

PIP-II	Plans and Procedures	
	Document Title:	PIP-II Quality Assurance Plan
	Document Number:	pip2-doc-142

# Proton Improvement Plan II (PIP-II) Quality Assurance Plan

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## Acronyms

CQC	Corporate Quality Control
DOE	Department of Energy
FESHM	Fermilab Environment, Safety, and Health
FRS	Functional Requirements Specifications
ICD	Interface Control Documents
IPT	Integrated Project Team
KPP	Key Performance Parameter
L2M	Level 2 Manager
L3M	Level 3 Manager
LBNF	Long Baseline Neutrino Facility
PEP	Project Execution Plan
PIP-II	Proton Improvement Plan II
POG	Project Oversight Group
PPD	Project Planning Document
PQC	Project Quality Control
QA	Quality Assurance
QAP	Quality Assurance Plan
QC	Quality Control
SEMP	Systems Engineering Management Plan
SPM	Sub-Project Managers
TRS	Technical Requirements Specifications
WBS	Work Breakdown Structure

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### Reference Documents

1	<a href="#">Project Management Plan for The Proton Improvement Plan-II Project DocDB # 172</a>
2	<a href="#">PIP-II Preliminary Project Execution Plan (PPEP) DocDB #115</a>
3	<a href="#">Fermilab Quality Policy</a>
4	<a href="#">Fermilab Quality Assurance Program Document (QAM Chapter 12002)</a>
5	<a href="#">Fermilab Quality Assurance Manual (QAM)</a>
6	<a href="#">DOE O 413.3B – Program and Project Management for the Acquisition of Capital Assets</a>
7	<a href="#">DOE O 414.1D – Quality Assurance</a>
8	<a href="#">PIP-II Systems Engineering Management Plan (SEMP) DocDB #2480</a>
9	PIP-II Project Planning Document (PPD) (refer to PMP)
10	<a href="#">PIP-II Technical Review Plan (DocDB 2483), ED0008163</a>
11	<a href="#">Fermilab Safety and Health Policy</a>
12	<a href="#">Fermilab Graded Approach Procedure (QAM Chapter 12070)</a>
13	<a href="#">PIP-II Document Management and Control Procedure DocDB #2946</a>
14	<a href="#">Fermilab Document Management and Control Policy</a>
15	<a href="#">Fermilab Records Management Policy</a>
16	<a href="#">PIP-II Configuration Management Plan #2937</a>
17	<a href="#">Fermilab Engineering Manual</a>
18	<a href="#">Fermilab Environment, Safety, and Health Manual</a>
19	<a href="#">FESHM Chapter 2110 - Ensuring Equivalent Safety Performance when Using International Codes and Standards</a>
20	<a href="#">PIP-II Prevention through Design Implementation (DocDB 2237)</a>
21	<a href="#">PIP-II Mission Need Statement</a>
22	<a href="#">PIP-II Value Engineering Plan (DocDB 2830)</a>
23	<a href="#">PIP-II Procurement Management Plan (DocDB 522)</a>

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24	<a href="#">FRA Procurement Policy and Procedures Manual</a>
25	<a href="#">Fermilab Quality Assurance Manual Chapter 12020 - Suspect/Counterfeit Items (S/CI) Program</a>
26	<a href="#">Fermilab Software Quality Assurance Program (OAM Chapter 12003)</a>
27	<a href="#">Fermilab ESH&amp;Q Self-Assessment and Inspection Program (OAM Chapter 12080)</a>
28	<a href="#">PIP-II Quality Assurance (QA) and Quality Control (QC) Planning Template (DocDB 2566)</a>
29	<a href="#">Fermilab Work Smart Set of Standards</a>
30	<a href="#">PIP-II Interface Management Plan ED0007942</a>
31	<a href="#">Department of Energy Administrative Records Schedule 17: Cartographic, Aerial, Photographic, Architectural, Engineering, and Facility Management Records</a>
32	<a href="#">PIP-II Lessons Learned Process DocDB 2964</a>
33	<a href="#">PIP-II Nonconformance Handling Procedure DocDB 3100</a>
34	<a href="#">Fermilab Quality Assurance Manual Chapter 12100 – Incoming Material Inspection and Acceptance Testing</a>

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## 1.0 Purpose and Objectives

As per the *Project Management Plan for the Proton Improvement Plan-II (PIP-II) Project* [1], the goal of PIP-II is to enhance the capabilities of the existing Fermilab accelerator complex to enable the delivery of 1.2 MW beam power to the Long Baseline Neutrino Facility (LBNF) production target, while simultaneously providing a platform for subsequent upgrades of the accelerator complex to multi-MW capability, as outlined in the Mission Need Statement. The central element of PIP-II is a new 800 MeV superconducting linac accelerating H-ions. The scope also includes upgrades to the existing Booster, Recycler and Main Injector accelerators. The PIP-II Project is responsible for design, construction, installation, and commissioning of the superconducting linac, conventional facilities, beamline, and cryogenic infrastructure. PIP-II represents the first DOE accelerator project to be built on U.S. soil with significant international participation. PIP-II will be organized as a DOE/Fermilab Project incorporating contributions from International Partners. Fermilab retains the direct responsibility for the successful completion of the PIP-II Project, under the direction of the DOE Office of Science (DOE-SC). The management and project execution processes for PIP-II are described in the *PIP-II Preliminary Project Execution Plan (PPEP)* [2].

To assure the success of the PIP-II Project, the integration of quality is critical throughout the project lifecycle. Quality Assurance (QA) is an integral part of all aspects and phases of the Project such as research and development, design, procurement, fabrication, construction, transportation, installation, commissioning, transition to operations, as well as project management. This document serves as the Quality Assurance (QA) Plan for the Proton Improvement Plan II (PIP-II) Project. The purpose of the *PIP-II Quality Assurance Plan* is to define the quality management structure and expectations for the PIP-II Project and its Partners. It is intended to provide guidance for assuring the quality of work on the PIP-II Project, meet the expectations of the U.S. Department of Energy (DOE), and fulfill contractual obligations. Moreover, this QA Plan provides the structure for assuring that PIP-II requirements will be met and the risks of not meeting requirements will be minimized. The PIP-II QA Plan is to be considered as a living document and expected to be updated throughout the lifecycle of the Project. The objectives of the PIP-II QA Plan include:

- Integrating quality and reliability into all phases of the Project;
- Integrating Fermilab Quality Assurance principles into all levels of management;
- Assuring all personnel conducting PIP-II work, including personnel at Partners and FNAL vendors/subcontractors involved in the Project understand and adhere to the requirements set forth in this PIP-II Quality Assurance Plan;
- Promoting early detection of problems to minimize failures and impacts to cost and schedule;
- Assuring proactive identification and management of risks;

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- Developing appropriate processes and procedures to support design, procurement, fabrication, transportation, assembly, installation, and operational requirements;
- Assuring all personnel performing work on the PIP-II Project have the necessary training and qualifications prior to performing critical activities, especially those activities that have potentially programmatic, environmental, safety, security, health, or quality consequences.

## 2.0 Scope

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Work performed at Fermi National Accelerator Laboratory (Fermilab) is done in accordance with various institutional policies, including the *Fermilab Quality Policy* [3]. The *PIP-II Quality Assurance Plan* adheres to the *Fermilab Quality Policy*, the *Fermilab Quality Assurance Program* [4], the *Fermilab Quality Assurance Manual (QAM)* [5], the DOE O 413.3B – *Program and Project Management for Capital Assets* [6], and DOE O 414.1D – *Quality Assurance* [7]. The PIP-II QA Plan aligns with the *Project Management Plan for the PIP-II Project* [1] and requirements set forth by the *PIP-II Systems Engineering Management Plan (SEMP)* [8]. This QA Plan reflects the systems, controls, and measures incorporated by the PIP-II Project to manage, plan, assess, and improve processes to deliver operational and scientific excellence in a consistent environment with minimal risk. This plan applies to all work performed for the PIP-II Project, including work performed by Partners, FNAL vendors/subcontractors as defined by the *PIP-II Project Planning Documents* [9] and Contractual Agreements. QA Plans developed by Partners, FNAL vendors/subcontractors will govern the work in their areas of responsibility and must comply with the requirements set forth in this document. The quality requirements identified in this PIP-II QAP provide the framework for a results-oriented project management system that focuses on performing work safely, meeting Key Performance Parameters (KPPs), and DOE expectations while allowing the PIP-II Project Division, Partners, FNAL vendors/subcontractors to operate efficiently.

For work performed by personnel outside the PIP-II Project Division (Partners, FNAL vendors, subcontractors, and Fermilab support) management controls should be established, responsibilities assigned, and methods of communication identified.

A Quality Assurance Plan will be requested from PIP-II Partners as well as FNAL vendors and subcontractors. The respective QA Plans will be reviewed for adequacy by the appropriate PIP-II Project personnel. A risk-based, graded approach will be applied to the review for adequacy with the level of rigor expected in a robust quality plan.

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### 3.0 Specific Project Risks and Considerations

The PIP-II Project is uniquely structured where it will incorporate significant in-kind contributions from International Partners. Per Project risk mitigation strategies, these in-kind contributions represent an opportunity to significantly advance the project schedule by reducing the funding required from the U.S. Department of Energy and by mitigating competition for resources within Fermilab. These opportunities are accompanied by a variety of risks that derive from the nature of the international partnerships, including cost, schedule, and performance risks.

Risk mitigation strategies includes:

Jointly agreed upon requirements and specifications for international deliverables:

- The Project utilizes Functional Requirements Specifications (FRS), Technical Requirements Specifications (TRS), Interface Control Documents (ICDs), and other technical documents to define requirements at the system or component level.

Demonstration of international partners' capabilities through the project development phase:

- The primary goal of the Project development phase is to establish capabilities among the International Partners aligned with their construction phase deliverables.

Verification of designs through formalized review processes:

- All design development and implementation follow a step-based process of Preliminary Design Review, Final Design Review, Procurement Readiness Review, Manufacturing Readiness Review, and in some cases Operational Readiness Clearance. These review processes are defined in the PIP-II *Systems Engineering Management Plan (SEMP)* [8] and *PIP-II Technical Review Plan* [10].

Active coordination by technical managers:

- The PIP-II project has designated Sub-Project Managers (SPMs) to serve as the technical points of contact with International Partners at the systems level.

Integration:

- The PIP-II Integration Team is charged to assure integration during the design process by ensuring the PIP-II project designs are compatible. The *PIP-II Configuration Management Plan* [16] describes the control, documentation, communication, and implementation of changes to the PIP-II Project baselines for design. The *PIP-II Interface Management Plan* [30] describes the process for managing systems level technical interfaces for the PIP-II Project.

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## 4.0 Resources and Communication

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### 4.1 Roles, Responsibilities, and Authorities for Quality Assurance

The *Project Management Plan for the PIP-II Project* [1] and this *PIP-II Quality Assurance Plan* define the roles, responsibilities, and authorities for personnel who manage, plan, perform, and verify work that affects quality. The *PIP-II Preliminary Project Execution Plan (PEP)* [2] describes the organizational and management oversight structure. The roles and responsibilities addressed in this plan include the following:

#### PIP-II Project Director (PD)

- Responsible for the successful execution of the PIP-II Project, in conformance with the requirements of DOE O 413.3B – *Program and Project Management for the Acquisition of Capital Assets* [6] and other applicable orders, and meeting the established goals for quality, technical, cost, schedule, safety, and environmental performance.
- Provides programmatic leadership, strategic planning, and general oversight of the PIP-II Project, and serves as the primary point of contact to external stakeholders, Partners, and collaborators.
- Responsible for ensuring that quality requirements are flowed down to all Partners and FNAL vendors/subcontractors as appropriate, and that performance is monitored throughout the course of the Project, and actions taken as necessary.

#### PIP-II Technical Director (TD)

- Reports to the PIP-II Project Director and has the responsibility and authority of all elements of the *Systems Engineering Management Plan* [8].
- Responsible for ensuring the SEMP aligns with this PIP-II QA Plan and appropriate quality elements are integrated in the SEMP.
- Leads the PIP-II Technical Integration Office which is responsible for the management of the SEMP throughout the lifecycle of the Project. The execution of the SEMP is the responsibility of all personnel and participants of the PIP-II Project under the coordination of each WBS Level 2 Manager.

#### PIP-II Project Manager (PM)

- Reports to the Project Director and has the responsibility and authority to manage the PIP-II Project to the approved scope, cost, and schedule.
- Responsible for identifying the necessary resources and filling vacancies with qualified personnel.
- Responsible for overseeing the financial, risk management, procurement, and logistics functions for the Project and ensuring appropriate integration of quality into those functions.

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**PIP-II Quality Assurance Manager**

- Reports to the PIP-II Technical Integration Office and is responsible for the development, implementation, assessment, and continual improvement of this QA Plan.
- Responsible for the integration, communication, and improvement of the requirements established within this plan in close collaboration with the Project Director, Project Manager, Level 2 Managers, Level 3 Managers, and Technical Integration Office.
- Responsible for ensuring compliance with this QAP is periodically assessed.

**PIP-II Quality Engineer**

- Reports to the PIP-II QA Manager and supports the QA Manager with the implementation and improvement of this plan.
- Works closely with the Level 2 and Level 3 Managers to assure implementation of the requirements established in this plan in their respective Systems and Subsystems.
- Responsible for developing implementing quality procedures, guidance, and training in alignment with this QA Plan.
- Responsible for overseeing the PIP-II Nonconformance Handling process; and monitoring identified nonconformances and identifying trends to escalate to the QA Manager for further action and resolution.

**PIP-II Level 2 Managers (L2Ms)**

The PIP-II Level 2 Managers (L2Ms) are also referred to as System Managers per their responsibility of a PIP-II System. They are chosen for their technical abilities and expertise and are responsible for implementing the requirements established in this QA Plan within their project Subsystems. The L2Ms are the designated design authority.

- Responsible for defining and implementing System-level QA Plans which describe the quality requirements of the respective Systems in alignment with this QA Plan.
- Responsible for communicating the System-level QA Plan requirements to their Level 3 Managers (L3Ms) for implementation in their respective Subsystems.
- Responsible for ensuring the PIP-II Partners and FNAL vendors/subcontractors meet the requirements established in this QA Plan for their respective scope of work via their own documented and accepted Quality Assurance and Quality Control documents which shall subsequently be reviewed prior to the start of work. This responsibility may be delegated to L3Ms or SPMs based on defined roles and responsibilities.

**PIP-II Level 3 Managers (L3Ms) and Sub-Project Managers (SPMs)**

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- Responsible for ensuring the expectations highlighted in this QA Plan are implemented throughout their respective Subsystems.
- Responsible for ensuring PIP-II Partners and FNAL vendors/subcontractors meet the requirements established in this QA Plan for their respective scope of work via their own documented and accepted Quality Assurance and Quality Control documents which shall subsequently be reviewed prior to the start of work.
- Responsible for immediately communicating issues or adverse conditions that may negatively impact safety, quality, technical performance, cost, or schedule.
- Responsible for developing Quality Control (QC) Plans for each deliverable within their areas of responsibility and promote collaboration with the Partners. The status of the L3 QC Plans shall be tracked via their corresponding systems QC Plan Tracker.

#### **PIP-II Project Division and Fermilab Matrixed Personnel**

- Responsible for complying with all applicable policies, procedures, and training requirements relative to the PIP-II Project. All employees are expected to stop work when conditions adverse to quality or safety require immediate corrective action. The Stop Work Authority applies to all PIP-II activities, and is intended to prevent any work, activity, or process that jeopardizes quality, personnel safety, health, or has the potential for adverse environmental impact. Stop Work Authority is one of the mechanisms used to ensure that planning or scheduling considerations do not override safety, health, environmental, or quality considerations.

#### **PIP-II Partners, FNAL Vendors and Subcontractors**

- Responsible for complying with the requirements established in this QA Plan and related documents.
- Responsible for ensuring that all technical and contractual requirements are met, and related work is performed in accordance with applicable codes, standards, and regulations.
- Personnel assigned to work related to PIP-II deliverables are adequately trained and have the responsibility to immediately communicate nonconformances or conditions adverse to quality, safety, or ability to meet technical requirements to their respective PIP-II L3M and respective Sub-Project Manager (SPM) for appropriate containment and corrective action planning. All requirements agreed upon in PIP-II Partner Project Planning Documents should be adhered to and deviations should be communicated to the Project, discussed, and approved by the Project. Refer to the Project Management Plan [1] for details relating to the Project Planning Documents.

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#### 4.1.1. PIP-II Organization Chart

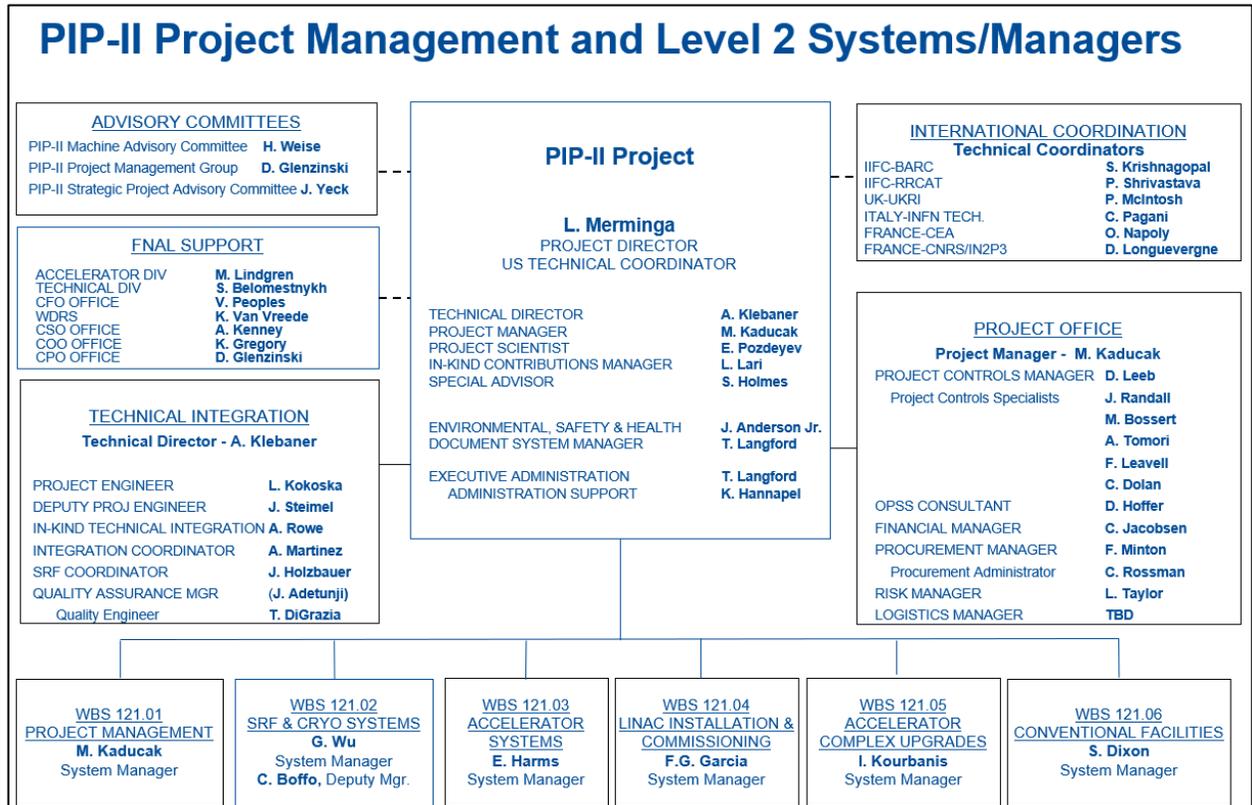


Image 1.0 - PIP-II Organization Chart v 27 Dec 2019 – PIP DocDB 2309

#### 4.2 Communication Management

Effective communication is imperative to the success of any program and it is especially imperative to the success of the PIP-II Project. The complexity of the structure of the PIP-II Project relies on effective communication. Communication management provides a structure to keep all personnel abreast of the current state in the Project including but not limited to cost, schedule, issues, risks, and achievements. It also provides a structure to create effective communication between the Project and its international Partners, FNAL vendors/subcontractors.

The PIP-II Project Director is responsible for defining the communication plan for the Project in collaboration with Partners. The development of the plan includes identifying the types of communication needed by Project stakeholders and participants. The Project participates in monthly Project Oversight Group (POG) meetings that communicates high-level project status and issues to the Laboratory Director and other laboratory stakeholders. The monthly Project Management Group (PMG) meetings communicate project details such as cost,

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schedule, technical, safety, and quality to lab management as well as other stakeholders. The Project’s communication plan should also include the expectations with international Partners due to their various work scopes, location, and personnel. The communication plan should include information the Project needs to stay well-informed on topics such as milestones, technical or engineering issues, personnel changes, job site location changes/infrastructure changes, facility issues, hold points, third party supplier issues, safety, and quality. The plan should also specify the medium in which the communication should occur, such as email, memo, formal status reports, meetings, online databases, project websites, for example. Communication planning is to be performed by the PIP-II Project Director, Technical Director, Project Manager, L2M/System Managers, and L3Ms. The communication plan must be developed and agreed upon per Partner unless otherwise noted by the Project Director.

## 5.0 Competence, Awareness, and Training

It is a requirement of the PIP-II Project that qualified personnel who possess the appropriate level of skill, experience, and academic qualifications are in place to support the achievements of the Project mission and performance objectives. The PIP-II Project Director is responsible for ensuring that all Project personnel are qualified and capable of performing assigned work in a safe and efficient manner and delegates this responsibility to the Project Manager and L2Ms for their respective work areas.

Personnel qualifications are based on factors such as the following:

- Previous experience, education, and training
- Performance demonstrations or tests to verify previously acquired skills
- Completion of training or qualification programs
- On-the-job training and continuing education as needed
- Training programs to introduce processes and controls (including prevention, detection, and disposition of Suspect and Counterfeit Items (S/CIs))

The L2Ms should have adequate verification methods to ensure that only adequately trained, qualified, and certified personnel are involved in the design, procurement, fabrication, testing, installation, and commissioning of components and systems.

FNAL employees and users from partnering institutions working at Fermilab receive training in accordance with the *Fermilab Safety and Health Policy* [11]. Personnel conducting work at partnering institutions are trained in accordance with the policies of those institutions. However, it is the PIP-II Project Director’s responsibility to ensure that adequate methods are in place to verify that only properly trained and qualified personnel are assigned to tasks related to PIP-II deliverables associated with a partnering institution. Where special safety or technical training is required, the associated Project Planning Document (PPD)

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should explicitly state these requirements along with the expectations for the Partner to fulfill these requirements. For example, welding activities must only be performed by qualified welders and weld inspectors.

The training needs of Fermilab employees and Fermilab users are identified via the Fermilab Individual Training Needs Assessment (ITNA) process. The training needs assessment is performed by the employee/user’s managing supervisor or approved delegate in the Fermilab Training Management database (TRAIN). It is imperative for the managing supervisor or approved delegate to be fully aware of the tasks being performed by the employee or user for the PIP-II Project to ensure that adequate training needs are identified and met.

Partners and FNAL vendors/subcontractors are required to provide their quality program documentation which should reflect their respective training program requirements. The PIP-II Project has the responsibility to ensure that only adequately trained and qualified personnel are involved with work related to the PIP-II Project. Circumstances may arise where training records of individuals tasked to work on PIP-II deliverables may be requested to review and verification by the PIP-II Project. Partnering institutions and FNAL vendors/subcontractors should immediately communicate changes in key personnel or qualified individuals assigned to PIP-II deliverables. This communication allows the Project to adequately assess the risks associated with the change and determine the related mitigations.

## 6.0 Graded Approach

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The PIP-II Project Team applies quality requirements using a graded approach. The Project refers to the *QAM Chapter 12070 – Graded Approach Procedure* [12]. The graded approach is designed to impose levels of control commensurate with the consequences of failure or occurrence of an adverse event. The graded approach is a process by which the level of analysis, documentation, and actions necessary to comply with requirements are commensurate with the following, but not limited to:

- Relative importance to safety, safeguards, security, or quality;
- Magnitude of any hazard involved as identified, analyzed, and controlled;
- Lifecycle stage of the facility/activity or Project;
- Impact/consequences on programmatic mission of the facility/activity or Project;
- Particular characteristics of the facility/activity or Project;
- Complexity of products or services involved;
- Environmental consequences and level of resource protection required;
- History of issues at a site, facility, or Project;
- Experience and expertise at Partnering institutions and vendors/subcontractors;

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- Level of risks related to activity, component, system, or deliverable

Application of the graded approach entails:

- Identifying activities that present significant Environment, Safety, & Health (ES&H), Security, or Quality risk.
- Defining the activity.
- Evaluating risk and control choice.
- Documenting and agreeing upon the application of the graded approach.

## 7.0 Quality Improvement & Lessons Learned

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The quality improvement framework for PIP-II encompasses issue prevention, detection, correction, and continuous improvement via the use of Lessons Learned and issues management (i.e. the handling of non-conformances or subpar results that could impact requirements). The quality improvement framework is applicable to all phases of the PIP-II, and the PIP-II management team is responsible for encouraging Project employees, Partners, and FNAL vendors/subcontractors in the quality improvement process by fostering a no-fault attitude. The PIP-II Project Director has the overall responsibility for quality improvement throughout the Project and is supported in this effort by the PIP-II QA Manager, the PIP-II Project Office, the PIP-II Technical Integration Office, and the L2Ms/System Managers. At the project level, the Project Director, in close collaboration with the Quality Manager, takes steps to detect and prevent quality problems, identify the cause and correction of quality issues, and provide input for improvement. At the subsystem level, these responsibilities belong to the Level 2 Managers. The Level 2 Managers are responsible for developing and documenting processes, making technical specifications for subsystem elements and executing QA procedures to ensure that products and procured items conform to these specifications.

The PIP-II Project has a defined approach to managing issues and nonconformances in the *PIP-II Nonconformance Handling Procedure* [33]. A graded approach is defined for the reporting and resolution of issues and nonconformances from the Partner or FNAL vendor/subcontractor to the appropriate L3M for the PIP-II scope of work. The handling of nonconformances shall be defined in the Partner QA Plans, and FNAL vendor/subcontractor plans, and aligned with the requirements of the PIP-II QA Plan and subsequent procedures.

Achieving quality is a line responsibility. The Project encourages personnel to minimize the occurrence of issues and improve performance by following established processes and identifying methods to improve existing processes. Processes in place to detect and prevent quality problems will be established, including:

- Technical Reviews;

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- Prevention-through-design (PtD);
- Incoming inspection and testing;
- In-process inspection/testing/hold-points;
- Equipment inspections, calibration, and verifications;
- Configuration Management;
- Work planning and control; and
- Self-assessments.
- Feedback

PIP-II will evaluate lessons learned from various projects, laboratories, programs, internally, as well as from Partners to determine opportunities to improve and strengthen the Project. The goal is to promote desirable outcomes, prevent unwanted outcomes, and minimize the impact of consequences to unwanted outcomes. It is imperative for the Project to establish clear and effective lines of communication between Partners for transparency and the reciprocity of information.

Inputs to the Lessons Learned Program include:

- Best Practices
- Nonconformances or Opportunities for Improvement
- Nonconformances at Partners and FNAL Vendors/Subcontractors
- Process Breakdowns/Gaps
- Safety Incidents / Near Misses
- Prevention-through-Design Implementation
- Cost Savings
- Other Projects' issues, opportunities, and lessons learned
- Formal Project Reviews
- Internal Project Reviews
- Assessments/Effectiveness Reviews
- [DOE OPEXShare](#)

The Lessons Learned roles, responsibilities, and expectations are defined in the *PIP-II Lessons Learned Process* [32]. Lessons learned will be documented on the PIP-II at work SharePoint site. The lessons learned will be evaluated by the PIP-II Quality Team, respective L2 Manger, and other SMEs to determine if actions will be taken.

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## 8.0 Documents, Records, and Configuration Management

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### 8.1 Document and Data Management

The PIP-II Project determines which documents require document control as part of the *PIP-II Document Management and Control Procedure* [13]. These documents are controlled for reasons such as traceability, historical, personnel safety, and/or legal purposes. These and other documents are maintained in a document database or Teamcenter which is accessible via the internet and is password-protected. Depending on their level of sensitivity, documents may or may not be accessible to the public and may even have restricted access within the Project and Partners. The Fermilab Core Computing Division maintains the software, administers the computing platforms, and performs backups of the database. Through these databases, each project document is assigned a unique identification number and its versions are tracked by date and submitter, with a record of the changes made. Databases managed by Partnering Institutions are not subject to Fermilab's *Document Management and Control Policy* [14].

### 8.2 Records Retention and Disposition

Records created by the PIP-II Project must be retained in accordance with the *Fermilab Records Management Policy* [15]. Records provide the permanent objective evidence that the PIP-II was designed and constructed in accordance with approved plans, specifications, and requirements. The types of PIP-II records that will be maintained include, but are not limited to:

- Training Records
- Technical Design Reports (TDRs)
- Design Review Documentation
- Meeting Minutes
- Design Verification Records
- Supplier Evaluations
- Design Drawings and Specifications
- Design Change Notices
- Assessment Reports
- Installation Inspections & Testing Records
- Measuring & Test Equipment (M&TE) Calibration Records
- Nonconformance Reports
- Corrective Action Documentation
- Manufacturing Inspection Plans (MIPs)
- Inspection & Test Records
- Completed Travelers
- Procurement Plans & Packages

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Partner Institutions are not subject to the *Fermilab Records Management Policy* [15], however, records generated as part of the PIP-II Project are subject to the Policy.

All records generated as part of the PIP-II Project shall also follow the Department of Energy's Administrative Records Schedule (ADM) 17 [31].

### 8.3 Configuration Management

Configuration Management is an essential element of quality management in the PIP-II Project. The *PIP-II Configuration Management Plan* [16] defines the Project's process for the systematic control, documentation, communication, and implementation of changes to the PIP-II Project baselines for design, cost, and schedule during the project lifecycle ending at CD-4. It provides traceability of requirements from preliminary design to final design to deployment.

A graded approach will also be defined and applied to software developed by the Project and to software developed by Partners for use by the PIP-II Project. Appropriate configuration management controls ensure the following requirements are met:

- Software releases are identified, controlled, and available,
- Changes to identified software releases are controlled and documented,
- Software standards adhere to industry recommendations, and
- Affected groups and individuals are informed of the status and content of software.

SQA is further discussed in Section 13.0.

## 9.0 Performance Criteria

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### 9.1 Design

The designs relating to the PIP-II Project will use sound engineering and scientific principles and appropriate standards as defined in the *Fermilab Engineering Manual* [17]. Processes have been established to provide requirements for the control of design inputs, outputs, verification, configuration changes, and technical and administrative interfaces that pertain to the importance of the design. Design verification is conducted via design reviews and is essential to prevent rework and ensure requirements can be achieved.

The design criteria implemented by the PIP-II Project are as follows:

- Design items and processes using sound engineering/scientific principles and appropriate standards.
- Incorporate applicable requirements and design basis in design work and design changes.

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- Identify and control design interfaces.
- Verify or validate the adequacy of design products using individuals other than those who performed the work.
- Verify or validate the work before approval and implementation of the design or changes to the design.
- Verify in-process testing, verification, and validation methods will assure that requirements will be met.

Changes related to the design are addressed in the *PIP-II Configuration Management Plan [16]*.

Equipment designed by Project personnel follows federal codes, the Fermilab Environment, Safety and Health Manual (FESHM) [18], Fermilab Work Smart Set of Standards [29], and other Laboratory standards, and accepted, applicable industry standards. Applicable engineering standards are cited in the Fermilab Engineering Manual [17] which includes technical instructions, national standards, and codes. Standards and guidelines related to safety are found in the FESHM. The PIP-II Project will adhere to the requirements set forth in the Fermilab Environment, Safety, and Health (FESHM) Chapter 2110 – *Ensuring Equivalent Safety Performance when Using International Codes and Standards [19]*. This FESHM chapter describes the process used to establish equivalent safety performance between U.S. and International engineering design codes and standards. This will enable the Laboratory to accept in kind contributions from International partners or purchase equipment designed per International standards while assuring an equivalent or greater level of safety. The PIP-II Project also employs Prevention through Design (PtD) to minimize hazards and risks early in the design process. The implementation of this methodology is outlined in the *PIP-II Prevention through Design Implementation* document [20]. All work is performed in accordance with Fermilab’s Work Smart Set of Standards [29], which are mandated in the Fermi Research Alliance Prime Contract with the Department of Energy. Any deviations from an FNAL requirement or standard will be handled on a case-by-case basis. FNAL will ultimately approve any deviations.

In instances where the Partner is executing the design of a particular PIP-II scope of work, Partners are required to submit any design changes to Fermilab for review and approval prior to proceeding. All design changes should be communicated and approved via appropriate design change control processes outlined in the *PIP-II Configuration Management Plan [16]*. All design work managed by partnering institutions are subject to the requirements established in the *PIP-II Configuration Management Plan [16]*. Refer to the Image 2.0 below.

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## Simplified PIP-II Change Control Flow Chart

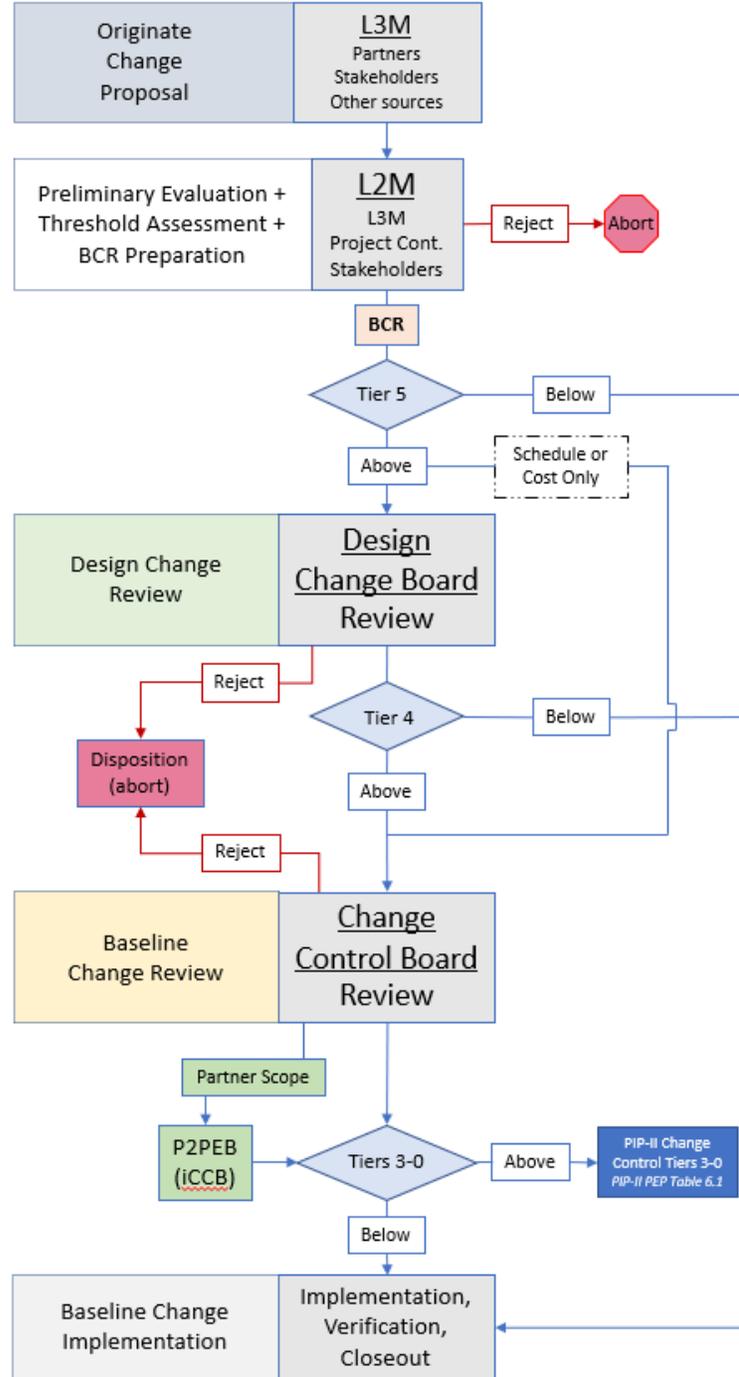


Image 2.0 - Consolidated PIP-II Change Control Process Flowchart (documented in the PIP-II Configuration Management Plan)

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### 9.1.1 Design Requirements & Requirements Control

The overall requirements framework for the PIP-II Project are established in the *PIP-II Mission Need Statement* [21]. The technical approach and Key Performance Parameters are outlined in the *PIP-II Project Execution Plan* [2]. The *PIP-II Systems Engineering Management Plan* [6] describes the requirements flow-down structure. Design control processes outlined in the *PIP-II Configuration Management Plan* [16] ensure that design input requirements are correctly translated into drawings and specifications. Design input/output alignment, including drawings, calculations/analyses, specifications, and supporting documentation, are integral parts of the design verification process and are performed during various phases of design. Constructability, Partner/FNAL vendor/subcontractor capability/performance/experience, component and system attainability, reproducibility, testability/acceptability, maintainability, sustainability, product acceptance testing, and inspection requirements will also be determined in the design phase. All requirements, specification documents, and drawings for the PIP-II systems, subsystems, and components are defined, formally approved, and maintained as controlled documents in Teamcenter.

### 9.1.2 Design Interface

Design interfaces are identified and controlled via Interface Control Documents (ICDs) as defined in the *PIP-II Systems Engineering Management Plan* [6]. The ICDs define the boundaries between one or more systems/subsystems as defined in the Project's Global Requirements Document. The interfaces between the partnering institutions and PIP-II L2M/System Managers are also defined in the ICDs. The controls include a description of responsibilities associated with the development, review, approval, release, distribution, revision, and management of design tasks. The PIP-II Integration Team is responsible for interface management across systems as described in the *PIP-II Interface Management Plan* [30].

### 9.1.3 Design Review

Technical design reviews are an essential feature of the quality management process. Formal design reviews are performed as defined in the *PIP-II Technical Review Plan* [10]. Design reviews are internal to the project and are conducted for the system, subsystem, and critical components at major milestones in the development and production processes. The level of a design review will be commensurate with complexity, cost, or safety importance of the design. Design reviews are attended by representatives who are independent of the work and concerned with the design including quality and safety aspects. For technically critical components, outside subject matter experts may be appropriate. Recommendations and actions identified from design reviews are recorded and tracked for consideration or action, and the

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appropriate follow up to be validated at subsequent reviews. While design reviews are primarily technical in nature and independent of management, cost, and schedule reviews, effective value engineering practices are an integral part of the design review process. The *PIP-II Value Engineering Plan* [22] document has been established and provides the methods employed by the Project to identify Value Engineering opportunities across the Project.

#### 9.1.4 Design Verification and Validation

Verification and Validation are important components of design quality assurance. Verification and validation plans and procedures are developed to ensure PIP-II Project systems, subsystems, and components have been adequately tested to ensure the final devices function in compliance with their requirements and intended use. All designs shall have pre-defined design acceptance and verification criteria. Design acceptance and verification criteria are defined early in the design cycle and focus on design features impacting safety and performance of a particular component or subsystem. A graded approach is used for design verifications where the design will be verified to an extent commensurate with its importance to safety, complexity of design, degree of standardization, uniqueness, and proven design approach. Verification activities will help to determine whether the system meets requirements and can include:

**Requirements Traceability** – Each requirement (defined in the Requirements Document) are verified through inspection, test or analysis, or a combination of these methods.

**(Design) Failure Mode and Effect Analysis (DFMEA)** – An analysis used to initially identify design function and possible failure mode and their effects on the scope of work or overall Project with corresponding severity and mitigations.

**Evaluation Criteria** – Design acceptance and verification criteria defined to ensure design adequately meets requirements.

**Test Procedures** – Test procedures are the actual step-by-step processes that are run to ensure the component, device, or assembly meets its requirements. Test procedures include inspection, confirmation and testing. The PIP-II Project will use travelers and other agreed upon methods for test procedures.

**Test Records** – Test records will be documented on data sheets and should include the test procedure, test results, and acceptance and verification criteria.

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**Qualification Tests** - May be used to verify adequacy of the design or portions of it in conjunction with other verification methods. These tests are conducted using approved procedures and include acceptance criteria that verify or validate acceptability of specific design features. Qualification tests are conducted on a timely basis under conditions that simulate the most adverse design conditions. Determination of the most adverse conditions takes into consideration operating modes and environmental conditions in which the item being tested is required to perform satisfactorily. Test results are documented, evaluated, approved, and retained. Equipment or components are put into operation only after successful completion of qualification tests.

**Requirement Verification Matrix** – Used to track what method will be used to validate each requirement ID. Also provides the verification plan and a list of any applicable documents.

Validation of design is concerned with checking that the system will meet the overall goals and parameters of the PIP-II Project. Design validation follows successful design verification. Designs shall be validated via Design Reviews before procurement, manufacture, or construction, and no later than acceptance and use of the item, in order to ensure the design:

- Meets the design-input requirements,
- Refers acceptance criteria, and
- Identifies those design characteristics that are crucial to the safe and proper functioning of the equipment or system.

Each independent inspection, test, or review will feed the evaluation process, which is a comparison of results with acceptance criteria to determine acceptance or rejection, or the need for corrective action. In some cases, the outcome may be to seek adjustments to requirements.

The formality of reporting will escalate as the significance of the review or test increases. Higher levels of Fermilab or Partner management should be aware of and participate in the correction of the most significant problems. Required design analyses and calculations will be performed and documented.

The Quality Assurance Plans from Partners and FNAL vendors/subcontractors should include verification and validation plans and procedures applicable to their respective scope of work. The linkage to the associated L2 System Quality Assurance Plan demonstrates traceability and effective collaboration which is imperative to the success of the PIP-II Project.

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### 9.1.5 Design Records Management

Procedures, agreements, and subcontract terms provide for collection, storage, and maintenance of design documentation and records, and shall be stored with the project files as defined in the *PIP-II Document Management and Control Procedure* [13]. Design records provide evidence that the design and design verification processes were adequately performed and can include the following as a minimum:

- Design input documents
- Documents prepared during critical design steps
- Calculations and design analyses
- Self-Assessments
- Design verification activities
- Formal design review report
- Computer simulations
- Design change documents
- Final design output and revisions
- Requirements, specifications, and drawings
- Quality inspections and tests; travelers
- Manufacturing inspection plans
- Acceptance tests

## 10.0 Procurement

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The *PIP-II Procurement Management Plan* [23] describes how the PIP-II Project will obtain goods and services required to successfully accomplish the goals of the Project. All FNAL procurements follow the processes and procedures established in the *FRA Procurement Policy and Procedures Manual* [24]. These procedures provide a detailed methodology for preparing, reviewing, and approving purchase requisitions, amendments to requisitions, procurement specifications, bid packages, and other procurement documents. These procedures ensure procured items and services meet established requirements and perform as specified.

Technical, administrative, quality, and safety requirements applicable to items or services being procured are identified and specified in procurement documents. These requirements include applicable codes, regulations, industry standards, tests, inspections, traceability, and special procedures or instructions. Procurement documents identify acceptance methods and criteria for acceptance or rejection of items or services. Items or services shall not be received until the criteria set forth by the procurement document has been reviewed and accepted. Procurement documents for items or services critical to safety, or having significant operational risks, identified via the technical requirements, are reviewed by the PIP-II ESH Manager, the responsible L2/L3 Manager, and/or a laboratory subject matter expert (SME).

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The procedures provide specific requirements and guidelines to initiate purchase requisitions, procurement specifications, and other procurement documents. These procedures define appropriate controls for the selection, suitability determination, evaluation, and receipt of items or services being procured. The Procurement program includes a process for procuring off-the-shelf, commercial grade items and dedicating these items for safety-related applications. Diligence is required by the responsible L2, L3, or designated PIP-II Project personnel defining the critical characteristics of the item and associated verification requirements. These items are subjected to specific inspections, tests, and/or evaluations to ensure they meet requirements and will perform properly in the safety-related application.

Fermilab has established procedures and processes to ensure the required clauses, policies, provisions, guidance, scopes of work, directives, and other terms and conditions are contractually flowed down to subcontractors. Additionally, procedures and processes are in place to provide tools and training to enforce appropriate subcontract performance. These procedures are written to ensure that three essential elements are provided in all subcontracts. These three elements are clear specifications and work scope, pre-qualification of FNAL vendors/subcontractors, and adequate oversight processes. Roles and responsibilities for the various exhibits/subcontract documents are specifically identified.

### 10.1 FNAL Vendor Selection and Evaluation

FNAL vendor selection and evaluation applies to the procurement of items, goods, and services that require rigorous procurement and inspection processes to prevent significant personal injury to the workforce and the public, environmental non-compliance, and to ensure requirements are adequately met. Prospective FNAL vendors/subcontractors are evaluated and selected on the basis of specified criteria, using a graded approach. Items or services are procured from FNAL vendors/subcontractors whose evaluation results satisfy the requirements of the procurement specifications and the demonstrated ability of potential FNAL vendors/subcontractors to provide acceptable items and services. The evaluation will include input from the PIP-II QA Manager, the PIP-II ESH Manager, the L2/L3 Manager, and other relevant SMEs. For procured products/services the vendor will be asked to submit a Quality Assurance Program description or Quality Assurance Plan and Quality Control (QC) Plan relative to the scope of work to effectively demonstrate the ability to produce quality products and meet requirements. These documents shall be reviewed by the PIP-II QA Manager, L2/L3 Manager(s), and other SMEs. Reviews of vendor's documentation and on-site assessments of the vendor's capabilities may be used for vendor selection based on the nature and application of items and services being procured. In addition, post-award audits may be performed on selected vendors/subcontractors to verify compliance with the procurement requirements.

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There is an expectation that PIP-II Partners and vendors/subcontractors possess or establish an adequate vendor selection or qualification and evaluation process as part of their respective procurement processes. Evaluation criteria for PIP-II work at Partners will be created using a collaborative approach by the Partner point of contact or Sub-project Coordinator, the appropriate L2M/L3M/SPM, and other SMEs. The PIP-II QA Manager in conjunction with L2M/L3M and SMEs will work closely with PIP-II Procurement personnel to ensure the evaluation criteria is established and communicated. This framework described in the *PIP-II Procurement Management Plan [23]* is to ensure that materials procured by Partners and/or vendors/subcontractors for use in PIP-II scope of work meet PIP-II Project requirements and thus minimizing risks to quality, safety, or performance. These processes should be reflected in the Partner Quality Assurance Plans, as well as FNAL vendor/subcontractor's Quality Assurance Plans, and should align with the requirements established in this PIP-II Quality Assurance Plan.

## 10.2 Product Acceptance

Processes shall be established and implemented to ensure services, product, or components received are acceptable. For work performed by a Partner, it is an expectation that a Partner QA is developed which defines how the requirements contained in this section will be applied to the specific scope of work. Quality-related procedures may be requested of PIP-II Partners for review by the PIP-II QA Manager and other SMEs. For work performed by an FNAL vendor, it is an expectation that the vendor submits a QA or QC Plan applicable to the scope of work for review and acceptance by the PIP-II QA Manager, L2M/L3M, or other SMEs during the FNAL vendor technical evaluation process. Associated Quality-related procedures may be requested for review.

The quality of in-kind contributions, purchased items, and services is verified at intervals during various phases of the fabrication or procurement process. Frequency or necessity of validation is determined by evaluation criteria requirements; applicable specifications, codes, and standards; uniqueness, complexity, application of the item; quantity and frequency of the procurement; and previous quality-related experience by the Partner or performance by the vendor. In instances where the Partner is executing the design for the work they perform, it is the responsibility of the Partner to seek Fermilab approval for any changes to the design prior to proceeding with the procurement process.

Items are accepted by one or more of the following methods: Source Verification, Receiving Inspection, or Post-Delivery Testing. Procured services may be accepted by the review and technical validation of data or reports produced, performance, or surveillance or audit of the activity. In-Kind contribution items may be accepted by the completion of pre-defined

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acceptance evaluation criteria. Receiving inspection and performance verification tests are established by the PIP-II SMEs based on requirements.

Quality control activities are achieved by use of in-house expertise as well as by procured services from qualified FNAL vendors/subcontractors. Purchased items, including off-the-shelf, commercial-grade, are routinely inspected for potential suspect or counterfeit part characteristics (refer to Section 10.3). If identified as a potential suspect or counterfeit part, the items are evaluated by the Fermilab Suspect/Counterfeit Item personnel and dispositioned as non-conforming items. There is an expectation for Partners and FNAL vendors/subcontractors to have a process for monitoring and handling S/CI items to prevent quality, safety, or performance issues in work performed under the PIP-II scope.

Procured items are put into service when the acceptance criteria have been satisfied. If an item does not meet a specified requirement, or has a documentation deficiency, a nonconformance or alternative reporting document is initiated to document such deficiency. Identified deficiencies are dispositioned and corrective action is taken and verified prior to use of the item. Information from these nonconformances and deficiency documents is used to identify possible trends or concerns that should be addressed with greater attention.

Post-maintenance, functional, or pre-operational testing is performed after installation of received items, when specified. These tests verify actual performance of the item against established criteria for the item and the system. Tests, inspections, and preventive maintenance programs monitor the performance of the item against established criteria, as applicable.

### 10.3 Suspect/Counterfeit Items

Guidance to help avoid the procurement and use of suspect/counterfeit items is incorporated into Fermilab design and engineering processes as prescribed by the Fermilab Quality Assurance Manual Chapter 12020 - *Suspect/Counterfeit Items (S/CI) Program* [25]. This includes development of technical requirements and/or determining critical characteristics of items for procurement, evaluating acceptance test results of purchased items, reviewing technical changes to/deviations from procurement documents, developing inspection methods for maintenance/inspection personnel to indicate acceptability of suspect items for engineering evaluation, and participating in audits or surveillances to verify supplier capability. PIP-II Partners and FNAL vendors/subcontractors are required to provide processes and procedures for inspecting materials for potential suspect or counterfeit parts. These processes should be reflected in the established incoming inspection criteria and noted in Partner QA Plans as well as FNAL vendor/subcontractor QA Plans.

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#### 10.4 Equipment and Services Procurement

The PIP-II Project procurement guidelines follow the Fermilab Procurement Policy and Procedures Manual [24]. This manual, created and maintained by the Fermilab Procurement Department, includes instructions for the preparation of purchase requisitions and dictates responsibility for review and approval.

The PIP-II Project Manager and the Project Procurement Manager have established levels of signature authority for purchase requisitions written against Project cost accounts. The Project is responsible for transmitting this information to the Procurement Department and for monitoring proper conformance to the pre-determined signature levels. A review by various Project personnel may be required, depending on the dollar amount and/or type of purchase requisition.

#### 10.5 Procurement Records

The handling of Procurement records generated by the PIP-II Project is described in the *PIP-II Procurement Management Plan* [23].

### 11.0 Inspection and Acceptance Testing

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The implementation of inspection procedures and the establishment of acceptance criteria are critical elements of the PIP-II Project. Fermilab's Quality Assurance Manual Chapter 12100 – *Incoming Material Inspection and Acceptance Testing* [34] provides guidance for the PIP-II Project to ensure items received meet the expectations of the Project prior to their intended user or installation. Inspection and acceptance apply to items that are fabricated for the Project at Fermilab or Partners, and items that are procured. The L2/L3 Manager is responsible for defining inspection and acceptance testing criteria and supporting processes based on the system and subsystem specific milestones. The L2/L3 Manager should develop inspection and acceptance testing criteria in collaboration with Partners where applicable. Acceptance and verification criteria should focus on features impacting safety and performance of a particular component or sub-system. These criteria should be generated at the lowest practical level to ensure higher-level integration and system-level performance are not impacted.

The criteria should include elements such as:

- Evaluation Criteria
- Initial incoming inspection at Fermilab
- Functional Tests
- Test Procedures

Testing requirements and processes may be documented in a Traveler or a standalone controlled procedure and referenced in the corresponding Partner or FNAL

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vendor/subcontractor QA Plan. It is the responsibility of the PIP-II L2Ms to create and maintain a System-level/L2 QA Plan and the PIP-II L3Ms to create and maintain a Subsystem-Level/L3 QC Plans. These plans will include required inspection and acceptance testing criteria.

### 11.1 Inspection

Inspections are performed in accordance with established requirements by the PIP-II Project. The designated responsible SME, with QA concurrence if appropriate, establishes level, extent, and acceptance criteria for inspections based on the critical characteristics or functional classification of the item. Personnel performing inspections are qualified for the areas inspected via formal training on that particular task or relative experience deemed by the L2/L3M and have the authority to access appropriate information and facilities to conduct inspections. Personnel performing inspections may come from PIP-II Project Team, Fermilab support staff, Partners, or from services procured from FNAL vendors/subcontractors. These individuals must be qualified to perform requirements included in Manufacturing Inspection Plans (MIPs), incoming/in-process inspection tests, and acceptance tests. The relative qualifications should be documented per training requirements established by the organization performing the work.

The QC Plans and MIPs are developed by L3Ms and/or Partners to ensure that inspection requirements are properly incorporated into fabrication processes. Inspection planning includes, at a minimum, item and process characteristics to be inspected, inspection techniques to be used, acceptance criteria (including tolerances), hold and witness points, in-process inspection or verification requirements, identification of the organization performing inspections, and sign-off by responsible person performing the inspection. MIPs should be instituted by Partners and FNAL vendors/subcontractors which should include the inspection planning aspects mentioned above. The MIPs should be reviewed and accepted by the respective L2 or L3 Manager with QA concurrence. Hold/witness points are critical milestones identified in the MIPs and identified via a collaborative means between the L2/L3 and the Partner or vendor.

When acceptance criteria are not met, nonconforming items and processes being inspected are controlled in accordance with the nonconformance control system as defined in this QA Plan and the *PIP-II Nonconformance Handling Procedure* [33]. After verification of corrective action implementation, the item or process is re-inspected to the original or approved alternative acceptance criteria prior to being used or returned to service. A graded approach has been established for the reporting of nonconformances identified by Partners or vendors/subcontractors to the respective L3M via the agreed upon method to ensure that adequate risk analyses and corrective action plans occur.

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PIP-II will use an electronic or paper traveler with each component throughout the assembly process. The Vector Traveler System will be used for internal Fermilab PIP-II work. Manufacturing Inspection Plans or other approved in-process traveler systems will be used at Partnering institutions and FNAL vendors for PIP-II work. The method should be defined in the PIP-II Project Planning Document or QA Plan of each respective Partnering institution. The Traveler will be developed by the designated task leader with support of the PIP-II QA Manager and the Traveler System owner. The information documented in travelers are used to identify processes related to inspection, testing, and fabrication, as well as to identify, report, correct, and trend nonconforming or situations adverse to quality performance. The Travelers will contain whatever historical information accompanies the equipment, list the specified operating parameters, assigned technicians/operators/engineers, and provide a place for testing results to be entered. The test results and certifications will then be compared to the required specifications and a determination will be made as to the final use or disposition of the item. It should be noted that testing and verification for performance within proper operating parameters will occur multiple times throughout the fabrication process in the Manufacturing Inspection Plan. This multi-tiered testing approach will ensure that improperly installed, faulty, or failed components are detected at the earliest possible opportunity and allow immediate remedial action to be taken without jeopardizing or negatively impacting performance.

Established controls for preventing the inadvertent testing, installation, or use of substandard or nonconforming materials or components include inspecting, tagging, and segregating of items however possible. Nonconforming materials or components should be documented and reviewed per the *PIP-II Nonconformance Handling Procedure* [33]. All project personnel are expected to report and document nonconforming items or conditions as soon as they are identified. The appropriate L2M/L3M, Sub-Project Manager, and PIP-II QA Manager should be notified; the PIP-II Procurement Manager should be notified if it involves an FNAL-related procurement.

Subsequent notification shall be made based on impact and severity of nonconformance. Nonconforming items subsequently reworked, repaired, or replaced shall be inspected and/or tested to meet either the original requirements or specified and approved alternative requirements. Any rework, repair, or replacement shall be authorized by the designated design authority and designated technical responsible parties. Such inspections or tests are conducted prior to the final acceptance of the item. Nonconformances identified during fabrication (in-process) should be documented via the traveler system used by the Project or the accepted system/method utilized by the Partnering institution or FNAL vendor/subcontractor. Nonconformances related to any aspect of PIP-II work identified by Partners or vendors/subcontractors should be communicated to their respective L2M/L3M using a previously established, documented, and agreed upon graded approach. The objective is to identify an issue, promptly report that issue to the appropriate level of management for

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containment and corrective action, and for management to take the necessary corrective action commensurate with the programmatic significance or importance of the problem. There is an expectation for Partners to communicate issues via established communication methods with their respective L2M/L3M.

Nonconformances will be tracked per the *PIP-II Nonconformance Handling Procedure [33]* and approved Partner QA Plans.

## 11.2 Acceptance Testing

PIP-II L2/L3 Managers are responsible for developing acceptance criteria using technically and scientifically defensible methodology. Acceptance testing of specified items, services, and processes is conducted using established acceptance and performance criteria. Acceptance test plans include initial inspections upon delivery, tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, and operational tests. These plans are structured to clearly distinguish between tests that verify design and performance requirements; and tests that verify operation within safety limits and requirements (e.g. Operational Readiness Clearance (ORC)). Acceptance test plans will be executed by Fermilab for components received from Partners. The Quality Control elements identified in the acceptance plans should resemble the same methods used by the Partner or vendor during the validation testing to obtain consistent results.

Item and process test requirements, including specified acceptance criteria, are provided, or approved by the design authority (L2 Manager). The design authority has the primary responsibility for establishing and approving test requirements and associated acceptance criteria. Designated Project personnel review the test packages for impact on, and interface with, operating systems and confirm that proposed testing will provide adequate validation that the equipment being tested will perform its design functions. Partners and FNAL vendors/subcontractors are required to meet these requirements by working to their own QA Plan that meets all the requirements of the PIP-II QA Plan.

MIPs and Acceptance test plans controls include the development, approval, and use of test procedures. These procedures include:

- Instructions and prerequisites to perform the test
- Requirements to ensure completeness and accuracy of data
- Use and calibration of test equipment
- Acceptance criteria
- Inspection hold/witness points as required
- Test configuration
- Training of personnel performing acceptance testing

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When items and processes do not meet documented test acceptance criteria, these deficiencies are documented on nonconformance reports and dispositioned. Corrective action plans are included as a part of test documentation. When deficiencies have been corrected, retesting is performed to verify that acceptance criteria are met. All deficiencies identified at Partners or FNAL vendors/subcontractors should be immediately communicated to the appropriate L2M/L3M for risk analysis and corrective action planning.

Managers must ensure that the documentation for items that require inspection and acceptance testing is maintained in accordance with the appropriate records retention schedules as per the Fermilab Records Management Policy.

### 11.3 Measuring and Test Equipment

Fermilab policies and procedures describe controls applicable to Measuring & Test Equipment (M&TE) and provide guidance relative to what equipment is considered M&TE. Equipment used for inspections and testing is calibrated and maintained, and traceability and accountability of this equipment are required. Calibration and traceability requirements for this equipment are defined and based on usage. Traceability includes traceability of the M&TE to the calibration standard used to establish its accuracy and traceability of the M&TE parts used to perform a particular inspection or test. M&TE typically includes instruments, tools, gauges, and nondestructive examination equipment.

Calibration of M&TE is performed at specified intervals or prior to and after use, as established by documented requirements. Calibration frequencies are based on required accuracy, intended use, frequency of use, stability characteristics, and other conditions affecting M&TE performance.

M&TE is labeled, tagged, or otherwise controlled to indicate calibration status. M&TE identification provides traceability to calibration and test data.

Accuracy of M&TE calibration standards is established to ensure equipment being calibrated will be within required tolerances. Calibration standards are traceable to national standards. If no national standards exist, the responsible organization will identify alternative standards.

M&TE determined to be out of calibration or tolerance is tagged or segregated and is not used until it has been either successfully recalibrated or replaced. Any data obtained during the period the M&TE was determined to be out of calibration or tolerance must be reviewed to determine whether the use of the M&TE resulted in the acceptability of items or processes becoming invalid. The basis for acceptance of these non-conforming items and processes is formally evaluated and documented.

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The QA Plan submitted by the Partner and FNAL vendors/subcontractors should reflect processes for the management and control of measuring and test equipment for work performed under the PIP-II scope.

## 12.0 Work Processes and Control

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### 12.1 Performance of Work

Work is defined as the design, operation, maintenance, modification, and construction of structures, systems, or components by PIP-II Project Team, Partner, FNAL vendor/subcontractor personnel. Lab-wide work control processes ensure that work is properly controlled, evaluated, reviewed, approved, implemented, inspected, tested, and documented.

The PIP-II Project Team is responsible for ensuring that trained and qualified individuals are assigned to perform work and that necessary resources to accomplish the work are provided. When work is subcontracted or performed by a Partner, these requirements are addressed by requiring Partners or FNAL vendors/subcontractors to perform work under the PIP-II QA Plan, or to provide a QA Plan or other work control documents to address these requirements. Programmatic requirements imposed on the Partner or vendor are defined by agreement or subcontract language. The Partner or FNAL vendor QA Plan will be reviewed and approved by the PIP-II Project Director, PIP-II Technical Director or designee, PIP-II QA Manager, L2M/System Manager, CAM/L3M, and other SMEs as applicable.

The PIP-II Project Director has ultimate responsibility for ensuring that all work performed in support of the PIP-II Project complies with applicable plans, specifications, procedures, and regulations. All work performed in support of the PIP-II Project will be properly planned, controlled, and evaluated. Planning will be done prior to commencement of work to ensure that sufficient time is allowed for:

- All stakeholders involved understand both their role in the work process and the associated hazards;
- Instructions and procedures to be prepared, reviewed, and approved; and
- Personnel to be properly trained and qualified to execute those procedures.

The work control program requires personnel with work approval authority to review the scope of work requests and provide approval prior to work commencement. These requests specify the necessary administrative controls, including lockout/tagout (LOTO), permits and quality inspections. The work control program provides for work and job planning functions that require preparation, review, and approval of work packages prior to initiation of work. Work packages consist of documents needed to perform work safely and successfully.

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All personnel assigned to or performing work for the PIP-II project are responsible for the quality of their work. It is the responsibility of the PIP-II L2Ms to create and maintain a System-level/L2 QA Plan and the PIP-II L3Ms to create and maintain a Subsystem-level/L3 QC Plans. These plans will include details of how work process requirements will be met. QC plans shall be developed during the design phases of their corresponding deliverable, presented during Technical Review activities, reviewed during procurement readiness phases, and accepted during to manufacturing readiness.

The PIP-II Project and the Partner will jointly identify appropriate oversight mechanisms of partner work control program for work performed under the PIP-II scope.

The PIP-II Project shall establish appropriate levels of oversight of FNAL vendor work control program for work performed under the PIP-II scope.

## **12.2 Identification and Control of Items**

Materials, software, equipment, components, accessories, assemblies, sub-assemblies, modules, parts, structures, subsystem units, and systems will be identified and controlled to ensure their proper use. These items shall be controlled and maintained (proper care to maintain reliability and performance) to prevent damage, loss or deterioration. Items must be traceable from initial receipt or fabrication up to and including installation, testing and commissioning. Fermilab’s Suspect/Counterfeit Item (S/CI) Program should be applied when inspecting incoming materials, equipment, products, or parts. The method for the identification and control of items established by Partners or FNAL vendors/subcontractors should be included in their respective QA Plans and accepted by the L2M/L3M and PIP-II QA Manager.

### **12.2.1 Handling, Storage, Transportation**

Criteria for handling, storing, shipping, cleaning, and preserving items to prevent damage, deterioration, or loss are defined in subcontract Terms and Conditions, Partner Agreements, and Fermilab procedures, as appropriate. Fermilab procedures also define instructions for marking and labeling items. PIP-II Project Planning Documents will reference Transportation Plans developed collaboratively by FNAL and the Partner and approved by FNAL. The Transportation Plans should include Partnering institutions plans for the proper handling, storage, and transportation of components and equipment from their site to another site, including to Fermilab per the *PIP-II Technical Review Plan* [10]. Transportation Plans shall be developed by the Project for all components that will be transported from one site to another despite the distance and referenced in the respective QA Planning document. The Project shall identify the most optimal storage locations and conditions for components and equipment inventory that arrive onto the Fermilab site via proper logistics planning and inventory

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control. Adequate logistics planning / inventory control minimizes the risks associated with components, assemblies, or equipment being inadequately handled and stored (e.g. damage, improper maintenance or care, environmental elements, etc.). If changes are made to previously agreed upon methods for handling, storage, or transportation, notification must be provided to the respective L2M prior to employing new methods.

### 13.0 Software Quality Assurance

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The design and development of software shall be accomplished in accordance to the Fermilab Software Quality Assurance (SQA) Program [26]. The Fermilab SQA Program ensures the development, management, and delivery of reliable software applications that meet or exceed established requirements and expectations through adequate planning, assessing, and improving. Software procured shall be verified and validated against defined acceptance criteria highlighted in the verification and validation plans associated with the Procurement Plans. Situations where the design method involves the use of computer software to make design calculations or dynamic models of the structure, system, or component's functionality, that software should demonstrate the ability to produce validated results. The demonstration of validated results shall be documented. However, exemptions may be made for: commercially available software that is widely used; codes with an extensive history of refinement and use by multiple institutions; and if the validation is evidently unlikely to reveal a problem and is difficult and/or expensive to complete. Requirements of the Fermilab SQA Program will be applied.

Critical computer codes, especially those codes that are involved in controlling the operation of the PIP-II controls network, shall also be subjected to review. Some items to be considered during computer code review are provided below:

- Technical adequacy of the design
- Elegance of the design
- Documentation
- Code validation testing scheme
- Consistency of structure of code to any applicable standards
- Compatibility of code with other systems that may use data
- Consideration of hardware requirements to support system
- Maintenance of code
- Backup Systems

Software acquired from Partners should also be verified and validated to ensure all requirements are met. The PIP-II Project is not allowed to test software from Partners if the source code is not provided. Partners should include the following elements associated with the software developed/sourced/procured for the PIP-II Project in the respective QA Plans:

- hardware system,

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- firmware information,
- program/code information,
- verification methods,
- review/acceptance process,
- software control methods,
- developers/owners, and
- dependencies

## 14.0 Assessments

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This section describes management and independent assessments that include systematic and focused efforts to identify and resolve PIP-II Project-related issues and evaluate effectiveness.

### 14.1 Management Assessments

Management assessments are a part of the Fermilab assessment and improvement processes and serve as a key feedback mechanism for management to measure the effectiveness of the Quality program. Fermilab's Quality Assurance Manual (QAM) chapter 12080 - *Self-Assessments* [27] directs PIP-II Project Management to plan and conduct regularly scheduled self-assessments of their projects to identify and correct problems that would hinder the achievement of their mission, objectives and performance requirements. These assessments will focus on performance and program implementation, and the effectiveness of the programs in meeting contractual and regulatory requirements. These assessments may include worker assessments of their own activities. Project management reviews and evaluates data from various internal and external sources, including knowledge based on their own experience, to identify problems that hinder the project's ability to achieve its mission and performance objectives. PIP-II management at all levels shall regularly evaluate achievement relative to performance requirements and shall appropriately validate and update performance requirement to assure quality expectations are fulfilled.

Management assessments will be performed as an ongoing activity to verify conformance to applicable requirements and identify opportunities to improve performance and cost-effectiveness. Integrated Project Team (IPT) meetings are also considered as management assessments. Self-assessments utilize an integrated management evaluation process to examine both facility and programmatic performance, with particular emphasis on areas or activities that could have an adverse impact on worker and public safety or on the environment. Reviews and workshops may be organized on an ad hoc basis for selected technical systems and components. These reviews are organized by the Project Director, Technical Director, Project Engineer, and/or L2 Managers. Moreover, the Project Director, Project Manager, and Technical Director have the authority to form a review team to investigate a QA or QC issue, nonconformances, or high-risk conditions if the need arises.

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Results and conclusions from these assessments will be documented and evaluated. Corrective actions will be taken to resolve identified problems and to achieve continuous improvement. Provisions will be included to track and follow up on planned corrective actions from these self-assessments.

## 14.2 Independent Assessments

Independent assessments are a part of the Fermilab assessment and improvement processes. Independent assessments are used to validate the PIP-II self-assessment efforts, perform reviews required by contract, and evaluate the effectiveness of corrective actions. Independent assessments may also be used to verify or validate conditions to fulfill directed senior management investigations. Independent assessments focus on performance of work with significant consideration given to compliance with requirements and safely performing work while achieving the goals of the organization. Their purpose is to improve performance and process effectiveness through assessing item and service quality, measuring adequacy of work performed and promoting improvement. Independent assessments are conducted by technically qualified and knowledgeable staff not responsible for supervising or performing the work being reviewed. They are separate from, and in addition to, management assessments. These may include formal Independent Project Reviews or Directors Reviews. There are also monthly Project Management Group meetings where the Directorate and DOE participate as members.

These assessments are routinely planned, scheduled, and conducted to verify conformance of items and processes to established requirements. These schedules, and the allocation of resources needed to meet these schedules, are based on the status, hazard, and complexity of the activity or process being assessed. Schedule flexibility allows performance of additional assessments of PIP-II Project Team and subcontractor activities for identified areas of concern. The assessment process includes follow-up to assure corrective actions are implemented when deficiencies are identified.

Assessment results will be tracked, and management has the responsibility for issue resolution as assigned within Fermilab's Issues Management System - iTrack. The need for follow-up review of areas found deficient during an assessment, including the need for extent of condition reviews, is determined by management. Organizations responsible for responding to item identified in assessment reports address the following, as applicable:

- Identification of cause
- Actions needed to correct the identified deficiencies
- Timeline for resolution

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- Actions required to prevent recurrence
- Lessons learned and actions to be taken for improvement of the activity or process

The qualifications for independent assessment personnel are established commensurate with the assessment purpose and scope, the experience and training of the assessor, and will be approved by the PIP-II QA Manager, Project Director, or Technical Director. Persons conducting and participating in independent assessments are often designated SMEs in their assigned discipline or are at least technically qualified and knowledgeable in the areas assessed. In addition to SMEs, cognizant technical or operational personnel may be included as team members to provide expert specialty knowledge. The assessment team leader is responsible for determining the need for specialized expertise to perform the assessment and for procuring the appropriate qualified and knowledgeable personnel to serve on the assessment team.

Assessments are performance-based, with emphasis on results and with compliance viewed as the baseline. Performance-based assessments, focusing on process improvement, evaluate and report on PIP-II Project Team, Partner, and FNAL vendor/subcontractor organizations in the achievement of quality and the effectiveness of the organization’s self-assessment programs. While conducting performance-based assessments, work is monitored to identify best practices, opportunities for improvement, problems, and substandard or non-compliant performance and their precursors. Any group performing independent assessments has sufficient authority and freedom to carry out its responsibilities. Personnel performing independent assessments do not have direct responsibilities in the area they are assessing.

## 15.0 Construction Quality Management

The PIP-II Project will consist of critical civil, mechanical, and electrical construction activities. It is imperative that appropriate levels of quality assurance and control are integrated into the planning and execution of all construction activities as well. The PIP-II Project L2/L3 Managers are responsible for assuring the FNAL subcontractor selected to perform the work can effectively meet all quality requirements established in this PIP-II QA Plan prior to awarding the subcontract. The FNAL subcontractor shall furnish with the bid or proposal a copy of their Corporate Quality Control (CQC) Plan. Failure to submit such a document could constitute a non-responsive bid or proposal. Following the receipt of award of Subcontract, the FNAL subcontractor shall furnish a Project Quality Control (PQC) Plan for review by FNAL per parameters established in the subcontract documents and the *PIP-II Procurement Management Plan* [23]. The FNAL subcontractor is contractually obliged to develop, execute, and maintain the Project Quality Control (PQC) Plan specifically for the work in the scope of the subcontract. The PQC Plan should contain the procedures, instructions, and reports the subcontractor will use during the Project. The PQC Plan must be submitted to the PIP-II Procurement Office after notice of award and prior to the start of

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work to allot time for sufficient review and acceptance by the respective L2M/L3M, QA Manager, and other SMEs. The construction work will not begin until the PQC Plan is accepted. The PIP-II Project will oversee the subcontractor’s PQC Program implementation to ensure the work performed conforms to specifications and drawings associated with the subcontract requirements. The subcontractor is required to perform all work specified in the subcontract and for fulfilling all requirements specified in the subcontract.

## 16.0 PIP-II Partner Deliverables and FNAL Vendor Oversight Planning

The PIP-II Project is a complex effort with significant in-kind contributions from International Partners. International Partners may have established processes that will be used to perform the work under their scope for the PIP-II Project or developing processes amid prototyping activities. The PIP-II Project will also procure items, services, or components from vendors/subcontractors who also have established processes for work performed. It is imperative that the PIP-II Project has confidence that the work performed by Partners and all vendors/subcontractors for the PIP-II Project will meet requirements and expectations. This PIP-II QA Plan describes the requirements established by the PIP-II Project to assure quality and meet or exceed the PIP-II Project expectations. A comprehensive Quality Assurance Program includes elements of oversight over processes and individuals performing work for the Project, especially in instance where the work is performed outside of the institutional organizational structure. In the case of the PIP-II Project, a significant amount of work will be performed outside of the immediate institutional organizational structure and control of the PIP-II Project Director.

To minimize the risks associated with this complex effort, it is the responsibility of the PIP-II Project to identify the level of oversight necessary for Partner deliverables as well as FNAL vendors/subcontractors. As noted in Section 6.0 of this QA Plan, the PIP-II Project employs a graded approach. The PIP-II Project consists of technical complexities such as multiple cryomodule types resulting in several interfaces to which a graded approach to quality is applied. The graded approach is applied based on the level of experience/expertise of the Partner or vendor.

Guidance has been created for the PIP-II Project relating to oversight for Partner deliverables. If the Partner has prior experience and proven expertise with the timely execution/delivery of the technology or fabrication of a component (or similar component) for the PIP-II Project, then less oversight effort may be necessary. However, if the Partner has minimal prior experience or expertise, then adequate levels of planning and oversight will be necessary. This determination will be made by the Project Director, Technical Coordinators, In-Kind Contribution Managers, and L2/L3 Managers, in collaboration with the Technical Integration Office and PIP-II QA Manager/QA Engineer for each set of deliverables for the PIP-II Project. Refer to Table 1.0 for guidance on the graded approach for Partners deliverables.

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Criterion	Raw Scores	Excellent / Experts (4)	Good / Advanced (3)	Adequate / Emerging (2)	Minimal / Novice (1)
<b>Prior Experience / Reputation</b>		Significant relevant experience; known as expert in the subject or technology	Several years of experience; positive reputation	Some prior experience; minimal reputation	No prior experience in the subject or technology; no reputation in the field
<b>Prior Known Successes</b>		Prior experiences have resulted in successful/positive outcomes	Prior experiences have resulted in positive outcomes with minor issues	Prior experiences have resulted in moderate issues and notable rework	No known experience
<b>Prior Known Significant Challenges / Issues</b>		Prior experience delivering similar technology demonstrate high confidence in delivery with minimal oversight required	Prior experiences have resulted in no significant challenges; minor issues	Prior experiences have resulted in delays or technical challenges/issues; notable rework	No known experience
<b>PPD Phase 1 - Preliminary Design Phase</b>		The capability to create and submit all PDR documentation without support; or Fermilab will develop all PDR related documents (100%)	The capability to create and submit PDR with minimal support from Fermilab	Moderate level of support from Fermilab required help to create and submit PDR related documents	Significant level of support from Fermilab required help to create and submit PDR related documents
<b>PPD Phase 2 - Final Design Phase</b>		The capability to create and submit all FDR documentation without support; or Fermilab will develop all PDR related documents (100%)	The capability to create and submit FDR with minimal support from Fermilab	Moderate level of support from Fermilab required help to create and submit FDR related documents	Significant level of support from Fermilab required help to create and submit FDR related documents
<b>PPD Phase 3 - Procurement, Manufacturing, Assembly Phase</b>		The capability achieve deliverables meeting requirements and specifications	The capability achieve deliverables meeting requirements and specifications with minimal support from Fermilab	Moderate level of support required from Fermilab to achieve the deliverables meeting requirements and specifications; or infrastructure development support required	Significant level of support required from Fermilab to achieve the deliverables meeting requirements and specifications; or minimal infrastructure available
<b>PPD Phase 4 - Delivery, Acceptance, Installation Phase</b>		The capability to deliver onsite (Fermilab) and meet specifications; with no support from Fermilab	The capability to deliver onsite (Fermilab) and meet specifications with minimal support from Fermilab	Moderate level of support required from Fermilab to deliver onsite (Fermilab) and meet specifications	Significant level of support required from Fermilab required to deliver onsite (Fermilab) and meet specifications
<b>Clearly Defined QA Plan</b>		QA Plan is finalized	QA Plan is near final (advanced draft)	QA Plan is in progress (early draft)	No Defined QA Plan

Table 1.0 -Graded Approach Evaluation for Partners Deliverables

As noted in the Table 1.0 above, there are various evaluation criteria and associated scoring. Using a defined weighted calculation, the oversight level of ‘high’, ‘moderate’, or ‘low’ can be generated. It is at the discretion of the Project Director to apply more or less controls if deemed necessary. For instances where ‘moderate’ or ‘high’ levels of oversight may be required, the Project will determine the method and application of the necessary oversight. It is the responsibility of the L2M, L3M, and Sub-Project Manager to ensure that the oversight planning is devised in conjunction with the Partner for each system/subsystem as applicable and documented in the respective System-level QA and Subsystem QC Plans. For items procured by FNAL vendors/subcontractors, depending on complexity or criticality of the deliverable, a separate oversight plan outside of the agreed upon hold/witness points in the Manufacturing Inspection Plans may not be necessary.

The oversight planning information should be included in the System-level QA Plans and include the following elements:

- Activity (e.g. procurement activities, readiness reviews, critical meetings)
- Source Document (e.g. link review information, MIP, PIP-II procedure)
- Where activity will take place (e.g. at Partner or Vendor site, via Teleconference)
- Responsible Person(s) to perform the activity (e.g. L2M, L3M, SPM, SME)
- Results/outcomes of activity (e.g. link to specification and MIP)
- Management of follow-up items or activities

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The ultimate goal of defining and collaborating on the necessary oversight of deliverables is to ensure all stakeholders are aligned with key activities, when they will occur, and the results of the activity to facilitate the partnership and communication. As previously noted in this document, varying levels of in-process inspection and testing is critical to ensuring the final product, component, or service will meet requirements. The System-level QA Plans and Subsystem QC Plans developed by the L2M and L3Ms, respectively, shall include the Partner or FNAL vendor oversight planning details that will be developed and maintained throughout the lifecycle of the Project for work performed by Partners or FNAL vendors/subcontractors. The Subsystem QC Plans will include:

- Roles and responsibilities including assignment of qualified personnel to serve as PIP-II Project representatives at the sites on a predetermined basis.
- A defined oversight methodology applicable to specific activities:
  - Key deliverables
  - Design Reviews and Manufacturing Readiness Reviews
  - Technical requirements & traceability
  - MIPs, Traveler reviews, Hold Points
  - Risk Management
  - Communication Plan
  - Partner / Vendor Visits
  - Issues Management (RCA, CAP, Effectiveness Reviews)
  - Specification/Requirement Verification
  - Equipment/Component transfer or storage verification process
  - Software Management and Control

Refer to the PIP-II QA and QC Planning Template [28].

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## Appendix I - Quality Assurance Plan Guidance Template and Expectations for Partners

The section below describes all elements required in the Quality Assurance Plans submitted by Partners as part of the Project Planning Documents package. At minimum, the Partner Institution is required to submit a detailed Quality Assurance Plan in accordance with the PIP-II QA Plan and include the sections highlighted below. It is imperative that Fermilab and its Partners demonstrate a high probability that systems will perform as intended as per specifications and requirements. Partners and the vendors/subcontractors with whom they work will demonstrate the ability to minimize process variation via reliable, repeatable, and documented processes. Parts, components, equipment, structures, and/or assemblies must meet expectations throughout the expected lifetime.

### **Section 1.0 – Purpose**

The Partner Institution is to describe the scope of this QA Plan relating to the PIP-II Project as it is reflected in the Project Planning Documents.

### **Section 2.0 – Roles, Responsibilities, and Authorities**

The Partner Institution is required to describe roles, responsibilities, and authorities relating to the PIP-II Project. This section should include the responsibilities for (as applicable):

- quality
- project deliverables
- design
- procurement
- fabrication
- maintenance and calibration of equipment
- in-process inspection and acceptance testing
- storage of equipment/components
- shipping/transportation
- final acceptance testing

This section should also include critical personnel assigned to the PIP-II work, including contingency plans for personnel changes.

### **Section 3.0 – PIP-II Deliverables**

The Partner Institution should describe the specific deliverables for the PIP-II Project as per the Project Planning Documents. This section should also include the method for managing delivery schedules and the responsibility for communicating events (e.g. change in fabrication

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site or manufacturing facility, changes in critical equipment) that could cause any changes to the scope or performance of the deliverables and/or the delivery schedules.

#### **Section 4.0 – Communications Plan**

The Partner Institution is strongly encouraged to follow the Communications Plan established by the PIP-II Project that describes the methods of communication to be utilized while conducting PIP-II work. For example, meetings held with PIP-II Project team and the method that should be used to provide notification of issues, nonconformances, or changes to the design, fabrication, assembly, key personnel, location of fabrication/manufacturing, transportation method, vendors or suppliers.

Elements of the Communications Plan will also be highlighted in the Partner Oversight Plan created by the PIP-II Project.

Please refer to the Communications Management Section of the PIP-II QAP.

#### **Section 5.0 – Competence, Training, and Awareness**

The Partner Institution is required to have trained and qualified personnel assigned to work relating to the PIP-II Project. The Partner should have adequate verification methods to ensure that only adequately trained, qualified, and certified personnel are assigned to work relating to PIP-II Project, including personnel at third party vendors or other institutions.

It is imperative that the Partner has established methods to prevent, detect, and disposition Suspect and Counterfeit Items. S/CI detection and monitoring processes should be incorporated in Incoming Inspection Procedures. Evidence of this expertise is required or will be provided by the PIP-II Project.

Please refer to the Competence, Training, and Awareness Section of the PIP-II QAP.

#### **Section 6.0 – Design and Configuration Management (Design Change Control)**

The *PIP-II Configuration Management Plan* establishes requirements for design change control. If the Partner Institution is responsible for the design of a component or system for the PIP-II Project, this section should include the description of the methods used to assure PIP-II requirements are met throughout each phase of the design. The Partner Institution is required to describe responsibilities relating to the design of the PIP-II Project deliverable. The Partner is also required to have an established design and process change control procedures, including the implementation and verification of the change. If third parties such as vendors or subcontractors are used by the Partner to fabricate components or provide a service relating to

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design for PIP-II, the Partner is required to provide the PIP-II Project with the processes for communicating design changes and corresponding plans to assure compliance to requirements.

For instances where the Partner is executing the design, any changes to the design must be submitted to the PIP-II Project for evaluation through the change control process and decision to approve prior to proceeding. See image 1.0 – Consolidated PIP-II Change Control Process Flow Chart below.

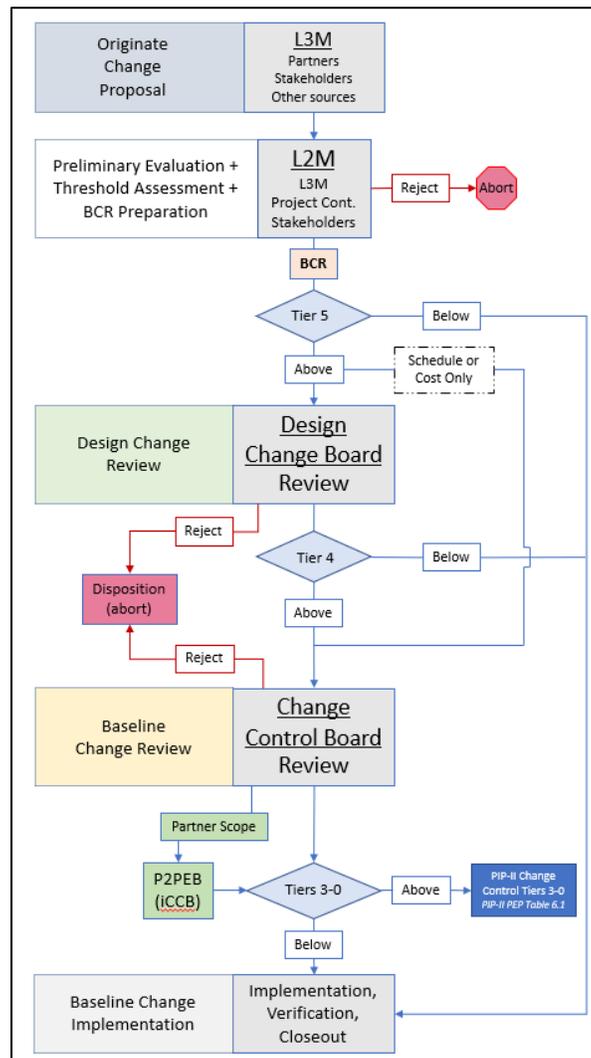


Image 1.0 - Consolidated PIP-II Change Control Process Flowchart (documented in the PIP-II Configuration Management Plan)

The PIP-II Project adheres to the requirements established in the Fermilab Environment, Safety, and Health (FESHM) Chapter 2110 – *Ensuring Equivalent Safety Performance when Using International Codes and Standards*. This FESHM chapter describes the process used to establish

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equivalent safety performance between U.S. and International engineering design codes and standards. The Partner is required to assure alignment with the International Codes and Standards requirements for components or systems fabricated by the Partner or third-party vendor or institution. The Partner must provide evidence of this alignment with the international codes and standards. Any deviations from an FNAL requirement or standard will be handled on a case-by-case basis. FNAL will ultimately approve any deviations.

The Partner Institution will be required to participate in Technical Reviews organized by the PIP-II Project to verify that design and fabrication processes meets requirements prior to fabrication. The preparation of the Technical Reviews requires adequate communication and scheduling and should be done in accordance with the *PIP-II Technical Review Plan* [10]

The Partner Institution is required to submit final design packages (drawings and traceability to specifications) to Fermilab as per agreed upon milestones.

Please refer to the Design Section of the *PIP-II QAP*.

### Section 7.0 – Design Verification and Validation

The Partner Institution is required to have an established process for the verification and validation of designs via the development of a Design Verification and Validation Plan. The Design Verification and Validation Plans and supporting procedures are developed to ensure that PIP-II Project systems, subsystems, and their components have been adequately reviewed or tested to ensure that the final devices function in compliance with their requirements and intended use. The Partner can include the following components in the Design Verification and Validation Plan:

- **Requirements Traceability** – Each requirement (defined in the applicable Requirements Document) are verified through inspection, test or analysis, or a combination of these methods in agreement with the PIP-II Project.
- **(Design) Failure Mode and Effect Analysis (DFMEA)** – An analysis used to initially identify design function and possible failure mode and their effects on the scope of work or overall Project with corresponding severity and mitigations.
- **Test Procedures** – Test procedures are the actual step-by-step processes that are run to ensure the device meets its requirements. Test procedures include inspection, confirmation and testing.
- **Test Records** – Test records are defined in the test plan; will be documented on data sheets and should include the test procedure, test results and acceptance

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criteria. The test records are required to be submitted with the PIP-II Project upon delivery of the component.

- **Qualification Tests** - May be used to verify adequacy of the design or portions of it in conjunction with other verification methods. These tests are conducted using approved procedures and include acceptance criteria that verify or validate acceptability of specific design features. Qualification tests are conducted on a timely basis under conditions that simulate the most adverse design conditions. Determination of the most adverse conditions takes into consideration operating modes and environmental conditions in which the item being tested is required to perform satisfactorily. Test results are documented, evaluated, approved, and retained. Equipment or components are put into operation only after successful completion of qualification tests.

Validation of design is concerned with checking that the system will meet the overall goals and parameters of the PIP-II Project. Design validation follows successful design verification. Designs should be validated via Design Reviews before procurement, manufacture, or construction, and no later than acceptance and use of the item, in order to ensure the design:

- Meets the design-input requirements,
- Contains or refers to acceptance criteria, and
- Identifies those design characteristics that are crucial to the safe and proper functioning of the equipment or system.

The Design Verification and Validation Plans are submitted to the PIP-II Project for review and verification.

Please refer to the Design Verification and Validation Section of the PIP-II QAP.

### **Section 8.0 – Vendor Management and Assurance**

The Partner Institution should have an established method/system for procuring/receiving parts, components, and services from suppliers, vendors, or subcontractors outlined in a Vendor Management Plan or description. L2M/L3M/SPM or other SMEs will review and concur with the method/system to ensure that all technical, safety, and quality requirements can continuously be met.

This section should also include a description of how the Partner manages issues and controls nonconformances that occur at the vendors or other institutions performing work for the Partner relating to the PIP-II scope of work. All issues and nonconformances are to be

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communicated to the PIP-II L3 Manager/SPM for awareness, impact/risk analysis, and aligned corrective action planning. The Partner is strongly encouraged to communicate all decisions to changes in supplier, vendors, or facilities during PIP-II work, including the reasons and associated impact/risk analysis relating to the change. If multiple vendors or institutions are used, the oversight management processes used for each vendor or institution is required. The Partner should incorporate the following elements:

- Quality requirements should be part of the vendor/supplier selection process established by the Partner;
- The Partner should establish and document supplier qualifications, requirements, acceptance criteria, processes, and vendor verification activities;
- All procurement activities should comply with applicable safety and quality requirements, including compliance to Fermilab International Codes and Standards requirements;
- Vendors should submit Quality Assurance Plans as part of the bid creation process;
- Procurement specifications should be complete, unambiguous, and under document control
- All vendors/suppliers should demonstrate that all specifications and requirements can be effectively and consistently met.

The Partner should provide processes that describe vendor management and assurance.

### **Section 9.0 – Manufacturing (In-Process) Inspection Planning**

The Partner Institution will establish and submit Manufacturing Inspection Plans (MIPs). The MIPs are developed to ensure that inspection requirements are properly incorporated into fabrication processes. The plans are required to be approved by the corresponding PIP-II L2M/L3M to ensure all critical elements are incorporated and agreed upon. Nonconformances or issues identified during fabrication by the Partner or third-party vendor or subcontractor are to be communicated to the PIP-II L2M/L3M/SPM per established nonconformance handling process. The implications and risks associated with the nonconformance or issue should be discussed and agreed upon among stakeholders. Using an established graded approach, nonconformances will be logged in the PIP-II Master Nonconformance Log for transparency, lessons learned, and continuous improvement.

At a minimum, the following elements are required for each quality control inspection activity during the incoming inspection and fabrication process in the MIP:

- The explicit item or process characteristic to be inspected/tested along with unique identifier

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- References to requirements and specification
- Description of the Production Line infrastructure (tooling, equipment, space layout, storage, utilities, etc.)
- Inventory (parts, raw materials, consumables, spares, etc.)
- Manufacturing activities (procedures, travelers, steps, sequencing, dependencies, concurrency, routing, shipment)
- Inspection Activities (inspection points, hold and witness points, acceptance criteria (including tolerances), measurements, testing, disposition, records)
- Verification of requirements
- Quantities and Throughput (Production quantities, throughput, learning curve, yield)
- Resources (assigned personnel, qualifications, training, signatures and dates)
- Measuring & Test Equipment and referenced calibration records
- Nonconformances and disposition, reference to corresponding Nonconformance Report (NCR)
- Reference to related standards, procedures, or work instructions.

Inspection and Tests should be conducted by trained or qualified personnel.

Hold points, notification points, approval points are required in all Manufacturing Inspection Plans. Communication of upcoming hold, notification, or approval points by the Partner to the respective L3M/SPM is imperative to ensure adequate surveillance and execution of hold points. Traceability of test results of critical components to specifications/requirements is critical and required.

If multiple vendors or institutions are used by the Partner, then the Partner is responsible for establishing adequate MIPs for each vendor or institutions. Vendors are required to deliver records of the associated fabrication, test plans, and test results, along with the hardware they are producing.

All MIPs will be provided to Fermilab during the manufacturing readiness phase and completed MIPs shall be provided upon the delivery of the finished component.

This section should describe the method for deriving, communicating, implementing, and controlling MIPs and in-process inspection activities for all PIP-II work.

Please refer to the Inspection and Acceptance Testing Section of the PIP-II QAP.

### **Section 10.0 – Product Acceptance**

FNAL and the Partner Institution will collaboratively establish methods for evaluating the acceptance of components or services from vendors or institutions. If there are multiple levels of

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acceptance throughout the supply chain, a Product Acceptance Plan should include the acceptance criteria established with each vendor and institution.

When items and processes do not meet documented test acceptance criteria, these deficiencies are documented on nonconformance reports and dispositioned. Corrective action documents are included as a part of test documentation. When deficiencies have been corrected, retesting is performed to verify that acceptance criteria are met. All deficiencies identified at partnering institutions or vendors should be immediately communicated to the appropriate L3M/SPM for risk analysis and corrective action planning.

Partners should ensure that the documentation for items that require inspection and acceptance testing is maintained and submitted to the PIP-II Project.

FNAL has the responsibility of final acceptance and should develop criteria in collaboration with the Partner.

This section should describe the method for adhering to the product acceptance requirements set forth by the PIP-II Project as noted above.

Please refer to the Inspection and Acceptance Testing Section of the PIP-II QAP.

### **Section 11.0 – Control of Nonconformances**

FNAL and the Partner Institution will collaboratively establish methods for effectively identifying, controlling, documenting, and reporting nonconformances identified throughout the entire lifecycle of the component, system, or service within their scope of work, from design to fabrication to shipment to Fermilab. Nonconformances should be documented in the Manufacturing Inspection Plans or Travelers per defined and accepted processes. Applying a graded approach, nonconformances should be communicated and tracked per defined Nonconformance Handling Procedures. All corrective action plans and timelines for resolution should be agreed upon with the respective L3 Manager.

Nonconformances which affect functional requirements or interfaces with subsystems at Partnering institutions should be communicated immediately and will be shared amongst the Partnering institutions for awareness and lessons learned. Deviations (i.e. when a deliverable will not meet an approved functional or interface requirement) require Technical Director and L2M written approval.

Suspect/Counterfeit Items fall within the scope of nonconforming product and should be reported and dispositioned through the normal NCR process.

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This section should describe the collaboratively established process for identifying, documenting, communicating, and resolving nonconformances identified at the Partner or vendor/institution. This section should also highlight how the lessons learned identified from nonconformances are captured will be used to improve current processes.

### Section 12.0 – Product Identification and Traceability

The Partner Institution should have an effective method for identifying components produced by and for the Partner. Product identification and traceability is a requirement. Materials and subcomponents should be traceable from procurement, to receiving inspection, to product fabrication and/or assembly, to storage/transportation, to final testing, installation, and commissioning. All travelers and MIPs should meet identification and traceability requirements.

The Partner Institution is required to submit an established method for ensuring product identification and traceability within their process , vendor, or other institution’s process which should be described in this section of the submitted QA Plan.

### Section 13.0 – Document and Data Management

The Partner Institution should have an established process for document and data control plan for review and acceptance. This process should adhere with the requirements established in the *PIP-II Document Management and Control Plan*. This section should describe how the Partner controls documents, manages the changes to documents, and method for integration into respective processes relating to their PIP-II scope of work. If the Partner is procuring items and services from vendors, the Partner should ensure the vendor has adequate document and data control. The vendor’s document and data control procedures are subject to review by the PIP-II Project and are part of the documentation deliverables.

All procedures relating to scope of the PIP-II work undergoing changes should be communicated to the PIP-II Project prior to the implementation of the change to discuss the potential risks and mitigations.

Assurance that the most current and approved documents or designs are referenced throughout the design, fabrication, transportation, and delivery processes is imperative.

Documents to be controlled include, but not limited to the following:

- Design Drawings
- Specifications
- Design calculations and simulations
- Design change requests

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- Manufacturing inspection plans
- Work instructions / standard operating procedures
- Manuals and checklists
- The QA Plan submitted for PIP-II work
- Nonconformance Reports

This section should describe the Partner’s document and data management process.

Please refer to the Document and Data Management Section of the PIP-II Quality Assurance Plan.

### Section 14.0 – Software Quality Assurance

The Partner is strongly encouraged to align with the Software Quality Assurance guidance established in the PIP-II QA Plan. If software is created, procured, or used for any aspect of the PIP-II Project, specific controls should be established. Software acquired from Partnering institutions will be verified and validated to ensure all requirements are met. Partners should include the following elements associated with the software developed/sourced/procured for the PIP-II Project in their respective QA Plans:

- hardware system,
- firmware information,
- program/ source code information,
- verification methods,
- review/acceptance process,
- software control methods,
- developers/owners, and
- dependencies

This section should describe the Partner’s method for adhering to the Software Quality Assurance requirements established by the PIP-II QAP.

Please refer to the Software Quality Assurance Section of the PIP-II QAP.

### Section 15.0 – Component Handling, Control, and Transportation/Shipping

Inevitably, the Partner Institution will store parts and components prior to shipping to Fermilab, which may include the storage at a vendor or other institution. It is suggested for the Partner to submit a Storage, Handling, and Transportation Control Plan or description in the respective QA Plan. Parts and components (in-process and assembled) should be controlled maintained to prevent damage, loss or deterioration. This section should include the

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requirements for the plan which should include, but not limited to, the following critical elements:

- responsible personnel
- storage location
- environment control
- special component requirements
- labeling and traceability requirements
- pre-storage / pre-shipment verification activities

The PIP-II Technical Review Plan references Transportation Plans that will be developed collaboratively by FNAL and the Partner and approved by FNAL. The Transportation Plans should include Partnering institutions plans for the proper handling, storage, and transportation of components and equipment from their site to another site, including to Fermilab.

The Partners will be required to participate in relevant Transportation Reviews and transportation planning and testing activities.

This section will be used to describe the Partner’s processes for component handling, control, transportation/shipping.

### **Section 16.0 – Measuring and Test Equipment (M&TE)**

The Partner should provide an established process for controlling measuring and test equipment. Equipment used for inspections and testing should be calibrated and maintained, and traceability and accountability of this equipment and related records are required. M&TE typically includes instruments, tools, gauges, and nondestructive examination equipment.

Devices used to monitor or verify product should be approved and appropriately maintained; appropriate calibration and inspection records should also be maintained and referenced in the MIPs. This section should contain the methods of calibration and inspection, as well as remediation for equipment found to be non-functional or out of tolerance while executing PIP-II work. All M&TE records generated by the Partner or vendor is subject to review by the PIP-II Project.

### **Section 17.0 – Continuous Improvement**

The Partner is strongly encouraged to actively participate in PIP-II processes for continuous improvement such as assessment activities and lessons learned. The identification of process improvements, root causes from nonconformances, opportunities for improvement should be

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communicated to the PIP-II Project for input into the PIP-II Lessons Learned Process. This section should describe the method established for active participation in this process.