

PRINCETON PLASMA PHYSICS LABORATORY (PPPL)

EQP-004, INSTITUTIONAL QUALITY ASSURANCE PLAN

REVISION 8

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1	12/18/92	J. Malsbury J. DeLooper D. Meade R. Davidson M. Johnson	Revision Revised to incorporate DOE Order 5700.6C, <i>Quality Assurance</i>
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Statement from the PPPL Director

The DOE Princeton Plasma Physics Laboratory is a Collaborative National Center for plasma and fusion science. Its primary mission is to develop the scientific understanding and the key innovations which will lead to an attractive energy source. Associated missions include conducting world-leading research along the broad frontier of plasma science and technology, and providing the highest quality of scientific education.

The PPPL Institutional Quality Assurance Plan provides the framework that enables each of us to carry out our work in an efficient and cost-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.

*Stewart Prager
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 each subcontractor's ability to provide quality support services — on-site or off-site.

This Institutional QA Plan meets the requirements of both 10 CFR 830.120 and DOE O 414.1C. At PPPL, 10 CFR 830.120 is applicable, in a graded approach, to all DOE facilities that conduct activities or operations involving radioactive materials in such form and quantity that a nuclear hazard potentially exists to the employees or the general public; there is no de minimus for such a hazard. 10 CFR 830.120 is not applicable to incidental use and generating of radioactive materials in a facility operation (e.g., check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines), or in transportation of radioactive materials. DOE O 414.1C, Quality Assurance, is applicable to all other activities.

Quality is an important element in ensuring that the Laboratory processes contribute to the success of the Laboratory's research mission. Quality is consistent with and supportive of the goals of the DOE Integrated Safety Management (ISM) Program described in DOE P 450.4 and the Laboratory's ISM System Description. A strong ISM program supports quality assurance

and, likewise, a strong quality assurance program supports ISM. The relationships between the ISM guiding principles and quality requirements defined in this QAP are documented in Appendix C of this Plan. Details on ISM and PPPL may be found in the PPPL Integrated Safety Management Plan. Likewise, this Plan is consistent with and supportive of the goals of the Contractor Assurance Program, as defined in Attachment 2 of DOE O 226.1, *Implementation of Department of Energy Oversight Policy*.

PPPL is a DOE radiological facility categorized as below category 3, per DOE-STD-1027. The Quality Assurance program is modeled after the Part 1 Requirements from ASME NQA-1 – 1997, Quality Assurance Requirements for Nuclear Facility Applications, tailored for the risks present at PPPL. Further information on this tailoring is contained in Appendix D.

With respect to research, Princeton Plasma Physics Laboratory, a research organization, combines the concepts and requirements of 10 CFR 830.120 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. Commensurate with the aforementioned philosophy, 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 should be determined by the use of a graded approach. The graded approach should take into consideration such factors as the relative importance of the work, the magnitude of any hazard involved, potential programmatic risk, condition and history of project or process, adequacy of existing safety systems, and complexity of the products or services involved. The graded approach provides the flexibility to design controls that best suit the project or activity.

Implementation 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 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 contained in the Appendix. Organizational Units may, at their option, develop their own QAPs as long as they are consistent with the requirements of this QAP and the policies contained in the Appendix. 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 and the Independent Assessment Program but is primarily assessed via the actual scientific results safely produced at PPPL.

10 CFR 830.4 (c) and DOE Order 414.1 (1)(e) indicate that this Plan, once approved by DOE, shall form the basis for assessments by personnel external to PPPL. If the PPPL Director believes that the implementation of any assessment result will require changes to this Plan, these changes must be approved in writing by DOE prior to the Director instructing PPPL managers to implement them.

The descriptions below contain the exact text from 10 CFR 830.120. Virtually identical requirements are contained in DOE O 414.1C.

2.0 Management/Program — Criterion 1

From 10 CFR 830.120: *(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 No. P-004, *Quality Assurance/Reliability*, 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 Plan. 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. The PPPL organizational structure is available at <http://www.pppl.gov/orgchart.cfm> . Primary responsibility for the quality of work rests with the individuals performing the work and with line management assuming responsibility for achieving quality objectives. The responsibilities of each organizational unit are defined in specific organizational/mission statements. Line management is responsible for implementing the requirements of this QAP using a graded approach. Other independent groups provide necessary support.
- 2.3. Each individual is expected to:
 - Accept responsibility for the quality of his or her work,
 - Assure that the standard of acceptable work performance is clearly understood,
 - Fully understand the requirements of the assigned task, as well as the capabilities and limitations of the tools and processes.
 - Perform the work under the established controls.
 - Provide feedback on the adequacy of the controls.
- 2.4. Line managers are responsible to:

- Determine the appropriate graded approach for their projects or activities.
- 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
- Identify the hazards associated with the work and implement appropriate controls to eliminate or reduce the hazards.
- Ensure that the personnel under their supervision are provided with the necessary training, resources, and administrative controls to allow for the successful completion of work in a manner commensurate with quality objectives,
- Review work and data related to the tasks for which they are responsible and ensure that quality objectives are satisfied, and
- Examine processes to adequately identify those areas in need of improvement and implement value-added improvements. Personnel performing a process should be included in process improvement activities.

2.5 Every PPPL employee has the authority to stop work until quality, health, environmental, or safety concerns are resolved. In practice, personnel are expected to use good judgment. If the activity is life-threatening, then a request to stop the activity is justified; if not life-threatening, then personnel need only notify the appropriate level of Management. In addition, the Quality Assurance personnel are provided with the independent authority to stop unsatisfactory work and the authority to control further processing, delivery, or installation of nonconforming items. When the independent authority to stop work is exercised, 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 10 CFR 830.120: (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, safety, health, and environment 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. It is the responsibility of management to assure that personnel assigned to a specific job function have the requisite background and/or receive sufficient training for that position.
- 3.3 Training programs are implemented to satisfy a variety of needs: facility orientation, personnel qualification and certification, procedure compliance, environment, safety and health issues, and other training 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 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 Head of Human Resources is responsible for evaluating training effectiveness.
- 3.5 The training program includes topics which require renewal at periodic intervals (such as Environmental, Safety, & Health courses) or retraining when the governing document changes (such as procedure revisions). Personnel are required to maintain training in those topics required to support their job function. If an individual does not maintain training, only that part of their job covered by the lapsed training is impacted.

4.0 Management/Quality Improvement — Criterion 3

From 10 CFR 830.120: (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 work to prevent recurrence as a part of correcting the problem. (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 Plan, 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 Trend Analysis Systems
- Safety Analysis Reports
- Management assessments
- Independent audits
- Independent inspections
- Identification and resolution of operational problems
- Increased employee involvement, e.g., Safety Forums

As appropriate, these systems allow for:

- The identification of potential or actual problems with items, services, or processes.
- Analysis of the problems to determine root cause.
- Actions taken to fix the specific occurrence of the problems.
- Actions taken to correct the root cause and thereby prevent recurrence.
- 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 must preserve a “no-fault” attitude and encourage the identification and reporting of problems. Management is responsible for initiating corrective action promptly, in a manner that remedies the problem and prevents recurrence, and verifying the effectiveness of the corrective action.

5.0 Management/Documents and Records — Criterion 4

From 10 CFR 830.120: (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 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.

6.0 Performance/Work Processes — Criterion 5

From 10 CFR 830.120: (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 their 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. In addition to achieving the end result, an emphasis of the processes should be to assure quality work is performed in a safe manner while minimizing the impact to the environment. Technical standards, instructions, procedures, 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. When appropriate and dependent upon job complexity, risk, and the experience levels of personnel involved, job briefings are held prior to the start of work to assure that all involved understand the work.
- 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 10 CFR 830.120: (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. These programs provide for the control of design requirements, processes, interfaces, technical standards, reviews, revisions, and records.
- 7.2 It is the responsibility of the Cognizant Person 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.
- 7.3 Based on a graded approach, internal design reviews are performed 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.
- 7.4 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 10 CFR 830.120: *“(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. Individuals responsible for a procurement specify what controls should be imposed to ensure that items and services perform as expected. These controls include the technical and quality requirements and are specified in the procurement documents (specification, statement of work, drawing, purchase order, etc.).
- 8.2. 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, environmental, safety, health, and quality assurance requirements contained in the procurement package. Supplier and subcontractor proposals are reviewed to assure that the specified requirements can be met.
- 8.3. Any exceptions originating from the supplier or subcontractor are resolved through negotiations. When appropriate, the procurement package is modified. This package is later reviewed and approved by the same procedure and method used for the original procurement package. Changes to the procurement package, after a supplier or subcontractor has been awarded a subcontract, are subject to the same system of

controls executed for the original package.

- 8.4. Suppliers and subcontractors are monitored, 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. Dependent upon the safety significance, receipt inspection of supplier- or subcontractor-furnished items is performed prior to use or installation

9.0 Performance /Inspection and Acceptance Testing — Criterion 8

From 10 CFR 830.120: (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 Each process is assigned a process owner who is responsible to assure that the process is effective and efficient.
- 9.2 Inspections and acceptance testing are the 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, when formally required, are performed by qualified personnel who are knowledgeable of both the acceptance criteria and the technical aspects of the work being assessed.
- 9.3 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. At that time a reinspection is performed to ensure that the original inspection/test criteria are satisfied.
- 9.4 Records of inspection/test results are maintained.
- 9.5 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 10 CFR 830.120: *Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.*

Managers and supervisors at PPPL are responsible for performing assessments of the functions under their control. Management assessments evaluate how well management systems meet the customer's requirements and expectations for safely performing work, and 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. The purpose of this type of assessment is to identify management aspects of performance and make improvements through an introspective self-analysis to determine if the management infrastructure is properly focused on achieving desired results. Overall responsibility for management assessment for a specific Organizational Unit is the responsibility of the senior manager for that area. 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 10 CFR 830.120: *(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 the group performing independent assessments. (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. 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 Associate Director for Best Practices/Outreach.

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

From DOE O 414.1C: *An S/CI prevention process must be developed and implemented as a part of the contractor's QAP and must be commensurate with the facility/activity hazards and mission impact. The*

QAP must be applied to identifying, analyzing, and removing S/CIs and preventing them from being supplied to DOE/NNSA and its contractors. [The order lists six elements applicable to this requirement.] Work processes must be developed and implemented using available S/CI information. [The order lists nine additional elements applicable to this requirement.]

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

13.0 Safety Software Quality Requirements

PPPL currently does not use safety software for the design of or review of PPPL facilities, for safety analysis purposes, for supervisory control and data acquisition purposes, or for programmable logic controllers (PLC) software. If future need for such software should arise, PPPL would apply a graded approach to software quality assurance depending upon the risk and safety applications. Such software applications would first be reviewed by persons competent in the field of software quality assurance to ensure that software quality assurance requirements are met.

Appendices

A - Implementing Policies

B - Definitions and Terms

C – Relationship between ISM Guiding Principles and QAP Requirements

D – Examples of differences between NQA-1 and the PPPL QA Program

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Appendix A - QAP Implementing Policies

Quality Assurance Plan	Implementing Policies	
2.0 Management /Program	P-001 P-004 P-012 P-084 P-087 O-xxx	Graded Approach Quality Assurance Stop Work Authority Management Safety Walkthroughs Roles and Responsibilities in PPPL Organizations Various organization mission statements
3.0 Management /Personnel Training and Qualification	P-008 P-028 P-037	Staff Training and Development Integration of ES&H into Subcontracted Work Software Quality Assurance
4.0 Management /Quality Improvement	P-007 P-026 P-083	Operational Problem Identification and Resolution Assessment and Oversight Lessons Learned and Their Promulgation
5.0 Management /Documents and Records	P-013 P-032 P-037 P-051 P-075	Use of Procedures Hierarchy of Documents Software Quality Assurance Review and Approval of Policies, Procedures, Plans, and Manuals Configuration Management
6.0 Performance /Work Processes	P-006 P-013 P-037 P-052 P-063 P-075 P-079 P-086 P-096	Conduct of Operations Use of Procedures Software Quality Assurance Special Processes Handling, Shipping, and Storage Configuration Management Identification and Control of Materials Specifying, Using, and Calibrating Measuring and Test Equipment Independent Verification
7.0 Performance /Design	P-010 P-037 P-075	Design Reviews Software Quality Assurance Configuration Management
8.0 Performance /Procurement	P-041 P-072	Suspect Parts Quality & Procurements
9.0 Performance /Inspection and Acceptance Testing	P-071 P-086	Inspection and Acceptance Testing Specifying, Using, and Calibrating Measuring and Test Equipment
10.0 Assessment /Management Assessment	P-026	Assessment and Oversight
11.0 Assessment /Independent Assessment	P-026 P-096	Assessment and Oversight Independent Verification
12.0 Suspect/Counterfeit Items	P-041 P-072	Suspect Parts Quality & Procurements

Administrative Controls	Provisions relating to organization and management, procedures, records keeping, assessment, and reporting necessary to ensure safe operation of a facility.
Cognizant Person	Person responsible for a specific work activity, which might include, among others, designing and maintaining a process or building and installing hardware,
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 any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, 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.

Appendix C – Relationship between ISM Guiding Principles and QAP Requirements

10 CFR 830, Subpart A, Quality Assurance Requirements, ¶ 830.120 (c) (2) requires the QAP to “Integrate the quality assurance criteria with the Safety Management System, or describe how the quality assurance criteria apply to the Safety Management System.” This QAP chose the second approach. The table below illustrates the relationship between the ISM Guiding Principles and the requirements of the PAAA Rules and this Quality Assurance Plan. The words in this table are taken directly from the source documents.

Further information on the PPPL Integrated Safety Management program may be found in the PPPL Integrated System Management System Description at http://www.pppl.gov/eshis/plans/PPPL_ISM.pdf. The PPPL ISM Program identifies the implementing policies, procedures, and other documentation that define the organizational structures, functional responsibilities, levels of authority, and interfaces for managing, performing, and assessing work to ensure protection of the environment and worker safety and health.

<p>Guiding Principles from the PPPL Integrated Safety Management System Description, which, in turn, satisfies the requirements of DOE Policy 450.4</p>	<p>Part 830 – Nuclear Safety Management 10 CFR 830.120, Quality Assurance</p>
<p><u>Line Management Responsibility for Safety</u></p> <p>Line management is directly responsible for the protection of the public, the works, and the environment.</p>	<p>From 10 CFR 830.3 Definitions: <i>Safety management program</i> means a program designed to ensure a facility is operated in a manner that adequately protects workers, the public, and the environment by covering a topic such as: quality assurance; maintenance of safety systems; personnel training; conduct operations; inadvertent criticality protection; emergency preparedness; fire protection; waste management; or radiological protection of workers, the public, and the environment.</p> <p>Criterion 1 – Management/Program (1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.</p>

Appendix C – Relationship between ISM Guiding Principles and QAP Requirements

<p>Guiding Principles from the PPPL Integrated Safety Management System Description, which, in turn, satisfies the requirements of DOE Policy 450.4</p>	<p>Part 830 – Nuclear Safety Management 10 CFR 830.120, Quality Assurance</p>
<p><u>Clear roles and responsibilities.</u> Clear and unambiguous lines of authority and responsibility for ensuring safety shall be established and maintained at all organizational levels within the Department and its contractors.</p>	<p>There is no direct correlation between the requirements of 10 CFR 830, Subpart A, and ISM. The closest is criterion 1, which is listed below. Criterion 1 – Management/Program (1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.</p>
<p><u>Competence Commensurate with Responsibilities</u> Personnel shall possess the experience, knowledge, skills, and abilities that are necessary to discharge their responsibilities.</p>	<p>Criterion 2 – Management/Personnel Training and Qualification (1) Train and qualify personnel to be capable of performing their assigned work. (2) Provide continuing training to personnel to maintain their job proficiency.</p>

Appendix C – Relationship between ISM Guiding Principles and QAP Requirements

<p>Guiding Principles from the PPPL Integrated Safety Management System Description, which, in turn, satisfies the requirements of DOE Policy 450.4</p>	<p>Part 830 – Nuclear Safety Management 10 CFR 830.120, Quality Assurance</p>
<p><u>Balanced Priorities</u></p> <p>Resources shall be effectively allocated to address safety, programmatic, and operational considerations. Protecting the public, the workers, and the environment shall be a priority whenever activities are planned and performed.</p>	<p>See definition of Safety Management Program above.</p> <p>Criteria 1 – Management/Program (2) Establish management processes, including planning, scheduling, and providing resources for the work.</p> <p>Criteria 3 – Management/Quality Improvement (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 work to prevent recurrence as a part of correcting the problem. (4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.</p>
<p><u>Identification of Safety Standards and Requirements</u></p> <p>Before work is performed, the associated hazards shall be evaluated and an agreed-upon set of safety standards and requirements shall be established which, if properly implemented, will provide adequate assurance that the public, the workers, and the environment are protected from adverse consequences.</p>	<p>Criteria 6 – Performance/Design (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.</p>

Appendix C – Relationship between ISM Guiding Principles and QAP Requirements

<p><u>Hazard Controls Tailored to Work Being Performed</u></p> <p>Administrative and engineering controls to prevent and mitigate hazards shall be tailored to the work being performed and associated hazards.</p>	<p>Criteria 1 – Management/Program (2) Establish management processes, including planning, scheduling, and providing resources for the work.</p> <p>Criterion 5 – Performance/Work Processes (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.</p> <p>Criteria 6 – Performance/Design (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.</p>
<p><u>Operations Authorization</u></p> <p>The conditions and requirements to be satisfied for operations to be initiated and conducted shall be clearly established and agreed-upon.</p>	<p>Criteria 1 – Management/Program (2) Establish management processes, including planning, scheduling, and providing resources for the work.</p> <p>Criterion 5 – Performance/Work Processes (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.</p>

Appendix D – Tailoring of NQA-1 – 1977 at PPPL

Reference: Quality Assurance Requirements for Nuclear Facility Applications, ASME NQA-1 – 1997 Edition, Part 1 Requirements

From NQA-1, 200 Applicability: “The requirements of PART 1 apply to activities which could affect the quality of structures, systems, and components of nuclear facilities. Nuclear facilities include facilities for power generation, spent fuel storage, waste treatment, waste storage and waste disposal, fuel reprocessing, plutonium processing, and plutonium fuel fabrication.”

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 major 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 are performed by inspectors who have been previously qualified elsewhere to the applicable standard. 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 encouraged for all audits, it is only required for audits of programs covered by 10 CFR 835..
- Qualification for lead auditor requires participating at least one audit in the three year period; participating in review of quality standards, codes, instructions, or procedures; or additional training.
- Requalification is performed every three years, instead of annually.

Appendix D – Tailoring of NQA-1 – 1977 at PPPL

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.

Appendix D – Tailoring of NQA-1 – 1977 at PPPL

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 ESHD 5008, Section 11, Chapter 1, 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

No differences.

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.

Appendix D – Tailoring of NQA-1 – 1977 at PPPL

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.