**Quality Assurance/Quality Control Plan Guidance Template and Expectations for Partner Institutions for In-kind Contributions**

This document describes all elements required in the Quality Assurance Plans submitted by Partner Institutions as part of the Project Planning Documents package. At minimum, the Partner Institution is required to submit a detailed Quality Assurance/Quality Control Plan in accordance with the EIC Quality Assurance Plan and include the sections highlighted below. It is imperative that Partners Institutions demonstrate a high probability that systems will perform as intended as per specifications and requirements. Partner Institutions, and the partners and vendors with whom they work, should 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.

# Purpose

The Partner Institution is to describe the scope of this QA/QC Plan relating to the EIC Project as it is reflected in the Project Planning Documents.

# Roles, Responsibilities, and Authorities

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

* quality
* project deliverables
* design
* procurement
* fabrication
* in-process inspection and acceptance testing
* storage
* shipping/transportation
* final acceptance testing

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

# EIC Deliverables

The Partner Institution should describe the specific deliverables for the EIC 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 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.

# Communication Plans

The Partner Institution is strongly encouraged to follow the Communications Plan articulated in the Project Planning Documents that describes the methods of communication to be utilized while conducting EIC work. For example, meetings held with EIC 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 or Vendor-specific Oversight Plan created by the EIC Project.

# Competence, Training, and Awareness

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

It is imperative that the Partner Institution 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 EIC Project.

Please refer to the Personnel, Training, and Qualification Section of the EIC Quality Assurance Plan.

# Design and Configuration Management (Design Change Control)

The EIC 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 EIC Project, this section should include the description of the methods used to assure EIC requirements are met throughout each phase of the design. The Partner Institution is required to describe responsibilities relating to the design of the EIC Project deliverable. The Partner Institution is also required to have an established design process and design change control procedures, including the implementation and verification of the change. If third party vendors or institutions are used by the Partner Institution to fabricate components or provide a service relating to design for EIC, the Partner Institution is required to provide the EIC Project with the processes for communicating design requirements and design changes to the vendor and corresponding plans to assure compliance to requirements.

For instances where the Partner Institution is executing the design, any changes to the design must be submitted to the EIC Project for evaluation through the change control process and decision to approve prior to proceeding. See Figure 1 – Consolidated EIC Change Control Process Flow Chart below.

*Figure 1 - Consolidated EIC Change Control Process Flowchart (documented in the EIC Configuration Management Plan)*

The EIC Project adheres to the requirements set forth in the BNL Environment, Safety, and Health Manual Chapter TBD – *Ensuring Equivalent Safety Performance when Using International Codes and Standards*. This ESH Manual chapter describes the process used to establish equivalent safety performance between U.S. and International engineering design codes and standards. The Partner Institution is required to assure alignment with the International Codes and Standards requirements for components or systems fabricated by the Partner Institution or third-party vendor or institution. The Partner Institution must provide evidence of this alignment with the international codes and standards. Any deviations from a BSA requirement or standard will be handled on a case-by-case basis. BSA will ultimately approve any deviations.

The Partner Institution will be required to participate in Design Reviews organized by the EIC Project to verify that design meets requirements prior to fabrication. The preparation of the Design Reviews requires adequate communication and scheduling and should be done in accordance with the EIC Technical Review Plan.

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

Please refer to the Design Section and Appendix A of the EIC Quality Assurance Plan.

# 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 EIC Project systems, subsystems, and their components have been adequately tested to ensure that the final devices function in compliance with their requirements and intended use. The Partner Institution should 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 EIC Project.
* **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 criteria. The test records are required to be submitted with the EIC 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 EIC 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 refer 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 EIC Project for review and verification.

Please refer to the Design Verification and Validation Section of the EIC Quality Assurance Plan.

# Vendor Management and Assurance

The Partner Institution should have an established method/system for procuring/receiving parts, components, and services from suppliers, vendors, and other institutions outlined in a Vendor Management Plan or description. L2M/L3M 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 Institution manages issues and control nonconformances that occur at the third-party vendors and institutions. All issues and nonconformances are to be communicated to the EIC L2M/System Manager for awareness, impact/risk analysis, and aligned corrective action planning. The Partner Institution is strongly encouraged to communicate all decisions to change supplier, vendors, facilities, or institutions during EIC work, including the reasons and associated impact/risk analysis relating to the change. If multiple vendors or institutions are used, the vendor/in-kind contribution oversight management processes used for each vendor or institution is required. The Partner Institution should incorporate the following elements:

* Quality requirements should be part of the vendor/supplier selection process established by the Partner Institution;
* The Partner Institution 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 EIC 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 Institution should provide processes that describe vendor/in-kind contribution management and assurance.

# Manufacturing (In-Process) Inspection Planning

The Partner Institution should 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 EIC L2M/System Manager to ensure all critical elements are incorporated and agreed upon. All nonconformances or issues occurred during fabrication by the Partner Institution or third-party vendor or institution are to be communicated to the EIC L2M/L3 as soon as it is identified. The implications and risks associated with the nonconformance or issue should be discussed and agreed upon among stakeholders. All nonconformances will be logged in the EIC Master Nonconformance Log for transparency, lessons learned, and continuous improvement. Inspections and Tests should be conducted by trained or qualified personnel.

At 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
* 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)

Hold points, Notification points, Approval points are required in all Manufacturing Inspection Plans. Communication of upcoming hold, notification, or approval points by the Partner Institution to the respective L2M/L3M 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 Institution, then the Partner Institution is responsible for establishing adequate MIPs for each vendor or institution. Vendors are required to deliver records of the associated fabrication, test plans, and test results, along with the hardware they are producing.

All MIPs should be provided to BNL upon the delivery of the finished component.

This section should describe the method for deriving, communicating, implementing, and controlling MIPs for all EIC work.

Please refer to the Inspection and Acceptance Testing Section of the EIC Quality Assurance Plan.

# Product Acceptance

BNL 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 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 L2M/System Manager for risk analysis and corrective action planning.

Partner Institutions should ensure that the documentation for items that require inspection and acceptance testing is maintained and submitted to the EIC Project.

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

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

Please refer to the Inspection and Acceptance Testing Section of the EIC Quality Assurance Plan.

# Control of Nonconformances

BNL and the Partner Institution will collaboratively establish methods for effectively identifying, controlling, and documenting nonconformances identified throughout the entire lifecycle of the component, system, or service within their scope of work, from design to fabrication to shipment to BNL/JLab. Nonconformances should be documented in the Manufacturing Inspection Plans or Travelers as applicable. Nonconformances should be immediately communicated to the respective L2M/System Manager, identified, and tracked. All corrective action plans and timelines for resolution should be agreed upon with the respective L2M/System Manager.

Nonconformances which affect functional requirements or interfaces with subsystems at Partnering institutions should be communicated to the L2M and Technical Director 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/System Manager written approval.

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

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

# Product Identification and Traceability

The Partner Institution should have an effective method for identifying components produced by and for the Partner Institution. 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 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 or a third-party vendor or institution’s process which should be described in this section of the submitted QA Plan.

# 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 set forth in the EIC Quality Assurance Plan. This section should describe how the Partner Institution controls documents, manages the changes to documents, and method for integration into respective processes relating to their EIC scope of work. If the Partner Institution is procuring items and services from vendors, the Partner Institution should ensure the vendor has adequate document and data control. The vendor’s document and data control procedures are subject to review by the EIC Project and are part of the documentation deliverables.

All procedures relating to scope of the EIC work undergoing changes should be communicated to the EIC 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
* Manufacturing inspection plans
* Work instructions / standard operating procedures
* Manuals and checklists
* The QA Plan submitted for EIC work
* Nonconformance Reports

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

Please refer to the Document and Records Section of the EIC Quality Assurance Plan.

# Software Quality Assurance

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

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

This section should describe the Partner Institution’s method for adhering to the Software Quality Assurance requirements established by the EIC Quality Assurance Plan.

Please refer to the Software Quality Assurance Section of the EIC Quality Assurance Plan.

# Component Handling, Control, and Transportation/Shipping

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

EIC Project Planning Documents will reference Transportation Plans developed collaboratively by BSA and the Partner Institution and approved by BSA. 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 BNL/JLab.

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

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

# Measuring and Test Equipment (M&TE)

The Partner Institution 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 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 EIC work. All M&TE records generated by the Partner Institution or third-party vendor/institution are subject to review by the EIC Project.

# Continuous Improvement

The Partner Institution is strongly encouraged to actively participate in EIC 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 communicated to the EIC Project for input into the EIC Lessons Learned Process. This section should describe the method established for active participation in this process.

# Transfer of Ownership

This section will describe the transfer of ownership of the equipment, component, system, etc. from the Partner Institution to BNL.

# BNL and Partner institution Responsibility Matrix or RACI Chart

TBD