PIP-II Systems Engineering Management Process, Design Review plans and procedures, and associated QA/QC process

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CM Workshop

BARC, Mumbai

5 September 2018

In partnership with:

India/DAE
Italy/INFN
UK/STFC
France/CEA/Irfu, CNRS/IN2P3

Outline

- Overview of the PIP-II:
  - Systems Engineering Management Plan
  - Design Review Plan
  - Quality Assurance Plan
- Summary

PIP-II Engineering

- All Engineering at Fermilab is governed by the Fermilab Engineering Manual (**FEM**) - a policy document.
- *"…5.0 Policy*

  All facilities and equipment designed for use in the laboratory shall be designed in accordance with the Fermilab Engineering Manual and generally accepted Engineering best practices…"

- The PIP-II SEMP is complement to the **FEM**
- The **SEMP** is supported by various other documents, procedures and templates (Design Review Plan, Design Deliverables Document, Interface Control Documents, etc.)

Overview

- **System Engineering Management Plan** (SEMP) defines **the overall project engineering process**: *design, fabrication, technical support of a procurement process, acceptance and testing, installation*

- **SEMP describes the implementation** of the PIP-II engineering process and its relationship to the project's management policies and procedures

Systems Engineering

- The Systems Engineering process is based on development of ***formal*** requirements, specifications, and interface documents which are reviewed, approved and controlled at the project level to reduce cost and minimize risk of delays through the project development phases

SEMP - scope

- The SEMP provides requirements applicable to all PIP-II project engineering tasks, performed by or for the PIP-II Project
- This plan addresses roles and responsibilities, technical reviews, acceptance and verification, methods for change control, value engineering, safety, QA/QC, etc.
- The SEMP defines the processes and related procedures that will be used to develop subsequent documents which define and control project requirements, design integrity and interfaces
- It covers Technical Integration process which ensures consistency between technical systems

Systems Engineering Approach

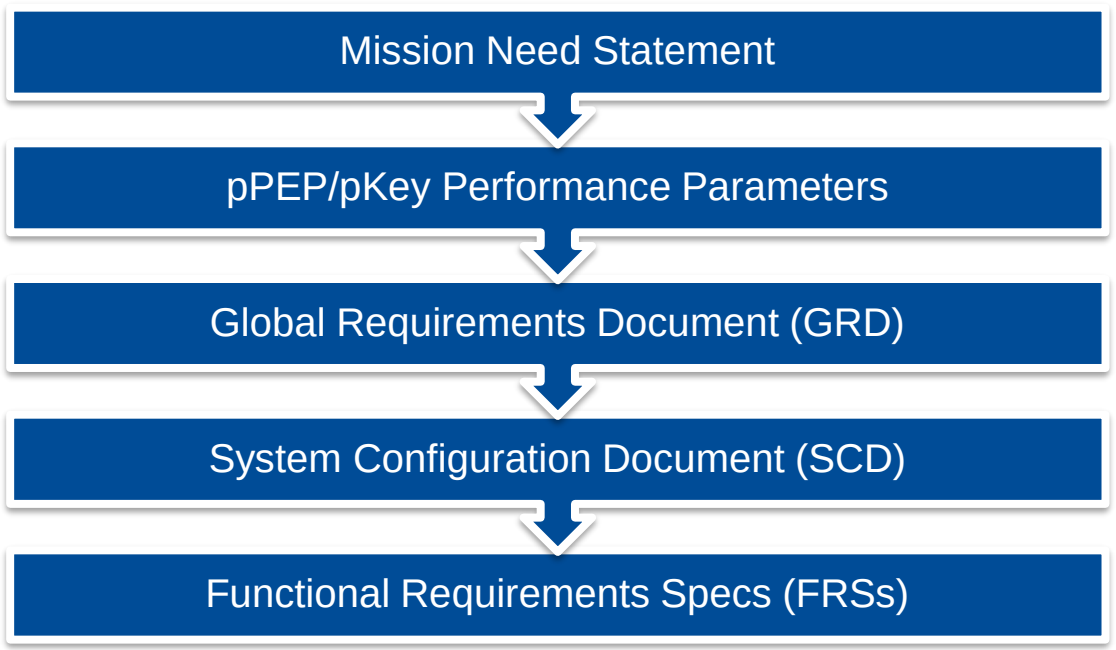
- This approach focuses on achieving the following objectives:
  - Document design responsibilities
  - Defined and control requirements and interfaces
  - Identify risks
  - Evaluate and document preferred (baseline) and alternative designs
  - Review designs
  - Document design outputs (deliverables)
  - Control baseline configuration

Design Responsibilities

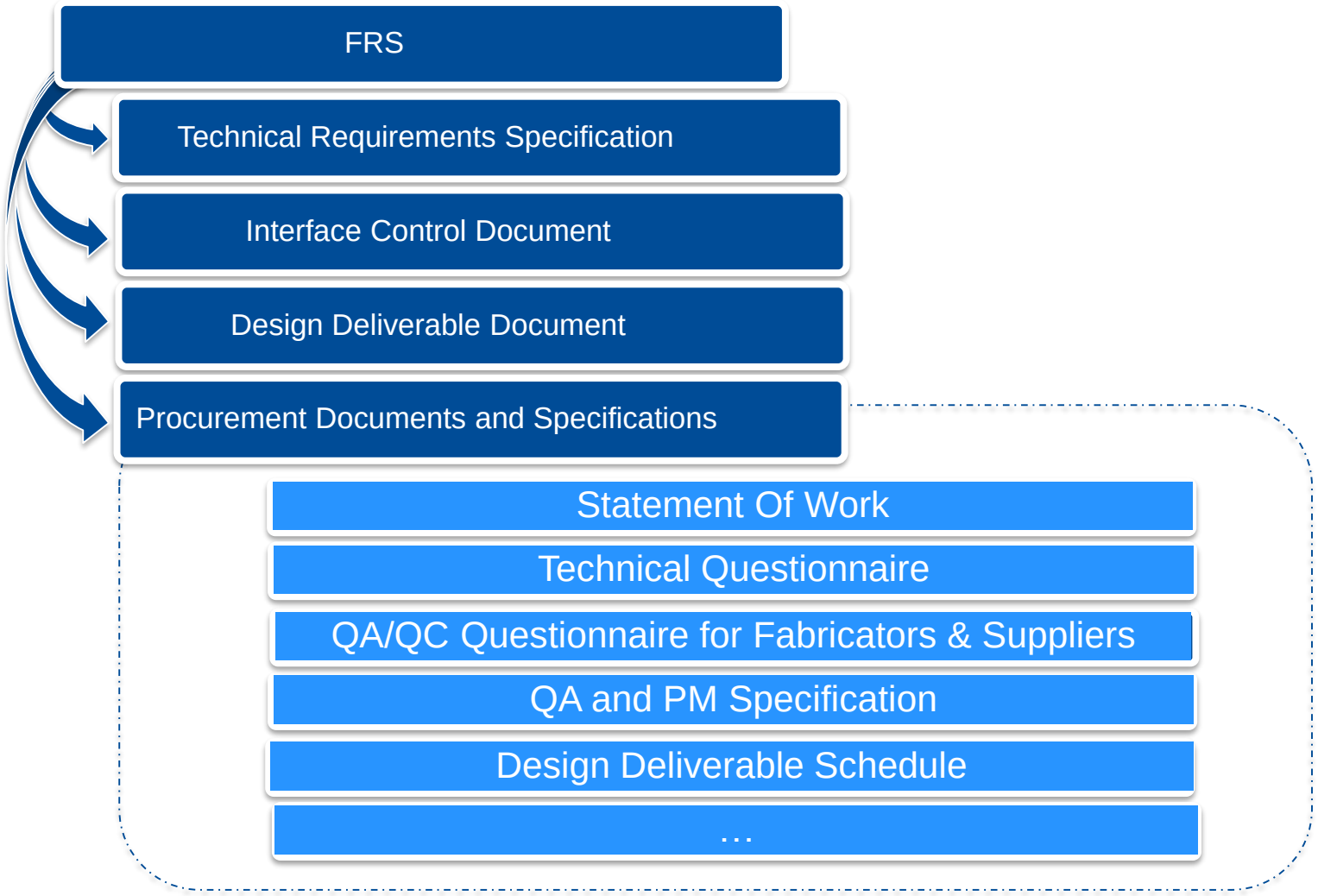
- System Managers(SMs), aka L2Ms
  - **Design Authority:** approve designs recommended by their L3/CAM
  - Develop system and sub system requirements
  - Manage interfaces with interconnected systems
- Sub Systems ICD and Functional Requirements Specifications(FRS) are assigned to the L3Ms/Control Account Manager(CAM)
- Integration Team supports requirements and interfaces definition process

Requirements Definition and Flowdown

- PIP-II **pPEP** ➔ preliminary Key Performance Parameters(**pKPP**)
- **pKPP**s are included in the *PIP-II Global Requirements* Document (**GRD**)
- **GRD** ➔ System Configuration Documents (**SCD**s)
- **SCD** ➔Functional Requirement Specifications (**FRS**s)



Requirements Definition and Flowdown (2)



Requirements Control

- All requirements, specification documents, and drawings (FRSs, TRSs, ICDs, etc.) for the PIP-II systems, sub systems and components defined and formally approved and maintained as controlled documents within Team Center (EPDM at L3)
- L2Ms approve changes to the FRSs and TRSs within their respective systems
- Any changes that may effect interfaces require approval of the Project Engineer via Design Change Request (DCR) process
- The PIP-II Project Director at Project Technical Director's recommendation approves changes that may impact GRD

Design Review Plan

- Design Review Plan is a stand alone document that defines the design review plan the PIP-II Project will use for systems, sub-systems, and components under development at Fermilab and International Partners
- Design Review Plan document – outlines the PIP-II design reviews process:
  - Classes of reviews
  - Roles and responsibilities
  - Procedure
  - Review deliverables
  - Close-out process

Classes of Reviews

- The level of a design review will be commensurate with complexity, cost, or safety importance of the design. The following types of project driven reviews are identified as follows:
  - Requirements and Specification Review (RSR)
  - Conceptual Design Review (CoDR)
  - Preliminary Design Review (PDR)
  - Final Design Review (FDR)
  - Production Readiness Review (PRR)
  - Transportation Readiness Review (TRR)
  - Installation Readiness Review (IRR)
  - Operations Readiness Review (ORR)

Design Review ➔ Roles and Responsibilities

- The L2Ms (Design Authorities) have overall technical and budget approval for their respective systems and sub-systems
- L2Ms responsibilities related to technical reviews are:
  - Develops Design Review Plan (DRP)
  - Assures design reviews are conducted as required for sub-systems within their respective authorities
  - Appoints the Review Coordinator
  - Approves the Review Committee Chair
  - Approves the Review Committee Members
  - Ensures that any recommendations arising from the review are adequately addressed

Design Review ➔ Procedure

- Provides guidelines for performing a design review to ensure that the reviews are consistent and critical elements of a review are covered. The procedure details:
  - Design review plan requirements
  - Presentation Materials and Support Documentation
  - Review deliverables
  - Review report
  - Announcement and Attendance

Design Plan and Deliverables

- L2Ms develop a Design Review Plan (DRP) that incorporates the relevant design review milestones into the PIP-II Project RLS
- The DRP will be approved by the Technical Director
- The plan lists specific design deliverables
- Design Deliverables Document will contain a list engineering documents expected to be produced
- Lists are defined by each L3Ms (and approved by L2Ms)
- Not all deliverables (documents) are in the project resource loaded schedule

Preliminary Design Review [~30-50% Design Maturity]

- Scope items:
  - Sub-system current organizational structure and team
  - Sub-system current scope and deliverables
  - Documented technical and Interface requirements (PRDs, FRSs, ESDs, ICDs)
  - Changes to baseline technical requirements
  - Preliminary engineering design and analyses, which should show predicted performance and expected margin to every requirement
  - Preliminary layouts, drawings, software requirements
  - Preliminary reliability and maintainability requirements
  - Assessment of risk areas
  - Safety by Design and Code compliance approach
  - Plan forward for obtaining required safety approvals
  - Preliminary QA and QC plan
  - Lessons learned from previous projects or experience
  - Closure of requests for action from previous review
  - Preliminary safety hazard assessments
  - Baseline cost and schedule

Alternative Analysis and Value Engineering

- The SEMP requires alternatives analysis, value management, and value engineering principles to be performed throughout the Project lifecycle
- L2Ms will evaluate alternative design approaches down to sub-system components as necessary to be confident proper design and technology choices are incorporated in the overall configuration of PIP-II.
- Value Engineering (VE) is linked to the alternatives analysis and function as a means to ensure the most cost-effective designs are chosen to achieve the lowest life cycle costs while meeting safety, reliability, and performance requirements
- Preferred design is baselined and is subject to a formal design change process

Design Change Request (DCR) Process

- DCR is a process of handling proposed alterations to a design that have been previously designated as approved. The process includes formal review under Integration Group leadership
- A DCR template will be provided to a requester. The template includes questions about:
  - Requested Change
  - Current Design Maturity
  - Reason for change
  - Subsystems/organizations to be notified
  - Affected WBS No. & Estimated Cost or (Savings)
  - Endorsements: DCR Requestor, Affected System Manager, Affected CAM, other stakeholders
- Approved DCRs will be recommended for the Baseline Change Request (BCR) process

Design Acceptance and Verification Criteria

- Document(s) that shows that Design conforms to Design Requirements
- Should have pre defined Design Acceptance 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 sub-system
- These documents should be generated at the lowest practical level to ensure higher-level integration and system-level performance are not impacted.
- Focus on characteristics of the design that are crucial to the safety and performance
  - Failure mode and affect analysis
  - Evaluation Criteria
  - Functional Tests
  - Test Procedure

Action Items Tracking and Resolution

The approach to track and resolve the Action Items generated in these meetings is as follows:

- Action Item List generated at each meeting
- Project Engineer maintains compiled Action Items List
- Action Item Owner is responsible for item closure
- L3/CAM has ultimate responsibility for action item closure in respective sub-systems.

Safety

- Safety Compliance
  - codes and standards are explicitly stated in FRS
- Safety by Design: a concept of minimizing hazards early in the design process
  - systematically identify hazards early in the design process
  - eliminate or minimize safety issues during the design cycle
  - continues risk evaluation using graded approach
  - capture lessons learned

Quality Management

- Systems engineering is an essential element of the quality management process.
- The Fermilab Quality Assurance Manual and the PIP-II Quality Assurance Plan (QAP) provide guidance to assure that work on the project meets DOE goals and requirements.
- The PIP-II QAP is currently being updated for the current stage of the project and shall remain as living document throughout the duration of the Project.

Essential Elements of the PIP-II QAP

- Essential elements of the PIP-II QAP include:
  - An effective systems engineering process
  - Robust processes and procedures to meet all requirements and specifications
  - Procurement management and assurance
  - PIP-II Partners, Subcontractors, and Vendors who can sufficiently and consistently fulfill the requirements of the PIP-II Project
  - A collaborative Partner/Subcontractor/Vendor Oversight Plans
  - Trained and qualified Project personnel at Fermilab, Partners, Subcontractors, and Vendors assigned to perform work
  - Robust Fermilab/Partner/Subcontractor/Vendor QC Plans, including Test Plans, and Manufacturing and Inspection Plans (MIPs)
  - Risk management processes
  - Change management processes
  - Issues Management
  - Effective communication and collaboration
  - A Graded Approach

Procurement Management & Assurance

- Procurement Quality requirements are part of the vendor/subcontractor selection process
- The Project establishes supplier qualifications, requirements, acceptance criteria, processes, and vendor verification activities
- All procurement activities comply with applicable safety and quality requirements
- Procurement specifications complete and unambiguous and under document control
- All Vendors/Subcontractors demonstrate that all specifications and requirements can be effectively and consistently met
- All Partners, Vendors, and Subcontractors shall have documented procurement processes and established supplier qualification requirements

Partner/Vendor/Subcontractor Oversight

- The Project establishes Oversight Plans for activities conducted at Partners, Vendors, and Subcontractors
- The plans 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 Production Readiness Reviews
    - Technical requirements & traceability
    - MIPs and Traveler reviews, Hold Points
    - Risks
    - Communication Plan
    - Issues Management (Effectiveness Reviews, etc.)
    - Specification/Requirement Verification
    - Equipment/Component transfer or storage verification process

Reliability

- It is imperative that Fermilab, Partners, Vendors and Subcontractors can demonstrate a high probability that systems will perform as intended as per specifications and requirements.
- Partners, Vendors, and Subcontractors will demonstrate the ability to minimize process variation via reliable, repeatable, and documented processes.
- Parts, components, equipment, structures, and/or assemblies shall meet expectations throughout the expected lifetime.

Personnel Training & Qualifications

- All Project personnel must be adequately trained and have the appropriate qualifications and experience to perform their assigned work in a safe and efficient manner. Achieving quality is **a line responsibility.**
  - This expectation is for Fermilab personnel, personnel at our Partners, Vendors, and Subcontractors performing work on the PIP-II Project.
  - Records of training and qualification are required.

Product Identification and Traceability

- Product identification and traceability is required
- Materials and subcomponents shall be traceable from procurement, to receiving inspection, to product fabrication and/or assembly, to final testing, through installation. Components provided by third-party suppliers shall also meet these requirements.
- All physical elements traced with an identifier. The identifier is the unique key to search for, and retrieve, all pertinent information gathered and stored during the life cycle of an element.
- All travelers and inspection records include product identification and traceability requirements.

Receiving and In-process Inspections

- Test Plans are derived and documented at Fermilab, Partners, and Vendors
- Inspection and testing steps are incorporated to ensure that products meet the defined requirements, this includes incoming inspection, in-process inspection, and complete assembly testing
- Traceability of test results of critical components to specification/requirements
- Records of these inspections and tests are maintained
- Devices used to monitor or verify product are approved and appropriately maintained; appropriate calibration and inspection records also maintained.
- All associated documents and records are subject to review by the PIP-II collaboration

Travelers, Procedures or Work Instructions

- All production is controlled using work instructions, procedures and/or ‘travelers’
- These documents serve to instruct production personnel on the sequence of work, as well as incoming inspections, acceptance testing, in-process inspections, and pre-shipment/storage verification activities.
- They provide a record of how the work was completed as well as to document non-compliance or issues with corresponding resolution
- Include criteria for maintaining, handling, storing, shipping, cleaning to prevent damage/deterioration
- Suppliers that are fabricating complex components (e.g. cavities) are required to deliver records of the associated fabrication, test plans, and test results, along with the hardware they are producing
- Documents are subject to Production Readiness Reviews
- Fermilab is using “Vector” electronic **traveler** system for cryomodules

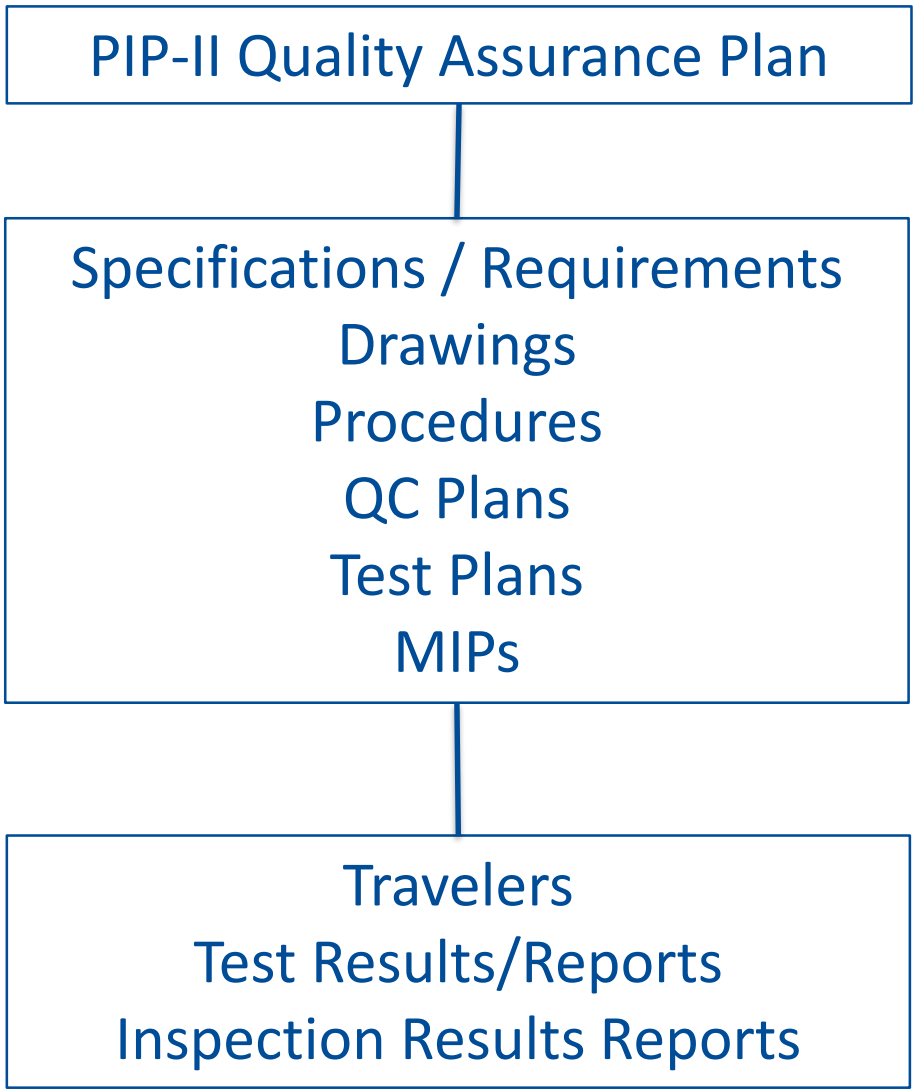
Manufacturing and Inspection Plans (MIPs)

- MIPs describes the technical infrastructure, parts and materials inventory, technical processes and operations, yield and throughput, inspection and test, and human workforce planned to produce, monitor, and control the project scope deliverables
- The plan should include:
  - 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, measurements, testing, disposition, records)
  - Quantities and Throughput (Production quantities, throughput, learning curve, yield
  - Resources (assigned personnel, qualifications, training)

Controlling Non-conforming Product

- Nonconformances should be communicated to the respective System Manager, identified, and tracked
- Nonconformances which affect functional requirements or interfaces with subsystems at Partnering institutions should be communicated to the Technical Director and will be shared amongst the Partnering institutions
- Deviations (i.e. when a deliverable will not meet an approved functional or interface requirement) require Technical Director and SM written approval
- Suspect/Counterfeit Items (S/CI) fall within the scope of nonconforming product, and should be reported and dispositioned through the normal NCR process
- The Discrepancy Report (DR) system are integrated in the travelers, since it is intended to use to resolve issues related to the production

Quality Documentation Hierarchy



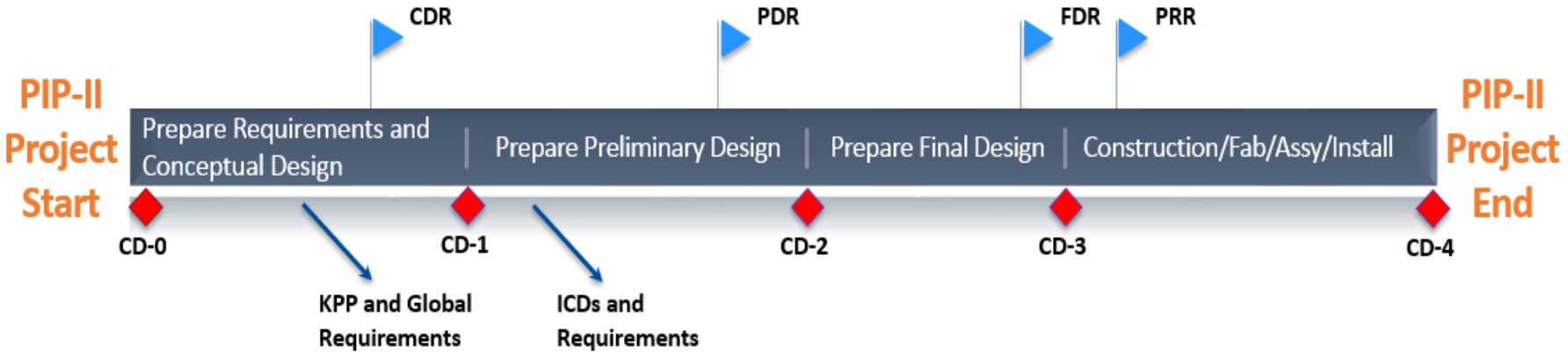
Summary

- The requirements of the Fermilab Engineering Manual and Quality Assurance Program flow down to the PIP-II Project, and subsequently to Partnering Institutions
- The PIP-II SEMP and QAP should be updated to have strong equivalency with IIFC processes while assuring that the quality of the work on the PIP-II Project will meet technical requirements and project goals
- PIP-II and IIFC processes should be reviewed to address gaps in either approach

Thank you!

Back-up

PIP-II Critical Decision Process



Tools

- Mechanical Design:
  - Siemens NX
- Electrical/Electronics Design:
  - Altium
  - AutoCAD
- Architectural Design
  - AutoCAD
  - Revit
- Engineering Documentation Management with revision control:
  - Siemens Teamcenter
- Engineering document database for DAE information transfer: Sangam
- Project Management Documentation: DocDB
- RLS: Primavera (P6)
- General Documentation Management: SharePoint
- Traveler and NCR Management: Vector
- Meeting/Conference Documentation: Indico
- Findings & Recommendations Management: iTrack
- Analysis tools: ANSYS, COMSOL, MARS, etc.

Assessments

- Internal Assessments (Self-Assessment) 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 QAP
- Independent Assessment (separate from, and in addition to, Internal Assessments). 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
- The Project shall conduct these assessment activities to identify opportunities for improvement.

Quality Improvement

- Quality Improvement encompasses issue prevention, detection, correction, and continuous improvement.
- The PIP-II Project encourages participation in the quality improvement process by fostering a no-fault attitude.
- The appropriate level of root cause analyses shall be conducted on issues to identify resolution to prevent recurrence in the same or similar fashion.
- Lessons Learned from other Projects or experiences shall be incorporated into processes and practices where applicable.
- Lessons Learned identified from this Project shall be captured and shared accordingly.

Records Management

- QAP requires maintaining the following records (at minimum):
  - Records of reviews, including presentations and reports
  - Procurement records, including purchase orders and associated specifications, supplier evaluations
  - Design records, including records of design basis, as-built drawings, and design change request approvals
  - Production records, including those from Partners and Vendors
  - Records of testing, including travelers, checklists and reports; also from Partners, Vendors, and Subcontractors
  - Components performance testing results, and a list of Nonconformance Reports
  - Nonconformance Corrective Action Plans
  - Meeting minutes and action items lists

Graded Approach

- The QA plan uses a graded approach to impose levels of control **commensurate with the level or risk, consequences of failure,** or occurrence of an adverse event:
  - Relative importance to safety, safeguards, and security
  - 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 within a project