OAK RIDGE National Laboratory

Material Plasma Exposure eXperiment

QUALITY ASSURANCE PROGRAM PLAN

MPEX-12-PLAN-001

REV. 1

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REVISION HISTORY

REVISION	DESCRIPTION OF CHANGE	REVISION TYPE	
		Major	Minor
0	Initial Issue. Redefined Quality Assurance Program/Supersedes MPEX Quality Assurance Plan version 0	☐	☐
1	Added Operations lead role, updated references to systems (ORNL Buy and Enterprise Document and Record Management), expanded definitions, Updated Software Quality Assurance, Work Control Planning align with project phases.	☒	☐
		☐	☐

CONTENTS

1. STATEMENT OF QUALITY POLICIES AND OBJECTIVES

The Oak Ridge National Laboratory (ORNL) Quality Assurance Program (QAP) supports excellence in in the lab's science and technology missions by developing a quality culture that contributes to scientific and operational excellence, research integrity, and continued improvement of processes to deliver quality products and services to both our internal and external customers.[1] In keeping with this objective, the Material Plasma Exposure eXperiment (MPEX) is committed to meeting and exceeding the requirements and expectations of internal and external customers by successfully designing, fabricating, and commissioning the performance of MPEX to produce valid and verifiable results that advance capability and preserve subject matter expert (SME) knowledge of linear plasma device technology.

The quality objective of MPEX is to establish and maintain a culture of excellence in scientific integrity, research, development, operations, and support processes. These objectives are accomplished by

- Planning, developing, communicating, and deploying credible and compliant program documentation and project procedures;
- Implementing safe, compliant, efficient, and reliable processes with timely deliverables;
- Providing appropriately trained and highly proficient staff;
- Conducting effective in-process peer reviews and independent quality assessments;
- Evaluating, reporting, and resolving quality issues; and
- Incorporating lessons learned.

2. INTRODUCTION

The US Department of Energy (DOE) Office of Fusion Energy Sciences (FES) has determined that the availability of future fusion devices, such as a fusion nuclear science facility or a demonstration fusion power station, greatly depends on the development of plasma-facing divertor components with long operating lifetimes. In response to this need, the ORNL has been selected to lead the MPEX project. The project is planned to design, fabricate, install, and commission a superconducting magnet, steady-state linear plasma device (LPD) to study the plasma material interactions of fusion reactors.

MPEX uses a new high-intensity plasma source concept based on radio frequency technology. This source concept will allow the experiment to cover the entire spectrum of expected plasma conditions in the divertor of a future fusion reactor. The project will enable the study of erosion and redeposition for relevant geometries with relevant target-facing electric and magnetic fields, allow for the exposure of a priori neutron-irradiated samples, and include diagnostics stations for more detailed material surface analysis.

The MPEX project is being developed in a staged approach with successively increased capabilities. As such, identified systems, components, and processes are also included to reduce project risk, including research on efficient plasma heating and plasma transport to the target. In addition, equipment checkout

[1] *Quality Assurance Program,* ORNL Standards Based Management System (SBMS), January 20, 2023.

and commissioning are required to confirm hardware performance and will be executed as part of the project scope.

2.1 Policy

Safety, health, and quality are the core values driving performance on the MPEX project. It is the MPEX project policy to provide consistent quality and fully compliant activities and services in a safe, secure, reliable, and cost-effective manner. The MPEX project is committed to meeting and exceeding internal and external customers' requirements and expectations by focusing on preventing rework and nonconformances, reducing variability, building quality into processes, and establishing an effective safety and quality culture.

The MPEX project is also committed to continuously improving the quality of products, facilities, and services by constantly evaluating and improving efficiency and effectiveness. Personal ownership of safety and quality is imperative for all members of the MPEX project team.

This quality assurance program plan (QAPP) identifies the essential requirements and process controls for activities affecting quality, including monitoring to ensure procedural compliance and performance effectiveness across the overall spectrum of project activities.

3. BACKGROUND

To compete with electricity, fusion energy must be made more cost-effective, which requires the design of fusion reactors with high availability. The major driver of high availability of fusion reactor is a long-lifetime power exhaust system, which must be replaced periodically. This exhaust system, the *divertor*, will be exposed to unprecedented heat and particle fluxes for long periods. These particles (ions, electrons, and neutrons) from the hot plasma will interact with the materials in the divertor and cause damage and erosion. Understanding these plasma-material interfaces (PMIs) by accelerated exposure of materials under relevant fusion reactor conditions of high fluxes, long duration, and at high temperatures is needed to develop plasma-facing components that can survive the conditions of fusion reactors for several years. This is why over the past decade, PMI and materials sciences have been repeatedly identified as high-priority issues by a variety of FES strategic planning and community-led activities.

In its 2007 Greenwald Report[2], the Fusion Energy Science Advisory Committee classified plasma-facing components and materials issues as the only Tier 1 (highest priority) item. In 2009, the community-based Research Need Workshop report identified "Taming the Plasma Material Interface" as one of the five major research themes. The report also identified the potential need for a series of new facilities, including dedicated test facilities to evaluate the performance of plasma-facing materials in the presence of intense plasma fluxes for long periods and at elevated temperatures.

In 2015, in response to strategic planning activities in 2012 and 2014 and a directive from Congress, FES commissioned several community-led Research Needs Workshops focused on previously identified high-priority research items, one of which was PMIs. The associated report from this community workshop identified four high-impact, cross-cutting research activities for addressing PMI issues, one of which was the development of a world-leading capability in the form of an LPD, specifically "a new high fluence, linear divertor simulator with flexible target stations."

[2] *Greenwald Panel Fusion Energy Sciences Advisory Committee Report*, October 2007, https://science.osti.gov/-/media/fes/fesac/pdf/2007/Fesac_planning_report.pdf

Considering these developments, the report *The Office of Fusion Energy Sciences: A Ten-Year Perspective*[3] (submitted to Congress in 2015) highlighted fusion materials science as one of five areas of critical importance. Furthermore, this report highlighted the expansion of materials research capabilities to enable exploration of previously inaccessible regimes as a high-priority objective for the next decade. The report states that "the overall motivation is to gain entry into a new class of fusion materials science wherein the combined effects of fusion-relevant heat, particle, and neutron fluxes can be studied for the first time anywhere." Consistent with the previously mentioned studies, this report also highlighted the important role that a dedicated LPD could play in advancing the understanding of PMI, materials, and component development.

The scientific demonstration of magnetic fusion energy as an environmentally sustainable and economically competitive energy source will require mastering of these material science issues, particularly those associated with the PMI. As such, FES places a high priority on gaining an improved understanding of the science of PMIs and materials degradation, particularly as it pertains to the development of high-performance materials for next-step devices and future fusion reactors.

4. PURPOSE AND SCOPE

This MPEX QAPP describes the applicable quality assurance requirements and identifies the policies and processes for designing, fabricating, and performing initial operations necessary to commission an integrated LPD capable of testing materials exposed to plasmas. It describes a systematic approach to achieving and maintaining process and product quality by ensuring that the stated and implied needs of interested parties are met. This QAPP applies to the scope of work associated with (1) completing a preliminary and final design, (2) procuring and fabricating all technical components, (3) modifying the facility to house the LPD, (4) installing the LPD, and (5) commissioning and operating the device.

The ORNL QAP supports excellence in science and technology missions through the development of a quality culture that contributes to scientific and operational excellence, research integrity, and continual improvement by defining the processes to deliver quality products and services to both internal and external customers. This QAPP describes the MPEX project's approach to integrating quality principles and methodologies identified under the ORNL QAP and DOE O 413.3B into project processes and products.

5. APPLICABILITY

This QAPP applies to MPEX efforts that develop, engineer, fabricate, and commission the project infrastructure necessary for fabricating components. MPEX designs will be deployed with a continued focus on improving efficiencies within design advancement initiatives.

MPEX efforts are organized into a work breakdown system (WBS) composed of elements assigned to control account managers (CAMs). The following list describes each WBS element:

- **Project Management and Support** comprises the project director, project manager, chief scientist, project controls, and quality assurance efforts necessary to perform oversight, risk management activities, and all required support to the management team in managing the project. In addition to

[3] *The Office of Fusion Energy Sciences: A Ten-Year Perspective (*2015–2025). https://science.osti.gov/-/media/fes/pdf/program-documents/FES_A_Ten-Year_Perspective_2015-2025.pdf

performing overall management of the project, this team coordinates with and provides accountability to the sponsor and ORNL line management.

- **Preliminary Design Management and Integration** coordinates all preliminary design activities, including overall systems design, integration, and engineering configuration management for all components.
- **Magnet System Design** supports development of the magnet system reference design as well as development of vendor specifications and selection criteria in preparation for magnetic system design, fabrication, and solicitation.
- **Plasma Source and Heating** provides MPEX plasma heating systems, including the helicon source, electron heating system (gyrotrons), and ion cyclotron heating system. This includes efforts associated with design drawings; calculations; modeling; and developing vendor specifications and selection criteria for the gyrotron, high-voltage power supply, and diamond window procurements.
- **Vacuum System Design** is responsible for the MPEX vacuum system, including the vacuum boundary and chambers, pumping and gas distribution systems, MPEX support structure, and target extraction and transport systems (e.g., track, cart components, auto couplers). This WBS element includes efforts associated with design drawings, calculations, and modeling as well as test articles for the periscope and key components of the target exchange chamber.
- **In-Vessel Components** focuses on MPEX in-vessel cooling components, including limiters, skimmers, microwave protection units, the plasma dump assembly, and the target assembly. This also includes drawings, calculations, modeling, specifications, and acceptance criteria.
- **Instrumentation & Control and Data Acquisition System Design** focuses on system requirements elaboration, operations narrative development, piping and instrumentation diagram development, hardware selection, custom electronic design, and layout of instrumentation & control architecture. This also includes defining data storage and local and remote user interaction concepts.
- **Diagnostics** is responsible for design of the MPEX hardware systems necessary to produce device-performance data outputs, including design of transferred diagnostic equipment from Proto-MPEX and new diagnostic systems (e.g., spectroscopy, interferometers, bolometers, infrared cameras).
- **Procurement and Fabrication** includes the efforts of the Design Authority and integration lead to oversee and coordinate procurement activities.
- **Final Design** includes the coordination of all final design activities, including overall systems design, integration, and engineering configuration management across all components.
- **Infrastructure** provides the design of required facility enhancements (e.g., structural modifications, radiological containment and safety systems, electrical system upgrades, and cooling circuit design); leads the design effort associated with facility reconfiguration (e.g., updating drawings to depict current facility and system configurations, demolition drawings, utility isolation lists, and contractor solicitation packages); and develops architecture/engineer design requirements in preparation for CD-3A solicitation.
- **Pre-Operations and Commissioning** includes startup and testing of the integrated MPEX device, commissioning with plasma, procedure development and training, operational readiness review, and turnover to operations.

6. QUALITY ASSURANCE MANAGEMENT SYSTEM

6.1 QAP Requirements

As a DOE national laboratory, ORNL has prime contract–imposed mandates and expectations for the laboratory's overall QAP. These are contained in DOE Order 414.1D, *Quality Assurance*, and in 10 Code of Federal Regulation (CFR) 830, Subpart A, "Quality Assurance Requirements," which apply to nuclear facilities, radiological areas, and programs and activities that have the potential to affect nuclear or radiological safety. The ORNL Standards-Based Management System (SBMS) translates these and other external requirements into laboratory-wide policies and procedures, as summarized in the laboratory quality assurance program description (QAPD). The QAPD is the highest-tier quality assurance (QA) document for the laboratory. The QAPD addresses sponsor requirements through either the imposition of a QAPP based on ANSI/ISO/ASQ(E) Q9001:2015, ORNL's baseline QA standard, or an alternate standard when it is advantageous or required to do so.

MPEX efforts conducted under the auspices of this plan invoke NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications*, including the NQA-1a-2009 Addendum (NQA-1-2008/9a). This standard including the 2009 addendum is hereafter referred to as simply NQA-1-2008.

This QAPP is also implemented by lower-tier quality plans, procedures, instructions, and guides that have been or will be developed to accommodate specific quality requirements. If there is a conflict between such implementing documents and this program document, this QAPP governs until the conflict is resolved.

The overall QAP is designed to evolve over time as processes are more fully understood and technical direction is determined.

6.2 Risk Management

Risk management, as described in MPEX-11-PLAN-005, *Risk Management Plan for the Material Plasma Exposure Experiment (MPEX) Project at ORNL,* is the process used to understand and influence conditions and control event uncertainties associated with project execution. A quantitative risk analysis process is used for the MPEX project to provide a systematic approach to identify potential risks, forecast impacts, and capture the best-suited mitigation recommendations so that overall project uncertainties associated with cost, schedule, and performance are reduced to an acceptable level. Risk management is factored into project decisions at all levels throughout the life of the project.

6.3 Graded Approach

The use of a graded approach is permissible under Section 4.1.3 of DOE G 414.1-2B, *Quality Assurance Program Guide*, which specifically references ASME NQA-1, Subpart 4.2 as guidance on implementing a graded approach. The purpose of the graded approach is to govern the selection of appropriate controls and verifications to be applied to all project items, activities, and processes based on risk. It defines the process by which the extent of documentation and degree of rigor for process controls are applied commensurate with potential risk factors, importance to safety, technological impact, and stage in project life cycle.

The graded approach used in the MPEX project is based on four quality levels. It provides the process and rationale for establishing the appropriate level of quality rigor and oversight for each item, activity, or

process. Activities with higher risks or greater consequences must implement a higher level of quality rigor and oversight.

Activities with lower risks or lesser consequences may require minimal quality controls and verifications. In no case may quality be graded to "zero." All project activities, even those of the lowest risk, must be compliant with the applicable quality assurance requirements, defined in this QAPP.

Depending on the approach, compliance with requirements may be achieved via a supplier's (Supplier's) QA program or via compliance with industry standards and codes or other specific quality requirements identified in engineering, procurement, construction, or startup testing documents.

6.4 MPEX Graded Approach to Quality

In addition to the approaches described in the previous section, MPEX implements a project-specific approach aligned with the ORNL graded approach to the quality process. Continued, adequate alignment with the ORNL graded approach will ensure that permanent ORNL facilities that are part of MPEX are assigned quality levels consistent with ORNL requirements and will be acceptable to end users. The following four MPEX quality levels define the extent to which quality requirements and verifications are applied:

Quality Level 1 – Applies to items, services, or projects (specific to work processes) whose functionality directly affects activities that are ***critical*** to the safe and reliable operation of components, systems, or structures. They include items, services, or activities whose failure could have severe consequences to public or personnel safety, the environment, compliance with the law, contract agreement or regulation, or ORNL's mission or public perception. Appropriate controls for items, services, or activities identified as quality level 1 provide reasonable assurance that the assigned function will perform reliably.

Quality Level 2 – Applies to items, services, or activities that are ***important*** to the safe and reliable operation of components, systems, or structures. They include items, services, or activities whose failure or malfunction could result in unfavorable conditions and are important to the mission but are of low to medium risk where quality controls are needed to verify risk attributes. This level includes some software with risks that warrant increased rigor and application of quality requirements above the standard (commercial controls) to ensure that the basic design characteristics are met and identified risks are reduced.

Quality Level 3 – Applies to items, services, or activities that have ***minor*** impacts on the safe and reliable operation of components, systems, or structures. They require some engineering or management controls to ensure the item or service will fulfill its intended function and maintain compliance with applicable programmatic documents and procedures. These include items, services, or activities whose failure would be unlikely to affect public or workers' health and safety adversely.

Quality Level 4 – Applies to items, services, or activities that have the ***lowest*** project risks and require *minimal* rigor. This level imposes the least amount of rigor and controls, allowing more flexibility for science and technology discovery. However, a minimal level of documentation is required to identify basic objectives, approach, assumptions and to anticipate results and conclusions.

In no case may quality be graded as quality level 0. All project activities, even those of the lowest risk, must be compliant with the applicable quality assurance requirements defined in this QAPP.

In addition to the approaches described, commercial controls described in Section 6.5 may be applicable for the level of controls for those items, activities, or processes evaluated as low risk requires no additional quality controls beyond the supplier's published or stated attributes of the item, services, activity, or process, general receipt inspections and/or acceptance processes ensure item, quantity, and basic design characteristics (documentation, physical condition count, form, fit, function, and materials).

A subset of this level is used when additional or enhanced quality controls are required over and above the standard commercial practices to reduce identified risks. The potential drivers for enhanced or minor quality controls flow from DOE O 414.1D, *Quality Assurance*, and include industry safety, environmental, radiological, and non-radiological hazards.

The MPEX project aims to balance the application of QA requirements and process controls that are necessary, appropriate, and sufficient to achieve mission objectives. Project procedures and task-specific procedures and instructions provide additional details that implement the graded approach. A crosswalk of NQA-1 requirements applicable to MPEX and the associated governing and implementing documents is provided in Attachment A, *Governance, and Implementing Documents.*

6.5 Graded Approach in Commercial Codes and Standards

A graded approach is also embedded in the standard commercial processes for engineering, procurement, construction, and startup. Industry standards and codes apply grading based on the risks to personnel, the public, and the environment. For example, the international building code considers the type of occupancy in a building, seismic risks, and other factors. Increased risks in these areas may necessitate enhancements and increased rigor in design, fabrication, and construction. The degree of oversight and quality verifications of these activities as part of standard commercial practices is also increased as the risk increases. It is important from a project effectiveness perspective not to disregard the quality controls inherent in industry codes and standards. The standard practices to grading that exist in industry codes and standards are considered part of the MPEX approach to grading as required by DOE O 414.1D.

7. QUALITY ASSURANCE CRITERIA DESCRIPTION IMPLEMENTING ELEMENTS

The following sections contain the specific QA criteria described in the NQA-1 QAP requirements. These criteria also address the quality requirements associated with DOE O 414.1D, *Quality Assurance,* and 10 CFR 830 Subpart A, "Quality Assurance Requirements."

7.1 Organization

The MPEX project reports to the Fusion and Fission Energy and Science Directorate (FFESD) at ORNL. Project support is provided by personnel matrixed from the Fusion Energy Division, the project management office, and ORNL quality and safety organizations. The project management structure is shown in Figure 1 (green boxes).

The DOE FES is the sponsor of the project (Figure 1, yellow boxes). The project is managed by an Integrated Project Team that meets biweekly (Figure 1, blue box).

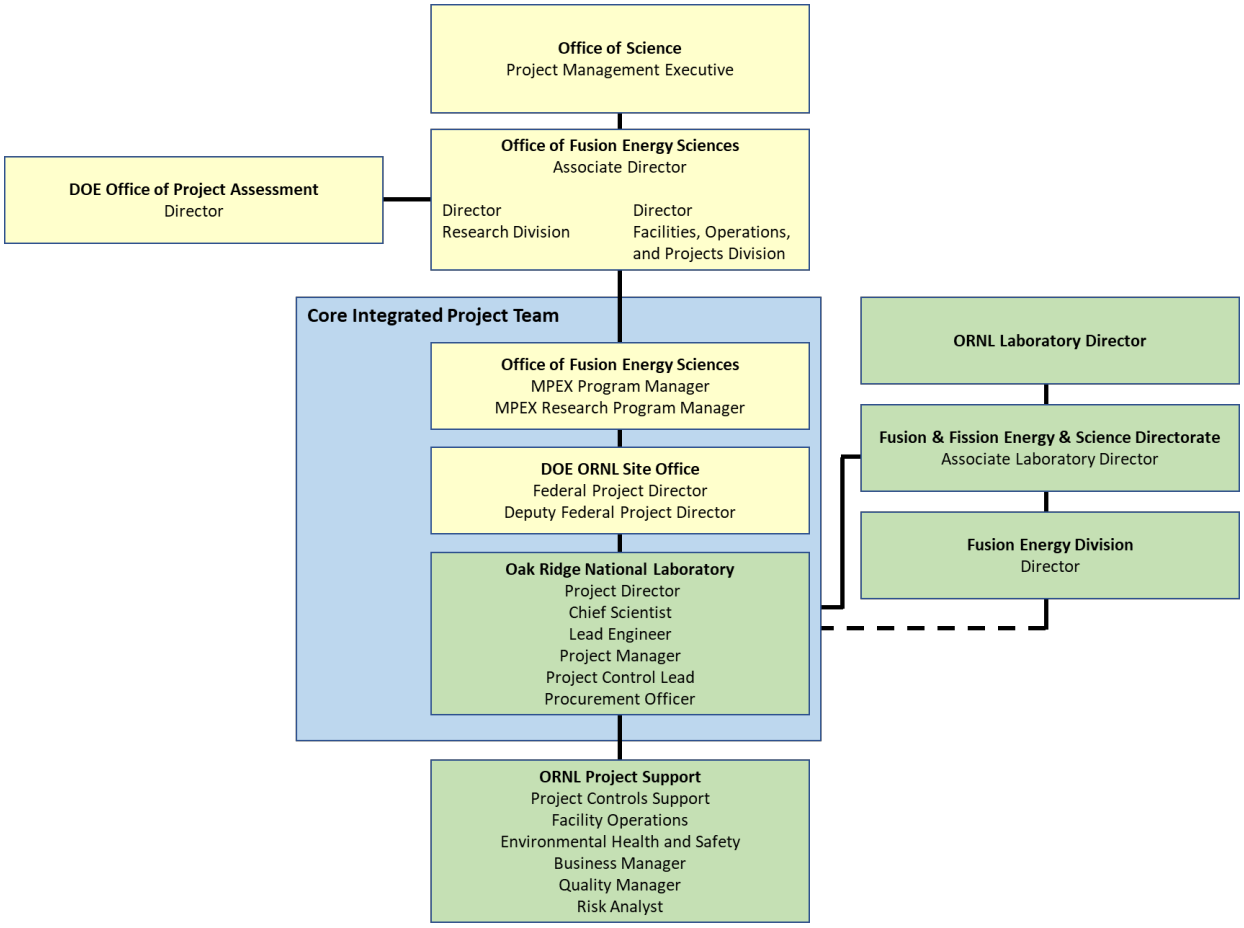

Figure 1. MPEX project management structure.

7.2 MPEX Management Structure

MPEX project management is responsible for defining the project technical work scope, plans, deliverables, reports, schedules, and quality objectives and for effectively communicating, tracking, and reviewing these items throughout the organization. Project management is also responsible for ensuring that adequate personnel and resources are provided to organizations performing quality-related activities.

The MPEX Preliminary Project Execution Plan establishes the project-specific organizational structure, roles, and responsibilities necessary for effective management. Organizational structures, interfaces, roles, and responsibilities specific to QA are defined in this QAPP.

MPEX management is continually in contact with project sponsors, vendors, technical integration staff, and operations staff and receives regular feedback regarding project performance and product quality.

Although project management may delegate aspects of management or execution of this plan to contractors, agents, or consultants, the overall responsibility for quality is retained by project management. Quality is achieved and maintained by those who have been assigned responsibility for performing work; the achievement of quality is verified by individuals not directly responsible for performing the work when verification is necessary.

Any individual(s) assigned any responsibility for ensuring effective execution of any portion of this plan at any location where activities subject to QA are being performed shall have direct access to and support from the levels of management necessary to perform their assigned function. The persons and organizations responsible for executing the project shall have sufficient authority and organizational freedom to identify quality problems; initiate, recommend, or provide solutions; and verify the implementation of solutions.

The MPEX project director is matrixed to the FFESD associate laboratory director for this project and reports directly to the director.

The MPEX project manager (PM) is responsible for the execution of the MPEX project scope of work. The MPEX PM has overall responsibility and accountability for establishing the QAP and has overall responsibility for the effective implementation of the QAP. CAMs are responsible for determining the procedures necessary to ensure assigned work is performed safely and for ensuring that individuals assigned the work are qualified and trained to those procedures. The MPEX PM is responsible for determining the procedures necessary for adequate performance of work activities.

The individual(s) or group(s) responsible for establishing and executing this QAP may delegate any or all of the work to others but shall retain responsibility and accountability implementing applicable requirements.

The MPEX project director, MPEX PM, and the quality manager shall approve this QAPP.

The PM will designate staff who will work on the project and will ensure that they are trained to the standards of this QAPP. All project staff are responsible and accountable for being knowledgeable of procedures; performing work in a compliant manner; identifying unsatisfactory procedures, processes, or products; and actively supporting continuous quality improvement. Staff have the authority to stop work, are responsible to report conditions adverse to quality (CAQs) (i.e., issues) to management, and resume work only upon approved resolution of the issue.

7.3 Roles and Responsibilities

This section describes the key program roles and responsibilities necessary for developing, implementing, and maintaining an effective QAP.

The organizational roles and responsibilities of the PM, CAMs, and other key program personnel are defined in this QAPP.

The project organization chart is maintained separately, and the latest version is available upon request.

7.3.1 Project Director

The project director is responsible for the following:

- Establishing and approving this QAP and ensuring compliance with its requirements
- Communicating the project's quality policy and objectives to project staff and stakeholders
- Overseeing and managing project work to ensure the overall quality of deliverables
- Ensuring that necessary personnel and resources are supplied to enable quality work

- Fostering a culture of continuous quality improvement and problem prevention
- Reporting quality-related issues as they occur and ensuring that corrective actions are taken

7.3.2 Project Lead Engineer

The MPEX project lead engineer provides all necessary support to the MPEX project director to effectively manage the project, including the following:

- Overseeing technical design and leading a project team in the design of the MPEX device
- Overseeing contracting and manufacturing of all hardware components for MPEX
- Ensuring that all quality standards are being administered in the manufacturing process for all hardware components
- Working with project CAMs to track project status and to identify problems that may affect the project

7.3.3 Project Manager

The MPEX PM assists the project director and project lead engineer in establishing the appropriate project planning, execution, and controls procedures to ensure that the project is executed within approved cost, schedule, and technical scope.

The PM has overall accountability for effective implementation of the QAP and has the following responsibilities:

- Managing the project within scope, schedule, and budget or available funding
- Reviewing and approving the QAPP and associated processes
- Ensuring that adequate levels of trained and proficient staffing are identified
- Providing direction to ensure that work is carried out on a timely schedule and within budget
- Ensuring that products and services are acquired in accordance with ORNL procurement requirements
- Serving as the official interface with the sponsor on all project commitments and project management issues
- Ensuring management assessments are performed to determine the effectiveness of QAP implementation
- Ensuring that the adequacy and effectiveness of the QAPP's implementation is assessed periodically
- Developing the project execution plan, the WBS, and other project documentation
- Working with project CAMs to track project status and to identify problems that may affect the project
- Maintaining the risk register and conducts monthly risk reviews
- Working with the federal project director and project director to coordinate all independent project reviews

7.3.4 Control Account Managers

Funding is distributed to projects that is supported by various work groups to perform related activities that contribute to the completion of program/project milestones. Program/project milestones are described in project management plans. CAMs are the leads assigned responsibility for WBSs, milestones, and the quality of the activities conducted to complete the milestones. They oversee the staff who conduct the technical activities necessary to fulfill the WBS milestones. The CAMs work with the project managers, who typically delegate responsibilities for executing project-associated activities.

CAMs are the focal point for quality within each WBS and are the SMEs and project contacts for line management and the quality representative (QR). In response to sponsor's expectations and requirements, each CAM develops the overall structure for the segment of work under their purview through planning documents such as project plans, test plans, procedures, and any other work-controlling documentation considered necessary. The CAM is responsible for satisfactorily meeting the applicable work scope specifications, processing plans, and test requirements and related quality requirements defined or referenced in the QAP. The CAM is also responsible for obtaining desired project results.

CAMs have overall responsibility for project execution and technical direction. CAMs are responsible for meeting requirements, achieving quality of the work, and implementing this QAPP in their areas of control. CAMs are responsible for the following:

- Developing appropriate procedures for assigned work
- Ensuring that the project incorporates and implements the applicable requirements and controls into project documents, processes, systems, and activities
- Ensuring appropriate and effective implementation of the QAPP, including continuous improvement of processes and systems
- Ensuring that the scope of work under their authority meets the sponsor, ORNL, and project requirements and objectives relative to quality
- Monitoring progress on corrective actions when required to resolve problems and conflicts that affect project implementation
- Managing document control and records
- Securing adequate staffing for execution of authorized work
- Providing input to the project baseline plan and necessary changes
- Executing work in accordance with the baseline and subsequent changes

7.3.5 Procurement Officer

The MPEX procurement officer is the project's point of contact for all procurement activities, including the following:

- Creating, reviewing, approving, and issuing requests for information and requests for proposal
- Reviewing and performing technical evaluations of vendor proposals
- Selecting and approving vendors
- Negotiating and awarding contracts

- Monitoring contract execution and making modifications as necessary
- Facilitating payments to the vendor

7.3.6 Quality Representative

The QR is a member of the ORNL Performance Analysis and Quality (PAQ) organization who supports the PM in ensuring that an appropriate QAPP is established and implemented. The QR is the primary point of contact for MPEX interfaces with the ORNL QAPD and assists the project staff with the following:

- Developing and maintaining the QAP
- Interpreting QAP requirements
- Performing independent quality assessments of work in progress, including document reviews against specifications
- Assessing the implementation of quality programs
- Coordinating internal and external assessments and responses to these assessments
- Ensuring that the QAP is executed as described in the QAPP
- Preparing and maintaining the QAPP and supporting QA procedures
- Participating in the resolution of CAQs, as appropriate
- Identifying quality-related problems and their impacts
- Initiating, recommending, or providing solutions to quality-related problems through designated channels
- Suspending or stopping work—including work performed by suppliers who provide materials and services to the project as coordinated through the ORNL procurement process—after consultation with project or line management when a CAQ cannot be satisfactorily resolved and verifying that adequate corrective actions are in place before permitting work to resume

7.3.7 Suspect/Counterfeit Items Representative

The project suspect/counterfeit items (S/CIs) representative is responsible for the following:

- Serving as the project point of contact for the S/CI program and interfacing with the ORNL S/CI program coordinator
- Ensuring documentation and closure of S/CIs as described in applicable procedures
- Ensuring the ORNL Occurrence Reporting Program manager and DOE Oak Ridge Site Office, Office of Inspector General are notified, as necessary
- Generating lessons learned for use in improving all S/CI activities
- Disseminating S/CI information to project personnel

7.3.8 Records Management Officer

The project records management officer (RMO) assists and advises the project in identifying, scheduling, and maintaining records in compliance with ORNL records management requirements and is responsible for the following:

- Serving as the organizational contact for electronic recordkeeping to capture, declare, and disposition electronic records
- Serving as a liaison between ORNL Records Management Services and organizational records contacts and owners
- Performing and/or participating in reviews, assessments, and internal and external audits as required
- Coordinating the transfer of project records to ORNL Records Management Services at project closeout

7.3.9 Document Management Coordinator

The document control coordinator is responsible for the following functions:

- Acting as the point of contact for the project document management system
- Ensuring that project documents are properly reviewed, approved, and entered into project records
- Assisting the RMO with scheduling and indexing project records

7.3.10 Lessons Learned Coordinator

The lessons learned coordinator is responsible for the following functions:

- Identifying, analyzing, and documenting project lessons learned
- Maintaining a register of lessons learned
- Interfacing with the QR to escalate lessons learned to site or DOE complex scope as appropriate
- Maintaining the formal lessons learned report to be provided at CD-2/3 and CD-4 and at intermediate independent project reviews as required
- Identifying relevant lessons learned from other DOE projects and communicating them to project management for appropriate action

7.3.11 Technical Project Officer

The technical project officer is responsible for the following functions:

- Controlling all technical interfaces with and providing technical direction to the subcontractor
- Providing the subcontractor with pre-job briefing when on-site work involves hazards and authorizing work to proceed
- Monitoring subcontractor’s work and providing oversight to make sure work is done in conformance with subcontract requirements

- Maintaining records documenting compliance with the subcontract, including documentation of technical direction provided as applicable
- Retaining appropriate files, including deliverables and submittals during subcontract performance and after subcontract completion and closeout
- Reporting any problems to the procurement officer, including threats to costs or schedule; changes needed to the subcontract; nonconforming products or services, including those previously accepted; unsatisfactory completion of delivery or performance; and other performance issues that need to be addressed with the subcontractor
- Participating in corrective actions for performance issues

7.3.12 Project Technical Staff

Technical staff members are responsible for ensuring quality and for continuous improvement at the working level. Quality is achieved and maintained by those who have been assigned responsibility for performing the work. The staff members performing activities in support of technical tasks are personnel with the recognized expertise necessary to complete program activities successfully within their assigned teams. All staff members are authorized to do the following:

- Prevent the occurrence of any potential nonconforming conditions
- Identify opportunities for actions and continuous improvement initiatives
- Verify the effectiveness of preventive or corrective actions and initiatives

Staff members also have the responsibility and authority to stop work that is considered to be a serious threat to their safety or health, the health and safety of other personnel, or the environment. They are authorized to stop work if they identify a potential impact to the quality of the work, the goals of the sponsor, or the reputation of the project. Management expectations and the process associated with stop-work actions are contained in ORNL SBMS subject area, “Stop Work,” under the Worker Safety and Health management system. In addition, each staff member is responsible for ensuring that equipment operates correctly and is calibrated to the accuracy necessary to support their planned work and for verifying that work-controlling documents are of the latest revision prior to starting work.

7.3.13 Operations Lead

The operations lead is responsible for operations, maintenance, safe operations, implementation activities, and requirements oversight, as well as the following functions:

- Implementing safety authorization documents with the approval of sponsors and project management
- Establishing conduct of operations programs and operations procedures
- Managing the operations to safely and compliantly oversee plasma material science research within the facility
- Supporting MPEX project management by reviewing technical and programmatic documentation.
- Working with CAMs, the MPEX Lead Chief Engineer, and MPEX project management to establish robust designs that support machine availability to perform the MPEX mission of plasma material science

- Ensuring safety envelope program requirements are being implemented
- Supporting the execution of Integrated Safety Management System guiding principles, work control in accordance with SBMS core functions, and MPEX safety culture
- Working with Division Safety to develop an MPEX-specific safety program that focuses on safety hazards relevant for MPEX and MPEX operations

8. QUALITY ASSURANCE PROGRAM

This section defines the processes and actions that meet the requirements of ASME NQA-1-2008, Requirement 2, *Quality Assurance Program.* MPEX project activities shall be planned, implemented, executed, and maintained in accordance with this QAPP. This MPEX QAPP ensures

- The identification and control of activities affecting quality to an extent consistent with their importance;
- Indoctrination, training, and qualification as necessary of personnel performing or managing activities affecting quality; and
- Regular management assessment of the adequacy and effective implementation of the quality assurance program.

The QAPP provides for the planning and accomplishment of activities under suitably controlled conditions by judiciously applying the requirements of NQA-1-2008 based on the NQA-1-2008 standard's Part IV, Subpart 4.2 guidance. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The QAP provides for special controls processes, test equipment, tools, and skills to achieve and verify the achievement of the required quality of activities and items.

Processes shall be established and implemented to detect and correct quality problems.

The QAPP is implemented by project management. The controls required by this QAPP are administrated on a graded basis with the importance of activities, consequence of failure, and the nature of the final deliverables as the grading criteria. The purpose of this approach is to control the work activities to the degree necessary to ensure that applicable requirements are met regarding the items and activities that affect each work scope and its success.

Project management has endorsed a set of expectations for ensuring that data and other deliverables are of a pedigree that will withstand any future use. This QAPP is intended to provide personnel the information necessary to meet sponsor expectations and requirements, which are based on NQA-1-2008.

The QAPP has been designed to ensure that appropriate planning is established and implemented commensurate with project responsibilities for the

- Health and safety of workers and the public;
- Environmental protection;
- Reliability and continuity of operations;
- Successful accomplishment of the program's mission and objectives; and
- Generation of valid results and completion of program deliverables.

This document is prepared and shall be reviewed, approved, issued, implemented, and maintained for ORNL staff responsible for performing quality-related activities governed by requirements imposed by the MPEX sponsor. Before project activities are closed out, opened, or not completed, quality-related action items shall be resolved, records shall be completed and transmitted and/or disposed of as required, and leftover or archival test materials shall be shipped or disposed of in accordance with applicable regulations and agreements between ORNL and DOE or any entities designated by DOE.

8.1.1 Work Planning, Control, and Documentation Considerations

The management controls described in this QAP—in conjunction with the ORNL Integrated Safety Management System, as defined in MPEX Safety Envelope—provide systems and processes that enable MPEX participants to deliver products that meet or exceed the expectations of project sponsors. MPEX construction work control will be applied per SBMS requirements or similar construction oversight organization, and operational and post construction work planning activities are expected to be controlled according to the *Work Controls* procedure . Quality controls shall be applied to the degree commensurate with the

- Planned or possible future function or end use of the deliverable,
- Consequence of failure (i.e., risk) associated with the deliverable,
- Importance of the data or information being collected or analyzed,
- Complexity of the equipment or software required to achieve the sponsor goals,
- Uniqueness of the deliverable or degree of standardization, and
- Degree to which functional compliance can be demonstrated through inspection or testing.

Activities that could affect the quality of the deliverables for which ORNL is responsible are defined as *quality-related activities*. The MPEX QAP shall control quality-related activities to an extent consistent with their importance to the results associated with the project deliverables. For planned future activities, the applicable MPEX Management Leadership Team, with guidance from the QR, shall determine the level of formality needed in the work-controlling documents before beginning the associated activity.

Implementing documents applicable to the project work scope shall translate the QAP requirements into work processes. The MPEX director and PM direct the activities and resources required to develop and implement this QAP and to ensure the following during work planning activities:

- The work scope and objectives are defined, and a list of the primary tasks involved is created.
- QA requirements are appropriately applied.
- Necessary activities and methods for accomplishing them are defined.
- The appropriate implementing documents are identified or developed.
- Testing equipment, software, or other equipment is identified.
- Prerequisites, special controls, environmental conditions, processes, or skills are identified.
- Applicable technical and management controls, required records, and verification activities are identified.
- Responsibilities are assigned.

- Training and qualification are complete.
- Project closeout activities

The technical activities undertaken to produce project deliverables are identified and documented in various information formats, including proposals, technical program plans, white papers, work breakdown structures, milestone listings, memorandum purchase orders, statements of work, and responses to requests for proposal. These documents will be revised to reflect priority changes and the course of work activities, and they will be updated by revising the original documents or by other means, depending on the organizations and operational requirements.

The rigor used when applying quality requirements may vary commensurately with the needs of different tasks within technical areas and with those tasks' varying effects on overall project quality. In every case, records shall be captured and maintained to fully support the conduct of work and the conclusions or deliverables resulting from each activity and to facilitate activity replication, if needed.

Records, procedures, plans, guidelines, drawings, or sketches shall be used to control the conduct of work. Other work-controlling methods include job-specific training, qualification for a specific task by demonstrating competence, and supervision of staff by project-level personnel. Testing activities may also be supplemented using recognized, proven methods that are described in national consensus standards and work methods and in the operating instructions contained in manufacturer's equipment manuals. In all cases, work control mechanisms shall clearly describe the controlled conditions needed to conduct each activity, including the use of appropriate equipment and standards; maintenance of the environmental conditions suitable for accomplishing the activity, if any are required; and processes and methods for ensuring that activity prerequisites are satisfied.

If necessary, work-controlling documents are modified during project activities and are updated using processes that ensure change control. To identify and mitigate any associated hazards, work control is implemented using ORNL processes described in SBMS subject area, "Work Control."

Project participants ensure that they are using the latest versions of documents. Documents that could affect the quality of MPEX activities shall be controlled, prepared, reviewed, and approved in accordance with the requirements described.

Additionally, technical staff are responsible for verifying that they are using the latest versions of standards and project and ORNL documents from all sources, such as the sponsor, and that these documents are appropriate for use.

This QAPP and the associated QA-implementing procedures shall be issued through ORNL's Enterprise Document and Record Management system and document repository via SharePoint…made available to all project participants through online access.

Additional work controls will be applied depending on the specific work activity and status of the design and construction according to applicable standards. Reviews to ensure the readiness of specific designs, equipment, systems, and functions will be implemented according to DOE O 425.1 [2].

8.2 Indoctrination, Training, Qualification, and Certification

8.2.1 Personnel Training and Qualification

Managers are responsible for implementing cost-effective, systematic, and efficient training, qualification, and certification programs for their employees.

Project managers responsible for planning, coordinating, and conducting the necessary indoctrination, performance-based training, and retraining. These activities are conducted to ensure that suitable proficiency is achieved, maintained, and documented for program tasks with the potential to affect the quality of work. The programmatic goal is to ensure the achievement and maintenance of the indoctrination, training, and qualification of personnel performing or managing activities affecting quality to a suitable proficiency by implementing a combination of ORNL SBMS procedures and MPEX project–specific procedures. ORNL SBMS Training & Qualification Management System subject area, "Training of Staff," SBMS procedure "Training and Certification," and subordinate procedures describe processes that ensure satisfactory qualification of personnel and ensure only those who meet the explicit indoctrination and training requirements are permitted to perform each activity.

Each organization has the flexibility to train personnel on a case-by-case basis for the particular technical task to be performed and is responsible for designating those activities that require qualification of personnel and establishing the minimum requirements for those involved. Considerations associated with indoctrination, training, and qualification include the education, training, experience, and proficiency of each individual and the scope, complexity, and importance of each technical or managerial activity.

The project director, PM, and CAM shall be responsible for deciding the level of formality of the indoctrination and training for personnel performing or managing activities with the potential to affect the quality of MPEX deliverables. In any case, technical and managerial staff shall be provided indoctrination information concerning their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and QAP requirements as needed for each assignment. The baseline for this information is the roles, responsibilities, accountabilities, and authorities (R2A2s) for program managers, principal investigators, and technical staff conveyed through ORNL SBMS subject area, "Roles, Responsibilities, Accountabilities, and Authorities." Subject matter expertise to ensure the proper implementation of the previously referenced SBMS subject area, "Training of Staff," is available from each line organization's training officer.

Some tasks may utilize the services of personnel assigned nondestructive examination (NDE), inspection, and/or testing responsibilities at ORNL. These personnel shall be qualified in accordance with ORNL-approved NDE, inspection, and/or testing processes.

8.2.2 Qualification Requirements

The indoctrination and training of personnel to support MPEX activities are the responsibility of each CAM. When needed, explicit training requirements for each activity are identified in the work control documents associated with that activity. Any required training records shall be identified in each work control document and shall be maintained to document technical training. These records may be stored in dedicated training files or in alternate files associated with the technical documents to which the training applies. In all cases, training files must be maintained so that they are protected from damage and are retrievable.

Training or qualification necessary to ensure the quality of MPEX results shall be documented when required and include the specific review of reading requirements; specific hands-on training requirements; and the specific requirements necessary to achieve, demonstrate, and maintain satisfactory proficiency.

Initial and continuing training programs shall be established to ensure that personnel are initially trained to achieve and maintain job proficiency and can adapt to changes in technology, methods, or job responsibilities. On-the-job training will be used if direct hands-on applications or experience is needed to achieve or maintain proficiency.

Program personnel are indoctrinated in the QAP requirements contained in this plan and in the applicable ORNL SBMS requirements. This indoctrination shall be planned and documented and shall include either attendance in a training session or the required reading of the requirements of this plan.

When applicable, CAMs are responsible for ensuring the identification of any special physical characteristics that personnel need to perform an activity, including the need for initial and subsequent physical and vision examinations. Project management and the QR are responsible for ensuring that QA audits performed at the programs or sponsor's request are conducted by auditing personnel with the competencies required in NQA-1-2008, Requirement 18. These competencies and the other NQA-1-2008 stipulations associated with the QA auditors and the auditing process are addressed through implementation of the following documents:

- ORNL SBMS subject area, "Audits and Assessments"
- ORNL SBMS procedure, "Qualifying Auditors and Certifying Lead Auditors"

ORNL has established and maintains records for indoctrination and training, auditor and lead auditor qualification and requalification, and inspection and test personnel qualification and requalification through implementation of the cited SBMS subject area.

In addition to QA personnel, ORNL uses technical specialists to address non-QA-related topics and subject areas during audits. ORNL has established the qualifications and requirements to use technical specialists for auditing QA programs prior to audit commencement.

The MPEX project will identify the training requirements and qualifications needed to perform work activities in project-specific procedures or plans. Training requirements and qualifications shall be in accordance with SBMS subject area "Training of Staff" procedures. ORNL institutional training requirements (ITRs) are primarily established by procedures issued through SBMS. ITRs target staff in multiple organizations who perform certain types of work for assigned roles and/or are exposed to specific job hazards. These requirements are managed as curricula assigned to staff in the ORNL SuccessFactors learning management system. The ORNL Office of Technical Training maintains a comprehensive listing of these curricula in the ORNL ITR Matrix, which relates job functions and assignments to required curricula and other relevant information.

Records maintained for indoctrination and training may include attendance sheets, training logs, or personnel training records. The records of indoctrination, training, and qualification, including requalification for auditors, lead auditors, and inspection and test personnel, shall be established and maintained by each project, CAM, or the ORNL training organization.

8.3 Design Control

Design is performed in-house by qualified engineers who employ applicable engineering and design principles and standards to prepare, modify, and review engineering documents for the maintenance and modification of MPEX systems and as required, installation of auxiliary facilities or equipment for support. MPEX engineers use applicable standards and principles as issued by organizations—including but not limited to the American Society of Mechanical Engineers (ASME), American Society of Civil Engineers, and Institute of Electrical and Electronics Engineers—and applicable laws, including but not limited to the CFR and state and local laws.

8.3.1 Basic Design Control Requirements

Design shall be defined, controlled, verified, and validated. Design inputs shall be specified on a timely basis and translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by individuals other than those who designed the item or computer program. Design changes shall be governed by control measures commensurate with those applied to the original design. The project shall apply design control using a graded approach, as defined in Section 6.3 of this QAPP.

8.3.2 Design Input Control

Applicable design inputs shall be identified and documented, and their selection shall be reviewed and approved. The design input shall be specified to the level of detail necessary to permit the design activities to be carried out correctly and to provide a consistent basis for making decisions, accomplishing design verification measures, and evaluating design changes.

Design inputs (such as design bases, performance requirements, regulatory requirements, codes, and standards) shall be controlled according to the following requirements:

- Design inputs shall be specified and approved in a timely manner.
- Design inputs shall provide the necessary details to permit design to be carried out in a manner that provides a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.
- Changes to design inputs shall receive the same level of review and approval as the original design input, and reasons for the changes shall be identified, approved, documented, and controlled.
- Design inputs based on assumptions that require verification shall be identified and controlled.

8.3.3 Design Process

The design process shall be controlled according to the following requirements:

- Design work shall be prescribed and documented to the level of detail to permit the design process to be carried out correctly and to permit verification that the design meets requirements.
- Design documents shall be adequate to support design, construction, and commissioning operations.
- Appropriate quality standards shall be identified and documented, and their selection shall be reviewed and approved.

- Design methods that apply sound engineering and scientific principles shall be selected and reviewed for suitability of application.
- Materials, parts, equipment, and processes that are essential to the function of the item being designed shall be selected and reviewed for suitability of application.
- Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to design personnel.
- Design drawings, specifications, or other design output documents shall be relatable to the design input by documentation in sufficient detail to permit design verification.
- Required inspections and tests, including appropriate acceptance criteria or reference to acceptance criteria, shall be specified.
- Design drawings, specifications, or other design output documents shall identify assemblies and components that are part of the item being designed. When such an assembly or component is a commercial-grade item, the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall be documented.

8.3.4 Design Analysis

Design analyses shall be planned, controlled, and documented. Design analyses shall be prepared with sufficient detail such that a person technically qualified in the subject can review and verify the adequacy of the results without recourse to the originator.

Computer program acceptability shall be pre-verified, or the results shall be verified with the design analysis for each application. Pre-verified computer programs shall be controlled in accordance with the following requirements:

- The computer program shall be verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed.
- The encoded mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application.

Design analysis documentation shall include the following:

- The objective of the analysis
- Design inputs and their sources
- Results of literature searched or other applicable background data
- Identification of assumptions and designation of those that must be verified as the design proceeds
- Any computer calculation, including computer type, computer program name, revision identification, inputs, outputs, evidence of reference to computer program verification, and the bases (or references thereto) supporting application of the computer program to the specific physical problem
- Review and approval

8.3.5 Design Verification

The following design control requirements shall be applied to verify adequacy of design:

- Design verification is required for design output documents.
- The particular design verification method used shall be documented by the responsible design organization.
- Results of design verification and the name of the verifier(s) shall be documented.
- Competent individuals or groups other than those that performed the original design (but may be from the same organization) shall perform design verification. If necessary, the verification may be performed by the lead engineer or designee if
  - The lead engineer or designee did NOT specify a singular design approach or rule out certain design considerations and did NOT establish the design inputs used in the design, or
  - The lead engineer or designee is the only individual in the organization competent to perform the verification.

Design verification shall be performed at appropriate times during the design process. Verification shall be performed before release for procurement, manufacture, or construction or release to another organization or discipline for use in other design work. In cases such as when insufficient data exist, it may be necessary to release unverified designs to other engineering organizations or disciplines to support schedule requirements. Unverified portions of the design shall be clearly identified and controlled. In all cases, design verification shall be completed before relying on the item or computer program to perform its function.

The extent of design verification required shall be a function of the design's importance to safety, complexity, degree of standardization, state of the art, and similarity with previously proven designs.

Use of previously standardized or proven designs shall be controlled according to the following requirements:

- The applicability of standardized or previously proven designs shall be verified with respect to meeting pertinent design inputs for each application.
- Known problems affecting standard or previously proven designs and their effects on other features shall be considered.
- The original design and associated verification measures shall be adequately documented and referenced in the records of subsequent application of the design.

Changes to resolve verification findings that modify design shall be verified prior to release or use. Such verification shall include evaluation of the effects of the changes on the previously verified design and on any design analyses upon which the design is based.

8.3.6 Design Verification Methods

Acceptable verification methods include but are not limited to the following:

- Design reviews
- Alternate calculations
- Qualification testing

8.3.6.1 Design Reviews

Design reviews are critical reviews to provide assurance that the final design is correct and satisfactory. As applicable, the design review process shall ensure the following:

- Design inputs are correctly selected and incorporated.
- Assumptions necessary to perform the design activity are adequately described, reasonable, and when necessary were identified for subsequent reverification before the completion of detailed design activities.
- Appropriate design methods and computer programs are used.
- Design output is reasonable compared with design inputs.
- Design inputs are correctly incorporated into the design.
- Design inputs and verification requirements for interfacing organizations are specified in the design documents or in supporting procedures and instructions, as necessary.
- Criteria specify suitable materials, parts, processes, and inspection and testing.

8.3.6.2 Alternate Calculations

Alternate calculations shall use alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, the computer program, its associated computer hardware and system software, or other calculation methods used shall also be reviewed.

8.3.6.3 Qualification Testing

Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. When tests are being performed on models or mock-ups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, when applicable, prior to use in the final design.

8.3.7 Design Change Control

Changes to design inputs, final designs, and field changes shall be justified and subject to design control measures commensurate with those applied to the original design. These measures shall include evaluations of the effects of those changes on the overall design and on any analysis upon which the design is based. Changes shall be approved by the same affected groups or organizations that reviewed and approved the original design documents. When responsibility changes occur, MPEX Engineering may designate new groups or organization responsible for the design, provided the new responsible organization has demonstrated competence in the specific design area of interest and adequately understands the requirements and intent of the original design.

When a design change is approved by means other than revision to the affected design documents, measures shall be established to incorporate the change into these documents, as appropriate.

When a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

8.3.8 Configuration Management

Procedures implementing configuration management requirements shall be established and documented at the earliest practical time prior to procurement or construction and be maintained for the life the project. These procedures shall include the responsibilities and authority of the organizations whose functions affect the configuration, including activities such as design, construction, authorization, and procurement.

Configuration management requirements shall include measures to ensure that changes that may affect the approved configuration are recognized and processed. Configuration management requirements include the following:

- The configuration shall be established and approved at the earliest practical time prior to project procurement or construction and maintained for the life of the facility.
- The configuration shall include, as applicable, characteristics derived from regulatory requirements and commitments, calculations and analyses, design inputs, installation and test requirements, supplier manuals and instructions, commissioning operations and maintenance requirements, and other applicable sources.
- Interface controls shall include the integration of activities of organizations that can affect the approved configuration.
- Documentation shall identify the design bases and the approved configuration.
- Measures shall be established and implemented to ensure that proposed changes to the configuration are evaluated for their conformance to the design bases.
- The implementation sequence for approved configuration changes shall be reviewed to confirm that the configuration conforms to the design bases.
- Approval by the design authority shall be required prior to implementation of a change to the design bases.
- The configuration of the facility shall be documented in drawings, specifications, procedures, and other documents and shall reflect the commissioning operational status of the facility, if applicable.
- The process to control the current revision and issuance of the documents shall account for the use of the document and the need for revision in support of the operation, if applicable.

8.3.9 Interface Control

Interface control shall include assignment of responsibility and establishment of procedures among participating design organizations for review, approval, release, distribution, and revision of documents involving design interfaces.

Design control interfaces shall be identified and procedurally controlled. Design information transmitted across interfaces shall identify the status of the design information or documents provided and identify incomplete items that require further evaluation, review, or approval. When it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document. Interface controls shall include the assignment of responsibility and the establishment of implementing documents among interfacing design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

8.3.10 Software Design Control

The requirements provided in the following Software Design Process and Software Configuration Management sections apply to computer software design control and shall be used instead of the requirements provided previously in the Design Input Control, Design Process, Design Verification, Design Change Control, and Configuration Management sections. For further information, refer to Section 8.20, Software Quality Assurance.

8.3.10.1 Software Design Process

The software design process shall be documented, approved, and controlled by the software quality assurance (SQA) program. The specific design processes for a given software project are defined by the software project team and approved in accordance with the SQA program. The software design process shall include activities described as follows.

Software design requirements shall be identified and documented, and their selection shall be reviewed and approved. Software requirements shall identify the operating system, functions, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program.

The software design shall be documented and shall define the computational sequence necessary to meet the software requirements. The documentation shall include, as applicable, numerical methods, mathematical models, physical models, control flow, control logic, data flow, process flow, data structures, and process structures. Software design documentation may be combined with the documentation of the software design requirements or with the computer program listings resulting from implementation of the software design.

8.3.10.2 Software Design Implementation

The software design shall be translated into computer program(s) using the programming organization's or design organization's programming standards and conventions.

8.3.10.3 Software Design Verification

Software design verification for safety system software shall be performed by a competent individual(s) or group(s) other than those who developed and documented the original design but who may be from the same organization. The originator’s supervisor may perform the verification in the following situations:

- The supervisor did not specify a singular design approach, rule out certain design considerations, or establish the design inputs used in the design.
- The supervisor is the only individual in the organization competent to perform the verification.

Cursory supervisory reviews do not satisfy the intent of the MPEX QAPP. The same competence and level of rigor are required for supervisory reviews as for design verifications that are not performed by the originator’s supervisor.

The results of verification shall be documented with the identity of the verifier clearly noted. Software verification methods shall include any one or a combination of design reviews, alternate calculations, and tests performed during computer program development. The extent of verification and the methods

chosen are commensurate with the complexity of the software, degree of standardization, similarity to previously proven software, and importance to safety.

8.3.10.4 Computer Program Testing

Computer program testing shall be performed in accordance with Section 8.20.

8.3.10.5 Software Configuration Management

This subsection describes the requirements applicable to software configuration management. Software configuration management includes but is not limited to configuration identification, change control, and status control. Configuration items shall be maintained under configuration management until the software is retired.

A software baseline shall be established at the completion of each activity of the software design process. Approved changes created subsequent to a baseline shall be added to the baseline. A baseline shall define the most recently approved software configuration. A labeling system for configuration-controlled items shall be implemented that

- Uniquely identifies each configuration-controlled item;
- Identifies changes to configuration-controlled items by revision; and
- Enables unique identification of each configuration of the revised software available for use.

Changes to software shall be formally documented. Documentation shall include the following:

- Description of the change
- Rationale for the change
- Identification of affected software baselines

The change shall be formally evaluated and approved by the organization responsible for the original design unless an alternate organization has been given the authority to approve changes. Only authorized changes shall be made to software baselines. Appropriate verification activities shall be performed for the change. The change shall be appropriately reflected in documentation, and traceability of the change to the software design requirements shall be maintained. Appropriate acceptance testing shall be performed on the change.

The status of configuration items resulting from software design shall be maintained current. Configuration item changes shall be controlled until they are incorporated in the approved product baseline. The controls shall include a process for maintaining the status of changes that are proposed and approved but not implemented. The controls shall also provide for notification of this information to affected organizations.

8.3.11 Design Documentation and Records

Design documentation and records shall include not only final design documents such as drawings, specifications, and revisions to those documents, but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design.

8.4 Procurement Document Control

Procurement documents including requisitions, orders, and specifications are developed to identify technical and QA requirements to prevent the introduction of S/CIs and to enable inspection to verify that items meet established requirements. The preparation, review, concurrence, and approval of all procurement documents shall be controlled per established processes and procedures.

Procurement is conducted in accordance with the subject areas and procedures in the ORNL Acquisition Management System (AMS). AMS procedures provide a detailed methodology for preparing, reviewing, and approving purchase requisitions, amendments to requisitions, procurement specifications, bid packages, and other procurement documents used to implement QA requirements for procurement document control.

Procurements that have significant impacts on quality or safety are identified as quality significant during the procurement process. The required elements to be included in procurement documents and records for quality-significant items include the following.

- The scope of work to be performed by the prospective supplier
- The design basis technical requirements, including applicable regulatory requirements, material and component identification requirements, drawings, specifications, codes and standards, special process instructions, and test and inspection requirements and acceptance criteria
- Applicable QA requirements—the extent of these requirements depends on the particular item or service being procured. When appropriate, 10 CFR 71.109 QA requirements shall be flowed down to sub-tier vendors.
- Requirements for handling nonconformances must be stated and be in accordance with 10 CFR 71.131
- As applicable, permission to access the plant facilities and records of the supplier(s) and sub-tier supplier(s) for inspection and audit purposes
- Identification of the documentation (e.g., drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedure qualifications, results of chemical and physical tests on material) that the supplier(s) must prepare, maintain, and submit to the purchaser for approval
- Identification of records that the supplier(s) must retain, control, and maintain, as well as records that the supplier(s) must deliver to the purchaser

Procurement documents for quality-significant items shall be reviewed by a Quality Significant Reviewer prior to release. Changes to procurement documents shall be subject to the same level of review used in the preparation of the original documents.

8.4.1 Basic Procurement Document Control Requirements

Applicable design bases and other requirements necessary to ensure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require suppliers to have a quality assurance program consistent with the applicable requirements of the MPEX QAPP. Supplier is a term used in place of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their sub-tier levels throughout this section.

The materials being used can influence the usefulness of the results during development. Procurement documents (including contracts, requisitions, purchase orders, and specifications) are developed to identify technical and QA requirements to enable inspection to verify that items meet established requirements and to prevent the introduction of S/CIs.

The requirements for SBMS procedure "Procurement Document Control" are implemented and applied in accordance with ORNL SBMS subject area "Purchasing Goods and Services." Project personnel in conjunction with ORNL SMEs will ensure that

- Applicable design bases and other requirements necessary to ensure adequate quality are included or referenced in the documents for procurement of items and services; and
- To the extent necessary, procurement documents shall require suppliers to have a QAP consistent with the applicable requirements of this standard.

MPEX-11-PROC-001, *Document Control and Records Management*, implements the MPEX controls for document management. Project personnel work in conjunction with the ORNL Contracts Division to ensure design basis documents and requirements are referenced in procurement documents with applicable QA standards.

8.4.2 Content of Procurements Documents

Procurement documents issued for items or services shall specify the following:

- A statement of the scope of work to be performed by the supplier
- Related technical requirements, including
  - Design bases identified or referenced in the procurement documents;
  - Specific documents (such as drawings, codes, standards, regulations, procedures, or instructions) describing the technical requirements of the material, equipment, or services to be furnished, along with the revision level or change status; and
  - Test, inspection, and surveillance requirements and acceptance criteria that will be used to monitor and evaluate the performance of the supplier to determine the acceptability of the item or service.
- The applicable requirements of the MPEX QAP consistent with the scope, nature, or complexity of the material, equipment, or service to be procured
- Right of access to supplier and sub-tier supplier facilities and records for surveillance, inspection, or audit by MPEX project personnel or other personnel designated by the MPEX project
- Surveillance/inspection hold or witness points beyond which work by the supplier cannot proceed without MPEX project and QA authorizations
- Documentation that is required to be submitted to MPEX for information, review, or acceptance, along with a document submittal schedule
- Retention times, disposition requirements, and record maintenance responsibilities for records to be maintained by the supplier
- Supplier corrective action requirements

Procurement documents issued for items or services must also contain the following provisions:

- The supplier must have processes in place before the initiation of work that meet the applicable quality requirements.
- The supplier must report nonconformances for items and services that do not meet procurement document requirements that require use as is or repair to MPEX in writing for approval of the disposition.
- The supplier must identify any spare and replacement parts or assemblies and the appropriate delineation of technical and quality assurance data required for ordering these parts or assemblies.
- Suppliers of items historically associated with S/CIs (e.g., piping/piping components, valves, fuses, molded case circuit breakers, motor starters, motor control centers, relays, welding materials, and fasteners) shall be required to have a program and procedures that address S/CIs
- The supplier must flow down the applicable procurement MPEX QAP requirements to all levels of sub-tier procurement documents, including reviews, assessments, inspections, and so on of their sub-tier suppliers to ensure they are capable of and continue to meet the specified technical and quality requirements.

8.4.3 Procurement Document Review

A review of the procurement documents and changes thereto shall be made and documented before a contract is awarded to ensure that documents transmitted to prospective supplier(s) include the applicable requirements specified to ensure that items or services will meet the specified requirements.

Technical and QA changes made as a result of the bid evaluation or precontract negotiations shall be incorporated into the procurement documents. The review of such changes and their effects shall be completed before contract award.

Procurement documents shall be reviewed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and the intent and scope of the procurement documents.

8.4.4 Procurement Document Changes

Procurement document changes affecting the technical or QAP requirements shall be subject to the same degree of control as used in the preparation of the original documents.

8.4.5 Price–Anderson Amendment Act Applicability

Applicability of the Price–Anderson Amendment Act (PAAA) depends upon whether the item or service affects or may affect the nuclear or radiological safety of DOE nuclear facilities or activities or has the potential to do harm if it failed. This determination requires an examination of the item or service, its functions, the possible ways in which it can fail or be caused to fail, and the effects of its failure. Also, work using non-radiological materials, performed in a non-radiological or nonnuclear area of ORNL, or performed off-site are potentially subject to PAAA based on the intended use of the deliverables. (For example, a consultant performing calculations to evaluate the reasons for failures of radiation safety equipment would be subject to PAAA).

In general terms, PAAA applies to activities and services that affect or may affect the safety of the public or workers at DOE nuclear and radiological facilities and activities. PAAA may apply to the purchase of an item or service in the following categories:

- Has the potential for adverse impact on the safety of the public or workers at any DOE radiological or nuclear facility or activity
- Has the potential to harm an individual from radiation or radioactive material or the potential to affect a radiological or nuclear facility or activity
- Involves the use or storage of radioactive material, radiation-generating devices, or radiation protection equipment that has the potential for adverse impact on the safety of the public or workers at any DOE radiological or nuclear facility or activity
- Relates to the design, analysis, manufacture, repair, or assembly of items (hardware, equipment, components, software, etc.) for use in or in support of a DOE radiological or nuclear facility or activity that has the potential for adverse impact on the safety of the public or workers

8.5 Instructions, Procedures, and Drawings Requirements

8.5.1 Basic Instructions, Procedures, and Drawings Requirements

Work shall be performed to established technical standards and administrative controls, documented and approved procedures, guides, instructions, and drawings. All activities affecting quality are prescribed by and performed in accordance with documented instructions, guides, procedures, drawings, or specifications that flow down the requirements of the MPEX QAP and include or reference appropriate quantitative or qualitative acceptance criteria for determining whether prescribed activities have been satisfactorily accomplished. Each activity shall be described to a level of detail commensurate with the complexity of the activity and the need to ensure consistent and acceptable results. The need for and level of detail in written procedures, instructions, and other related documents is determined based upon

- The complexity of the task,
- The significance of the item or activity,
- Work environment,
- Worker proficiency and capability (education, training, experience), and
- The need to ensure consistent, reproducible, and acceptable results.

In addition, the documents shall be written in sufficient detail to achieve the desired results on a recurring basis when used by trained, AND qualified personnel.

The PM and CAMs are responsible for ensuring quality-related services are prescribed by and performed in accordance with documented instructions, procedures, drawings, and other related documents. Where applicable, these documents shall contain or reference appropriate quantitative or qualitative acceptance criteria to ensure each activity is performed satisfactorily.

Documented instructions, procedures, and drawings are appropriate for activities when

- They have potential impacts on the quality and timeliness of project deliverables;
- They have potential for prohibitive impacts to cost;

- They involve significant risk of noncompliance with regulatory, legal, safety, or quality requirements; or
- Other risks are present that necessitate that the action proceed in a controlled manner.

Instructions, procedures, and drawings shall be prepared, reviewed, issued, and maintained as approved, version-controlled documents in accordance with MPEX-11-PROC-001, *MPEX Document Control and Records Management.* MPEX uses plans, instructions, procedures, technical documents, drawings, and other document types as defined in this procedure.

Management is responsible for ensuring instructions, procedures, drawings, and other related documents are current and maintained to reflect actual work practices. These documents shall be readily available to the individuals performing the work.

In accordance with SBMS subject area "Document Management," documents used for MPEX activities are reviewed for accuracy and appropriateness at designated intervals as identified by the review date for the approved procedure.

8.5.2 Specific Requirements

MPEX documents are divided into administrative procedures, project management and functional procedures, and technical procedures and guidelines. Administrative procedures define the communications and coordination activities necessary to carry out the project's quality-related activities, management control programs, and design control program. Project management procedures are used to perform and control activities performed by multiple project functions. Project functional procedures are used to describe activities performed by a single function (such as Engineering or Procurement). Technical procedures prescribe precisely how to accomplish the various technical tasks associated with engineering, commissioning, readiness, and testing.

These documents shall be readily available to the individuals performing the work. Documents shall flow down (include or reference) the following requirements, as appropriate, for the work to be performed.

- Responsibilities of the organization affected by the document
- Quality, technical, and regulatory requirements, including those for environmental, safety, health, and safeguards and security
- Description of the work to be performed (inspections, tests, and other commissioning)
- Quantitative or qualitative acceptance criteria sufficient for determining that prescribed activities have been satisfactorily accomplished
- Prerequisites, limits, precautious, and required environmental conditions
- In-process witness points and hold points
- Methods for demonstrating that the work was performed as required
- Identification of records generated by the document

All personnel shall be accountable for performing work in accordance with approved management requirements documents.

When a document warrants Design Authority approval or control, written approval or concurrence from the Design Authority shall be obtained prior to use.

8.5.3 Stop/Suspend Work

A process for stop work, work suspension, and the subsequent resumption of work shall be established. Stop work applies to situations in which a task or activity poses imminent danger to human health or the environment or in certain instances involving a significant CAQ. The process shall establish measurable criteria for the resumption of work. Records shall be maintained.

8.6 Document Control

8.6.1 Basic Document Control Requirements

The preparation, issuing, and changing of documents that specify quality requirements or prescribe activities affecting quality, such as instructions, procedures, and drawings, shall be controlled to ensure that the correct documents are being employed. Such documents and changes thereto shall be reviewed for adequacy and approved for released by authorized personnel.

8.6.2 Document Control and Changes

The document control system shall ensure that documents are prepared, reviewed, approved, distributed, and used by personnel. Documents specifying quality requirements or prescribing quality-affecting activities shall be controlled in accordance with this section. Documents include procedures, guides, design requirement documents, design basis documents, engineering specifications, instructions, drawings, calculations, procurement documents, computer codes, technical reports, models, and data. The types of controlled documents managed by the MPEX project are listed in Table 1.

Table 1. Types of controlled documents managed by the MPEX project.

Document category	Document type
Project documents	Charters
	Plans
Internal procedures	Procedures
	Process descriptions
	Instructions
General documents/technical documents	Guides
	Lists
	Forms
	System requirements documents
	Design analysis calculations
	Technical component specification
	Technical process specification
	Test plans, test scripts, test instructions
	Test reports

Drawings and diagrams	Subsystems and support drawings and diagrams
	System drawings and diagrams
	Process drawings and diagrams

Documents used during construction and startup affecting quality or as input in design documents shall be controlled.

The document control system shall identify documents to be controlled and their specified distribution. Controlled documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, and establish design. Documents specifying quality flow-down requirements, or prescribing quality-affecting activities, shall be reviewed in accordance with applicable procedures for adequacy, correctness, and completeness before approval and issuance. Documents shall specify effective and timely release, distribution, and implementation. Methods shall be established to ensure the correct documents are being used.

Controlled documents shall be made available online to employees, and appropriate controls will be implemented to ensure that the correct documents are being used. The distribution and use of documents, including changes and editorial corrections to documents, shall be controlled in accordance with the following:

- Changes to documents shall be reviewed for adequacy and completeness and approved prior to issuance.
- Individuals responsible for the preparation, review, approval, and distribution of controlled documents shall be identified.
- Major (intent) changes shall receive the same depth of review and level of approval as the initial version and shall be reviewed and approved by the same organization that performed the original review and approval. When appropriately authorized, alternative groups may be used based on their individual capability and knowledge of the original criteria used for the approved document and shall have access to pertinent background data or information upon which to base their approval.
- Minor (non-intent) changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. To prevent omission of a required review, the types of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.

8.7 Control of Purchased Items and Services

Control of purchased materials, equipment, and services within MPEX is directed by ORNL SBMS requirements and MPEX QA procedures. All items and services purchased for MPEX are procured through the ORNL AMS.

The procedures defined in the AMS implement the controls necessary to ensure that

- Purchased materials, equipment, and services conform to the procurement documents;
- Suppliers are properly evaluated and selected;
- Objective evidence of quality is furnished by the supplier;
- The introduction of S/CIs is prevented; and

- Received items are inspected and accepted prior to use.

The AMS defines a graded approach based upon a determination of the quality significance of the purchased material, equipment, or service. For the purposes of MPEX, the controls applicable to quality-significant items will be invoked for the procurement of any material, item, or service if its failure has the potential to significantly affect

- Test results;
- Environment, safety, or health;
- Mission of a program or project (i.e., cost, schedule, or performance);
- Safe operation of facilities or activities; or
- Any other criteria specified in the ORNL SBMS Purchasing Quality-Significant (including PAAA) Materials/Services Decision Tool.

SBMS subject area "Purchasing Goods and Services" procedures provide requirements and steps for acquiring and receiving items and services and for the administration of contracts. SBMS subject area "Purchasing Goods and Services" implements the controls necessary to ensure that

- Suppliers are properly evaluated and selected;
- Purchased items and services conform to the procurement documents;
- Objective evidence of quality is furnished by the supplier;
- The introduction of S/CIs is prevented; and
- Received items are inspected, tested, and accepted in accordance with project requirements prior to use.

Generally, a statement of work (SOW) or specification is required for services. The ORNL AMS Guided Procurement System provides guidance and SOW templates for use by MPEX staff. However, customer requirements take precedence when ordering materials or services. For procurements intended for nuclear safety applications, radiological use, or where a high level of confidence is needed that the item or service will perform as intended, MPEX staff refer to the ORNL AMS exhibit "Determining Quality Significance and PAAA Applicability." MPEX staff consult with the MPEX QR and consider if quality-significant materials or services must be procured from an evaluated vendor.

When customer specifications, customer contracts, or customer procurement documents specify that MPEX must purchase goods and or services from evaluated suppliers or vendors, MPEX will consult with the MPEX QR to develop a procurement strategy. ORNL SBMS procedure "Evaluate Supplier" provides requirements for selecting vendors and suppliers and other PAQ procedures as applicable (e.g., PAQ-AP-003, *Supplier Evaluation Desk Review*). For procurement of quality-significant items, use of unknown suppliers with no evaluation or history shall be avoided. MPEX staff reference the ORNL Evaluated Suppliers List and contact the MPEX QR or ORNL Evaluated Supplier Program coordinator for assistance.

MPEX lead auditors must be qualified and maintain qualifications per PAQ-AP-005, Qualifying Auditors and Certifying Lead Auditors. SBMS exhibit "Types of Supplier Evaluations" can be used to determine the type of evaluation to be conducted. Desk survey evaluations are performed per the ORNL procedure.

At-site supplier evaluations are performed per PAQ-AP-007, *Instructions for Conducting an At-Site Supplier Evaluation.*

MPEX receipt inspection requirements shall be specified. Receipt inspection shall be coordinated with a review of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection. ORNL SBMS procedure "Inspect and Accept Received Items" applies to the goods recipient or end user responsible for inspecting and accepting received items. Items that are procured with special inspection instructions noted on the purchase requisition, items on SBMS exhibit "Critical Items Inspection/Testing (Initial and Periodic)," and items designated by ORNL staff as "Special Inspection Required" are inspected by trained and qualified receiving inspectors per Facilities and Operations Surveillance and Inspection personnel per S&I-ACP-100, *General and Special Receipt Inspection*.

To successfully meet program, project, and sponsor requirements, management shall identify items and services critical to project objectives to achieve effective development. Methods used to accept an item or service from a supplier shall be identified.

The ORNL SBMS provides a Purchasing Quality-Significant (Including Price–Anderson Amendments Act) Materials/Services Decision Tool to assist in identifying quality-significant items. The procurement requirements for the acquisition of items and services that are project essential must be fully applied throughout all project phases to ensure validity and reliability.

Items and services are purchased to accomplish program and project activities. When procuring these quality-significant items, suppliers that have been evaluated and qualified shall be used. For purchase of an item where there are no previously evaluated suppliers, the relevant history of new suppliers will be considered in the development process.

The ORNL AMS also controls the methods that may be used to acquire parts and materials for the MPEX project. These controls ensure that the customer's technical and quality requirements are addressed during the procurement process. Any exceptions to the customer's technical or quality requirements are resolved prior to completing the acquisition agreement.

8.7.1 Basic Control of Purchased Items and Services

The procurement of items and services shall be controlled to ensure conformance with specified requirements. Such control shall provide for the following, as appropriate:

- Source evaluation and selection
- Evaluation of objective evidence of quality furnished by the supplier
- Source inspection
- Surveillance activities,
- Audit, and
- Examination of items or services upon delivery or completion

8.7.2 Supplier Evaluation, Selection, and Monitoring

Prior to awarding a contract, MPEX shall evaluate the supplier's capability to provide items or services in accordance with the requirements of the procurement documents. The results of the supplier evaluation and selection shall be documented and shall include one or more of the following:

- Supplier's history of providing an identical or similar item that performs satisfactorily in actual use, provided the supplier's history also reflects current capability
- Supplier's current records supported by documented qualitative and quantitative information that can be objectively evaluated
- Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the supplier's QA program, as appropriate

MPEX shall ensure that approved suppliers continue to meet the specified technical and applicable quality requirements through periodic reevaluations, surveillances, inspections, tests, audits, or assessments.

Suppliers shall be monitored with regard to the effectiveness of their quality management system and the quality of their products. The sponsor (DOE) and its contractors shall reserve the right to perform quality surveys and inspections at the supplier locations.

8.7.3 Bid Evaluation

A bid evaluation shall include a determination of the supplier's capability to conform to the technical and QA requirements. Prior to the award of the contract, the MPEX project shall resolve or obtain commitments to resolve unacceptable technical and QA conditions resulting from a bid evaluation.

Any unacceptable quality conditions identified during a proposal or bid evaluation shall be verified to have been resolved prior to the affected work being released for performance.

8.7.4 Control of Supplier-Generated Documents

Procedure controls shall be implemented to ensure that supplier-generated documents are submitted and evaluated in accordance with the procurement document requirements. Controls shall identify documentation required, indicate records to be submitted or maintained, and specify record retention and disposition requirements. These controls shall provide for the acquisition, processing, and recorded evaluation of the QA, technical, inspection, and test documentation or data against acceptance criteria.

8.7.5 Acceptance of Procured Items, Materials, and Services

Prior to offering the item or service for acceptance, the supplier shall verify that the item or service being furnished complies with the procurement requirements. The extent of MPEX verification activities shall depend on the relative importance, complexity, and quantity of the item or service procured and the supplier's quality performance. When required by code, regulation, or contract, documentary evidence that items conform to procurement requirements shall be available prior to installation or use.

8.7.5.1 Methods of Acceptance

The method(s) used to accept an item or service from a supplier shall be documented. Methods of acceptance include a supplier certificate of conformance, source verification, surveillance activities

(including closure of an open supplier corrective action request), receiving inspection, post-installation testing at the facility, or a combination of these methods.

Certificate of Conformance

When a certificate of conformance is used, the following minimum criteria shall be met:

- The certificate shall identify the purchased material or equipment, such as by the purchase order number.
- The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the requirements or by providing on-site a copy the purchase order and the procurement specifications or drawings, together with the certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.
- The certificate shall identify any procurement requirements that have not been met, explain the reasons for the nonconformances, and identify the means for resolving the nonconformances.
- The certificate shall be signed or otherwise authenticated by a person who is responsible for authenticating certificates of conformance and whose function and position are described in the MPEX project or supplier's QAP.
- The certification system, including the procedures for filling out a certificate and the administrative procedures for reviewing and approving the certificates, shall be described in the MPEX project's QAP or supplier's QAP.
- Means shall be provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier or independent inspection or testing of the items. Such verification shall be conducted at intervals commensurate with the supplier's past quality performance.

Source Verification

When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service and shall include monitoring, witnessing, or observing selected activities. Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon acceptance of source verification, documented evidence of acceptance shall be furnished to the MPEX project and to the supplier.

Receiving Inspection

When receiving inspection is used, purchased items shall be inspected to verify conformance to specified requirements. Source verification, audit activities, and the demonstrated quality performance of the supplier may be taken into consideration during performance of receiving inspections.

Receiving inspection personnel shall verify conformance of an item using objective evidence such as the following:

- Configuration
- Identification

- Dimensional, physical, and other characteristics
- Freedom from shipping damage
- Acceptance criteria listings
- Review of supplier documentation when not performed under source verification
- Cleanliness

Receiving inspection shall be coordinated with the review of supplier documentation when procurement documents require supplier documentation to be furnished prior to receiving inspection.

Post-Installation Testing

When post-installation testing is used, post-installation test requirements and acceptance documentation shall be mutually established by the MPEX and the supplier.

When post installation testing by the supplier is specified or required to verify proper functionality or operation, post installation test requirements and acceptance documentation shall be submitted to and approved by MPEX and to the extent consistent with security requirements and prior to performance by the supplier.

8.7.5.2 Acceptance of Services Only

In cases involving procurement of services only (such as third-party inspection, engineering, or consulting services; auditing; or installation, repair, overhaul, or maintenance work), MPEX shall accept the service by any or all of the following methods:

- Technical verification of data produced
- Surveillance or audit of the activity
- Review of objective evidence for conformance to the procurement document requirements

8.7.6 Control of Supplier-Generated Nonconformances

Methods for the control and disposition of supplier nonconformance (repair or use as is) for items and services that do not meet procurement document requirements shall include the following:

- Evaluation of nonconforming items
- Submittal of a nonconformance notice by the supplier, as directed. The submittal shall include the supplier-recommended disposition and technical justification; nonconformances to the procurement requirements or MPEX-approved documents that consist of one or more of the following shall be submitted for approval of the recommended disposition.
  - Technical or material requirement is violated
  - Requirement in approved supplier documents is violated
  - Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework

  - Item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired

- MPEX disposition of supplier recommendation
- Verification of the implementation of the disposition
- Maintenance of records of nonconformances submitted by the supplier

8.7.7 Dedication of Commercial-Grade Items and Services

When commercial-grade items or services are used, the requirements of NQA-1a-2009 Part II, Subpart 2.14, "Quality Assurance Requirements for Commercial Grade Items and Services," shall apply. Those requirements are an acceptable alternative to the other requirements of this section, except that supplier evaluation and selection, when determined necessary by MPEX, shall be performed in accordance with Section 8.7.2 of this QAPP and with SBMS procedures "Purchasing Goods and Services" and "Obtain and Dedicate Commercial Grade Items for Nuclear Safety Applications."

Requirements of NQA-1a-2009, Part II, Subpart 2.14 for dedication shall be satisfied by completion of one or more of the following dedication methods that satisfy the acceptance criteria for identified critical characteristics:

- Method 1 – Special test(s), inspection(s), or analyses
- Method 2 – Commercial-grade survey of the supplier
- Method 3 – Source verification
- Method 4 – Acceptable supplier item or service performance record

Processes are established and implemented for use of items and services with safety functions (quality level 1 quality-significant items and services) when the supplier does not have, maintain, and implement an NQA-1-based QAP. This approach is compliant with NQA-1, Subpart 2.14. A similar process based on commercial-grade dedication principles is used for the acceptance of quality level 2 items and services.

8.7.8 Records

Records shall be established and maintained to document the performance of the following activities:

- Supplier evaluation and selection
- Acceptance of items or services
- Supplier nonconformance to procurement document requirements, including evaluation and disposition

8.8 Identification and Control of Items

8.8.1 Basic Identification and Control of Items Requirements

Controls shall be established to ensure that only correct and accepted items are used or installed. Identification shall be maintained on the items or, in documents traceable to the items, or in a manner that ensures identification is established and maintained.

8.8.2 Implementation and Responsibilities

A management system shall implement methods to identify, maintain, and control items and to prohibit the use of incorrect, unaccepted, or unidentified items.

Managers and supervisors shall be responsible for ensuring that all applicable materials, parts, and components are properly identified. Staff and contractors shall be responsible for establishing procedures to identify and control materials, parts, and components that are used for work activities.

8.8.3 Identification Methods

Identification requirements for items shall be stated in design or other specifying documents. Item identification methods shall ensure that traceability, as required, is established, and maintained in a manner that allows an item to be traced to applicable design or other specifying documents. Items of production (batch, lot, component, part) shall be identified from the initial receipt and fabrication of the items up to and including installation and use.

Item identification methods shall include the use of physical markings to the maximum extent possible. If physical markings are impractical or insufficient, other appropriate means shall be employed (e.g., physical separation, labels or tags attached to containers, or procedural control).

Physical markings, when used, shall

- Be applied using materials and methods that provide a clear and legible identification,
- Not detrimentally affect the function or service life of the item,
- Be transferred to each part of an identified item when the item is subdivided, and
- Not be obliterated or hidden by surface treatments or coatings or hidden after installation unless other means of identification are substituted.

8.8.4 Specific Requirements

Control for items shall address the following requirements, as applicable:

- When codes, standards, or specifications include specific identification or traceability requirements (e.g., identification or traceability of the item to an applicable specification or grade material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), identification and traceability methods shall provide that level of control. Identified items shall have traceability documentation to ensure the item can be traced from its source through installation or end use.
- Items having limited calendar or operating life cycles shall be identified and controlled to preclude the use of items past their shelf or operating life expirations.
- If items must be stored, then methods that are commensurate with the planned duration and conditions of storage shall be established to control item identification. Such methods shall provide for the following, as applicable:
  - Maintaining or replacing markings and identification tags damaged from handling or aging
  - Protecting identification markings subject to excessive deterioration resulting from environmental exposure

  - Updating related records

- Instructions for markings and labeling items shall be established, as necessary, to adequately identify, maintain, and preserve the items and to indicate the presence of special environments or the need for special controls.
- Items shall be maintained to prevent damage, loss, and deterioration.

8.9 Control of Special Processes

8.9.1 Basic Control of Special Processes Requirements

Special processes that control or verify quality, such as those used in welding, heat treating, and NDE, shall be performed by qualified personnel using approved procedures. Special process control procedures shall prescribe or establish the requirements for planning and developing special processes, establishing special process objectives, and providing tools for measuring those objectives to ensure that special processes and resulting products meet the requirements.

Special processes will be implemented in accordance with SBMS subject area "Welding, Burning, and Hot Work" and division procedures.

If the specific task or requirement is not covered by the SBMS subject area or other requirements referenced in this document, specific procedures or controls will be developed to implement those activities safely and with quality.

Examples of special or unique processes might include the following:

- Materials testing or characterization
- Welding
- Heat treatment
- NDE
- Component or system fabrication, assembly, or disassembly
- Special optics, cameras, or sensors

8.9.2 Process Control and Records

Implementing documents, including instructions, procedures, specifications, drawings, checklists, and and/or travelers, shall be used to identify and control special processes to minimize product variability and nonconformances. Each special process shall be performed in accordance with the appropriate special process instruction, which shall include or reference the following:

- Responsibility of the organization performing the special process to adhere to the approved procedures and processes
- Training and qualification requirements for personnel
- Procedures, including any necessary equipment qualification requirements or procedures
- Conditions necessary for accomplishment of the special process, including control of equipment, specified environment, controlled parameters of the process, and calibration requirements

- Requirements of applicable codes and standards, including acceptance criteria for the special process

Qualification of welding personnel and control of welding processes and weld materials are contained in MPEX-approved procedures and processes.

For special processes not covered by existing codes and standards, or where the quality requirements specified exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures, or equipment shall be specified or referenced in procedures or instructions.

Records shall be maintained for qualified personnel, processes, and equipment of each special process.

8.10 Inspections

8.10.1 Basic Inspection Requirements

Inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service shall be planned and executed. Characteristics subject to inspection and inspection methods shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.

8.10.2 Inspection Activities

Each organization that has responsibility for conducting inspections within the scope of the MPEX QAPD shall provide documented management controls for such actions. Inspections shall include receipt inspections, in-process inspections, source inspections, and NDE. Inspections shall be conducted on activities or items affecting quality and safety to verify conformance with applicable codes, standards, regulatory requirements, procedures, and procurement documents or because of specific management requests.

Inspection activities shall be documented and controlled by instructions, procedures, specifications, drawings, checklists, travelers, or other appropriate means. Inspection of specified items, services, and processes shall be conducted under controlled conditions using established acceptance and performance criteria. Inspection requirements and results shall be documented.

Inspection requirements and acceptance criteria shall include the specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization.

8.10.3 Inspection Planning and Sampling

Procedures shall require that inspection planning and sampling be performed, documented, and include the following:

- Identification of each work operation (design document) for which inspection is necessary to ensure quality
- Identification of the characteristics to be inspected and when, during the work process, inspections are to be performed
- Identification of inspection or process monitoring methods to be employed

- Planning of the final inspection to determine conformance of the item to specified requirements
- Identification of the qualification requirements for personnel performing inspections
- Identification of acceptance criteria approved by the applicable design or technical organization
- Methods to record objective evidence of inspection results
- Selection and identification of the measuring and test equipment (M&TE) to be used to perform the inspection

When sampling is used to verify item acceptance, the statistical sampling method shall be controlled by the applicable procedure and based on standard statistical methods approved by Engineering.

8.10.4 Inspection Hold/Witness Points

When mandatory hold/witness points are used to control work that shall not proceed without the consent of the organization placing or establishing the hold/witness point, then the specific hold/witness points shall be indicated in implementing documents. Consent to waive specified hold/witness points shall be documented and approved by the organization placing or establishing the hold/witness points before continuing work beyond the designated hold/witness point.

8.10.5 In-Process Inspection and Monitoring

Items under construction or otherwise in process shall be inspected when necessary to verify quality. If inspection of the processed items is impossible or disadvantageous, then the processed items shall be indirectly controlled by monitoring of processing methods, equipment, and personnel. Inspection and process monitoring shall be conducted when control is inadequate with only one method. A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to ensure that the specified requirements for control of the process and the quality of item are met throughout the duration of the process. Controls shall be established and documented for the coordination and sequencing of inspections and monitoring at established inspection points during successive stages of item manufacturing or construction. Process monitoring shall be performed by qualified personnel or qualified automated means.

8.10.6 Resolution of Nonconformances

Final inspections shall include a records review of the results and resolutions of any nonconformances identified by prior inspections.

8.10.7 Inspection Requirements

Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, and other characteristics, as required, to verify the quality and conformance of the item to specified requirements.

8.10.8 Modifications, Repairs, or Replacements

Modifications, repairs, or replacements of items performed after final inspection shall require reinspection or retest, as appropriate, to verify acceptability. The acceptance of an item shall be documented and approved by qualified and authorized personnel.

8.10.9 Storage and In-Service Inspection

Periodic inspections (e.g., storage and in-service inspections) or surveillance of shall be planned and executed to ensure the continued performance of their required functions. This planning includes inspections required by preventative maintenance analyses, passive design features subject to degradation evaluations, or codes and standards.

8.10.10 Inspection Records

Appropriate records shall be established and maintained that at a minimum identify the following:

- Item inspected
- Date of inspection
- Inspector
- Type of observation
- Results or acceptability
- M&TE used during the inspection, including identification number and calibration due date or most recent calibration date
- Action taken in connection with nonconformances

8.11 Test Control

8.11.1 Basic Test Control Requirements

Tests required to collect data (such as for sitting or design input), to verify conformance of an item to specified requirements, or to demonstrate satisfactory performance for service shall be planned, executed, documented, and evaluated. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with acceptance criteria evaluated.

8.11.2 Testing Requirements

Specified items, services, and processes shall be tested under controlled conditions using established acceptance and performance criteria. Tests are conducted to ensure that requirements are met. Testing requirements and results shall be documented.

Test requirements and acceptance criteria shall be provided or approved by the responsible design organization. Required testing (including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, preoperational tests, and operational tests) shall be controlled. Required tests shall be controlled under appropriate environmental conditions using the tools and equipment necessary to fulfill test requirements and acceptance criteria. The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance.

Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design documents or other pertinent technical documents that provide approved requirements.

If temporary changes to the approved configuration of a system are required for testing purposes, approval by the design authority is required before performing the test.

8.11.3 Test Procedures

Test procedures shall include or reference the test configuration and objectives. Test procedures shall also include provisions for ensuring that the prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and the necessary monitoring is performed. Prerequisites shall include the following, as applicable:

- Calibrated instrumentation
- Appropriate equipment
- Trained personnel
- Condition of test equipment and the item to be tested
- Suitable environmental conditions
- Appropriate provisions for data acquisition

8.11.4 Use of Other Testing Documents

As an alternative, other testing documents such as American Society for Testing and Materials methods, specifications, supplier manuals, or other related documents containing acceptance criteria may be used. If such documents are used, they shall include or be supplemented with the. appropriate criteria detailed in this QAPP to ensure adequate procedures are available for the test.

8.11.5 Test Results

Test results shall be documented, and their conformance with acceptance criteria shall be evaluated by a qualified individual within the responsible organization to ensure test requirements have been satisfied. Test results for design qualification tests and software design verification shall be evaluated by the responsible design organization.

8.11.6 Test Records

Test records shall be established and maintained to indicate the ability of the item to satisfactorily perform its intended function or to meet its documented requirements. Test records vary depending on the test type, purpose, and application but shall contain the following information, at a minimum:

- Item tested
- Date of test
- Tester or data recorder
- Type of observation
- Results and acceptability
- Action taken in connection with any deviations
- Person evaluating test results

8.12 Control of Measuring and Test Equipment

Tools, gages, instruments, and other M&TE used for activities affecting quality shall be controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits.

8.12.1 Measuring and Test Equipment Requirements

M&TE used for process monitoring, inspections, tests, product certifications, and acceptance shall be calibrated, and its accuracy shall be certified. M&TE (tools, gages, instruments, etc.) used for these purposes shall be recertified periodically or before use. M&TE found to be defective or overdue for recertification shall not be used until recertified. Also, when M&TE is found to be lost, damaged, or out of tolerance, action shall be taken to review its previous use and to determine corrective measures. This evaluation shall be from at least the last acceptance calibration of the M&TE. The evaluation and resulting actions shall be commensurate with the significance of the condition.

8.12.1.1 Measuring and Test Equipment Selection

Selection of M&TE shall be based on the type, range, accuracy, and tolerance needed to obtain the measurements required for determining conformance to specified requirements.

8.12.1.2 Calibration and Control

M&TE shall be calibrated at prescribed times or intervals and whenever the accuracy of the M&TE is suspect. Calibrations shall be performed against and traceable to certified equipment or reference standards having known, valid relationships to nationally recognized standards or to international standards known to be equivalent to corresponding nationally recognized standards. When no such standards exist, the basis for calibration shall be defined and documented.

Calibration procedures shall identify or reference the required accuracy and shall define the methods and frequency of checking accuracy. The calibration method and calibration interval shall be based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting performance. M&TE that is overdue for calibration, damaged, providing suspect readings, or found to be out of tolerance during calibration shall not be used and shall be tagged and/or segregated or otherwise controlled to prevent its use until the M&TE has been repaired, as needed, and recalibrated. M&TE consistently found to be out of tolerance shall be repaired or replaced.

M&TE shall be

- Traceable to application and use;
- Properly handled and stored to maintain accuracy;
- Used and calibrated in environments that are controlled to the extent necessary to ensure that the required accuracy and precision are maintained; and
- Suitably marked, tagged, labeled, or otherwise identified to indicate calibration status and establish traceability to calibration records.

M&TE and reference standards submitted for calibration shall be checked and the results recorded before any required adjustments or repairs are made.

The requirements of ORNL SBMS subject area "Calibration" will be implemented. Providers of calibration services shall document traceability of calibrations and standards to nationally or internationally recognized standards. Calibration documentation shall identify or reference the required accuracy for each instrument. Methods and frequency of checking the accuracy of calibrated M&TE shall follow established ORNL calibration procedures or the associated manufacturers' recommendations provided with the equipment.

Calibration and control measures are not required for commercial equipment such as rulers, tape measures, and levels if such equipment provides the required accuracy.

8.12.1.3 Calibration Records

Records shall be established and maintained to indicate calibration status and the capability of M&TE to satisfactorily perform its intended function.

Calibration reports and certificates reporting the results of calibration shall include the information and data necessary to interpret the calibration results and to verify conformance to applicable requirements.

8.13 Handling, Storage, and Shipping

8.13.1 Basic Handling, Storage, and Shipping Requirements

Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. These activities shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity.

8.13.2 Special Requirements

When required, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environment conditions (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified and provided and their existence verified.

8.13.3 Procedures

When required, specific procedures for handling, storage, packaging, shipping, and preservation shall be used for critical, sensitive, perishable, or high-value items.

8.13.4 Tools, Equipment, and Operators

Special handling tools and equipment shall be used and controlled when necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures at specified intervals or prior to use. Personnel and operators of special handling and lifting equipment shall be experienced or trained in the use of the equipment.

8.13.5 Marking or Labeling

Marking or labeling shall be used, as necessary, to adequately maintain and preserve the item and to indicate the presence of special environments or the need for special controls.

8.14 Inspections, Tests, and Operating Status

8.14.1 Basic Inspection, Tests, and Operating Status Requirements

The statuses of inspection and test activities shall be identified either on the items or in documents traceable to the items as necessary to ensure that the required inspections and tests are performed and that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated.

Statuses shall be maintained through indicators such as physical location, tags, markings, shop travelers, stamps, inspection records, or other suitable means. The authority for application and removal of tags, markings, labels, and stamps shall be specified.

Status indicators shall also be used to indicate the operating status of systems and components of the facility, such as tagging valves and switches to prevent inadvertent operation.

8.15 Control of Nonconforming Items

8.15.1 Basic Control of Nonconforming Items Requirements

Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation, use, or shipment. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items as well as notification to the affected organization. Requirements for controlling nonconforming items are implemented through the ORNL SBMS subject area “Nonconformance Control.”

8.15.2 Identification and Segregation

Nonconforming items shall be identified on the item, the container, or the package containing the item by legible marking, tagging, or other methods not detrimental to the item, either on the item, the container, or the package containing the item.

Nonconforming items shall be segregated when practical by being placed in a clearly identified and designated hold area until properly dispositioned. If segregation is impractical or impossible because of physical conditions such as size, weight, or access limitations, other precautious shall be employed to preclude inadvertent use.

8.15.3 Disposition

Nonconforming items shall be evaluated, and recommended dispositions shall be proposed in a timely manner. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the documented evaluation and an approved disposition by authorized personnel.

The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined. Responsibility for the control of further processing, delivery, installation, or use of nonconforming items shall be defined and documented.

Personnel performing evaluations to determine an item’s disposition shall have the following:

- Demonstrated competence in the specific area they are evaluating

- An adequate understanding of the requirements
- Access to pertinent background information

The disposition (such as use as is, reject, repair, or rework) of nonconforming items shall be identified and documented. The technical justification for the acceptability of a nonconforming item that has been dispositioned repair or use as is shall be documented.

Items that do not meet original design requirements and that are dispositioned use as is or repair shall be subject to design control measures commensurate with those applied to the original design. If changes to the specifying document are required to reflect the as-built condition, then the disposition shall require action to change the specifying document to reflect the accepted nonconformance. Any document or record change required by the disposition of the nonconformance shall be identified in the nonconformance documentation. When each document or record is changed, the justification for the change shall identify the nonconformance documentation.

The disposition of an item to be reworked or repaired shall contain a requirement to reexamine (inspect, test, or NDE) the item to verify acceptability. Reworked items shall be reexamined in accordance with applicable procedures using the original acceptance criteria. Repaired items shall be reexamined in accordance with applicable procedures using the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

8.16 Corrective Action

8.16.1 Basic Corrective Action Requirements

CAQs shall be identified promptly and corrected as soon as practicable. In the case of a significant CAQ, the cause of the condition shall be determined, and corrective action shall be taken to preclude recurrence. Identifications and causes of and corrective actions for significant CAQs shall be documented and reported to appropriate levels of management. Completion of corrective actions shall be verified.

8.16.2 Issues Management

Managers who are assigned responsibility for CAQs (issues) shall ensure that corrective actions addressing the cause are planned, implemented, and tracked to closure. Completion of corrective actions shall be verified. For significant CAQs, corrective actions effectiveness shall be verified.

Additional measures (e.g., immediate compensatory measures) shall be taken in the case of a significant CAQ. The cause and the extent of a significant CAQ shall be determined, and corrective action shall be taken to correct the condition and preclude recurrence.

Corrective action plans, action closures, and issue closures for significant conditions shall be verified to ensure that those actions address the causes and extents of the conditions and that closures are complete, effective, and supported by required evidence. Lessons learned shall be captured and communicated internally for use in process improvement.

MPEX implements the ORNL SBMS subject area “Issues Management and Analysis,” which promotes and assists in the achievement of effective quality improvement initiatives. This subject area proposes the appropriate means for the identification; cause and corrective action determination; and the reporting of issues that result from defects, noncompliance, or inefficient practices. This subject area includes procedures which describe the expectations and provide the processes to address CAQs such as

deficiencies, deviations, nonconformances to requirements, inadequate processes or procedures, adverse quality trends, audit findings, events, and customer feedback to ensure these items are identified, documented, evaluated for cause, and resolved.

Issues are graded as Organizational Trending, Minor, Important, or Serious based upon the identified severity and consequences to the laboratory and customer base. Issues and corrective actions from events, programmatic reviews, audits, or other assessment activities are documented and tracked to completion in the ORNL Assessment and Commitment Tracking System. Corrective action completion and issue resolution is verified by the QR and the appropriate line management using the procedures in ORNL SBMS subject area "Issues Management and Analysis."

8.17 Quality Assurance Records

8.17.1 Basic Quality Assurance Records Requirements

The control of QA records shall be established in line with the schedule for accomplishing work activities. QA records shall furnish documentary evidence that items or activities meet specified quality requirements. QA records shall be identified, generated, authenticated, and maintained and their final disposition specified. Record control requirements and responsibilities for these activities shall be documented and implemented consistent with the schedule for accomplishing work activities using MPEX-approved processes and systems. These controls shall ensure that records are identified, generated, reviewed, approved, collected, indexed for accountability and retrievability, and protected in storage for required retention periods and that their final disposition is specified in accordance with the requirements of SBMS subject area "Records Management."

The MPEX RMO is responsible for working with the PM, MPEX CAMs, and MPEX staff to facilitate implementation of records requirements to capture, declare, maintain, and disposition physical and electronic records. Sufficient records shall be maintained to demonstrate conformance to specified requirements and effective deployment of the MPEX QAP. The ORNL SBMS subject area "Records Management" establishes criteria for record maintenance, including for the identification, processing, storage, retrieval, and disposition of records. The generation, authentication, and receipt control processes for MPEX records and the associated responsibility for management of records is defined in MPEX-11-PROC-001, *Document Control and Records Management*, and the SBMS subject area "Records Management."

8.17.2 Generation of Records

Records to be generated, supplied, or maintained shall be specified in applicable documents, such as design specifications, procurement documents, test procedures, and operational procedures. Records generated as a result of implementing the MPEX QAP shall be legible and traceable to the associated items and activities and shall accurately reflect the work accomplished or information required.

8.17.3 Authentication of Records

Documentation and records generated to implement the MPEX QAP shall be considered valid, authenticated records only if stamped, initialed, signed, and dated by authorized personnel. Corrections to hard copy documents shall be reviewed and approved by the responsible individual from the originating or authorized organization. Electronic documents shall be authenticated with comparable information, as appropriate, with identification on the electronic media or with authentication information contained within media or linked to the documents.

8.17.4 Classification of Records

Records shall be classified as lifetime or nonpermanent and shall be maintained in accordance with the following requirements, and consistent with applicable regulatory requirements. Lifetime records are those that meet one or more of the following criteria:

- offer significant value in demonstrating capability for safe operation;
- indicate significant value in maintaining, reworking, repairing, replacing, or modifying an item;
- afford significant value in determining the cause of an accident or malfunction of an item; or
- provide required baseline data for in-service inspections.

Lifetime records are required to be maintained for the life of the particular item, while it is either installed in the facility, or stored for future use.

Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements of the MPEX QAPP, but do not need to be retained for the life of the item because they do not meet the criteria for lifetime records. Nonpermanent records shall be maintained for the identified retention period.

Control of Records – Each organization that is responsible for the receipt of records shall designate a person or organization responsible for receiving the records. The designee shall be responsible for organizing and implementing receipt controls for permanent and temporary storage. Receipt controls shall provide a method for identifying the records received, for receipt and inspection of incoming records, and for submittal of records to storage.

8.18 Storage of Records

8.18.1 General Requirements

Records shall be either permanently or temporarily stored at a predetermined location(s) in facilities, containers, or a combination thereof constructed and maintained in a manner that minimizes the risk of loss, damage, or destruction from the following:

- Natural disasters such as winds, floods, or fires
- Environmental conditions such as high and low temperatures and humidity
- Infestation of insects, mold, or rodents
- Dust or airborne particles

Activities detrimental to the records shall be prohibited in the storage area. Access to the areas for processing, storage, and retrieval of records shall be limited to authorized personnel. Provisions shall be made to prevent damage from harmful conditions, as applicable to the specific media used for record storage.

8.18.2 Receipt, Control, Retention, and Maintenance of Records

The project RMO(s) and CAMs, or their delegates, are responsible for the receipt of records and for organizing and implementing receipt controls for permanent and temporary storage. Receipt controls provide a method for identifying and inspecting incoming records, indexing the incoming records for future retrievability, and placing records into record storage.

Record retention periods shall be specified and documented, and records shall be maintained for specified retention periods in accordance with the Laboratory Records Management Application (Electronic Records System). At the conclusion of the project, all project records will be delivered to ORNL Records Management Services for retention according to the established records schedule.

The following controls shall be established and implemented for maintaining records:

- Records shall be protected for damage or loss.
- Records controls shall provide for retrievability within planned review times based upon the record type or content.
- Methods for record changes shall be documented.
- Provisions shall be established to ensure no unacceptable degradation of the electronic record media occurs during the established retention period.
- Provisions shall be made to ensure the records remain retrievable after hardware, software, or technology changes.
- Provisions shall be established to ensure the following when records are duplicated or transferred to the same media or to a different media for the purpose of maintenance or storage.
  - Duplication or transfer is appropriately authorized.
  - Record content, legibility, and retrievability are maintained.

8.19 Audits, Assessments, and Surveillances

The PM is responsible for ensuring that internal assessments are conducted to confirm that the QAP is adequately implemented and for ensuring that identified problems are corrected. All elements of the QAP shall be subject to independent, external, and customer audits. Audits and assessments shall be planned, scheduled, and conducted to ensure coverage is commensurate with current and planned activities in accordance with ORNL SBMS subject area “Audits and Assessments.”

Internal and independent assessments may be scheduled and conducted by organizations such as the ORNL PAQ Division, FFESD, Independent Oversight, DOE, and other sponsors of work activities. Such assessments shall be coordinated, scheduled, conducted, and reported to the PM by the assessing organization. Identified issues from all audits and assessments shall be subject to the corrective action processes identified in Section 8.16 of this plan.

Any NQA-1 audits shall be conducted by qualified personnel not having direct responsibilities in the area they audit and in accordance with preplanned and approved audit plans or checklists. The requirements of PAQ-AP-005, *Qualifying Auditors and Certifying Lead Auditors,* shall be invoked to approve lead auditors, auditors, and non-QA technical specialists for participation in QA audits.

Audits and assessments shall be performed to verify compliance with QAP requirements, to verify that performance criteria are met, and to determine the effectiveness of the quality management system. Results shall be documented and reported to and reviewed by management responsible for the work activities being audited. Follow-up action shall be taken when indicated.

Surveillance is an assessment technique that uses observation or monitoring to provide confidence that ongoing processes and activities are adequately and effectively performed. Surveillances provide timely data on performance and identify quality issues before they have a significant impact on safety and reliability. Surveillances must be documented in sufficient detail to identify the activity covered, identify individuals conducting the surveillances, and document results and any necessary corrective measures.

Audit and assessment records include audit plans, audit reports, checklists, written replies, and the record of completion of corrective action. These records shall be retained in accordance with Section 8.1 of this plan.

8.20 Software Quality Assurance

The MPEX project uses a wide variety of software applications to support overall management of programs, projects, research and development processes, and data management activities. The SQA program combines the core elements of SQA and software engineering to ensure that software used by MPEX is fit for its intended use and is properly managed and controlled.

Computer programs are used for design analysis, operations and process control, and control of database or document control registers. These software applications include custom-developed, commercial-off-the- shelf, or otherwise acquired software for in-house configuration or for use as is. SQA requirements for acquiring, developing, modifying, upgrading, and using software are implemented in accordance with SBMS procedure “Determine SQA Applicability and Categorization” as well as any project specific SQA plans or procedures.

MPEX software applications shall be identified and assigned a software owner who is responsible for the management and control of the software from its acquisition or development until retirement from service. Software applications shall be evaluated and categorized based on their impacts and consequences of failure and registered in the ORNL Software Registration System (SRS). Based on software characterization, grading, and type, software work activities and QA requirements are applied across the entire software life cycle using a risk-based, graded approach for the planning, acquisition, development, operation, maintenance, and retirement of software. The appropriate requirements are implemented through the policies, procedures, SQA plans, specifications, or work practices that provide the framework for software engineering activities.

Requirements in Sections 8.4 and 8.7 of this QAPP shall be applied to the procurement of software and software services. The software owner shall be responsible for the appropriate requirements of this section upon accepting the software or related item (e.g., programmable device). Procurement documents for safety software shall identify requirements for supplier’s reporting of software errors to the software owner and, as appropriate, the purchaser’s reporting of software errors to the supplier.

8.20.1 Controls and Applicability

This section establishes software controls to ensure that software used by the MPEX project is appropriate and suitable for its intended use and that the software is properly managed and controlled. Specific design control requirements for safety system software and the use of software for design activities are provided in Section 8.3 of this QAPP. The controls apply to all organizations that develop and implement computer software programs that may affect safe, secure, and reliable operation; processing of environmental data; or achievement of programmatic missions.

8.20.2 Software Categorization

Software is categorized into one of two main sources: off the shelf or custom developed. All applicable requirements shall be met, and approval shall be granted before the software is placed into production use.

8.20.3 Software Graded Approach

A risk-based graded approach for performing SQA activities is achieved by assigning quality levels and determining the SQA activities appropriate for each level. A quality level is determined by reviewing the use of the software to support mission, financial, and programmatic goals, including health, safety, environment, and security.

The quality levels implemented in the MPEX SQA program are for safety affecting, risk critical significant, and general. The SQA personnel works with the software owner and the software project team as appropriate to establish the quality level. This team approach brings the software owner, user, technical support, and SQA organization into the evaluation process.

Once the quality level is assigned, a graded approach is used to determine the required software deliverables and level of rigor and detail for documentation, level of oversight, testing, and configuration management. The graded approach considers the following:

- Quality level
- Software source
- Intended use of the software
- Expected size and duration of the software deployment

SQA requirements incorporate industry best practices in areas of software quality, cybersecurity, and software engineering processes.

8.20.4 Test Procedures for Safety System Software

Test requirements and acceptance criteria for safety system computer programs shall be provided by the organization responsible for the use of the computer program and shall include the following, as applicable:

- Software design verification testing shall demonstrate the capability of the computer program(s) to provide valid results for test problems encompassing the range of documented permitted usage.

- Computer program acceptance testing shall comprise exercising or evaluating a system or system component by manual or automated means to ensure that it satisfies the specified requirements and to identify differences between expected and actual results in the operating environment.
- In-use computer program testing shall demonstrate required performance over the program's full range of operation and intended function or process.

The following requirements shall apply to testing safety system computer programs and, as appropriate, the computer hardware and operating system:

- Computer program test procedures shall provide for demonstrating the adherence of the computer program to documented requirements. For computer programs used in design activities, computer program test procedures shall provide for ensuring that the computer program produces correct results. For computer programs used for operational control, computer program test procedures shall provide for demonstrating required performance over the range of operation of the controlled function or process. The procedures shall also provide for evaluating technical adequacy through comparison of test results from alternative methods such as hand calculations; calculations using comparable, proven programs; or empirical data and information from technical literature.
- In-use computer program test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system.
- In-use computer program test procedures shall be performed after the computer program is installed on a different computer or when significant changes are made in the operating system. Periodic manual or automatic self-check tests for in-use computer programs shall be prescribed and performed for computer programs whose errors, data errors, computer hardware failures, or instrument drift can affect required performance.
- Test procedures and plans shall specify the following, as applicable:
  - Required tests and test sequences
  - Required ranges of input parameters
  - Stages at which testing is required
  - Criteria for establishing test cases
  - Requirements for testing logic branches
  - Requirements for hardware integration
  - Anticipated output values
  - Acceptance criteria
  - Reports, records, standard formatting, and conventions
- Computer program test results shall be documented and evaluated by a responsible authority to ensure that test requirements have been satisfied. Software design verification shall be evaluated by the responsible design organization
- Computer program test records shall be established and maintained to indicate the ability of the item to satisfactorily perform its intended function or to meet its documented requirements. Test records vary depending on the test type, purpose, and application but shall contain the following information, at minimum:

- Computer program tested, including system software used
- Computer hardware used
- Test equipment and calibrations, as applicable
- Date of test
- Tester or data recorder
- Simulation models used, as applicable
- Test problems
- Results and applicability
- Action taken in connection with any noted deviations
- Person evaluating test results
- Acceptability

The SQA program shall ensure that software performs its intended functions when used. MPEX software applications in the SRS are reviewed by the software owner annually to determine if reevaluation is needed. In addition, software applications that generate or manipulate data used in design, analytical, operational, or compliance-related decisions are subject to internal, independent review as part of the annual ORNL SQA assessment process.

8.21 Suspect/Counterfeit Items

The purpose of the S/CI program is to establish, document, and implement effective controls and processes that will ensure the following:

- Items and services meet specified requirements.
- S/CIs are prevented from entering into the supply chain.
- Detection, control reporting, and disposition of S/CIs are accomplished.

The requirements of DOE Order 414.1D, Attachment 3, *Suspect/Counterfeit Items Prevention Titled Suspect/Counterfeit Items,* are implemented and applied in accordance with the ORNL SBMS subject area "Suspect/Counterfeit Items and Defective Items."

The S/CI program must

- Include an S/CI oversight and prevention process commensurate with the facility or activity hazard and mission impact;
- Identify the position responsible for S/CI activities and for serving as a point of contact for MPEX;
- Provide for training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs);
- Prevent introduction of S/CIs into work when maintaining, replacing, or modifying equipment by the following methods:
  - Engineering involvement

  - Developing procurement specifications wherein technical; QA; and environment, safety, and health requirements are identified
  - Inspection and testing
  - Accepting only items that comply with procurement specifications, consensus standards, and commonly accepted industry practices
  - Inspecting inventory and storage areas to ensure identification, control, and disposition of S/CIs

- Include processes for inspection, identification, evaluation, and disposition of S/CIs that have been installed in safety applications and other applications that create potential hazards; and
- Address the use of supporting engineering evaluations for acceptance of installed S/CIs and the marking of installed S/CIs to prevent future reuse.

CAMs or their designees are responsible to ensure that purchased items and services (including software) meet specified requirements to prevent entry of S/CIs into project development activities. CAMs or their designees shall ensure the following:

- Engineering evaluations are conducted and used in the disposition of identified S/CIs installed in safety applications and systems or in applications that create potential hazards. Evaluations must consider potential risks to the environment, the public, and workers; costs and benefits; and schedules for replacement (if required).
- Evaluations are performed to determine whether S/CIs installed in non-safety applications pose potential safety hazards or may remain in place.
- S/CIs identified during routine maintenance or inspections are disposed of to prevent future reuse in non-safety applications.
- S/CIs are reported to the DOE Inspector General (IG) in accordance with DOE O 221.1B, *Reporting Fraud, Waste, and Abuse to the Office of Inspector General.*
- The most accurate, up-to-date information on S/CIs and suppliers is collected, maintained, disseminated, and used.
- Trend analyses are conducted and used to improve the S/CI prevention process.
- The DOE IG is contacted before S/CIs are destroyed or disposed of and is provided with corresponding documentation to allow the IG to determine whether the items and documentation need to be retained for criminal investigation or litigation.
- S/CIs are reported in accordance with the occurrence notification and reporting procedure.

8.21.1 MPEX Implementation of Suspect/Counterfeit Item Requirements

The MPEX program for the control of S/CIs is based on two key safety and quality principles, defense in depth and graded approach. Under the MPEX QAP, a comprehensive network of controls and verification provides for defense in depth by preventing the introduction of S/CIs during the design, procurement, construction, and commissioning/startup of the MPEX device.

ORNL's S/CI program applies a graded approach to safety systems, non-safety systems, and mission-critical facilities, including critical load paths of lifting equipment, rigging, fall protection, and other nonpermanent equipment and materials, as well as non-safety components when the introduction of S/CIs

has high potential for creating unsafe conditions. MPEX is responsible for coordination, oversight, reporting, and notification to the ORNL S/CI program. MPEX implements the S/CI program for the prevention and detection of indeterminate and suspect items, maintained in the overall ORNL S/CI program for initiation of investigations of indeterminate and suspect items, and notifies appropriate S/CI Coordinator or SME.

9. ACRONYMS AND DEFINITIONS

ACRONYMS, ABBREVIATIONS, AND INITIALISMS	
AMS	Acquisition Management System
ASME	American Society of Mechanical Engineers
CAM	control account manager
CAQ	condition adverse to quality
CFR	Code of Federal Regulations
DOE	US Department of Energy
FES	Office of Fusion Energy Sciences
FFESD	Fusion and Fission Energy and Science Directorate
IG	Inspector General
ITR	institutional training requirement
LPD	linear plasma device
MPEX	Material Plasma Exposure eXperiment
M&TE	measuring and test equipment
NDE	nondestructive examination
NQA	nuclear quality assurance
FFSED	Fusion Fission Science Energy Directorate
ORNL	Oak Ridge National Laboratory
PAAA	Price–Anderson Amendment Act
PAQ	Performance Analysis and Quality
PM	project manager
PMI	plasma-material interface
QA	quality assurance
QAP	Quality Assurance Program
QAPD	quality assurance program description
QAPP	quality assurance program plan
QL	quality level
QMS	quality management system
QR	quality representative
R2A2	roles, responsibilities, accountabilities, and authorities
RMO	records management officer
S&I	surveillance and inspection
S/CI	suspect/counterfeit item
SBMS	Standards-Based Management System
SME	subject matter expert
SOW	statement of work
SQA	software quality assurance
SRS	Software Registration System

ACRONYMS, ABBREVIATIONS, AND INITIALISMS	
WBS	work breakdown system

10. DEFINITIONS

DEFINITIONS	
acceptance criteria	Specified limits placed on the performance, results, or other characteristics of an item, process, or service defined in codes, standards, or other requirement documents. [NQA-1-2008]
administrative controls	The provisions relating to organization and management, procedures, record keeping, assessment, and reporting necessary to ensure safe operation of a facility. [DOE O 414.1D]
assessment	A review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively. [DOE O 414.1D] The act of reviewing, evaluating, inspecting, testing, checking, conducting surveillances, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements. The terms *assessment* and *verification*, as used in DOE Order 414.1D, Admin Chg 1, are synonymous; their use is determined by who is performing the work. Assessments are performed by or for senior management. Verifications are performed by the line organization.
audit	A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should NOT be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance. [NQA-1-2008]
audit, external	An audit of those portions of another organization's QAP NOT under the direct control or within the organizational structure of the auditing organization. [NQA-1-2008]
audit, internal	An audit of those portions of an organization's QAP retained under its direct control and within its organizational structure. [NQA-1-2008]
certificate of conformance	A document signed, or otherwise authenticated, by an authorized individual certifying the degree to which items or services meet specified requirements. [NQA-1-2008]
certification	The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items, in accordance with specified requirements. [NQA-1-2008]
characteristic	Any property or attribute of an item, process, or service that is distinct, desirable, and measurable. [NQA-1-2008]
commercial-grade item	A structure, system, component (or part thereof that affects its safety function) that was NOT designed and manufactured in accordance with the requirements of NQA-1. [NQA-1a-2009, Subpart 2.14]

DEFINITIONS	
	A structure, system, component (or part thereof that affects its safety function) that was not designed and manufactured as a basic component. Commercial-grade items do not include items in which the design and manufacturing process requires in-process inspections and verifications to ensure that defects or failures are identified and corrected (i.e., one or more critical characteristics cannot be verified). [ASME NQA-1-2008 and 2009 Addenda]
commercial-grade service	A service that was NOT provided in accordance with the requirements of NQA-1 that affects the safety function of an SS or SC item. [NQA-1-1a-2009, Subpart 2.14]
computer program	A combination of computer instructions and data definitions that enables computer hardware to perform computational or control functions. Computer programs covered by the QAP are those used for the following: • Design analysis • Operations or process control • Database or document control registers when used as the controlled source of quality information for (a) or (b) above To the extent that computer programs are a physical part of plant systems (e.g., digital reactor protection systems, digital instrumentation), they are included in the term item. [based on NQA-1-2008]
condition adverse to quality	An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one that, if uncorrected, could have aserious effect on safety or operability. [NQA-1-2008]
configuration	The physical, functional, and operational characteristics of the structures, systems, components, or parts of the existing facility. [NQA-1-2008]
configuration item (software)	A collection of hardware or software elements treated as a unit for the purpose of configuration control. [NQA-1-2008]
configuration management	The process that controls the activities and interfaces among design, construction, procurement, training, licensing, operations, and maintenance to ensure that the configuration of the facility is established, approved, and maintained. [NQA-1-2008]
corrective action	Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition. [NQA-1-2008]
critical attribute	A generic, collective term for features, design elements, or characteristics that are selected for analysis and identification of mitigative measures to control risks. Critical attributes apply to critical characteristics (QL1), risk attributes (QL2), and design features (QL3–4).
critical characteristics	Important design, material, and performance characteristics of an item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function. [NQA-1-1a-2009 Subpart 2.14]

DEFINITIONS	
dedication	An acceptance process performed in accordance with NQA-1 to provide reasonable assurance that a commercial-grade item or service will perform its intended safety function and, in this respect, is deemed equivalent to an item or service designed and manufactured or provided under the requirements of NQA-1. This assurance is achieved by identifying the critical characteristics of the item and verifying its acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial-grade surveys; product inspections or witness at hold points at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of NQA-1 Part I. [NQA-1-1b-2009 Subpart 2.14]
defense in depth	Refers to the multiplicity of design features, controls, and actions taken to ensure public and worker safety.
design authority	The organization having the responsibility and authority for approving the design bases, the configuration, and changes thereto. [NQA-1-2008]
design bases	That information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be • Restraints derived from generally accepted state-of-the-art practices for achieving functional goals; or • Requirements derived from analysis (based on calculations and/or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals. [NQA-1-2008]
design change	Any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto. [NQA-1-2008]
design, final	Approved design output documents and approved changes thereto. [NQA-1-2008]
design input	Those criteria, performance requirements, codes and standards, design bases, regulatory requirements, or other design requirements upon which detailed final design is based. [NQA-1-2008]
design output	Drawings, specifications, and other documents used to define technical requirements of structures, systems, components, and computer programs. [NQA-1-2008]
design process	Technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents. [NQA-1-2008]
design review	A critical review to provide assurance that the final design is correct and satisfactory. [NQA-1-2008]

DEFINITIONS	
deviation	A departure from specified requirements. [NQA-1-2008] A deviation can be a condition in which characteristics of an activity or service do not conform to prescribed limits; a document that is not available or is inadequate; or a procedure that does not yield the desired results. Deviations can occur at any point in designing, constructing, handling, shipping, storing, installing, producing, or operating an item or process; performing a service; or executing quality assurance activities.
document	Any written, pictorial, or electronic information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is NOT considered to be a QA record until it satisfiesthe definition of a QA record, as defined in NQA-1. [NQA-1-2008]
document control	The act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed. [NQA-1-2008]
electronic document	A document stored in a form (i.e., magnetic, or optical media) that is typically accessible only by a computer. [NQA-1-2008]
graded approach	The process of ensuring that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with • The relative importance to safety, safeguards, and security; • The magnitude of any hazard involved; • The life cycle stage of a facility or item; • The programmatic mission of a facility; • The particular characteristics of a facility or item; • The relative importance to radiological and non-radiological hazards; and • Any other relevant factors. [DOE O 414.1D]
hazard controls	Measures to eliminate, limit, or mitigate hazards to workers, the public, or the environment, including • Physical, design, structural, and engineering features; • Safety structures, systems, and components; • Safety management programs; • Technical safety requirements; and • Other controls necessary to provide adequate protection fromhazards. [DOE O 414.1D]
hold point	A point identified within an inspection/test plan, procedure, or instruction, beyond which work must NOT proceed until the requirement for an independent verification has been satisfied or waived by the organization that specified the hold point. [based on NQA-1-2008, Part I, Requirement 10—Inspections, section 300]

DEFINITIONS	
inspection	Examination or measurement to verify whether an item or activity conforms to specified requirements. [NQA-1-2008]
inspector	A person who performs inspection activities to verify conformance to specific requirements. [NQA-1-2008]
item	An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit. [NQA-1-2008]
management assessment	A periodic introspective self-analysis, conducted by management, to evaluate management systems, processes, and programs ensuring the organization's work is properly focused on achieving desired results. [DOE O 414.1D]
may	Denotes permission (neither a requirement nor guidance).
measuring and test equipment (M&TE)	Devices or systems used to calibrate, measure, gauge, test, or inspect in order to control or acquire data to verify conformance to specified requirements. [NQA-1-2008]
nonconformance	A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate. [NQA-1-2008]
objective evidence	Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity based on observations, measurements, or tests that can be verified. [NQA-1-2008]
procedure	A document that specifies or describes how an activity is to be performed. [NQA-1-2008]
process	A series of actions that achieves an end result. [DOE O 414.1D]
procurement document	Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase. [NQA-1-2008]
qualification (of personnel)	The characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests that qualify an individual to perform a required function. [NQA-1-2008]
qualified automated means	Automated methods of controlling or monitoring processes that have been demonstrated to produce required quality within controlled limits. [NQA-1-2008]
quality	The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations. [DOE O 414.1D]
quality assurance	All those actions that provide confidence that quality is achieved. [DOE O 414.1D]
quality related	The composite of activities intended to achieve quality and those intended to ensure the achievement of quality.
quality assurance program	The overall program or management system established to assign responsibilities and authorities, define policies and requirements, and providefor the performance and assessment of work. [DOE O 414.1D]
qualified procedure	An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose. [NQA-1-2008]

DEFINITIONS	
quality assurance record	A completed document that furnishes evidence of the quality of items and/or activities affecting quality. Types of record media may include paper, electronic (magnetic or optical), or specially processed media such as radiographs, photographs, negatives, and microforms. The term *record*, as used throughout the QAP, is to be interpreted as QA record. [NQA-1-2008]
quality level	A designator of the level of control(s) and independence that must be applied to an item or service in order to mitigate risk associated with the critical characteristics designated by Engineering or risk attributes designated by the SSC owner.
quality standard	A code or standard that provides design inputs, acceptance criteria, or other criteria necessary to assure the quality of the designated item. [NQA-1-2008]
receiving	Taking delivery of an item at a designated location. [NQA-1-2008]
repair	The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does NOT conform to the original requirement. [NQA-1-2008]
rework	The process by which an item is made to conform to original requirements by completion or correction. [NQA-1-2008]
right of access	The right of an MPEX representative to enter the premises of a supplier for the purpose of inspection, surveillance, or QA audit. [NQA-1-2008]
risk	The degree of exposure to an event or condition that might happen to the detriment of a program, project, or activity. It is the combination of the probability that the event or condition will occur and the consequence or the extent of loss from the occurrence.
risk attribute	Features that need to be verified to ensure identified risk has been mitigated.
safety	An all-inclusive term used synonymously with environment, safety, and health to encompass protection of the public, the workers, and the environment. [DOE O 414.1D]
safety function	The performance of an item or service necessary to achieve safe, reliable, and effective utilization of nuclear energy and nuclear material processing. [NQA-1-2008]
safety management program	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 QA; maintenance of safety systems; personnel training; conduct of operations; inadvertent criticality protection; emergency preparedness; fire protection; waste management; or radiological protection ofworkers, the public, and the environment. [10 CFR 830]

DEFINITIONS	
safety software	Includes the following: *Safety system software*: software for a nuclear facility that performs a safety function as part of a structure, system, or component and is cited in either (a) a DOE-approved documented safety analysis or (b) an approved hazard analysis per DOE P 450.4, Safety Management System Policy, dated 10-15-96, and the Department of Energy Acquisition Regulation (DEAR) clause. Per 10 CFR 830, QA requirements apply to all DOE nuclear facilities including radiological facilities. (See 10 CFR 830, DOE-STD-1120, and the DEAR Integrated Safety Management System [ISMS] clause.) *Safety and hazard analysis software* and *design software*: software that is used to classify, design, or analyze nuclear facilities. This software is NOT part of an SSC but helps to ensure the proper accident or hazards analysis of nuclear facilities or an SSC that performs a safety function. *Safety management and administrative controls software*: software that performs a hazard control function in support of nuclear facility or radiological safety management programs or technical safety requirements or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment as addressed in 10 CFR 830, 10 CFR 835, and the DEAR ISMS clause. [DOE O 414.1D]
service	The performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation. [NQA-1-2008]
shall	Denotes a requirement. [based on NQA-1-2008]
should	Denotes guidance. [based on NQA-1-2008]
software	Computer programs and associated documentation and data pertaining to the operation of a computer system. [NQA-1-2008]
special process	A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality CANNOT be readily determined by inspection or testing of the product. [NQA-1-2008]
structures, systems, and components (SSCs)	Term that refers collectively to the following three things. *Structures* are elements that provide support or enclosure such as buildings, freestanding tanks, basins, dikes, and stacks. *Systems* are collections of components assembled to perform a function such as piping; cable trays; conduits; and heating, ventilation, fire protection, and air conditioning. *Components* are items of equipment such as pumps, valves, relays, dollies, or carts and elements of a larger array such as computer software, lengths of pipe, elbows, and reducers.
supplier	Any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their sub-tier levels. [NQA-1-2008]
surveillance	The act of monitoring or observing to verify whether an item or activity conforms to specified requirements. [NQA-1-2008]

DEFINITIONS	
suspect/counterfeit item	An item is *suspect* when visual inspection or testing indicates that it may NOT conform to established government or industry-accepted specifications or national consensus standards or whose documentation, appearance, performance, material, or other characteristics may have been misrepresented by the supplier or manufacturer. A *counterfeit item* is one that has been copied or substituted without legal right or authority or whose material, performance, or characteristics have been misrepresented by the supplier or manufacturer. Items that do NOT conform to established requirements are NOT normally considered S/CIs if nonconformity results from one or more of the following conditions (which are controlled by site procedures as nonconforming items): • Defects resulting from inadequate design or production quality control • Damage during shipping, handling, or storage; • Improper installation • Deterioration during service • Degradation during removal • Failure resulting from aging or misapplication • Other controllable causes [DOE O 414.1D]
testing	An element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions. [NQA-1-2008]
traceability	The ability to trace the history, application, or location of an item and like items or activities by means of recorded identification. [NQA-1-2008]
use-as-is	A disposition permitted for a nonconforming item when it has been established that the item is satisfactory for its intended use. [NQA-1-2008]
validation	The process of (a) evaluating a system or component during or at the end of the development process to determine whether it satisfies specified requirements, or (b) providing evidence that the software and its associated products satisfy system requirements allocated to software at the end of each life cycle activity, solves the right problem (e.g., correctly models physical laws, implements business rules, uses the proper system assumptions), and satisfies the intended use and user needs. [DOE O 414.1D]
verification (not for software)	The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements. [NQA-1-2008] The terms *assessment* and *verification*, as used in DOE Order 414.1D, Admin Chg 1, are synonymous; their use is determined by who is performing the work. Assessments are performed by or for senior management. Verifications are performed by the line organization.

DEFINITIONS	
verification (for software)	Providing objective evidence that the software and its associated products conform to requirements (e.g., for correctness, completeness, consistency, accuracy) for all life cycle activities during each life cycle process (acquisition, supply, development, operation, and maintenance); satisfies standards, practices, and conventions during life cycle processes; and successfully completes each life cycle activity and satisfies all the criteria for initiating succeeding life cycle activities (e.g., building the software correctly). [DOE O 414.1D]
waiver	Documented authorization to depart from specified requirements. [NQA-1-2008]
witness point	A point identified within a surveillance plan, inspection plan, test plan, procedure, or instruction beyond which work must NOT proceed until the requirement as established in the plan or other procurement document for notification to or waiver by the organization that specified the witness point has been satisfied.
work	A defined task or activity such as research and development; operations; environmental remediation; maintenance and repair; administration; safety software development, validation, testing, and use; inspection; safeguards and security; or data collection and analysis. [DOE O 414.1D]

11. REFERENCES

10 CFR 830, Subpart A, "Safety Quality Assurance Requirements"

11 DOE G 414.1-2B, *Quality Assurance Program Guide*

DOE O 221.1B, *Reporting Fraud, Waste, and Abuse to the Office of Inspector General*

ANSI/ISO/ASQ(E) Q9001:2015, *Quality Management Systems*

11.1 ORNL SBMS Documents

The following ORNL SBMS documents referenced in this document provide lab-wide requirements used by the MPEX QAPP when and where applicable.

11.1.1 Subject Areas

Audits and Assessments

Calibration

Configuration Management

Engineering Design

Document Management

Engineering Design

Event Reporting and Follow-Up

Inspection and Acceptance Testing

Issues Management and Analysis

Nonconformance Control

Records Management

Safety and Security Regulatory (SSR) Program

Software Quality Assurance (SQA)

Suspect/Counterfeit Items and Defective Items

Training of Staff

Welding, Burning, and Hot Work

Work Control

11.1.2 Procedures

Control Configuration

Create Engineering Designs

Critiques and Investigations

Determine SQA Applicability and Categorization

Develop, Revise and Control Other Controlled Documents

Division Training Program Management

Evaluate Supplier

Evaluate, Report, and Resolve Occurrences

Identify Configuration Items

Identify, Handle, Report and Verify Suspect/Counterfeit and Defective Items

Identify, Report, and Close Nonconformances

Inspect and Accept Received Items

Inspect and Acceptance Test In-Process & Final (Completed) Items, Processes, and Services

Maintain Records

Manage Issues

Manage Training and Certification Requirements

Obtain and Dedicate Commercial Grade Items for Nuclear Safety Applications

Perform Analysis and Trending

Perform Causal Analysis

Perform Effectiveness Reviews

Perform Extent of Condition Review

Perform Occurrence Notification

Perform SQA Assessments

Purchase Goods and Services Report, Track, and Close SSR Non-compliances

Respond to Notice of Violation

Screen Issues

11.1.3 Exhibits

Critical Items Inspection/Testing (Initial and Periodic)

11.1.4 Program Descriptions

Quality Assurance Program

Safety and Security Regulatory Compliance Assurance Program

Suspect/Counterfeit Items (S/CI) Program

11.1.5 Other

Acquisition Management System, Management System Description

Roles, Responsibilities, Accountabilities, and Authorities (R2A2s)

11.2 ORNL Facilities and Operations Procedures

The following ORNL Facilities and Operations procedures referenced in this document provide processes used by the MPEX QAPP when and where applicable.

S&I-ACP-100, *General and Special Receipt Inspection*

11.3 ORNL PAQ Procedures

The following ORNL PAQ procedures referenced in this document provide processes used by the MPEX QAPP when and where applicable.

PAQ-AP-003, *Supplier Evaluation Desk Review*

PAQ-AP-005, *Qualifying Auditors and Certifying Lead Auditors*

PAQ-AP-007, *Instructions for Conducting an At-Site Supplier Evaluation*

11.4 ORNL Systems

The following ORNL systems referenced in this document are used by the MPEX QAPP when and where applicable.

Assessment Commitment Tracking System (ACTS)

Electronic Records System (ERS)

Enterprise Document and Record Management System

Evaluated Supplier List (ESL)

Software Registration System (SRS)

Standards-Based Management System (SBMS)

11.5 Interfacing References

ASME NQA-1a-2008, *Quality Assurance Requirements for Nuclear Facility Applications*, Parts I and II

ASME NQA-1a-2009, Addenda to ASME NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications*

DOE O 414.1 D, *Quality Assurance*

12. ATTACHMENTS

Attachment A. *Governance and Implementing Documents*

ATTACHMENT A
GOVERNANCE AND IMPLEMENTING DOCUMENTS

MPEX NQA-1 Governance and Implementing Documents						
NQA-1-2008/2009a Requirement	**Applicability**				**Governing Document(s)**	**Implementing Documents**
	QL4	QL3	QL2	QL1		
Requirement 1 – Organization	●	●	●	●	ORNL QAPD Criteria 1, 10 MPEX QAPP, Section 7.1	- MPEX Organization Chart - ORNL SBMS subject area, "Stop Work" - ORNL SBMS program description, "Quality Assurance"
Requirement 2 – Quality Assurance Program	●	●	●	●	ORNL QAPD Criteria 1, 2, 10 MPEX QAPP, Section 8.0	- MPEX-11-PROC-001, *Document Control and Records Management Procedure* - ORNL SBMS procedure, "Training Records" - ORNL SBMS subject area, "Audits and Assessment" - ORNL SBMS subject area, "Roles, Responsibilities, Accountabilities, & Authorities (R2A2s)" - ORNL SBMS subject area, "Training of Staff" - PAQ-AP-005, *Qualifying Auditors and Certifying Lead Auditors*
Requirement 3 – Design Control		●	●	●	ORNL QAPD Criterion 6; MPEX QAPP, Section 8.2	- MPEX-11-PROC-001, *Document Control and Records Management Procedure* - MPEX-01-ENG-001, *MPEX Systems Engineering Plan* - MPEX-00-ENG-001, *MPEX Project Requirements* - MPEX-01-ENG-004, *MPEX Engineering Document Review and Approval Procedure MPEX-01/ENG-010, MPEX Document Review and Approval Matrix* - MPEX-01-PROC-ENG-XXX, *Design Control (TBD)* - MPEX-01-ENG-011-XXX, *Design Change Control Process* - MPEX-00-ENG-001, MPEX Project *Requirements* - MPEX-01-ENG-PROC-006, *Design and Analysis Calculations* - ORNL SBMS procedure, "Create Engineering Designs" - MPEX-11-PLAN-011 Configuration Management Plan for Material Plasma Exposure Experiment at ORNL - ORNL SBMS subject area, "Configuration Management" - ORNL SBMS subject area, "Design"

MPEX NQA-1 Governance and Implementing Documents						
NQA-1-2008/2009a Requirement	**Applicability**				**Governing Document(s)**	**Implementing Documents**
	QL4	QL3	QL2	QL1		
Requirement 4 – Procurement Document Control	●	●	●	●	ORNL QAPD Criterion 7; MPEX QAPP, Section 8.4	- MPEX-11-PROC-001, *Document Control and Records Management Procedure* - MPEX-11-PROC-003, *MPEX Supplier Document Management* - MPEX-01-ENG-003, *MPEX Statement of Work Development Guide* - MPEX-01-ENG-002, *MPEX Technical Specification Development Guide* - ORNL SBMS subject area, "Purchasing Goods and Services"
Requirement 5 – Instructions, Procedures, and Drawings	○	●	●	●	ORNL QAPD Criteria 4, 5; MPEX QAPP, Section 8.5	- MPEX-11-PROC-001, *Document Control and Records Management Procedure* - MPEX-01-ENG-012, *MPEX Engineering Drawing Procedure* - ORNL SBMS procedure, "Develop, Revise and Control Other Controlled Documents" - ORNL SBMS subject area, "Document Management"
Requirement 6 – Document Control	●	●	●	●	ORNL QAPD Criterion 4; MPEX QAPP, Section 8.6	- MPEX-11-PROC-001, *Document Control and Records Management Procedure* - ORNL SBMS procedure, "Develop, Revise and Control Other Controlled Documents" - ORNL SBMS subject area, "Document Management" - ORNL SBMS subject area, "Information Protection"
Requirement 7 – Control of Purchased Items and Services	●	●	●	●	ORNL QAPD Criterion 7; MPEX QAPP, Section 8.7	- ORNL SBMS Purchasing Quality-Significant (including PAAA) Materials/Services Decision Tool - ORNL SBMS Acquisition Management System - PAQ-AP-009, *Monitoring Performance of Evaluated Suppliers on the Evaluated Suppliers List (ESL)*
Requirement 8 – Identification and Control of Items	●	●	●	●	ORNL QAPD Criteria 5, 8; MPEX QAPP, Section 8.8	- *MPEX-12-PROC-002-, Material Receipt Inspection* - *MPEX-12-PROC-002, Acceptance of Items and Services* - *MPEX-12-PR0C-001, MPEX Acceptance Criteria List Procedure* - *S&I-ACP-100, General and Special Receipt Inspection*
Requirement 9 – Control of Special Processes	○	○	●	●	ORNL QAPD Criterion 5; MPEX QAPP, Section 8.9	- ORNL SBMS subject area, "Welding, Burning, and Hot Work"
Requirement 10 – Inspection		●	●	●	ORNL QAPD Criterion 8; MPEX QAPP, Section 8.10	- ORNL SBMS subject area, "Identify, Handle, Report, and Verify Suspect/Counterfeit Items and Defective Items"

						- ORNL SBMS subject area, "Inspection and Acceptance Testing"
Requirement 11 – Test Control		○	●	●	ORNL QAPD Criteria 8, 10; MPEX QAPP, Section 8.11	- ORNL SBMS subject area, "Inspection and Acceptance Testing"
Requirement 12 – Control of Measuring and Test Equipment	○	○	●	●	ORNL QAPD Criteria 5, 8; MPEX QAPP, Section 8.12	- ORNL SBMS subject area, "Calibration"
Requirement 13- Handling, Storage, and Shipping	○	○	●	●	ORNL QAPD Criteria 5, 8; MPEX QAPP, Section 8.13	TBD*

MPEX NQA-1 Governance and Implementing Documents						
NQA-1-2008/2009a Requirement	**Applicability**				**Governing Document(s)**	**Implementing Documents**
	QL4	QL3	QL2	QL1		
Requirement 14 – Inspection, Test, and Operating Status	○	○	●	●	ORNL QAPD Criterion 5; MPEX QAPP, Section 8.14	TBD*
Requirement 15 – Control of Nonconforming Items		●	●	●	ORNL QAPD Criteria 3, 10;	- ORNL SBMS subject area,

					MPEX QAPP, Section 8.15	"Nonconformance Control"
Requirement 16 – Corrective Action	○	○	●	●	ORNL QAPD Criterion 3; MPEX QAPP, Section 8.16	- ORNL SBMS subject area, "Issues Management and Analysis"
Requirement 17 – Quality Assurance Records	●	●	●	●	ORNL QAPD Criterion 4; MPEX QAPP, Section 8.17	- ORNL SBMS subject area, " Publications and Other Scientific Communications" - ORNL SBMS subject area, "Records Management"
Requirement 18 – Audits	○	○	●	●	ORNL QAPD Criteria 9, 10; MPEX QAPP, Section 8.19	- ORNL SBMS subject area, "Audits and Assessments" - PAQ-AP-005, *Qualifying Auditors and Certifying Lead Auditors*
Software Quality Assurance (NQA-1 Requirement 3 and Subpart 2.7)	○	○	○	●	ORNL QAPD – Software Quality Assurance; MPEX QAPP, Section 8.20	- ORNL SBMS procedure, " Determine SQA Applicability and Categorization" - ORNL SBMS subject area, "Software Quality Assurance"
Suspect/Counterfeit Items (DOE O 414.1D)	○	○	○	●	ORNL QAPD – Suspect/Counterfeit (S/CI) Items Prevention Process MPEX QAPP, Section 8.21	- ORNL SBMS procedure, "Identify, Handle, Report, and Verify Suspect/Counterfeit Items and Defective Items"
Risk Management (DOE O 414.1D)	○	○	○	●	ORNL QAPD – Risk Management MPEX QAPP, Section 8.22	- *MPEX-11-PROC-005, Risk Management Plan*

○ **Graded** applicability and implementation of NQA-1 requirements specified in the QAPP
● **Full** applicability and implementation of NQA-1 requirements specified in the QAPP
*** TBD:** To be determined