



CLASSIFICATION
Unclassified

iDOCS UID
US_D_22HHAQ

EXTERNAL REFERENCE
PPPL-US-ITER-PLAN-QAP

VERSION CREATED ON / VERSION / STATUS
10 Apr 17 / 1.2 / Approved

PA/TA NUMBER(s)

PPPL Quality Assurance Plan for US ITER Work

Abstract or description:

This document supplements the Princeton Plasma Physics Laboratory (PPPL) Institutional Quality Assurance Plan with additional requirements for US ITER activities.

<i>Workflow Role</i>	<i>Name</i>	<i>Action</i>
<i>Signatory</i>	JEDIC B.	10 Apr 17:signed
<i>Co-signatories</i>		
<i>Reviewers</i>	FEDER R. MURDOCH G.	12 Apr 17:recommended 13 Apr 17:recommended
<i>Approver</i>	CASELLA F.	17 Apr 17:approved

<i>Change Log</i>			
PPPL Quality Assurance Plan for US ITER Work (22HHAQ)			
<i>Version</i>	<i>Latest Status</i>	<i>Issue Date</i>	<i>Description of Change</i>
v1.0	Signed	02 Oct 13	
v1.1	Approved	10 Jun 16	Updated to reflect changes in the US ITER QA Requirements and documents and to better clarify how PPPL satisfies these requirements
v1.2	Approved	10 Apr 17	Updated signature cover page to reflect current organization roles. Updated to add references to additional required ITER procedures "Requirements for DA/Supplier/Subcontractors Deviations and Nonconformities", "Requirements for Producing a Contractors Release Note", "Requirements for Producing a Manufacturing and Inspection Plan", "Inspection Plan (IP) Template" as well as US ITER Procedures "Contractor Release Note Procedure", "Quality Clauses for Procurement - US ITER Guide", "Software Control and Validation Procedure", and "Software Screening Checklist". Updated related document section and updated reference names where needed. Minor editorial changes made to improve readability.

PPPL Quality Assurance Plan for US ITER Work

PPPL-US-ITER-PLAN-QAP

Rev. 3

March 2017

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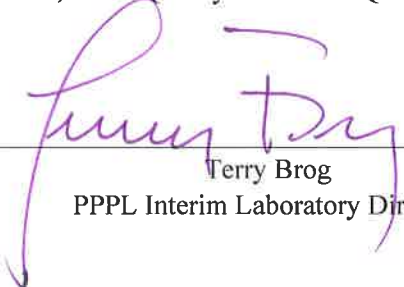
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RECORD OF REVISIONS

Revision	Date	Resp. Ind.	Description of Change
0	04/2009	J. Malsbury	Initial Release of a procedure relevant to PPPL procurements for US ITER, declared to be a QA Plan.
1	10/2011	J. Malsbury	Revised to include all aspects of US ITER QA Requirements
2	09/2015	J. Malsbury	Updated to reflect changes in the US ITER QA Requirements and documents and to better clarify how PPPL satisfies these requirements
3	03/2017	B. Jedic	Updated signature cover page to reflect current organization roles. Updated to add references to additional required ITER procedures "Requirements for DA / Supplier / Subcontractors Deviations & Nonconformities", "Requirements for Producing a Contractors Release Note", "Requirements for Producing a Manufacturing and Inspection Plan", "Inspection Plan (IP) Template" as well as US ITER Procedures "Contractor Release Note Procedure", "Quality Clauses for Procurement - US ITER Guide", "Software Control and Validation Procedure", and "Software Screening Checklist", . Updated related document section and updated reference names where needed. Minor editorial changes made to improve readability.

1.0 PURPOSE

This document supplements the Princeton Plasma Physics Laboratory (PPPL) Institutional Quality Assurance Plan (EQP-004, available at http://www.pppl.gov/eshis/PPPL_docs.shtml) with additional requirements for US ITER activities.

2.0 APPROACH

PPPL is a partner in the US ITER Domestic Agency. PPPL activities for the US ITER Domestic Agency (DA), such as Procurement Arrangements and Task Agreements, will be accomplished under the PPPL Institutional Quality Assurance Plan and the ITER requirements identified in this Plan. The procedures referenced in this document will be followed during ITER activities to ensure that PPPL and its suppliers meet the requirements stated. In the unlikely event of a conflict between procedures, the US Domestic Agency will be consulted as needed to ensure we meet the requirements of both ITER and the US Domestic Agency.

3.0 RELATED DOCUMENTS

The following are related documents (current versions unless otherwise specified):

3.1 Memorandum of Agreement No. MOA-UTB-2006226 between UT-Battelle, LLC, The U.S. Contributions to ITER Project Office, Princeton University, and Savannah River Nuclear Solutions, LLC

3.2 ITER

- | | | |
|----|---------------|---|
| 1. | ITER_D_2832CF | <i>Design Review Procedure</i> |
| 2. | ITER_D_QV7GQF | <i>Inspection Plan (IP) Template</i> |
| 3. | ITER_D_24VQES | <i>Quality Classification Determination</i> |
| 4. | ITER_D_22F53X | <i>Requirements for DA / Supplier / Subcontractors Deviations & Nonconformities</i> |
| 5. | ITER_D_22F52F | <i>Requirements for Producing a Contractors Release Note</i> |
| 6. | ITER_D_22MDZD | <i>Requirements for Producing a Manufacturing and Inspection Plan</i> |
| 7. | ITER_D_22MFMW | <i>Requirements for Producing a Quality Plan</i> |

3.3 US DA

- | | | |
|-----|-------------|---|
| 1. | US_D_22HH9B | Baseline Change Control Plan |
| 2. | US_D_228CP6 | Conducting Quality Assessments |
| 3. | US_D_22NEFV | Contractor Release Note Procedure |
| 4. | US_D_22KRN7 | Creation and Management of US ITER Project Records Procedure |
| 5. | US_D_227HSR | Design Analyses and Calculations |
| 6. | US_D_22M5G7 | Design Change Procedure |
| 7. | US_D_22ME42 | Design Readiness Review Procedure |
| 8. | US_D_22A94F | Deviation Requests |
| 9. | US_D_22AMMS | Document Control Procedure |
| 10. | US_D_223LSJ | Document Reviews and Approvals Procedure |
| 11. | US_D_22J4DV | Document Review and Approval Procedure Matrix |
| 12. | US_D_227FU8 | Drawing Management Procedure |
| 13. | US_D_22YBGC | Manufacturing Readiness Review |
| 14. | US_D_22GMTF | Nonconformance Report Procedure |
| 15. | US_D_22JCPY | Quality Assurance Program, United States Contributions to ITER, R06 |
| 16. | US_D_22JW5A | Quality Clauses for Procurement - US ITER Guide |

17. US_D_224URT QA Non-Conformance Report Form,
18. US_D_22EAKZ Quality and Safety Classification Checklist
19. US_D_22EEBU Quality and Safety Classification Procedure
20. US_D_22KGWH Quality in Acquisitions
21. US_D_23EG78 Quality Plan - Template for Suppliers and Subcontractors
22. US_D_22ZWJ6 Receipt Inspection Procedure
23. US_D_22NXGB Software Control and Validation Procedure
24. US_D_22D3TF Software Screening Checklist
25. US_D_2225ZV Specification and Statement of Work Development and Approval
26. US_D_22PKL9 Test and Acceptance Program Procedure
27. US_D_22K35M Value Engineering Plan
28. US_D_22LWLS Value Engineering Implementation Guidance

3.4 PPPL Documents

1. EQP-004 PPPL Institutional Quality Assurance Program (IQAP)
2. ENG-006 Preparation, Review, and Approval of Specifications and Statements of Work
3. ENG-033 Design Verification
4. QA-002 PPPL Audit Program
5. QA-003 Procurement Quality Assurance
6. QA-005 Control of Nonconformances
7. QA-025 Management Assessments

4.0 GRADED APPROACH

- 4.1 Quality-assuring actions shall be applied commensurate with risks and in accordance with *US ITER Quality and Safety Classification Procedure (US_D_22EEBU)* and *ITER Quality Classification Determination (ITER_D_24VQES)*. This procedure requires evaluation and formal grading regarding safety and quality risk. See the procedure for excluded items. WBS Team Leaders or their designees are expected to consult with PPPL QA whenever classifications are being determined. Note that the classifications for lower level components may differ than that defined for an associated larger scope of work. Lowering an ITER Organization (IO) assigned classification requires a justification and acceptance by the IO TRO and/or IO QA RO.

5.0 CRITERION 1 - PROGRAM

- 5.1 Princeton Plasma Physics Laboratory is a partner to the US Domestic Agency (DA), herein referred to as US ITER, within Oak Ridge National Laboratory. As such, PPPL is required to satisfy the requirements of the US ITER Quality Assurance Program.
- 5.2 The PPPL US ITER program is managed by the Head of ITER Fabrication, who reports to the PPPL Deputy Director of Operations.
- 5.3 PPPL adheres to the Institutional PPPL Quality Assurance Plan except where additional quality requirements are imposed by either US ITER or IO.
- 5.4 Specific individuals associated with ITER work will be defined in the Quality Plans specific to a Procurement Arrangement or Task Agreement. This will be done via table and/or organizational chart within the plan.

6.0 CRITERION 2 – PERSONNEL TRAINING AND QUALIFICATION

- 6.1 PPPL will complete US ITER required training. PPPL will rely on the US ITER automated system for tracking training status. PPPL also has specific training requirements based on the type of work being performed, typically defined via internal training matrices or work specific documents. This training is tracked by PPPL.

7.0 CRITERION 3 – QUALITY IMPROVEMENT

- 7.1 Issues associated with items, services, and processes that do not conform to specified requirements shall be identified and controlled to prevent their unintended use utilizing a nonconformance report (NCR). The report will be processed in accordance with US ITER Nonconformance Report Procedure (US_D_22GMTF) and ITER *Requirements for DA / Supplier / Subcontractors Deviations & Nonconformities (ITER_D_22F53X)*. Nonconformities originating at a supplier or at PPPL will use their internal NCR system, with that form attached to the USITER form for processing. NCRs will be classified as Minor or Major as defined in the procedure. Major NCRs require the IO's formal approval of the disposition before implementing the corrective action. All NCRs shall be distributed to US ITER for further distribution to IO.

8.0 CRITERION 4 – DOCUMENTS AND RECORDS

- 8.1 The development, revision, maintenance, and control of US ITER Project generated or received documents shall follow *US ITER Document Control Procedure (US_D_22AMMS)*. This procedure covers documentation under configuration control as part of the US ITER technical baseline. It covers both US ITER and supplier generated, controlled documents.
- 8.2 The development, revision, maintenance, and control of CAD models and drawings that are deliverables under an agreement with the ITER Organization shall follow *US ITER Drawing Management Procedure (US_D_227FU8)*.
- 8.3 The review and approval process for documents is defined in US ITER's *Document Reviews and Approvals Procedure (US_D_223LSJ)* and *Document Review and Approval Procedure Matrix (US_D_22J4DV)*.
- 8.4 The management of drawings used on the US ITER Project is defined in *US ITER Drawing Management Procedure (US_D_227FU8)*.
- 8.5 The process for records is defined in *US ITER Creation and Management of US ITER Project Records Procedure (US_D_22KRN7)*.

9.0 CRITERION 5 – WORK PROCESSES

- 9.1 Fabrication for US ITER, whether in-house or procured, shall follow US ITER procedure *Quality in Acquisitions (US_D_22KGWH)*.
- 9.2 When required Manufacturing Inspection Plans will be developed in accordance with ITER *Requirements for Producing a Manufacturing and Inspection Plan (ITER_D_22MD7D)* and *ITER Inspection Plan (IP) Template (ITER_D_QV7GQF)*.
- 9.3 Software developed and/or procured for ITER work will be screened using *US ITER Software Screening Checklist (US_D_22D3TF)*. The checklist screens software for its functionality which includes design analysis and its use in operations. It addresses potential effects on worker and equipment safety as well as its effect on operations. If applicable based on the checklist results, *US ITER Software Control and Validation Procedure (US_D_22NXGB)* will be implemented.
- 9.4 Where no specific US ITER requirements indicate otherwise, the normal PPPL work processes shall be followed.

10.0 CRITERION 6 – DESIGN

- 10.1 Design reviews for ITER follow *ITER Design Review Procedure (ITER_D_2832CF)* with the caveats listed in *US ITER Design Readiness Review Procedure (US_D_22ME42)* for reviews required by the Project. Reviews required by PPPL, but not by ITER, shall be conducted in accordance with the PPPL procedure *Design Verification (ENG-033)*.
- 10.2 Analyses and calculations required by US ITER for an existing, modified, or proposed structure, system, or component (SCC), including computer calculations, shall be processed via *US ITER Design Analyses and Calculations (US_D_227HSR)*.
- 10.3 Deviations from an IO specified or approved requirement, typically found in Procurement Arrangements (PAs), Task Agreements (TAs), System Requirements Documents and other IO controlled documents shall be performed per *US ITER Deviation Requests (US_D_22A94F)* and *ITER Requirements for DA / Supplier / Subcontractors Deviations & Nonconformities (ITER_D_22F53X)*.
- 10.4 Changes to the US ITER Project Baseline are controlled per *US ITER Baseline Change Control Plan (US_D_22HH9B)*. These changes include technical scope, cost, schedule, and credit baselines.
- 10.5 Changes to the US ITER Project Technical Baseline shall be implemented per *US ITER Design Change Procedure (US_D_22M5G7)*. Three events could trigger a Design Change Request (DCR):
- A US ITER Project participant recommends a change to a document that is part of the US ITER project technical baseline.
 - The IO proposes a change through their Project Change Request (PCR) process that impacts a document that is part of the US ITER project baseline.
 - A supplier to the US ITER Project submits a Deviation Request (DR) or Nonconformance Report (NCR) that initiates a change that is part of the US ITER project baseline.
- 10.6 Value engineering, when required for ITER, shall be performed according to US ITER's *Value Engineering Plan (US_D_22K35M)*, and *Value Engineering Implementation Guidance (US_D_22LWLS)*.
- 10.7 Where software is involved in producing the design, or incorporated within the design in terms of performance of the design, the US ITER's *Software Screening Checklist (US_D_22D3TF)* and *Software Control and Validation Procedure (US_D_22NXGB)* will be followed.

11.0 CRITERION 7 – PROCUREMENT

- 11.1 US ITER requirements for the quality aspects of procurements are specified in *US ITER Quality in Acquisitions (US_D_22KGWH)*.
- 11.2 Procurements are given a quality and safety classification per *US ITER Quality and Safety Classification Procedure (US_D_22EEBU)*, using *US ITER Quality and Safety Classification Checklist (US_D_22EAKZ)*. Exceptions to the rule are listed in the procedure. Specific actions for each classification are defined in this procedure.

- 11.3 The acquisition of items, services, designs, and research and development (R&D) activities shall follow PPPL procedure *Procurement Quality Assurance (QA-003)* with additional controls from *US ITER Quality in Acquisitions (US_D_22KGWH)* if required by Procurement Arrangement (PA) or Task Agreement (TA). This can include the flowdown of Manufacturing Inspection Plans (MIPs) as defined in the ITER requirements to the suppliers and their subcontractors.
- 11.4 Specifications and Statements of Work shall be developed per PPPL procedure *Preparation, Review, and Approval of Specifications and Statements of Work (ENG-006)* which aligns with *US ITER Specification and Statement of Work Development and Approval (US_D_2225ZV)*. Both PPPL QA Clauses for Procurement Documents and the *Quality Clauses for Procurement - US ITER Guide (US_D_22JW5A)* will be used as references in establishing the quality requirements for procurements.
- 11.5 It is preferred, but not required, that Subcontractor and Supplier Quality Plans use *US ITER Quality Plan - Template for Suppliers and Subcontractors (US_D_23EG78)*. Some Subcontractors and Suppliers may already have existing formats for their Quality Plans that are appropriate for their work and are consistent with the IO requirements for Quality Plans found in *ITER Requirements for Producing a Quality Plan (ITER_D_22MFMW)*.
- 11.6 Production Readiness Reviews, where required, shall be conducted prior to authorizing production for any customer equipment that forms part of the US ITER in-kind contributions. The applicable procedure is *US ITER Manufacturing Readiness Review (US_D_22YBGC)*.
- 11.7 Acceptance of Quality Level 1 and 2 items and services shall follow the requirements of *US ITER's Receipt Inspection Procedure (US_D_22ZJ6)* and *Document Reviews and Approvals Procedure (US_D_223LSJ)* together with *US ITER Document Review and Approval Procedure Matrix (US_D_22J4DV)* for acceptance of other work products (e.g., technical documents).

12.0 CRITERION 8 – INSPECTION AND ACCEPTANCE TESTING

- 12.1 Site visits and receipt inspections shall be conducted in accordance with *PPPL Procurement Quality Assurance (QA-003)*.
- 12.2 Test Readiness Reviews, where required, shall be conducted prior to authorizing testing for any customer equipment that forms part of the US ITER in-kind contributions. The applicable procedure is *US ITER Manufacturing Readiness Review (US_D_22YBGC)*.
- 12.3 Acceptance testing of hardware that will be delivered to the ITER Plant will be performed per *US ITER Test and Acceptance Program Procedure US_D_22PKL9)*.
- 12.4 Acceptance testing of software that will be delivered to the ITER Plant will be performed per *US ITER Software Control and Validation Procedure (US_D_22NXGB)*.
- 12.5 A Contractor Release Note is issued when appropriate for the delivery of good and/or services to ITER in accordance with *US ITER Contractor Release Note Procedure (US_D_22NEFV)* and *ITER Requirements for Producing a Contractors Release Note (ITER_D_22F52F)*.

13.0 CRITERION 9 – MANAGEMENT ASSESSMENT

13.1 If management assessments are performed at the request of US ITER, then the applicable procedure is *US ITER Conducting Quality Assessments (US_D_228CP6)*. Otherwise, the PPPL Management Assessment program, *Management Assessments (QA-025)* is applicable.

14.0 CRITERION 10 – INDEPENDENT ASSESSMENT

14.1 Independent assessments will be performed via the *PPPL Audit Program (QA-002)*.