Culham Specification		CD/S/C001
SUPPLIER QUALITY ASSURANCE REQUIREMENTS		Issue: 2
		Date: September 2010
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0 DOCUMENT CONTROL

0.1 Changes made

0.1.1 Reference to ‘Quality Programme’ changed to ‘Quality Plan’ and reference to ‘Quality Plan’ changed to ‘Control Plan’.

0.2 Changes Expected

0.2.1 None

1 SCOPE

1.1.1 Where specified, this document defines the Quality Assurance requirements for the supply of equipment and services to the Culham Centre for Fusion Energy (CCFE).

2 GENERAL REQUIRMENTS

2.1 Quality System

2.1.1 The Supplier providing equipment or services to CCFE will have an adequate and currently operational quality system and organisation capable of meeting the technical requirements of the Contract.

2.2 Audit and Surveillance

2.2.1 Audits, reviews, surveillance and inspection of the Supplier's quality assurance arrangements will be carried out as required by CCFE or the appointed representative. These activities may be extended to cover sub-suppliers. In respect of any deficiencies revealed, the Supplier will implement, or ensure that sub-suppliers implement, corrective actions in accordance with an agreed timescale.

2.2.2 CCFE will be informed of the Supplier's audits, reviews, surveillance, and inspection activities relating to the Contract including those involving sub-suppliers.

2.2.3 The Supplier will provide CCFE with access to documentation, personnel and to their sub-supplier's premises during all stages of the contract for purposes of audit, review, surveillance and inspection.

2.2.4 CCFE reserves the right to make unscheduled visits to the Supplier or sub-supplier's works and free access is to be provided at all times.

2.3 Traceability

2.3.1 The Supplier shall maintain the identification and traceability of plant, equipment, materials and documentation supplied as part of the works.

2.4 Non-conformance and Deviations

2.4.1 All items and services that do not meet the requirements of the Contract or Technical Specification must be recorded as non-conformities (NCR).

2.4.2 If the NCR negates a requirement of the Contract or Technical Specification the supplier must stop work and immediately notify CCFE. A repaired item is deemed to negate the Contract/Technical requirements and as such repairs must not be undertaken without prior approval from CCFE. CCFE will review proposed corrections and notify the Supplier of the agreed action to be taken. All non-conformances will be retained as part of the Contract records.

2.4.3 If the Non-conformance does not negate a requirement of the Contract or Technical Specification the Supplier may take action to resolve the NCR within their own quality management system. In such a case the Supplier must note the detail of the non-conformity and correction on a supplier Non-Conformance Report and send a copy to CCFE for information immediately.

2.4.4 Requests to deviate from specified requirements or to change the requirements of the Contract or Technical Specification must be submitted in writing to CCFE.

2.5 Competence

2.5.1 Personnel engaged by the Supplier shall have appropriate authority and be suitably trained and qualified for their duties to meet the requirements of safety regulations, applicable codes, standards and specifications. Evidence must be provided if requested by CCFE.

2.6 Records

2.6.1 Records must be retained for an agreed retention period such that prevents damage, deterioration or loss of the information stored.

3 BEFORE IMPLEMENTATION

3.1.1 When required by the Contract, the Supplier must prepare a contract specific ‘Quality Plan’ and submit this to CCFE for approval. Guidance on typical content is defined in (appendix 1). Once approved, no changes must be made without CCFE prior agreement and formal approval.

3.1.2 The Supplier must prepare a ‘Control Plan’ for all contracts. The Control Plan must lists all activities in order of sequence ranging from design, verification, manufacture, test and assembly, installation and commissioning and any other activity associated with the quality. A suggested template for a Control Plan is attached in (appendix 2) of this document; however, alternative formats may be submitted for approval. CCFE will review the Control Plan and add inspection points at relevant activities. Once approved, no changes must be made without prior agreement and formal approval.

3.1.3 All other Documents required in the Contract must be reviewed by CCFE prior to their use e.g. Time schedules, drawings, procurement specifications, special process specifications, test specifications and any document necessary for the effective implementation of quality assurance requirements. Once approved, no changes must be made without prior agreement and formal approval.

3.2 Sub-suppliers

3.2.1 The Supplier must inform CCFE of all activities to be performed by a sub-supplier.

3.2.2 The Supplier must ensure that each of their sub-suppliers has an adequate and operational quality organisation, or failing this, they will undertake all the necessary actions to establish and maintain the quality in the sub-supplier's premises.

3.2.3 The requirements of this specification apply to sub-suppliers. The Supplier will be responsible for disseminating these requirements where appropriate. Where the supply chain extends beyond direct sub-suppliers to the Supplier it is the responsibility of the Supplier to ensure adequate requirements are in place throughout the supply chain.

4 DURING IMPLEMENTATION

4.1.1 Control Plan – The Supplier must use the approved Control Plan and referenced documents therein to control work without exception unless agreed otherwise by CCFE. The Supplier will notify CCFE or their representative when witnessing or approval in relation to activities is required in sufficient time as to allow their participation. The Supplier must not proceed beyond any Hold Point without obtaining approval from CCFE.

4.1.2 All activities and operations will be carried out in controlled conditions using only those documents approved by CCFE and must be directly accessible to those performing the work.

4.1.3 A suitable document management system must be implemented to ensure that only current issues of the relevant documents are held at each work or process location.

4.1.4 Documents related to the Contract must be accessible in order to verify the implementation of the Quality Assurance requirements at the Supplier's/sub-supplier's works.

4.1.5 All equipment used for inspection and testing shall be maintained and calibrated in accordance with maker's instructions and national standards. Evidence must be provided if requested by CCFE.

4.1.6 The Supplier will compile the Quality documentation as the work proceeds and the documentation must be available for review by CCFE on request.

5 ON COMPLETION

5.1.1 On completion of the work the supplier must check that the documentation required by the Contract is complete in all respects.

5.1.2 Documentation shall include but not be limited to operation manuals, instruction manuals and maintenance manuals where relevant.

5.1.3 Before delivery the Supplier will complete an Inspection Release Note (IRN) (attached). It is the supplier's responsibility to request information from CCFE to complete section 1 of the form. The IRN confirms that all necessary tests and inspections have been completed satisfactorily and that all necessary documents required by the Contract are complete in all respects. Equipment may not be accepted onto Culham Site if section 1 of the IRN is not signed by CCFE.

5.1.4 CCFE shall check the condition of the equipment (e.g. cleanliness, marking etc.) and the completeness of all relevant functional tests before signing and dating section 1 of the IRN for release.

5.1.5 The IRN with Section 1 completed and signed by CCFE, together with the equipment and documentation package will be sent by the Supplier to CCFE. The documentation package may be supplied at a later stage providing prior agreement has been obtained from CCFE and recorded on the IRN.

5.1.6 On receipt of Equipment and/or documentation, CCFE shall check to make sure that the equipment, technical and quality documents required by and stated in the contract are received and complete and that all necessary test and inspections have been completed satisfactorily. Section 2 of the IRN will be completed on acceptance by CCFE.

5.1.7 A copy of the completed IRN will be sent to the Supplier to indicate that the equipment and/or documentation package has been accepted.

5.1.8 The Supplier shall ensure that equipment is delivered in accordance with any special requirements defined in the Contract.

Appendix 1; Quality Plan Guidance

a) Organisation

- Chart showing organisational and functional responsibilities involved, including the Contract Liaison Officer, the Quality Manager, relevant supervisory staff, all personnel authorised to sign relevant documents.

b) Quality Manual

- Chart showing the QA Organisation;
- Chart showing the procedure for approval of design, Code/Specification compliance, procurement, manufacture, etc.

c) Sub-Suppliers

- List of all sub-suppliers to be employed on the Contract;
- Supplier/Vendor appraisal.

d) Design Control

- Provision of a Code of Design Practice and Procedures;
- Identification and control of design interfaces;
- Preparation and maintenance of drawings, specifications, procedures and instructions;
- Consideration of statutory requirements including those for health and safety;
- Design reviews.

e) Procurement

- Procurement specifications, purchase orders, material certification, inspection and verification of purchased material;
- Critical procurement delivery times should be indicated.

f) Control of Documentation

- Availability of appropriate documents;
- Written procedures describing how functions are controlled, extent of control and responsibilities.

g) Quality Control in Manufacture, Assembly and Installation

- Written work instructions and procedures;
- Clean conditions with details of working conditions, controls;
- Special processes, i.e. welding, brazing, soldering, cleaning, heat treatment;
- Control Plan which lists all operations on each component, sub-assembly, etc.

h) Inspection and Test

- Qualification of personnel;

- Test Procedures;
- Accuracy and suitability of test equipment.

i) Concessions and Non-Conformities

- Segregation procedures, analysis and remedial actions.

j) Audits

- Planned and documented audits to verify compliance with the Technical and Quality aspects of the Contract.

k) Inspection Release Note

- All documents required by the Contract

l) Packaging and Delivery

- Packaging and delivery specifications, provision for short and long term storage.

Appendix 2

CONTROL PLAN

SUPPLIER NAME:		**CONTROL PLAN NO :**
CONTRACT/PROJECT TITLE:		**CONTRACT NO:**
REVISION:		**DATE:**
PREPERED BY:	**APPROVED BY:**	**ACCEPTED BY:**

Symbol Code	
HP Hold Point: Activity to be held pending agreement of party(s) to proceed. 10 days notice required.	**D Document Review:** Required document review. Work may proceed during review.
W Witness: Activity to be witnessed by agreed party(s). Work must not proceed without witness. 10 days notice required.	**AP Approval:** Approval of documentation or activity by agreed party(s). Activities requiring approved documents must not proceed before approval. 10 days notice required.
N Notification: Notification of approaching activity. Notice to be given 5 days before activity. Work may continue in absences of customer response.	**S1 100% Inspection:** Measure of inspection by nominated party(s).
R Report Required: Documented report required for activity.	**S2 Random inspection:** Measure of inspection by nominated party(s).
C Customer Discretionary Review: Optional review of documents. Work may continue in absence of customer review.	
Description of Work/Item(s):	

Standard Activities/Inspections		Control of Activity	Specifications, Procedures, Standards, Reference	Inspection Authority				Output	Instruction
				Supplier Signature & Date		UKAEA Culham Signature & Date			

INSPECTION RELEASE NOTE (IRN)

Section 1	To be completed by the Supplier and Customer before delivery
N.1 Title of the Contract *(to be completed by supplier)*	
N.2 Contract Number *(to be completed by supplier)*	
N.3 QRN Number *(to be completed by supplier)*	
N.4 Name of Customer Contact *(to be completed by supplier)*	
N.5 Name and Address of Supplier *(to be completed by supplier)*	

N.6 Delivery to Culham Site and Acceptance of (describe equipment and quantity) **:**
(to be completed by supplier)

N.7 List and status of technical and quality documents as required by the contract. Please use extra sheet if needed.
(to be completed by supplier)

Document Reference	Included with delivery (yes/no)	Reason (if no)	Date to be supplied

N.8 Supplier Comments (if any)**:**
(to be completed by supplier)

N.9 Supplier (the above information has been checked and is correct)

Name	Signature	Date

N.10 Authorisation for delivery by Customer (The Condition of the equipment and the completeness of all relevant functional tests have been checked and are satisfactory.)

Name	Signature	Date

Guidance for the completion and use of this document is given in Culham Division Document CD/S/C001

Section 2	To be completed by the Customer after delivery

N.11 Customer Comments (if any)**:**
(to be completed by customer)

N.12 Customer Approval (the equipment, technical and quality documents required by and stated in section 1 have been received, checked and are complete.)

Name	Signature	Date

N.13 Customer Quality Officer Comments (If any)**:**
(to be completed by customer)

N.14 Customer Quality Officer (the above form has been completed by all relevant parties and documentation received for filing.)

Name	Signature	Date

Guidance for the completion and use of this form is given in Culham Document CD/S/C001