PRINCETON PLASMA PHYSICS LABORATORY (PPPL)

EQP-004, INSTITUTIONAL QUALITY ASSURANCE PROGRAM

REVISION 12

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9	10/11	J. Malsbury S. Baumgartner A. Boozer J. DeLooper P. Efthimion D. Johnson J. Levine K. MacPherson J. Menard S. Murphy-LaMarche G. H. Neilson M. Williams J. R. Wilson E. Winkler A. Cohen M. Zarnstorff S. Prager M. DiKeakos, DOE/PSO	Revision to reflect the issuance of DOE O 414.1D and the use of the 2008 version of NQA-1, as the national standard, instead of the 1997 version. Re-titled to indicate that the document is a description of the PPPL QA program.
10		J. Malsbury S. Baumgartner A. Boozer J. DeLooper P. Efthimion D. Johnson J. Levine K. MacPherson J. Menard S. Murphy-LaMarche G. H. Neilson M. Williams J. R. Wilson E. Winkler A. Cohen M. Zarnstorff S. Prager	Revised to reflect lessons learned from the Skid Steer incident
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12	3/17	A. Bhattacharjee, Theory & Computation; D. Carle, Facilities and Site Services; M. Cohen, Interim Information Technology and CIO; P. Efthimion, Plasma Science & Technology; K. Fischer, Business Ops, CFO; R. Hawryluk, NSTX-U Recovery Project ; L. Hill, IOI Project; J. Levine, ES&H; J. Menard, NSTX-U Research; A. Moten, Interim Human Resources; R. Nazikian, ITER & Tokamaks; G. H. Neilson, Advanced Projects/ITER Fabrication; V. Riccardo, Engineering & Infrastructure; A. Zwicker Office of Communications and Outreach	Updated names on approval cover sheet. Updated the Statement from the PPPL Director Minor edits on section numbering. Updated organizational names. Revised Section 13.0 on Software QA. Added reference to Order 420.2C. Added reference to ESH-025. Removed reference to obsolete Procedure GEN-029.

Statement from the PPPL Director

The Princeton Plasma Physics Laboratory (PPPL) is an innovative and discovery leader in plasma and fusion science and engineering. It is the only Department of Energy (DOE) Laboratory devoted to these areas, and it is the lead U.S. institution investigating the science of magnetic fusion energy.

For over six decades PPPL has been a world leader in magnetic confinement experiments and nationally leading programs in plasma theory and computation, and plasma science and technology. PPPL is a partner in the U.S. contributions to the international ITER Project and hosts multi-institutional collaborative work on the National Spherical Torus Experiment – Upgrade facility. The Laboratory also hosts smaller experimental facilities used by multi-institutional research teams and collaborates strongly by sending scientists, engineers and specialized equipment to other research facilities in the U.S. and abroad.

The PPPL Institutional Quality Assurance Plan provides the framework that enables each of us to carry out our work in an efficient and effective manner. This plan recognizes that responsibility for the quality of work resides with the responsible individual and the cognizant line manager.

I encourage each of you to continually review your work for opportunities for improvement and to establish an environment that fosters, encourages, and requires the best performance from every individual. Using these objectives, PPPL will continue to be a world leader in plasma science and fusion science research.

Terry Brog
Interim Director

1.0 Overview

The purpose of this document is to define the Princeton Plasma Physics Laboratory (PPPL) Institutional Quality Assurance Program (QAP). This document defines the roles of personnel, levels of authority, and interactions between the Laboratory's organizations. Additionally, the QAP defines policies that pertain to subcontractors' responsibilities to provide quality support services — on-site or off-site.

This Institutional QA Plan meets the requirements of DOE O 414.1D. PPPL is a DOE radiological facility. When NSTX-U returns to operation it will be classified as an accelerator under DOE 420.2C, *Safety Of Accelerator Facilities.* The Quality Assurance program is modeled after the Part 1 Requirements from ASME NQA-1 – 2008, Quality Assurance Requirements for Nuclear Facility Applications, tailored for the risks present at PPPL. Further information on this tailoring is contained in Appendix C.

Quality assurance is consistent with and supportive of the goals of Integrated Safety Management (ISM), described in the Laboratory's ISM System Description. A strong ISM program supports quality assurance and, likewise, a strong quality assurance program supports ISM. In addition, QA is a key component in the Laboratory's Contractor Assurance Program, as required by contract clause H.50, Contractor Assurance System.

With respect to research, Princeton Plasma Physics Laboratory combines the concepts and requirements of DOE O 414.1D with the guidance provided in ANSI Z1.13-1999, American National Standard Quality Systems Guidelines for Research, including hiring the most qualified personnel and using peer reviews to continually assess PPPL projects or activities. This QAP is applicable to all phases of an experiment until data taking and operational activities end.

The scope and depth of the QAP's application to a specific activity is graded based on such factors as the

- Mission/program impact
- Environmental, Safety, and Health (ES&H) impact
- The costs including both development and damage to a facility
- And potential and significance of compliance issues

The graded approach provides the flexibility to design controls that best suit the project or activity.

Realization of the QAP is accomplished at the highest level through Laboratory policies and, at lower levels, by Laboratory wide and Project, Department, and Division procedures. A list of applicable PPPL policies and procedures to satisfy the requirements of this QAP is contained within Appendix A. Each Project, Department, or Division (hereafter called Organizational Units) must implement the requirements of this QAP and the policies and procedures contained in the Appendix. Organizational Units may develop project or activity-specific QAPs to further define how the PPPL QAP is to be implemented within their organization. Concurrence from the Head, Quality Assurance (QA) is required.

Terms used in this QAP are defined in Appendix B.

The effectiveness of this QAP is best determined via the achievement and improvement of quality. This is partially assessed via the Management Assessment Program, the Independent Assessment Program, DOE assessments, and is ultimately determined by examining the results achieved by PPPL operations.

2.0 Management/Program — Criterion 1

From DOE O 414.1D: *(1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. (2) Establish management processes, including planning, scheduling, and providing resources for the work.*

2.1. The Laboratory Director through Policy P-004, *Quality Assurance,* has developed and issued a documented quality assurance policy statement that commits the Princeton Plasma Physics Laboratory to the task of implementing a formal Quality Assurance Program. The Laboratory Director retains and exercises overall responsibility for the scope and implementation of the PPPL Institutional Quality Assurance Program. The QAP is binding on all personnel. All management, as a pertinent part of the program, acts to ensure that the QAP is understood and implemented.

2.2 Each management system and its associated processes are assigned an owner who is responsible to assure that the system and processes are effective and efficient. Systems and processes for which significant issues have been identified are either redesigned or improved.

2.3 The PPPL organizational structure is available at http://www.pppl.gov/orgchart. The functional responsibilities of each organization are defined in mission statements and charters. Primary responsibility for the quality of work rests with the individuals performing the work and with line management assuming responsibility for achieving quality objectives. Line management is responsible for implementing the requirements of this QAP using a graded approach. Other independent groups provide necessary support.

2.4 Individual responsibilities include:

- Understanding the requirements of the assigned task, as well as the capabilities and limitations of the tools and processes and, if not, seeking guidance from supervision.

- Confirming that he or she has the appropriate level of knowledge and skills to perform the assigned work.
- Accepting responsibility for the quality of his or her work.
- Assuring that the standard of acceptable work performance is clearly understood.
- Performing the work under the established controls.
- Providing feedback on the adequacy of the controls.
- Stopping work until identified quality, health, environmental, or safety concerns are resolved.

2.5 Line managers at all levels are responsible to:

- Identify the hazards and risks associated with their projects or activities and then determine the appropriate approach to mitigate them. These hazards may involve quality, ES&H, costs, schedules, or technical.
- Implement the requirements of this QAP using a graded approach.
- Plan and design the work processes, identify the required goals, and determine appropriate standards, procedures, or instructions commensurate with the complexity and importance of the work.
- Provide resources for the work
- Ensure that the personnel under their supervision, both PPPL and subcontractors, are provided with the necessary training, resources, and administrative controls to allow for the successful completion of work in a manner commensurate with quality and safety objectives,
- Review work and data related to the tasks for which they are responsible on a periodic basis and ensure that quality and ES&H objectives are satisfied, and
- Examine processes to adequately identify those areas in need of improvement and implement value-added improvements. Representatives of personnel working under a process should be included in process improvement activities.

2.6 Quality Assurance personnel, as part of their QA role, are authorized to stop unsatisfactory work and to control further processing, delivery, or installation of nonconforming items. When a stop work is given, the responsible manager is advised of the circumstances and requested to take appropriate action. If the responsible manager considers the stop work action inappropriate, the issues move up the Management chain with the Office of the Director having the final decision.

3.0 Management/Personnel Training and Qualification — Criterion 2

From DOE O 414.1D: *(1) Train and qualify personnel to be capable of performing their assigned work. (2) Provide continuing training to personnel to maintain their job proficiency.*

3.1 A comprehensive training, qualification, and certification program has been established at PPPL under Human Resources. The objective of training is to assure that personnel are proficient within their respective areas of responsibilities and job functions. Training also provides the

means for personnel, both PPPL employees and subcontractors, to attain and expand their knowledge and competencies in the areas of quality and ES&H so that the Laboratory mission may be achieved in a safe and environmentally sound manner.

3.2 Personnel are assigned to positions based upon an evaluation of their education, experience, previous training, and existing job skills and capabilities. Management is responsible to assure that personnel assigned to a specific job function have the requisite background and/or receive sufficient training for that position. Where deficiencies in training or qualifications are identified, management is responsible to establish and implement plans to correct the deficiencies.

3.3 Training programs are implemented to satisfy a variety of needs: facility orientation; personnel qualification and certification; compliance to regulatory commitments, procedures, quality assurance program requirements, and ES&H requirements; and to promote professional development. Training programs are developed with the support of technical experts within the Laboratory, are conducted by knowledgeable personnel, and are documented through auditable records.

3.4 On-the-job training is used if direct hands-on application or experience is needed to achieve and maintain proficiency.

3.5 Training is subject to an on-going review to determine the effectiveness of the program. Training sessions are periodically evaluated for content and presentation. Training programs are revised when the need for improvement is recognized or expressed or to continuously improve their effectiveness. The Director of Human Resources evaluates the effectiveness of the training. In addition, every employee has the responsibility to identify potential training deficiencies to their line management or the Director of Human Resources.

3.6 The training program includes topics which require renewal at periodic intervals (such as ES&H courses) or retraining when the governing document changes (such as procedure revisions). Personnel who do not maintain training are not permitted to perform the part of their job covered by the lapsed training until they are retrained.

4.0 Management/Quality Improvement — Criterion 3

From DOE O 414.1D: *(1) Establish and implement processes to detect and prevent quality problems. (2) Identify, control, and correct items, services, and processes that do not meet established requirements. (3) Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning. (4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement*

4.1 As indicated in the Director's Introduction to this document, the goal is to continually improve the quality of the work performed by PPPL staff. In support of this goal, Princeton Plasma Physics Laboratory has established and implemented processes designed to prevent problems and improve quality. They include, but are not limited to:

- Staff meetings
- Design reviews/Peer reviews
- Management Safety Walkthroughs
- Other less formal line and facility management and supervisory walkthroughs
- Tracking and Trending Analysis Systems

- Safety Analysis Reports
- Management assessments
- Independent assessments (audits)
- Independent inspections
- Identification and resolution of operational problems
- Increased employee involvement, e.g., Safety Forums
- Root cause analyses
- Extent of Condition analyses
- Processes for the design of new or improvement of existing processes
- Lessons Learned
- Pre- and Post-job briefs
- STOP cards
- Stop Work Authority
- Job Hazard Analyses
- Safety Assessment Documents
- Activity Certification Committee (ACC) Reviews

As appropriate, these systems allow for:

- Sharing of lessons from other organizations
- The identification of potential or actual problems with items, services, or processes.
- Actions taken to fix the specific occurrences of the problems.
- Analysis of the problems to determine root cause.
- Actions taken to correct the root cause and thereby prevent recurrence.
- Actions taken to correct the problems identified in an extent of condition analysis.
- Analysis of the effectiveness of the actions taken.
- Tracking of the problems to final resolution.
- Multi-problem trend analysis to identify common causes and actions taken as a result.
- Documentation to support the above items.

4.2 The goal of these systems is to effect improvements, both immediate and long-term. Therefore, management has adopted a "no-fault" attitude that encourages the identification and reporting of problems. Management is responsible for initiating corrective actions promptly, in a manner that remedies the problem and prevents recurrence, and verifying the effectiveness of the corrective actions.

4.3 Items that do not conform to specified requirements are controlled per the PPPL Non-conformance Reporting system to prevent inadvertent installation or use.

4.4 Additional information is contained in the PPPL Assurance System Description.

5.0 Management/Documents and Records — Criterion 4

From DOE O 414.1D: *(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. (2) Specify, prepare, review, approve, and maintain records.*

5.1 Laboratory systems have been established for the preparation, review, approval, distribution, revision, and storage of Laboratory plans, policies, and procedures, technical procedures for experimental facilities, and drawings. Organizational units are responsible to establish methods to control the preparation, review, approval, distribution, revision, and storage requirements of other document types and to control the distribution of these documents to assure that

organizations responsible for the work have the latest versions. These methods must ensure that the documentation is adequate, accurate, and incorporates appropriate requirements affecting quality. Changes to controlled documents must receive the same review and approval as the original.

5.2 Laboratory systems have been established for the distribution of, use of, and protection of manuals and other information provided by manufacturers and suppliers that provide information supporting the safe usage and maintenance of such equipment or material.

5.3 Records are completed documents or other media that provide objective evidence of an item, service, or process. They are defined, controlled, and maintained by Laboratory systems or by the organizational unit responsible for the work, as appropriate, using an appropriate graded approach. The records management system must ensure that appropriate records are maintained and must include provisions for identification, retention, protection, preservation, changing, traceability, accountability, and retrievability of records, as appropriate to each specific project or activity. While in storage, records should be protected from damage, loss, and deterioration. These records may be generated by PPPL or a supplier.

6.0 Performance/Work Processes — Criterion 5

From DOE O 414.1D: *(1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, or other appropriate means. (2) Identify and control items to ensure their proper use. (3) Maintain items to prevent damage, loss, or deterioration. (4) Calibrate and maintain equipment used for process monitoring or data collection.*

6.1 Processes are established for work to assure that work is planned, authorized, and accomplished under controlled conditions. Such processes include the Work Planning System, the use of work specific procedures, and the Job Hazard Analysis, among others, with a graded approach based on risk. In addition to achieving the end result, an emphasis of the processes includes assuring quality work is performed in a safe manner while minimizing the impact to the environment. Technical standards, instructions, procedures, equipment manuals, or other means of detailed direction shall be used commensurate with the complexity and risk attributable to the task. These instructions, procedures, and other forms of direction are developed, reviewed, validated, and approved by technically competent personnel and include information found in manufacturer's manuals or supplier provided documentation, when appropriate. Pre-job briefings are held prior to the start of work to assure that all involved understand the work. The level of and formality of the job briefings are dependent upon job complexity, risk, and the experience and knowledge levels of personnel involved.

6.2 While determining these processes, the responsible person determines (1) what special actions are required, including the identification and control of material, parts, components, and partially fabricated assemblies, to assure appropriate traceability and to prevent the use of incorrect or defective items and (2) the requirements for handling, preserving, storing, cleaning, packaging, and shipping items to prevent damage or loss, and to minimize deterioration. The results of these determinations are included in the documents providing direction for the task.

6.3 Measuring and test equipment used for measurements during the work processes and upon which action will be taken are to be calibrated to assure accurate results. See section 9.0 of this QAP.

7.0 Performance/Design — Criterion 6

From DOE O 414.1D: *(1) Design items and processes using sound engineering/scientific principles and appropriate standards. (2) Incorporate applicable requirements and design bases in design work and design changes. (3) Identify and control design interfaces. (4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work. (5) Verify or validate work before approval and implementation of the design.*

7.1 Design control systems are established to ensure that design related activities are carried out in a planned, controlled, and orderly manner. Examples include design reviews, calculation checks, and control of drawings. These programs provide for the control of design requirements, processes, interfaces, technical standards, reviews, revisions, and records.

7.2 Processes have been established for the design of new processes or the improvement of existing ones. The design of processes falls under two categories – the clean slate approach for either the design of a new process or a significant redesign of existing processes and the improvement of an existing process, where it is anticipated that selected aspects of the process will be redesigned to address identified concerns, and result in improved efficiency and effectiveness .

7.3 Responsibility resides with the assigned individual and line management to (1) ensure that sound engineering and scientific principles, appropriate standards, applicable requirements and design bases, and the PPPL design control systems are incorporated into their designs, and (2) ensure that applicable design inputs are correctly translated into design outputs. Design outputs may take the form of specifications, drawings, procedures, and instructions.

7.4 Based on a graded approach, conceptual, preliminary, and final design reviews are performed, as appropriate, throughout the design process to ensure acceptability of the design. The reviews consist of in-process checking and approval of design calculations, system descriptions, specifications, drawings, procurement documents, and other design documents, as appropriate. Errors and deficiencies detected during internal design reviews are documented and appropriate corrective action instituted. These design reviews are performed by qualified personnel independent of the work under review.

7.5 Design reviews are supplemented by design verification, prototyping, and alternate calculations, as required. These supplements take into account the complexity and uniqueness of the design, as well as any associated risks.

8.0 Performance /Procurement — Criterion 7

From DOE O 414.1D: *(1) Procure items and services that meet established requirements and perform as specified. (2) Evaluate and select prospective suppliers on the basis of specified criteria. (3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.*

8.1. Each requisition is assigned an individual or technical representative with overall responsibility to assure that all aspects of the procurement are identified and satisfied. This technical representative or requisitioner specifies the controls, dependent upon the risks associated with the procured items and services, including cost, schedule, and performance. These controls include technical, quality, and ES&H requirements and are specified in the procurement documents (specification, statement of work, drawing, purchase order, etc.). Quality Assurance is available to support the technical representative in identifying the appropriate quality requirements. The Procurement Division is responsible to negotiate and manage Laboratory procurements and to ensure that the procurement process is in compliance with Laboratory practices and procedures.

8.2. Wherever possible, specifications and statements of work should reference national standards or regulations. Any required references to PPPL policies, standards, or procedures should be limited to the minimal applicable set possible, with copies of or links to these PPPL policies, standards, or procedures incorporated into the specifications or statements of work.

8.3. As appropriate to the item or service, potential suppliers and subcontractors are evaluated to determine the degree to which the supplier or subcontractor can satisfy technical, commercial, ES&H, and quality assurance requirements contained in the procurement package. Supplier and subcontractor proposals are reviewed to assure that the specified requirements can be met.

8.4. After award, suppliers and subcontractors are monitored by the Princeton Technical Representative (PTR), Procurement, and Quality Assurance within their areas of expertise, commensurate with the complexity of the items or services provided and history of performance, to ensure continued acceptability of items and services. Problems are identified and, via the PPPL Procurement Program, resolved.

8.5. Technical and quality requirements must be satisfied and nonconformances resolved before procured items are used or placed in service. The technical representative determines and performs an appropriate level of receipt inspection of purchased items or services prior to use or installation.

8.6. Should the procurement be for on-site services, the Princeton Technical Representative is responsible to assure that

- individuals from the contracted services are appropriately qualified for the work as indicated in the subcontract,
- individuals from the contracted services are trained and made aware of all applicable PPPL requirements and
- the work performed by these individuals is properly completed taking into consideration technical, quality, and ES&H considerations.

9.0 Performance /Inspection and Acceptance Testing — Criterion 8

From DOE O 414.1D: *(1) Inspect and test specified items, services, and processes using established acceptance and performance criteria. (2) Calibrate and maintain equipment used for inspections and tests.*

9.1 Inspections and acceptance testing are processes for verifying that the work or product meets requirements. Each person is responsible for the quality of his or her own work, including ongoing and final reviews and inspections, to verify that process requirements are met. However, final acceptance of work is based on inspections or tests conducted by persons other than those performing the work being accepted. The types, numbers, and stringency of acceptance inspections and tests are dependent upon the complexity and importance of the work and are performed by qualified personnel who are knowledgeable of both the acceptance criteria and the technical aspects of the work being assessed.

9.2 Dependent upon risks, items or services that fail to meet inspection or test criteria should be considered to be placed on hold or the service suspended until the problem is corrected. When applicable, items should be tagged out of service to prevent their usage and non-conformance reports generated. Once the problem is corrected, a re-inspection is performed to ensure that the original inspection/test criteria are satisfied.

9.3 Records of inspection/test results are maintained for an appropriate time, dependent upon the significance of the item being inspected and tested. A small subset of these records should be

maintained for the lifetime of a project. These might include records that document the capability of an item to be safely operated, might be valuable when investigating the cause of an accident or malfunction, or provide a baseline for future inspections.

9.4 The calibration system for the measuring and test equipment (MT&E) used in the inspection or acceptance testing process assures that these tools are tested, re calibrated, and readjusted to confirm results. MT&E shall be calibrated to standards traceable to the National Institute of Standards and Technology, when applicable.

10.0 Assessment/Management Assessment — Criterion 9

From DOE O 414.1D: *Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.*

Management assessments evaluate how well management systems meet the customer's requirements and expectations for safely performing work in addition to organizational mission, goals, and objectives. The emphasis of management assessment is on management issues that affect performance processes such as: strategic planning, qualification, training, staffing, organizational interfaces, communication, cost control, and mission objectives. Overall responsibility for management assessment for a specific Department is the responsibility of the Department Head. The results of management assessments shall be documented and include the actions taken to resolve any identified concerns.

The effectiveness of the management assessment program is reviewed under the PPPL QA Audit Program.

11.0 Assessment/Independent Assessment— Criterion 10

From DOE O 414.1D: *(1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. (2) Establish sufficient authority, and freedom from line management, for independent assessment teams. (3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.*

Independent assessments evaluate the performance of work processes with regard to requirements, compliance, and expectations for safely performing the work and achieving the goals of the organization. The focus of independent assessments should be on the items and services produced and associated processes with the objective of improving the product/service performance and process effectiveness. Independent assessments are implemented via the Quality Assurance Audit Program. The assessment program covers both work performed by PPPL staff and work performed by suppliers or subcontractors. Schedules for the independent assessments are chosen on a graded approach taking into consideration requirements for assessments, hazards, and risks. Potential schedules are also integrated with DOE/PSO to ensure the appropriateness of assessments. As necessary, the assessment team is augmented by additional individuals who are technically qualified and knowledgeable in the areas assessed. These individuals are identified by Quality Assurance.

Quality Assurance personnel have sufficient authority and freedom from line management in the organization by reporting directly to the Head of QA/QC.

12.0 Suspect/Counterfeit Item (S/CI) Prevention Process

From DOE O 414.1D, Attachment 3: *To set forth requirements for DOE and its contractor organizations, as part of their QAPs, to establish, document and implement effective controls and processes that will: (1) ensure items and services meet specified requirements; (2) prevent entry of Suspect/Counterfeit Items (S/CIs) into the DOE supply chain; and (3) ensure detection, control, reporting, and dispositioning of S/CIs." [The order lists ten specific requirements applicable to S/CIs.]*

It is PPPL's goal to prevent the introduction of suspect/counterfeit items into the Laboratory. Therefore processes have been designed to support this goal including:

- Providing restrictions and requirements within specifications and procurement documents for items that have an increased likelihood of involving S/CI
- Requiring receipt inspections for items identified as most frequently found to be S/CI
- Publicizing information regarding counterfeit or substandard parts and equipment on the employee web site
- Providing training on S/CI concerns
- Providing support via the Quality Assurance Division and the Suspect/Counterfeit Items Committee
- Reviewing the DOE Occurrence Reporting criteria to determine if reporting in ORPS is required. (GEN-006)

13.0 Software Quality Requirements

Software quality assurance will be applied using a graded approach. This applies to software that is procured from an established software supplier; developed via contracted services; and software developed by individuals at PPPL, whether for PPPL use or supplied by PPPL to collaborators. Appropriate planning, testing, and reviews will be conducted of software /firmware (hereafter referred to as software). Controls will be more rigorous and thorough for software that is deemed to be "critical". Critical software is defined as software which can:

- affect the safety of personnel
- adversely impact experimental equipment operations
- have a detrimental effect on the quality of data that can negatively affect PPPL's mission in regard to research.

When a review of new software identifies it as critical, a software QA plan will be established. This plan will assure:

- The software is tested via a test plan that demonstrates the software will satisfactorily perform its intended functions in its operating environment.
- Necessary controls are established to permit authorized and prevent unauthorized access to software.
- User documentation is established.
- Configuration management is established.

All new PPPL Critical Software must be added to the Critical Software list and changes must be controlled via ENG-010 "Control of Drawings, Software, and Firmware".

Appendices

A - Implementing Policies and Procedures
B - Definitions and Terms
C – Examples of differences between NQA-1 and the PPPL QA Program

Quality Assurance Plan	Implementing Policies	Implementing Procedures/Manuals/Plans[2]
2.0 Management /Program	P-001 Graded Approach P-004 Quality Assurance P-012 Stop Work Authority P-084 Management Safety Walkthroughs P-087 Roles and Responsibilities in PPPL Organizations O-xxx Various organization mission statements	This QA Plan PPPL Assurance System Description PPPL Mission Readiness System Description for Facilities and Infrastructure Integrated Safety Management (ISM) System Description
3.0 Management /Personnel Training and Qualification	P-008 Staff Training and Development P-072 Procurement Assurance (Technical, Safety, and Quality Requirements)	TR-001 Laboratory Training Program TR-005 Instructor Qualification and Requalification TR-006 Establishing Qualification and Certification Requirements TR-007 Guidelines for Developing Training Matrices ENG-xxx A series of qualification procedures for various types of technicians
4.0 Management /Quality Improvement		PPPL Assurance System Description QA-005 Control of Nonconformances QA-012 Corrective Action Request QA-019 Root Cause Analysis QA-023 Design and Improvement of Processes QA-025 Management Assessments GEN-006 Investigation and Follow-up of Adverse Events and Conditions including Occurrence Reporting and Price Anderson Amendment Act Reviews GEN-011 ES&H Deficiency Reporting
5.0 Management /Documents and Records	P-013 Use of Procedures P-032 Hierarchy of Documents P-051 Review and Approval of Policies, Procedures, Plans, and Manuals P-075 Configuration Management	Most PPPL procedures have requirements for documents and records. The key procedures are: GEN-001 Policy, Procedure, and Mission Statement Development, Review, and Approval GEN-003 Document Distribution Control GEN-023 Records Management

[2] Some of these items are implemented in part by many different procedures, plans, or manuals. Only the more significant ones are listed.

6.0	Performance /Work Processes	P-013 Use of Procedures P-063 Handling, Shipping, and Storage P-075 Configuration Management P-079 Identification and Control of Materials P-086 Specifying, Using, and Calibrating Measuring and Test Equipment P-096 Independent Verification	ENG-010 Control of Drawings, Software, and Firmware ENG-012 Identification and Control of Items ENG-014 Hydrostatic and Pneumatic Testing ENG-030 PPPL Technical Procedures for Experimental Facilities
7.0	Performance /Design	P-010 Design Reviews P-075 Configuration Management	PPPL Engineering Standards ENG-010 Control of Drawings, Software, and Firmware ENG-033 Design Verification ESH-025 Operations Hazard Classification Criteria and Safety Certification System IT-010 Configuration Change Control Procedure (for IT Department only) QA-023 Design and Improvement of Processes
8.0	Performance /Procurement	P-041 Suspect Parts P-072 Procurement Assurance (Technical, Safety, and Quality Requirements)	PPPL Procurement Policies and Procedures Manual QA-003 Procurement Quality Assurance ENG-006 Preparation, Review, and Approval of Specifications and Statements of Work
9.0	Performance /Inspection and Acceptance Testing	P-071 Inspection and Acceptance Testing P-086 Specifying, Using, and Calibrating Measuring and Test Equipment	QA-004 PPPL Site Inspection Program ESH-025 Operations Hazard Classification Criteria and Safety Certification System
10.0	Assessment /Management Assessment		QA-025, Management Assessments
11.0	Assessment /Independent Assessment	TCR-EQP-004, Rev. 10-003 P-096 Independent Verification	QA-002 PPPL Audit Program
12.0	Suspect/ Counterfeit Items	P-041 Suspect Parts P-072 Procurement Assurance (Technical, Safety, and Quality Requirement)	QA-020 Identifying and Dispositioning Suspect Parts

Administrative Controls	Provisions relating to organization and management, procedures, records keeping, assessment, and reporting necessary to ensure safe operation of a facility.
Document	Recorded information that describes, specifies, reports, certifies, requires, or provides data or results. A document is not a record until it meets the definition of record.
Hazard	A source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to personnel or damage to a facility or to the environment (without regard to likelihood or credibility of accident scenarios or consequence mitigation).
Item	An all-inclusive term used in place of appurtenance, assembly, component, equipment, material, module, part, structure, product, software, subassembly, subsystem, system, unit, or support systems.
Organizational Units	A term used to represent the appropriate level of the PPPL Organization for specific policies or procedures. Typically, the term represents a Project, Department, Division, or Office.
Process	A series of actions that achieves an end or result.
Project	A general term used to indicate both traditional PPPL projects such as NSTX and planned undertakings performed by various PPPL Organizational Units. Examples of the latter are GPP projects or the development of software programs.
Quality	The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.
Quality Assurance	All those actions that provide confidence that quality is achieved.
Record	A completed document or other media that provides objective evidence of an item, service, or process.
Service	The performance of work, such as design, construction, fabrication, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

Reference: Quality Assurance Requirements for Nuclear Facility Applications, ASME NQA-1 – 2008 Edition, Part 1 Requirements

From NQA-1, Introduction, 200 Applicability: "The requirements of PART 1 apply to activities which could affect the quality of nuclear material applications, structures, systems, and components of nuclear facilities. Examples of nuclear facilities are facilities for power generation, spent fuel storage, waste management, fuel reprocessing, nuclear material processing, fuel fabrication, and other related facilities."

The nuclear risks at PPPL are significantly lower. There are no nuclear structures, systems, or components; there is no nuclear power generation; there is no spent fuel storage, fuel reprocessing, or work with plutonium. PPPL is not a nuclear facility as implied by the above definition.

However, NQA-1 is a standard that has successfully been used for decades within the United States and has been successfully used as a model by the PPPL Quality Assurance Program since the mid 1970s. This appendix highlights the significant differences between NQA-1 and the PPPL QA Plan, where the requirements from NQA-1 are the major headings below.

Requirement 1 – Organization

NQA-1 contains the requirement "quality achievement is verified by those not directly responsible for performing the work." At PPPL, the need for independent verification is risk based. Project or line management determines the need for inspections, scope of the inspections or tests, acceptance criteria, and personnel performing the verifications. The Quality Assurance Division reserves the right to independently verify work, independent of project or line management requests for such inspections.

Requirement 2 – Quality Assurance Program

The Quality Control inspectors are part of the Quality Assurance Division and perform in-process electrical, electronics, and mechanic inspections. Weld inspections are performed by an American Welding Society Certified Weld Inspector. Nondestructive Examinations for special inspections such as radiography, magnetic particle, ultrasound, or liquid penetrant are performed by inspectors who have been previously qualified elsewhere to the applicable standard. Current qualification is not required. Should such an inspector not be available, the work will be subcontracted.

Likewise, the Lead Auditor qualification program is modeled on NQA-1 with the following exceptions:

- While the use of qualified Lead Auditors is required by NQA-1 for all audits, it is only required at PPPL for audits of programs covered by 10 CFR 835.
- Qualification for lead auditor per NQA-1 requires participation in a minimum of five (5) quality assurance audits within a period of time not to exceed 3 years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to qualification. The PPPL program requires a minimum of five audits within a period of time not to exceed 5 years and does not require a nuclear quality audit

NQA-1 requires an annual assessment to maintain Lead Auditor status. At PPPL, requalification is performed every three years, instead of annually.

Requirement 3 – Design Control

PPPL has established systems for documenting design inputs and design outputs. Design verification is typically performed via calculation checks, prototyping, comparisons to already working systems, and peer and formal design reviews. The Laboratory has defined the general objectives and inputs for the four levels of reviews (peer, conceptual, preliminary, and final). Line and/or project management determines the specific design inputs and outputs and required verifications for any specific work activity. Due to the below category III classification, PPPL does not have a commercial grade items procurement and modification program.

Configuration is maintained via control of procedures and drawings. The level of configuration control is determined by line and/or project management.

Commercially available software is used for most design analyses, supported by Laboratory developed code where there does not exist appropriate commercial code. The results of all analyses are independently verified on a graded approach. The grading takes into consideration the confidence associated with the code, the complexity of the analysis, and the risks associated with the system under design.

The design of PPPL generated software is covered by the same design control systems as hardware.

Requirement 4 – Procurement Document Control

No differences.

Requirement 5 – Instructions, Procedures, and Drawings

No differences.

Requirement 6 – Document Control

No differences.

Requirement 7 – Control of Purchased Items and Services

The quality requirements for procurements and oversight of suppliers are tailored to the risks involved but include the basic steps of this requirement: supplier evaluation and selection, bid evaluation, control of supplier-generated documents, and acceptance of item or services. The level of oversight ranges from the relatively informal, primarily performed by the technical requisitioner, to complex requirements, evaluation boards, pre-award audits, etc. Due to the below category III classification, PPPL does not have a commercial grade items procurement program.

Requirement 8 – Identification and Control of Items

These requirements are imposed on a case by case basis by line and/or project management, dependent upon the risks.

Requirement 9 – Control of Special Processes

No differences

Requirement 10 – Inspection

Formal inspections meeting the requirements of this section are performed when either line and/or project management requests them or Quality Assurance identifies the need. Informal inspections may be performed by line personnel, when deemed appropriate.

Requirement 11 – Test Control

Formal tests using formal procedures with documented results are implemented on a graded approach as determined by line and/or management. Operations classified as High Hazard per ESH-025, require an ES&H Executive Board approved Safety Certificate prior to starting or resuming operations. One of the criteria for approval is an appropriate pre-operational test procedure.

Requirement 12 – Control of Measuring and Test Equipment (MTE)

The most significant difference is that the line organization specifies when calibrated MTE are required.

Requirement 13 – Handling, Storage, and Shipping

No differences

Requirement 14 – Inspection, Test, and Operating Status

PPPL is a research and development facility. Inspections and tests are performed on systems and components required for employee and community health and safety and the protection of the environment. Records are maintained. The requirement for inspection, test, and operating status of other components are determined by the responsible line and/or project manager on a case-by-case basis.

Requirement 15 – Control of Nonconforming Items

No differences.

Requirement 16 – Corrective Action

No differences

Requirement 17 – Quality Assurance Records

No differences.

Requirement 18 – Audits

The requirements are implemented, except audit teams may include individuals involved in the work activity as long as the Lead Auditor is independent.