Supplemental Quality Assurance Plan

For the

[Title]

Thomas Jefferson National Accelerator Facility

Office of Science

U.S. Department of Energy

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PLAN APPROVAL

**REVISION LOG**

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**ACRONYMS**

|  |  |
| --- | --- |
| APM | Acquisition Policy Manual |
| CAM | Cost Account Manager |
| DOE | Department of Energy |
| ES&H | Environment, Safety and Health |
| EVMS | Earned Value Management System |
| FAC | Facility Advisory Committee |
| GeV | Giga Electron Volt |
| POM | Procurement Operations Manual  |
| QA | Quality Assurance  |
| QAPD  | Quality Assurance Program Description  |
| QC  | Quality Control  |
| SQAP | Supplemental Quality Assurance Plan  |
| TJNAF | Thomas Jefferson National Accelerator Facility |
| TR | Technical Representative |

# Introduction

# Purpose

# Scope

The scope of this SQAP covers three main areas: Quality Planning, Work Processes, and Documentation. The level of detail in the SQAP is appropriately defined to address the QA requirements of the [Title] project. Specific instructions for the actual processes belong in the working-level procedures and are therefore excluded from this document.

Plans for addressing unique [Title] QA requirements that are not covered in the TJNAF- QAPD shall be explicitly addressed in this document. Plans for additional QA requirements that are beyond the existing scope of the project will be evaluated on a case-by-case basis and subjected to SQAP revision control. In cases where QA plans that are provided by the [Title] project differ from those of the TJNAF-QAPD, the TJNAF-QAPD plans shall take precedence.

Due to the inherent differences in the scope of work between cryomodule and cryoplant, a separate section of the SQAP is included to address any unique cryoplant QA processes.

# Quality Planning

## Organizational Structure

The organizational structure for the [Title] project within TJNAF is designed for mission success in meeting project goals in a safe and effective manner. The TJNAF [Title]Project Organizational Chart provides a high-level view of the staff structure. Subsequent changes to the organizational chart are quickly communicated to the project team. The project management process, as well as the line of communication, primarily flows from top-down to the working level. The Senior Technical Lead guides the team where project goals, requirements, schedule, and costs are continually reviewed for progress tracking. As with many common types of projects involving cross-functional groups, including those from inter-department and/or external collaborators, information exchange and two-way communication are necessary to ensure project success.

## Roles & Responsibilities

Defining the roles and responsibility is important for effective and efficient project implementation. Each TJNAF division has its own core competency and area of responsibility (i.e. Accelerator Division for SRF Research, Operation and Cryomodule Production; Engineering Division for cryoplant and engineering design services; Environmental, Safety, Health for environment, safety and health; and Performance Assurance for quality). Within each division, individual roles and responsibility are defined further based on the specialty and in accordance to the scope of work for their department. In essence, staff members perform the same type of work as part of their daily functions, but are now applied to the scope of [Title] project. Quality Assurance is an integral part of everyone’s job responsibility.

### Senior Technical Lead

The Senior Technical Lead is the authority on project planning and implementation and overall project coordination. The Senior Technical Lead ensures that the project is on target with requirements such as schedule, costs, technical performance, and product deliverables. The Senior Technical Lead also serves as the high-level liaison for the partnering collaborating labs.

### Deputy Senior Technical Lead

The Deputy Senior Technical Lead supports the Senior Technical Lead by overseeing the project implementation and communicates project status and pressing issues to the Senior Technical Lead. The Deputy Senior Technical Lead also oversees the technical design requirements, production, and qualification of the XXXX.

### 4.2.3 Control Account Manager (CAM)

The CAM is responsible for managing the implementation of their respective body of work within the Work Breakdown Structure. In the case of the cryoplant, the CAM is responsible for both the design and performance requirements of the plant. The CAM is responsible for regularly communicating project status to the Senior Technical Lead and the project team.

### Project Engineer

The Project Engineer provides technical support for design requirements, functional performance, and fabrication of the XXXX. The project engineer works closely with the internal project team as well as the external collaborators to ensure design goals are met. The project engineer also supports the Deputy Senior Technical Lead with project implementation.

### 4.2.4 Systems Integration Engineer

The Systems Integration Engineer provides support to integrate the various system requirements of the LCLS-II project. This includes researching, evaluating and communicating system requirements, ensuring proper planning for system-level reviews, and making recommendations to the project team.

### Environmental and Safety Manager

The Environmental and Safety Manager is responsible for ensuring that the appropriate environmental and safety requirements are met for the project. This includes both internal TJNAF requirements as well as those required for the [Title] project.

### Procurement Manager

The Procurement Manager ensures that procurement functions are properly supported for the [Title] project. The Procurement Manager monitors the procurement process throughout the stages of project implementation and performs TJNAF’s internal procurement functions as well as those with the partner labs.

### Technical Representative (TR)

The SOTRs provide technical input and design evaluation on the components and assemblies for which they are assigned. The TRs work closely with the procurement team in material sourcing for the project; and also with the production team throughout the manufacturing process of the XXXX. TRs are responsible for defining the QA/Quality Control (QC) requirements for the procured material as well as the sub-assemblies and the end products. The TRs work jointly with the staff at partner labs in the procurement efforts for the [Title] project.

* + 1. Production Leader

The Production Leader is responsible for developing and implementing the manufacturing plan for the XXXX. The production leader works with the project team to ensure functional and QA/QC requirements are met within the production process. Externally, the production leader works with the staff at partner labs to align manufacturing practices between the two manufacturing sites.

### QA Manager

The QA Manager develops and maintains a Quality Assurance Plan for the [Title] project and ensures alignment between the quality systems and quality practices from the lab to the project. The QA Manager advises the project team of quality matters, provides QA services and recommendation in the planning, development and production processes for the cryomodule construction. The QA Manager conducts evaluation and quality audits of the QA/QC processes for the project.

## Project Management

Under the guidance of the TJNAF [Project Control System Manual,](http://www.jlab.org/div_dept/directorate/proj_mgmt/manual/manual.pdf) the budget size of the [Title] project requires a deployment of the Earned Value Management System (EVMS) for project organization, planning, measure, and control. Refer to the latest version of the lab-wide manual for instructional details. Records and documents associated with the EVMS process are filed in accordance with the guidelines of the TJNAF Project Management Office.

## Communication

Good communication is an essential element for project success. Listed below are some of the typical forums for reviewing the statuses of the [Title] project. Depending on the type of reviews, the frequency and format could be defined by a DOE order, by operating manual, governing policy, or established solely by the individual program need.

* **Project Level** - TJNAF Project Management Office uses the EVMS for project planning and tracking. Lehman Reviews, Critical Decision Reviews, Facility Advisory Review Committee (FAC) Reviews, collaboration meetings, and other high-level reviews are also used for project communication.
* **Implementation Level** - Product Design Reviews, Technical Peer Reviews, Manufacturing Reviews, and Sourcing Committees are included in the process. Other communication tools include production planning meetings and Quality Board Reviews. Process assessment and audits are conducted to ensure acceptable project performance.

## Graded Approach

For the [Title] project, TJNAF follows the graded approach process per the [QA25kd Graded Approach Procedure.](https://jlabdoc.jlab.org/docushare/dsweb/Get/Document-16594) This procedure provides direction for determining the degree of control, verification, and documentation to meet Environment, Safety, and Health (ES&H) requirements at the appropriate programmatic risk level. Instilling an overabundance of control on a minor task could paralyze a project; however, applying too little control could result in injury. The goal is to apply an appropriate level of mitigation to reduce or eliminate unfavorable conditions.

## [Title] Design

### 4.6.1 Design

### 4.6.2 Design Input

Design input includes requirements related to product function, product performance, layout, assembly, quality, life cycle, environmental, health, and safety. The level of detail should be adequate to enable design activities to transform product requirements into an appropriate set of engineering document and product specification. The design team uses the appropriate engineering standards, manuals, or civil codes for guidance on product design. Specific design input areas that may have differences in application at TJNAF and partner labs are identified below. If during the project other areas of design input are identified, the SQAP will be revised accordingly.

* + - * **Pressure Systems Programs** - For pressure systems, TJNAF will conform to its ES&H Manual Chapter 6151, written to comply with 10CFR851.
			* **Welding Program** - For design, procurement, and assembly of welded components, TJNAF will follow its guidelines in the ES&H Manual Chapter 6122. The program integrates aspects that follow national consensus codes for welding, including inspection and examination requirements.
			* **Seismic** - For seismic design, TJNAF will conform to XXXX.
			* **Oxygen Deficiency Hazards (ODH)** - For design and procurement of XXXX.

### 4.6.3 Design Output

A complete set of timely approved engineering design documents permits smooth project transition from the design phase to the procurement process and subsequently for a quality manufacturing of the cryomodules. The design output includes, but is not limited to, documents such as an Interface Control Document, Engineering Design Specification, engineering drawings, and technical engineering notes. Another major document is the derivation of a manufacturing plan, with inclusive items such as process documents, assembly/test procedures, and inspection/acceptance processes and criteria.

### 4.6.4 Design Development

Design Development is conducted to ensure that the design requirements are appropriate to the needs of the customer and that the final design meets the applicable design requirements. While the customer has the ultimate say, design alternatives, cost reduction, and design limits, can be explored as part of the development process. The design development process consists of technical research and calculations, technical design reviews, peer reviews, prototype testing, or by comparing the actual to the expected performance.

### 4.6.5 Product Verification

Product verification ensures that the cryomodules meet the specified requirements. The production team is responsible for implementing the process of qualification, testing, and acceptance checks. This may include certain acceptance criteria to be integrated into the process travelers and/or other types of acceptance documentation that have been agreed upon by the customer. The verification process is reviewed by the project team to ensure that a common agreement exists among the partner labs. During the construction process, the documents and test results from the verification process are filed in a secured location and be made readily retrievable when needed.

## Procurement

Procurements for the [Title] project follow the guidance of the TJNAF [Acquisition](https://www.google.com/url?q=http%3A//www.jlab.org/div_dept/admin/business/procurement/Acquisition_Policy_Manaul.pdf&sa=U&ei=NAm7U-TmEsGV7AbL94DQCQ&ved=0CAYQFjAA&client=internal-uds-cse&usg=AFQjCNGOjP7rUhXOIq6wP5gH_fLr537uqw) [Policy Manual](https://www.google.com/url?q=http%3A//www.jlab.org/div_dept/admin/business/procurement/Acquisition_Policy_Manaul.pdf&sa=U&ei=NAm7U-TmEsGV7AbL94DQCQ&ved=0CAYQFjAA&client=internal-uds-cse&usg=AFQjCNGOjP7rUhXOIq6wP5gH_fLr537uqw) (APM) and the [Procurement Operations Manual](https://www.google.com/url?q=http%3A//www.jlab.org/div_dept/admin/business/procurement/OpsManual.pdf&sa=U&ei=NAm7U-TmEsGV7AbL94DQCQ&ved=0CAkQFjAC&client=internal-uds-cse&usg=AFQjCNE69npaePflFE5J0cQmTnCVmlKDcw) (POM). Formal plans, reviews, and approvals are part of the standard procurement process. In unique circumstances, when the scope of the procurement activities falls outside of the APM or POM requirements, the Senior Technical Lead or Deputy Technical Lead is notified and the issues are addressed accordingly with the procurement department.

Quality Assurance requirements are included in the procurement documentation process. Sourcing of the XXXX is distributed between TJNAF and XXXX.

To ensure product consistency of material, and ultimately performance consistency of the cryomodules, TJNAF and FNAL will develop and execute a plan to assign procurement and QA responsibilities. The plan will include TR/component responsibilities; specification and drawing requirements; Source Evaluation Board; and an agreement on technical, processing, inspection, and acceptance requirements.

# Work Control Processes

## Work Control

Work control processes are necessary to enable safe, effective, and efficient production of the intended products. The Production Leader is responsible for developing and implementing a manufacturing plan for the production of the XXXX. The manufacturing plan includes a set of work control processes to ensure traceability of material as well as control of non-conforming material. The plan also includes a process for documentation and records control to facilitate usage of the latest document versions.

## Travelers

The SRF procedure on document control process ([Document Control QA-P-001](https://jlabdoc.jlab.org/docushare/dsweb/Get/Document-49961/QA-P-001%20Document%20Control%20Process%20Rev%20C.docx)) is used for work center processing of the XXXX. This procedure includes a formal traveler approval and revision control process. Travelers specify the appropriate processing/functional parameters, the product acceptance criteria, work flow details, and references to any processing documents, instructions, or procedures. Typical information recorded in travelers includes inspection data, raw test data, converted data, process information, and/or other file attachments. To obtain maximized benefit of the traveler system, staff members complete their respective duties in all parts of the traveler processing cycle in a timely fashion.

## Control of Non-conforming Product

The SRF procedure for controlling non-conforming product ([Control of](https://jlabdoc.jlab.org/docushare/dsweb/Get/Document-48061/MAI-P-004%20Rev%20B%20Control%20of%20Non-Conforming%20Product.docx) [Nonconforming Product MAI-P-004](https://jlabdoc.jlab.org/docushare/dsweb/Get/Document-48061/MAI-P-004%20Rev%20B%20Control%20of%20Non-Conforming%20Product.docx)) is followed. Process actions are documented, and the non-conforming material is controlled until a disposition is made by the responsible staff. Reworked materials are subject to re-verification to demonstrate conformity to the requirements.

Due to the “parallel” production lines at TJNAF and XXXX, the project team ensures proper control of non-conforming products at a collaboration level. The project team establishes, using a graded approach, the critical parameters or features that require technical review and joint resolution by partner labs.

## Inventory Control and Material Traceability

The SRF inventory control procedure ([Inventory Control PR-P-005](https://jlabdoc.jlab.org/docushare/dsweb/Get/Document-41056/Inventory%20Control%20PR-P-005%20-%20Released.doc)) is used for inventory control and material traceability. All materials are handled with care, cleanliness maintained where appropriate, and protected from damage throughout the production cycle. A plan for part-identification and serialization is established for the [Title] project. Requirements for identification of incoming material are included in the Statement of Work of the vendor procurement process. Examples of requirements include but not limited to the serialization scheme, marking type, method, and location. Except for those where the differences between nominally identical parts would have negligible impact on product functions, individual part traceability is maintained throughout the production process, from incoming receiving, to assembly and test, and to the final shipment of the cryomodules.

## XXXX Shipment

## Corrective Action and Continuous Improvement

The SRF procedure for corrective, preventive, and continuous improvement actions ([Corrective, Preventive, and Continuous Improvement Actions MAI-P-00](https://jlabdoc.jlab.org/docushare/dsweb/Get/Document-45326/MAI-P-001%20Rev%20A%20Corrective%2C%20Preventive%2C%20and%20Continuous%20Improvement%20Actions.docx)1) is used for issues management arising from production. Issues can be identified and addressed in numerous ways. The general guidelines within this document are followed for the [Title] project. Corrective and improvement actions are documented using the appropriate set of available tools.

# Documentation

## Document Control

The SRF document control procedure ([Document Control QA-P-001](https://jlabdoc.jlab.org/docushare/dsweb/Get/Document-49961/QA-P-001%20Document%20Control%20Process%20Rev%20C.docx)) describes the process used for this project for the control of certain production documents and prescribes a formal mechanism for the review and approval by authorized staff.

The design ownership of the XXXX. The project team will establish a process of document exchange to ensure availability of accurate documents and versions at the appropriate time and point-of-use locations.

## Record Retention

The SRF records retention procedure ([Records Retention QA-P-002](https://jlabdoc.jlab.org/docushare/dsweb/Get/Document-62616/Records%20Retention%20QA-P-002%20Rev%20A.docx)) is used to provide objective historical evidence and the results of project requirements, both in product performance and compliance to regulatory requirements. With certain types of documents, the official records reside in the responsible TJNAF department or division (i.e. Procurement Office, Project Management Office, Finance, etc.)

## Assessments/Audits

Assessments and audits are conducted to ensure that the project requirements are met for processes internal to TJNAF as well as those of the vendors. For the [Title] project, assessments and audits are conducted following the guidelines of the TJNAF QAPD. In addition, independent project type assessments (i.e. [Title] Facility Advisory Committee Review) may apply at the appropriate stages of the project.

# Cryoplant

# References

* 1. XXXX Quality Assurance Plan
	2. TJNAF Quality Assurance Program Description (QAPD)
	3. TJNAF [Title] Organizational Chart
	4. TJNAF Project Control System Manual

* 1. QA25kd Graded Approach Procedure
	2. Seismic Design Specification for Buildings, Structures, Equipment and Systems: 2014 (SLAC-I-720-0A24E-001-R004)
	3. TJNAF Acquisition Policy Manual
	4. TJNAF Procurement Operations Manual
	5. Document Control QA-P-001
	6. Control of Nonconforming Product MAI-P-004
	7. Inventory Control PR-P-005
	8. Corrective, Preventive, and Continuous Improvement Actions MAI-P-001
	9. Records Retention QA-P-002

8.14 Conduct of Engineering Manual ENG-AD-01-001