

The Implementation Of The Project And Quality Management Systems In The EU Supply Activities

IAEA Technical Meeting on Synergies in Technology Development between Nuclear Fission and Fusion for Energy Production June 6th-10th, 2022

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OUTLINE

- □ ITER Quality Assurance Requirements
- **QMS Implementation in ENEA Fusion Department**
- F4E Management & Technical Specification
- □ (PQMP) topics for a Supply Contract to ITER through F4E
- Project & Quality Management Specifications
- Document Management System (DMS)
- □ Time Schedule Management (PMS)
- Risk Management System (RMS)
- Nuclear Safety Management Requirements
- Subcontractor Management & Supply Chain
- Lessons Learned of P&Q Management Implementation



ENEA Mission and Research Centers

ENEA, the Italian National Agency for New Technologies, Energy and the Environment is a public undertaking operating in the fields of energy, the environment and new technologies to support competitiveness and sustainable development.

ENEA mission is:

- to promote and carry out basic and applied research and innovation technology activities, also by prototypes and product industrialization;
- to disseminate and transfer
 technologies, encouraging their use
 in productive and social sectors;
- to provide high-tech services, studies, tests and evaluations to both public and private bodies and enterprises.

Offices and Research Centres





ITER Quality Assurance Requirements

- For the construction of ITER, a complex and FOAK fusion plant, the French Nuclear Safety Authority (ASN), requested ITER Organization (IO) and then to the seven Domestic Agencies (DAs) involved to adopt a QA Program.
- The EU DA Fusion for Energy (F4E) defined the Supplier Quality Requirements in the QA document F4E-QA-115 and in other accompanying QA docs.
- Quality Management is ensured in Project Management.
- As stated in IAEA TECDOC 1910 "Quality is a key element of a Management System".
- The different links of the IO & DAs roles are shown in the next slide.



ITER Quality Assurance Requirements



Rationale for adopting PM & QM System in ENEA Fusion Department

Since the start of the ITER Project, ENEA Fusion Department has been involved in the technology transfer in the field of nuclear fusion from R&D scope to the execution of large projects together with industry.

Subsequently, it has been outlined the importance of working in Nuclear Fusion by a Quality Management System (QMS) and of applying the principles of the Project Management.

On the other side, the possibility to get large contracts directly from ITER or F4E was linked to the implementation of a compliant PM & QM System with the evolution of the ITER project over the years.



QMS Implementation in ENEA Fusion Department

- 1. When?: decision taken in 2009.
- 2. How?: through ISO 9001 with the certification got in 2011.
- 3. Why?: voluntary strategic decision taken to cope with:
 - request of supplies (design and constr.) from ITER / F4E
 - existence of a competitive "market": growing number of institutions/labs/industries involved in ITER supplies to compete and interact with (competitors or partners).
 - high complexity of the activities.
 - managing external financing / orders.

Until then, the QA and PM requirements required by F4E / ITER were managed by dedicated Quality Plans.



Supplies for ITER Project Management or Quality Management?

- 1. Supplies for ITER (through F4E or not) to be carried out, at the very beginning, under the umbrella of Quality Management System requirements which included already the basic principles of Project Management.
- 2. A kind of misunderstanding between PM and QM clarified with the time.
- 3. Some EU R&D Organizations decided to comply with QMS requirements defined by ITER or F4E.
- 4. ENEA Fusion Department made, instead, the challenging choice to implement its own QMS according to the ISO 9001 Standard.
- 5. Quite challenging for a Governmental Research body, and the nature of the activities (ITER construction), novelty, mostly based on R&D to be industrialized.



Quality Management System ISO 9001:2015 Certification



Design, development and experimental tests of components and systems for nuclear fusion plants, including construction of related test prototypes. Advanced studies to support the nuclear fusion. Activities of metallographic analysis and environmentally radiometry



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Ing. Mario Romersi

President of CISO

President of IQNET

Registration Number: IT - 112377

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* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



F4E Supplier Project Management and Quality Requirements (QA-115)

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		EXTERN	AL REFERENCE
		Quality Document	
•	4E-QA-115 - Sup	plier Project Managemer	nt and Quality
		Requirements	
This doc For Ener	ument contains the genera	I Project Management and Quality Requ	irements applicable to Fusion
	57		
		Approval Process	
	Name	Action	Affiliation
Author	Creus Oleart E.	02 October 2018:signed	PM
leviewers	Baker K.	02 October 2018:recommended (East Track)	PM
Previous	Cobben R.	03 September 2018:recommended v5.2	ITERD
Versions	Esposito V.	03 September 2018:recommended v5.2	ADM
Reviews	Jahreiss H.	03 September 2018:recommended v5.2	ADM
	Barabaschi P.	03 September 2018:reviewed v5.2	BA
	Leidenfrost G.	28 August 2018:recommended v5.2	COMM
	Filhol J M.	03 September 2018:recommended v5.2	ITERP
	Rodrigues D.	31 August 2018:recommended v5.2	ADM
hpprover	P4C-Director S. J.	BO: Popescu Marcel-Stefan (E4E)	DIR
Read Access	LG: F4E QAO, AD: IDM Users. GG:	IAS Audit on Document Management, project administr	ator, RO, LG: PT Magnets Support Team
	(view), LG: Magnets QA, LG: Admir	istration, AD: IDM-A10_HEAD, AD: F4EN-A90, AD: IDM I	E-MG-00-00 Magnets, AD: IDM IE-TS-CA-
	00 Drawing Office-CAD, GG: IAC, LC	G: RH-PT-PRO, LG: F4E-GR	
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Applicable Documents

The following F4E Applicable documents and templates can be downloaded the following link: External Link

AD 01. F4E-QA-113 - Supplier Nuclear Safety Requirements

AD 02. F4E-QA-114 - Instructions for Contractors Performing Design Analysis

AD 03. F4E-QA-117 - F4E Dimensional Metrology Handbook

AD 04. F4E-QA-119 - Requirements Management and Verification (RMV)

- AD 05. F4E-QA-135 Supplier CE Marking Requirements
- AD 06. F4E CAD Manual
- AD 07. F4E-QA-111 Supplier Risk and Opportunity Management Instruction
- AD 08. Deviations and Contract Modifications Portal (DACC) Rules of Use
- AD 09. F4E-Supplier Documentation Exchange
- AD 10. Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006
- AD 11. Restriction of Hazardous Substances Directive 2002/95/EC, (RoHS 1)
- AD 12. Configuration and Documentation List Template
- AD 13. Management and Manufacturing and Inspection Plan Template
- AD 14. Declared Components List DCL Template
- AD 15. Declared Materials List DML Template
- AD 16. Declared Mechanical Parts List DMPL Template
- AD 17. Declared Processes List DPL Template
- AD 18. FMEA / FMECA Template
- AD 19. P-FMEA / P-FMECA Template
- AD 20. Control Point Notification Template
- AD 21. Release Note / Certificate of Conformance Template
- AD 22. Requirements Propagation Matrix Template
- AD 23. <mark>Risk Register Template</mark>
- AD 24. Supply Chain Acceptance Register Template
- AD 25. F4E-QAP-ITER EUDA QA Programme for ITER Project



F4E Management & Technical Specification

FUSION FOR ENERGY idm@F4E UID / VERSION 2HV3PF / 1.2 VERSION CREATED ON / STATUS 29 July 2019 / Approved EXTERNAL REFERENCE	FUSION Annex B Technical Specification Idm@F4E # F4E_0_23W92A Call # F4E_0_02W92A Page 1/46
F4E Document F4E-FPA-327-SG07: Annex A Management Specifications	TECHNICAL SPECIFICATION FOR THE ENGINEERING SUPPORT IN THE AREA OF TEST BLANKET
Ageroval Process Author Brescen C. 29 July 2019-signed PM Co-Authors PM PM PM Co-Authors PM PM PM Reviewerz Bricherd B. 29 July 2019-recommended ITERD Quintans Buil G. 29 July 2019-recommended ITERD Approver Baker K. 30 July 2019-seproved PM Approver Baker K. 30 July 2019-seproved PM Roviewerz LG: PPO-FPA327, LG: Istesys, AD: IDM_F4E, GG: LAC, project sofministrator, RO Original Document MD5#: 6615595DBEDEFR99DFD91C0DA789AAA3	MODULE (TBM) SYSTEMS DESIGN AND TECHNOLOGICAL DEMONSTRATION
	Abstract This Technical Specification concerns the provision of engineering services in the area of Test Blanket Module (TBM) Systems design and technological demonstration. Specific Task Orders for engineering support will be placed during the duration of the Framework Contract (36 months).
Printed copies are not controlled. Confirm version status through the F4E document management system (idm@;F4E) Generated on 30 July 2019	Last printed 21 Nov. 2011



F4E Management & Technical Specification





Project & Quality Management Plan (PQMP) topics for a Supply Contract to ITER through F4E

- Documentation and Information Management
- Configuration Management

Project Management

- ➢ Objectives and Activities → Project WBS
- Organizational Structure (including Sucontractors) and Responsibilities
- Submission of contractual documents
- Time Schedule Management
- Control Plan (with Control Points: W, HP/ATPP, NP/W, R,)
- Risk and Opportunity Management
- Project Meetings and Reports

> Quality Management

- Quality Plan
- Control Plan

PROJECT's CONTROL POINTS:

Hold Point (HP/ATPP): Identifies an operation/activity after which works cannot proceed without a formal clearance by F4E by means of an Authorization to Proceed Point (ATPP). **Notification Point (NP/W):** Identifies an operation/activity that must be notified in advance to F4E for potential witnessing (W). Review (R): Identifies a document or report that must be reviewed and accepted.

- Nonconformities and Deviation management
- > QA Requirements for Design, Manufacturing and Assembly
- QA Requirements for Acceptance and Delivery



ENEA Document Management System (DMS) Home-Made



ENEA-FSN WBDMS



Developed internally^(*) compliant to ISO 9001 requirements § **7.5 Documented information** Pro and cons of this choice:

- Precisely suited for own needs
- Modifications quickly implemented
- It also manage the measuring equipment
- No access to other software communities (SharePoint[™], Alfresco[™], IDM@ITER IDM@EUROfusion)
- Strict dependence on internal IT experts

http://www.dante.enea.it/ Accessible outside the VPN

(*) written in PHP, accessible by Apache Webserver, and interfaced to MySQL DBMS



Project Management Software used @ENEA Primavera P6 EPPM™

- For planning and scheduling ITER supply projects (e.g. WBS, Time Schedule, etc.), use of Oracle's Primavera P6 EPPM™, <u>mandatorily imposed by F4E, compliance with ITER Organization</u> <u>Specification</u>.
- 250 Primavera Projects managed @ ITER with 350,000 project relationships, 3 days required to integrate all projects together by scheduling.
- Each Primavera Project file for a supply contract, contains all the related info. CMS approach adopted → the files are stored in a dedicated Primavera server, (accessible by client or by web server tool).
- The updated Time Schedule for each specific supply contract is requested by F4E to be updated and issued usually every month.
- Need @ ENEA for training a group of planners acting in the supply contracts.



Project & Quality Management Specifications Primavera P6[™] Work Breakdown Structure

		WBS-OMF331 L2 T4-01 Rev. 0	2	21-Dec-15 Rev DM #: F4E_D_	. 0 24GCAP
WBS Code	WBS Name		Total Activities	BL Project Duration	
🗁 OMF331 L2 T4	TO#4 OMF 331 L2	04/01/2016	54	140.8d	
	TASK-0 [Project Manage	ment & QA]	39	140.8d	
	Contractual		17	136.5d	
	Project Management & G	A	17	118.3d	
	Progress Reports		4	73.6d	
📕 OMF331 L2 T4.0.PM.QP	Provisional & Execution	Quality Plan - F4E Review Cycle	8	35.2d	
MF331 L2 T4.0.D	Milestones and Deliveral	bles	5	97.1d	
	Sub task-1- TBM SYSTE	MS INTERFACES DESCRIPTION	9	77.9d	
	Collection of the most up	dated interfaces sheet	4	31.9d	
📕 OMF331 L2 T4.1.B	Analysis of the interfaces	sheet content and description of interfaces	5	77.9d	
	Sub task-2- PRELIMINA	RY INTERFACE DESIGN IMPACT ASSESSMENT	6	55.6d	
	Assessment of the consis	stency and design impact analysis on the TBS sub-system	6	55.6d	

VBS Projects WBS Ac	tivities Resource As	sianı	ment	s													>
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Project & Quality Management Specifications Primavera P6[™] Time Schedule

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Project & Quality Management Specification Configuration & Documentation List

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Contract Title:	CDL- SO	ORGENTIN	IA-RF			Proje	ect #:	SORGENTINA-R	-03		PA/	ITA Ref	erence:			
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Prepared K. Voukelatou	R	eviewed P. Agostini		A.	Pietropaolo		Ac	ceptance		Type: Annex 2 Deliverable#: A Cat: Category: Supplier ID: Su Expected Miles Configuration:	for types and ccording to DUA, IP+ (if pplier code tone	d acronym Technical applicable	s Specification)			
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Preliminary Project & Quali Management Plan (PQMP) SORGENTINA-RF	ity for	DL		NA	PQMP- S	SORGEN	NTINA-RF -01	. 15-Jun-20	K. 19 P. A.	Voukelatou Agostini Pietropaolo	N	N		ACC	АРР	PQMP- SORGENTINA-RF-01 v1.0 The updated version v2.0 of the Preliminary PQMP will be completed in February 2021 after implementing the latest updates related to the technical part of Task 2.
Provisional Project & Qualit Management Plan (PQMP) SORGENTINA-RF	ty for	DL		NA	PQMP- S	ORGEN	NTINA-RF -02	15-Sep-20	21 P. A.	Voukelatou Agostini Pietropaolo	N	N		ACC		
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Project & Quality Management Specification Supplier Risk Plan

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1	Threat		Consortium	4,3 Quality	Open	Slow or inefficient	Activities	Time delay			Unlikely (2)	Negligible	Negligible	Low (2)	8	LOW	Reducing	QA actions,	action	action		Not	Negligible	Negligible	Low (2)	8
2			F4E	4.3 Quality	Open	process of Administrative delay in	slow Activities	Time delay			Likely (4)	(1) Negligible	(1) Negligible	Medium (3)			Reducing	Weekly Press F4E.				Credible (1) Not likely	(1) Nealiaible	(1) Negligible	Low (2)	
	Ihreat		0	100.0		F4E	slow down	-			12-1-70	(1)	(1)	11-1-10	36	MEDIUM		work on				(3)	(1)	(1)	N	8
3	Threat		F4E/IO	4,3 Quality	Open	process of	in	Time delay, Technical			Likely (4)	Medium (3)	LOW (2)	Hign (4)	64	HIGH	Reducing	progress				(3)	Medium (3)	LOW (2)	Medium (3)	8
4	Threat		Consortium	4,3 Quality	Open	Slow or inefficient	More time is	Time delay,			Likely (4)	Medium (3)	Low (2)	Medium (3)	36	MEDIUM	Reducing	Strict				Not likely	Low (2)	Low (2)	Low (2)	8
5	Threat		Consortium	4,3 Quality	Open	Delay in the reception	Activities	Time delay			Not likely	Negligible	Negligible	Low (2)	12	LOW	Reducing	QA Control				Unlikely (2)	Negligible	Negligible	Low (2)	8
6	mour		Consortium	4.3 Quality	Open	of input data from Wrong milestone	slow down Difficulty in	Time delay			(3) Unlikely (2)	(1) Negligible	(1)	Low (2)		2011	Reducing	(Tracking An				Not	(1) Neoligible	(1) Negligible	Neoligible	·
	Threat			.,		sequence	achieving	minor			c	(1)	2011 (2)	2011 (2)	8	LOW		alternative				Credible (1)	(1)	(1)	(1)	8
7	Threat		Consortium/ F4E	4,3 Quality	Open	Inaccurate cost estimates and	Renegotiati on of	Time delay			Unlikely (2)	Low (2)	Medium (3)	Low (2)	18	LOW	Reducing	Frequent verification				Unlikely (2)	Low (2)	Low (2)	Low (2)	8
8	Threat		Consortium	5,2 Ocertra dan	Open	Loss or unavailability	Technical	Time delay,			Likely (4)	Medium (3)	Negligible	Medium (3)	36	MEDIUM	Reducing	Redundanc				Not likely	Low (2)	Negligible	Low (2)	8
9	Threat		Consortium	5,2	Open	Team members	Activity	Time delay			Not likely	Negligible	Low (2)	Medium (3)	27	MEDILIM	Reducing	Prioritizatio				Unlikely (2)	Negligible	Low (2)	Low (2)	8
10	mout		Consortium	Contractor 6.1	Pronosed	overload or A technology	slow down Simpler or	Time delay			(3) Unlikely (2)	(1) High (4)	Low (2)	Low (2)	21	INCOION	Exploit	n of sub-					(1)			
	Opportunity			Technology		innovation changes	cheaper				o		2011 (2)	2011 (2)	32	MEDIUM	Librar									8
11	Threat		Consortium	5.1 Supply Chain	Open	Delay of KoM	Administrat ve orders	Time Delay			Likely (4)	Low (2)	Low (2)	Medium (3)	36	MEDIUM	Reducing	Prioritize order				Not likely (3)	Low (2)	Low (2)	Low (2)	12
						D.1	rework											issuing								
12	Threat		Consortium/ F4E	5.1 Supply Chain	Open	Delay of KoM	Prices are updated	Cost increase			Unlikely (2)	Negligible (1)	Medium (3)	Low (2)	18	LOW	Reducing	Prioritize order				Unlikely (2)	Negligible (1)	Low (2)	Low (2)	8
10			0	10.1	0	Functional shareh		True delay			Mat Blacks	1	1 (0)	Marking (0)			Arrest	issuing				Hallach (0)	1	1 (0)	1 (0)	
13			Consortium	10.1 Testing	Open	Functional check	device is	for			Not likely (3)	Low (2)	Low (2)	Medium (3)			Accept	actions to				Unlikely (2)	Low (2)	LOW (2)	Low (2)	
							not working	replacemen										speed up								
	Threat						expected	equivalent							27	MEDIUM		replacemen								8
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Supplier Nuclear Safety Management Requirements



aod Access LG: F4E_QAQ, AD: IDM_Users, GG: IAS Audit on Document Management, project administrator, R0, LG: F4E Safety, LG: EC UL_NIER Technical Support, IG: EC UL_Extended Design Team, AD: IDM 747, AD: IDM IF-PF-00-00 Antennas and Plasma Engineering, GG: IAC, IG: EC UL_Eagle & Procurrement, IG: EC UL_Quilty III.

Original Document MD5#: D7D0BC1C224BFB6A1A8777D32992F3D8

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This QA document is applied to all External Interveners (defined in [*]) in the F4E Supply Chain (Suppliers and Subcontractors), in charge of Contracts dealing with Protection Important Components (PICs) or Protection Important Activities (PIAs).

PICs defined as specific category of SSCs in art. 1.3 of [*] Activities classified as PIA in art. 1.3 of [*] (they cover design, prototype and/or qualification, fabrication, installation, testing and commissioning, maintenance, handling, transportation, storage, ... during the different phases of the project).

Great importance is given to the propagation of all the requirements of QA-113 to the entire Supply Chain

SSCs = Structures, Systems and Components

[*] Arrêté du 7 février 2012:

external interveners any natural or legal person other the operator and employees who provide service and goods Who participate in PIC or PIA

• Who participate in an action in application of the Arrêté du 7 février 2012 Suppliers, Subcontractors, service providers, experimenters and users



IAEA Technical Meeting

June 6th-10th, 2022

Subcontractor Management & Supply Chain

Document be submitted to F4E for approval is the <u>Supply Chain Acceptance Register</u>, then define their involvement in the <u>Subcontracting Schedule</u> and eventually assess its performance in the <u>Subcontractor Assessment</u>.

SUPPLY·CHAIN·ACCEPTANCE·		[LOGO]4 SUBCONTRACTOR- SCA#dat
[Supplier.Logo]x CTS#12 P REGISTERX PageA 1./-41 Rev. 12	SCHEDULE: SCS###	
Template-F4E_D_243HFR-v4.0	1 mgu- 11 m 1001	Contract+grant+caineetencej
GENERAL-INFORMATION		•3.8 Supplier®
Reference-Number# (Reference-number-of-contract-/-grant-/-call,-e.gF4E-OPE-XXXX)#	SOBCONTRACTING. UNDER	•4.¤ Subject/item/title¤ ¤
Titled (Title-of-contract/grant/call)#	Pages 1/1 Rev.	
Quality-Class# (Quality-class of contract-/-grant/-call-(from-14))#	FAE reference: Contract / grant / call reference)a SEE CLISTOMED ref = IRA/TA/TA/D/codemocela	• 5.¤ Subcontractor-Name¤
F4E-Customer-Reference# (PA-/-ITA-reference,-filled-by-F4E-before-providing-template)#	3.1 Supplers s 4.5 Subjection Mite s	• 6.¤ Subcontractor Locations¤
1 ADDROVAISH		•
By-submittine-this-Supply-Chain-Acceptance-Register-(SCAR), the-supplier-declares-and-confirms-that-the-(proposed)-	Supplem F4E= Notes & accordings	• 7Scope-targeted-#
subcontractor(s)-are-compliant-with-insurance-and-other-legal-requirements.x	Anne, Sgn & Cetet Anne, Sgn & Cetet Anne, Sgn & Cetet OP = Quality Plant CP = Costrol Plann	* (Tasks: estimated number of working nours)
The-SCAR-is-submitted-by-the-supplier's-representative-through-the-Contract-Tracker-System-(CTS)-on-the-date-and-	Cohestration (15, Taylor Cohestration (25, 5 a)	•8. Relevant-experience¤
time-indicated-therein.vine-acceptance-or-the-SCAR-by-r4t-signifies-acceptance-or-the-supply-chain-on-the-date-and- time-indicated-therein #	Identitye Item/Service/Qualitye Controls Identitye Item/Service/Qualitye Controls Identitye	 (references of activities, Code and Standard applicable)
1	[name]] [tem]1 [Assessment][Control [name]] [tem]1 [Assessment][Control [name]] [taciity: [contract ref][Ref]1 Plan: [taciity: [contract ref][Ref]1 Plan: [address]]	R 9. Existent Quality-Certifications#
SUPPLY-CHAINX	address)# (QP-or- Ref.)# address)# (QP-or- Ref.)# waiver-ref;# waiver-ref;#	• (e.g. ISO-9001, EN-ISO-17025, EN-ISO-3834, etc.)
1 Cumpling/single-legal-entity-or-groun-leader-in-sace-inforce-interter-		(<u>attach</u> copies)¶
Full-company-name-including- [Address]#		10. Capacity relevant for targeted scope#
Name-of-Legal-Entity# legal-form]# Registered-Officett		(human-resources, machines, etc.)
VAT-Numberat (VAT-number)#		11 Int of documentations
Volue in Eurola Volue in Eurola Forecasted Start (dd/mm/ywyla		(e.g. general procedures, etc. relevant for targeted scope and verified by the Supplier)
Value of Works Dates		я
Scope-of-Workt [Description-of-the-work-to-be-performed-by-the-subcontractor]#		12. Supplier's survey to the Subcontractor# (dates of visits performed and results achieved by the Subcontractor#
Activity#		(date of future visits)¶
PIC-/-PIAX [Yes-/-No]x Quality-Classx [Quality-class of contract-/grant-/- coll-(from:14)]x		 If applicable, additional measures to be implemented #
Project-and-Quality- [CTS-Ref-for-CTS-Ref-of- Quality-Man [Standard]-[Expiry-date]#		• ¶
ICTS-Ref-(or-CTS-Ref-of- ICTS-Ref-(or-CTS-Ref-of- Technical- Identification-of-document-where-		Supplier's statement of compliance with F4E requirements
Control-Plank waiver)]k Specificationk requirements-are-propagated]k		•¶
Comments (Comments by supplier)#		•1
1.1. → Subcontractor—Level-1-(insert-new-table-for-each-subcontractor)¤	the field with the extremely discussed and the state of the line of the state of th	For-critical activities
Name-of-Legal-Entity# [Full-company-name-including- [Address]#	Come server music de expendeer — roins and commons to income an internation or an excessing servini 1	• 15.ª Quality-Plan¤
VAT Numbert 0/4T numbert		■16.¤ Control-Plan¤
Technology-Codes# [Insert-2-technology-codes]#		
Value-of-Work¤ [Value-in-Euro]# Forecasted-Start- [dd/mm/yyyy]# Date¤		Supplier# Notes:1
Scope-of-Work# [Description-of-the-work-to-be-performed-by-the-subcontractor]#	4	Name, Sign & Date Name, Sign & Date
Critical-Quality-Item-/- [List-critical-quality-item/activity-as defined-in-QA-115]# Activity#	1.cF4E:reference:¤ [contract/grant/call reference]¤ 2.:F4E:CUSTOMER:ref::¤ [FA/ITA/DWO reference]¤	
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Project-and-Quality- (CTS-Ref-(or-CTS-Ref-of- Quality-Man (Standard)-{Expiny-date]# Management-Plan# waiver)]# System-Certificate#	5	
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waiver][x Specificationx requirements-are-propagated]# Commentstit (Comments-by-supplier)#	Prepared-by:= Approved-by= Acceptance= ¶ Name, Sign & Date¶ Name, Sign & Date¶ Name, Sign & Date¶ QP.:=-Quality-Plant	
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Project & Quality Management Implementation Lessons Learned #1

- The experience of working with F4E & ITER under QA and PM specs has been very useful in general, but sometimes at the beginning of our collaboration the request of documents have been excessive (e.g. reporting the results of the same activity in three different documents).
- The implementation of the Project & Quality Management System in the research field is not always easy considering that planning the scientific research activities is different from each other, they are not part of a production in series as those of the industrial sector.
- EFDA, then EUROfusion, organized training courses (2011-2014) for researchers and engineers, involved in the ITER related contracts on Planning PM tools, Configuration Management, Design Management tools (CATIA PLM), Requirements Management & Verification, Document Management, Risk Management, Nuclear Safety to fill the existing gap.



Project & Quality Management Implementation Lessons Learned #2

- The basic principles of PM, required in R&D, activities were easily to implement than being compliant with all requirements of ISO 9001.
- The QMS implementation within the ENEA Fusion Department has been successful, but it must be admitted that it was not an easy task for the nature of R&D activities.
- In view of the continuous improvement of the QMS, it's necessary to define KPIs. They were defined for the overall activities of the ENEA Fusion Department. It is more difficult to define, when required, for single research activities, which are different ones from each other.
- The challenging activities are performing internal audits and the top management review, mandatory for ISO 9001.
- Non-conformities have been felt, sometime, as a punishment rather than a way of improvement.
- Other demanding issue was to keep measuring equipment under control (calibration status, metrologic confirmation, etc.).



THANK YOU FOR YOUR ATTENTION



Nadia.Voukelatou@enea.it







SPARE SLIDES



7

Training Courses & Certificates of Competence

Additional courses with certificates of competence:

- Primavera P6 Project Management R.8.3 Client and Web (Rome 14-15-21-22 January 2015)
- Project planning and control course on Oracle / Primavera P6 software (Rome 3-4 October 2019)
- Oracle / Primavera P6 Advanced Course (Rome 9 October 2019)
- Course of the Manager of European Projects (Bologna 20 February 1 December 2006)
- Course on Risk Management Systems: The UNI ISO 31000: 2018 standard Basic Course - (Bologna 14-17 May 2018)
- Advanced course on Risk Management and Risk Assessment Techniques (Bologna 14-17 May 2018)
- PQM-NET- KIT-1 Training Course Existing Quality Management Systems for ITER related contracts - (Karlsruhe 25 -27 June 2013)
- PQM-NET- KIT-2 Training Course Planning tools & Documentation Management Systems in use for ITER - related contracts - (Karlsruhe 13-15 October 2015)
- PQM-NET Training Course Quality Systems for ITER related contracts: A Safety and Systems Engineering Approach - (Lisbon 3-5 November 2014)
- Pearce Mayfield: Certificate of completion in Practical Project Management 3-day course - (U.K. 2-5 April 2014)
- Lead Auditor of Quality Management Systems" course 24 h Florence 14-15-16 June 2016 - successful final exam
- Course "Basic module for Auditor and Lead Auditor", Florence 28-29 June 2016 - final exam
- Training Course for Workers General Part 16 hours: from 03-03-2016 to 17-03-2016 through the E LEARNING Platform of the ENEA Agency, passing the required learning tests.
- Certificate of technical suitability for carrying out the task of firefighting officer -Certificate and examination on 22 / October / 2014
- Refresher course for "Fire Fighting Officer" Certificate of attendance and examination on 10 / October / 2018.
- FSN-ING Training Courses for 2021 of 20 hours within ISO 9001: 2015 §7.2 298 kills⁹ through Training



Project & Quality Management Specification Final remarks

- The management of quality documents has reached a high level of reliability and punctuality.
- The use of all available IT tools (Primavera, IDM @ F4E, DANTE) has contributed to the high level cited above, enabling a proper documentation management, also including the technical one (deliverables).



Project & Quality Management Specification Responsibilities

Project's Responsibilities

Project Management

Supplier Technical Responsible Pe	erson (STR)
Marco Utili Tel.: +39 0534 801203 Fax: +39 0534 801250 E-mail: marco.utili@enea.it Supplier Quality Representative (SG	ENEA FSN-ING Unità Fusione e Sicurezza Nucleare 40032 Camugnano (Bologna) Italy
<mark>Konstantina Voukelatou</mark> Tel∴ +39 0534 801413 Fax: +39 0534 801250 E-mail: <u>nadia.voukelatou@enea.it</u>	ENEA FSN-ING-PAN Unità Fusione e Sicurezza Nucleare 40032 Camugnano (Bologna) Italy
Supplier Quality Representative (SG	R)
Konstantina Voukelatou Tel.: +39 0534 801413 Fax: +39 0534 801250 E-mail: <u>nadia.voukelatou@enea.it</u>	ENEA FSN-ING-PAN Unità Fusione e Sicurezza Nucleare 40032 Camugnano (Bologna) Italy



The Project Management Team for the FPA 372 SG04 is made of:

The **STR** for this Specific Grant is the Supplier Contact Person (**SCP**) for the F4E-TRO in charge of this Specific Grant.

The **STR** coordinates and manages all activities related to implementation of the Specific Grant (SG) and has also the responsibility for issuing progress reports during its execution. He is responsible for issuing the Implementation Plan of the SG. The STR and SQR are duly informed on the progress of the activities and maintain their respective roles in front of F4E. The **SQR** is the Supplier Quality Responsible for the Specific Grant and is the contact person for the F4E-QRO in charge of this Specific Grant. During the execution of the SG 04 he is supported by the ENEA Quality Manager (EQM). The ENEA Quality Manager will support the Project Leadership for the management issues for the SG04: planning, administrative and financial issues and documentation.



Document Management System Brief Description of the ENEA DANTE DMS

ANTE 48 types of documents managed by the ENEA DMS DANTE

ENEA-UTFUS WBDMS

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HOME NEW DOCUMENT CURRENT WORKS SETTINGS SEARCH BROWSE LOG OUT (ldipace)

Type of Document	TDC coding	Type of Document	TDC coding
Meeting Agenda	AA	QMS Procedure	PGQ
Acceptance Data Package	ADP	Presentation	PPT
Administrative Act	AMM	Progress Report	PR
Acceptance Note	AN	Procedure	PRO
Background Declaration Form	BDF	Operating Support Procedures	PSO
Communication	COM	Quality control plan	QCP
Change request	CR	Quality Plan	QP
Contractual doc of the customer	DCC	Audit Report	RA
Drawing	DD	Risk Card	RC
Flow-Chart	DDF	Internal Report	RI
Deviation Notice	DNO	Release Note	RN
Deviation Order	DOR	Risk Plan	RP
Deviation Request	DR	Technical Report	RT
Other docs required by the customer	DRC	Registrazione di verifica	RV
Documentation Schedule	DS	Work Sheet	SC
Document Transmittal	DT	Technical Specification	SPT
Check Report	IR	Customer Satisfaction Form	SSC
Work Instruction	ISL	Subcontracting Schedule	SS
Quality Manual	MAQ	Task Specification	TAS
Meeting Minutes	MM	Technical Economic Offer	TEO
Technical Manual	MTC	Test Report	TR
Non conformity Report	NCR	Time Schedule	TSC
Technical Note	NT	Work Breakdown Structure	WBS



Project & Quality Management Specification Implementation Plan & related Annexes

-NFN	Document ID	QP - OMF	331 L2 T01 - 01	Pa	ge 1/ 4
	TITLE	EXECUTION IMPLEM	MENTATION PL	AN FOR	Rev 4.1
varuhe Institute of Technology	TITLE	the SPECIFIC CONT	RACT Task Ord	er No. 1 22	/04/20
EXE	CUTION the	I IMPLEMEN SPECIFIC (NTATION CONTRA	I PLAN F CT	OR
TASK OI	RDER No.	1 "Design of Ho Systems	CLL and HC in	PB-TBS An	cilla
v	iew of the	ITER-IO Conce	ptual Desig	n Review"	
F4E Contr	act Ref.No.	F4E-OMF-331-02-0)1-01		
idm@F4E R	ef.:	F4E D 24ZSNR			
Contract 1	ïtle	Design of HCLL a in view of the ITE Specific Contrac Contract F4E-OMF of TBS Ancillary ITER	nd HCPB-TBS / R-IO Conceptua t of Enginee F-331-LOT 2: P subsystems ar	Ancillary System al Design Revie ering Framewo reliminary Desig nd integration	ns w. rk gn in
Abstract		This document is the first specific contra specifies the manag ENEA-KIT joint team according to t F4E_D_24ZSNR of related to LOT 2 (Qui	Execution Implen ct for LOT 2 of ement provisions n to comply with he manageme the Call for Prop ality Class 1).	rentation Plan of t FPA OMF 331. implemented by t F4E's requiremer nt specificatio osals F4E-OMF-3	he It he nts ns 31
					_
ENEA-KIT	Joint Team	Authors	Reviewers	Approver	_
Na	me	B.Ghidersa, M. Utili,	L. Di Pace	A. Aiello	
		K. Voukelatou	I. Ignatiadis		_
Sian	ature				
	1	1			

Annex ST1_Exec_WBS OMF331 L2 T01-01_Rev4_0.pdf Annex ST2_Progress Report_PR-OMF331 L2 T01-01.docx Annex ST3_Control Plan PR-OMF331 L2 T01-01.docx Annex ST4 Documentation Schedule DM-OMF331 L2 T01-01.docx Annex ST5_Subcontracting schedule SS-OMF331 L2 T01-01.docx Annex ST5_Non Conformity Report NCR-OMF331 L2 T01-01.docx Annex ST7_Deviation Request DR-OMF331 L2 T01-01.docx Annex ST7_Deviation Request DR-OMF331 L2 T01-01.docx Annex ST8_Risk Paln RP-OMF331 L2 T01-01.docx Annex ST9_Release Note RN-OMF331 L2 T01-01.docx Annex ST9_Release Note RN-OMF331 L2 T01-01.docx Annex ST10_Exec_Time schedule TSC-OMF331 L2 T01-01_Rev4_0.pdf Annex ST11_List of People involved LP-OMF331 L2 T01-01.docx QP-OMF331 L2 T01-01_v4_1_Execution Impl Plan.docx



Specific Contracts & Specific Grants with F4E as ENEA-KIT Joint Team

Since 2012 the ENEA Fusion Department has been involved in the technology transfer of its knowledge in the field of nuclear fusion from the R&D scope to the execution of large projects together with industry, it has been outlined the importance of working by a quality management system (QMS) and of applying the principles of the Project Management. On the other side the possibility to get large contract directly from ITER or from F4E was linked to the establishment of a compliant PM & QM System which evolved through the years.

Project & Quality Management Responsible for Specific Contracts and Specific Grants with F4E in the following contracts ENEA–KIT Joint Team coordinating:

- Engineering support in the area of Test Blanket Module (TBM) systems design and technological demonstration.

- F4E-OMF 331 L2 Task Order#1 Design of HCLL and HCPB-TBS Ancillary Systems in view of the ITER-IO Conceptual Design Review. Specific Contract of Engineering Framework Contract F4E-OMF-331-LOT 2: Preliminary Design of TBS Ancillary subsystems and integration in ITER
- 2. F4E-OMF 331 L2 Task Order#2 Specific Contract of Engineering Framework Contract F4E-OMF-0331-LOT 2: Preliminary engineering assessment of the HCLL and HCPB Neutron Activation System.
- 3. F4E-OMF 331 L2 Task Order#3 Complementary activities in view of the CDR and in preparation of the PD phase.
- 4. F4E-OMF 331 L2 Task Order#4 Consolidation of TBM systems interfaces.
- 5. F4E-OMF 331 L2 Task Order#5 Elements of Preliminary Design of the TBM Ancillary Systems.
- Framework Partnership Agreement for the R&D experimental activities in support of the conceptual and preliminary design of the European Test Blanket Systems.

6. F4E-FPA 372 SG04 (ENEA Coordinator) - Specific Grant 04 of Framework Partnership Agreement F4E-FPA-372: Experimental tests in support of the Preliminary design of the European TBS.



Specific Contracts & Specific Grants with F4E as ENEA-KIT Joint Team

7. WP ENS project launched within the EUROfusion Consortium: ENS (Early Neutron Source): Neutron source for DEMO materials qualification- Neutron source for the qualification of materials for the DEMO Fusion reactor. Application of PRIMAVERA P6 to Project Management, Oversight and Support of DONES (EUROfusion) – WPENS project.

At the level of work performed on the activities of the **Project & Quality Management** of the projects mentioned above, I followed:

Project Monitoring & Reporting, & Schedule Management by issuing progress reports monthly and presenting the updated Time Schedule. In addition to this, I also followed the Risk Management for all projects with F4E, ITER & EUROfusion, presenting the risk analysis and implementing risk-based approach in the planning and execution of the activities of the related Task Orders & Specific Grants, and updating the documents related to the project's monitoring & status monthly or every three or six months with respect to the rules set for each contract. As responsible for the Planning Management using Primavera P6 software, producing since the beginning of the project the Work Breakdown Structure and the planning of the projects in progress, and subsequently the issue of Primavera Time Schedule related to the process of checking monthly the progress status.

Furthermore, we followed activities related to P&Q Management also in the following EUROfusion projects:

8. WCLL-TBS (Water Cooled Lithium Lead - Test Blanket System) Part B- PHASE I:" areas of Ancillary Systems Design, Modelling, Instrumentation Development", concerning the design activities to be implemented in 2018 in preparation of the Conceptual Design Review of the WCLL-TBS (foreseen by mid-2020).

9. WCLL-TBS (Water Cooled Lithium Lead - Test Blanket System) Part B-: PHASE II: "areas of Ancillary Systems Design, Modelling, Instrumentation Development", concerning the continuation of the technical activities related to the WCLL-TBS Ancillary Systems Design (including elements of System Engineering) in view of the completion of the conceptual design & through the implementation of the one year technical activities to evaluate the possibility to address what was requested by ITER Organization (IO) for the Conceptual Design Review (CDR) of the WCLEATER Internation of the one year technical activities to evaluate the possibility to address what was requested by ITER Organization (IO) for the Conceptual Design Review (CDR) of the WCLEATER Internation of the one year technical activities to evaluate the possibility to

Specific Contracts & Specific Grants with F4E as ENEA-KIT Joint Team

- 10. HPH-DPD
- 11. F4E-FPA-327
- 12. F4E-OPE 421
- 13. F4E-OPE 841
- 14. F4E-OPE 956-01
- 15. F4E-GRT-403-HRNS
- 16. FPA 395
- 17. IVVS
- 18. JT60-SA
- 19. F138





P Project & Quality Management Specification Progress Meetings & Progress Reports

2. Progress Meetings and Progress Reports

- In addition to progress meetings, technical meetings were organized and executed between the ENEA Project Team and F4E representatives to address in more detail one or several tasks, and/or to review achieved technical results before endorsing a decision (hold-point/milestone).
- ENEA Project Team prepared and sent to F4E, every month, a signed **Progress Report** with updated documents as appropriate.
- The following updated documents will be appended to the Progress Report, if applicable in the reporting period:
 - Time Schedule (to be prepared by Primavera) [ref. WBS structure],
 - Management Control Plan [ref. WBS structure],
 - Configuration & Documentation List,
 - other Annexes.



Project & Quality Management Specification Document Management

- The exchange of all documentation and information between F4E and ENEA Project Team was conducted between F4E's TRO and the STR.
- Documents produced inside the Task Order or Specific Grant sent, after internal management process through DANTE (ENEA Documentation Management System) as agreed to the STR for official transmission to F4E.
- The Supplier used a Documentation Exchange Area in idm@F4E for the documentation exchange relative to the Project's area. Other documents and data files (managed by specialized CAD software; e.g. CATIA), were subject to other requirements to be specified in the Implementation Plan of related TO or SGs.
- After approval from F4E, documents were uploaded to the specific Supplier area in the idm@F4E



Project & Quality Management Specification Activities completed 100%

		Document ID		PR-O	R-OMF331 L2 T01-10		Page 1/10
			Progress Report for the Specific Contract F4E			c Contract F4E	Poy 1.0
		TITLE	0101	J	anuary 2014		Rev. 1.0 04/02/2014
		BBOO	DECC DE	POPT	2014		
Sectio	on 1 – Repor	t References	KE33 KE		anuary 2014		
Repo	enort Number: 10.01/2014			Revis	sion: 1.0		
1. F4	1. F4E reference:			E4E Customer ref			
2. Supplier DMS# PR -OMF 3311 2 T01		1L2 T01-10)				
3. Su	ipplier:	ENEA/KIT J	ointTeam				
Sectio	on 2 – Repor	rting					
4. Pro	ject Status	Check		Contract	period (weeks)		
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Project & Quality Management Specification Progress Meetings

1. Project Meetings

- Kick-off-Meeting (KOM)
- Progress meetings (every month)
- Final meeting

Kick-Off-Meeting					
Туре	Video Meeting				
Size /	TRO, STR, KTR, EQR, other persons as per KOM-				
Participants	Agenda				
Location	F4E premises Barcelona				
Meeting Agenda	TRO (issue)				
Meeting Minutes	TRO or SCP [tbd]				
Outline Agenda	(compare KOM-Minutes) [tbd]				

Progress Meetings				
Туре	Presence / Video Meeting [tbd]			
Size / Participants	TRO, STR, ETR, KTR, [other persons tbd]			
Location	[tbd]			
Meeting Agenda	TRO (issue) [tbd]			
Meeting Minutes	TRO or SCP [tbd]			
Frequency	bi-weekly			

Final Meeting (Acceptance review of deliverables & Contract closure)					
Туре	Presence / Video Meeting [tbd]				
Size / Participants	TRO, STR, ETR, EQR; KTR, KQR, SQR [other persons tbd]				
Location	[tbd]				
Meeting Agenda	TRO (issue) [tbd]				
Meeting Minutes	TRO or SCP [tbd]				

