements could be proposed by the participants.

Confidentiality

(a) The following data is considered to be of limited distribution:
  (i) All the information collected during the audit
  (ii) The Audit Checklists
  (iii) The Audit Report
  (iv) The Action Plan

(b) Limited distribution means that the information access is limited to the following:
  (i) Audit Team members
  (ii) F4E Director, QA HoU, F4E Quality Manager, SAC and members of the QACB
  (iii) From F4E on the: Contract/ Grant QA Officer, Technical Officer(s), Program manager, Project manager, Head of Department, Process owner

(c) 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). This is ensured by the Lead Auditor.

(d) 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)

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

Documentation Sign-Off Authority

Sign-Off Authority is defined in PM-28 QMS Audits and Supplier Audits (22H84F) .