QAM 12130: QUALITY ASSURANCE PLANNING GUIDELINES FOR FRA PROJECTS

Revision History

Author	Description of Change	Revision Date
Jemila Adetunji	Added guidance for Lessons Learned information. See Section 5.0	February 2022
Jemila Adetunji	Initial release	September 2021

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1.0 INTRODUCTION AND SCOPE

Quality Assurance (QA) is a critical component to the success of any program or project. Early integration of QA into a program or project ensures appropriate and adequate processes, personnel, and equipment are in place to meet or exceed expectations. Quality Assurance also provides the means to adequately identify and mitigate potential risks. This chapter describes the expectations regarding the implementation of QA in the various types of projects executed by the Fermi Research Alliance (FRA) both at the main Batavia site and any leased spaces.

New projects with a total cost of greater than $50M, or at the discretion of the relevant DOE Under Secrettary for Projects with a total cost between $10-50M (such as new or upgraded High Energy Physice experiments, civil construction, or infrastructure upgrades) are required to follow DOE Order 413.3B – *Project and Project Management for the Acquisition of Capital Assets*. FRA may choose to undertake focused facility upgrade projects using General Plant Project (GPP) or Accelerator Improvement Project (AIP) funding. FRA also has the option of undertaking less extensive upgrades using Operations budgets. For Projects that fall below the DOE O 413.3B threshold, FRA utilizes a tailored approach, including Quality Assurance, as described in the Fermilab Conduct of Project Management Values and Standards.

DOE O 413.3B projects require designated Quality Assurance roles and a Quality Assurance Plan (QAP). The Quality Assurance roles can include: a Quality Assurance Manager, Quality Engineering Specialist, a Quality Coordinator, or any combination of these roles depending on the size and complexity of the project. GPP, AIP, and other smaller projects should include Fermilab Quality Section personnel in the organizational structure of the project or designate a Project Quality liaison in order to ensure there is focus on instituting the appropriate QA framework along with other project personnel. It is also recommended that projects executed using Operations budgets engage the Fermilab Quality Section for support and guidance on how to integrate QA into the project. It is important to note that the Project Manager and Project Director (if one is designated) bear the ultimate responsible for quality in their project.

2.0 DEFINITIONS & ACRONYMS

Quality Assurance – All planned and systematic actions that provide confidence that quality is achieved.

Quality Control – A set of activities for ensuring the qualification of products or services. The activities focus on identifying defects and out of specification conditions in the products produced or services provided.

3.0 RESPONSIBILITIES

Responsibilities are listed below for specific members of the project.

3.1 Project Director and/or Project Manager

- Ultimately responsible for achieving quality in their project.
- Applying the graded approach to ensure that appropriate controls are in place for project activities.
- Scheduling or identifying self-assessments as appropriate.

3.2 Quality Manager or Quality Coordinator

- Developing the overarching Quality Assurance Plan (QAP) for the Project.
- Supporting the implementation and continuous improvement of the QAP.
- Supporting the development of subsequent Project QA Plans (e.g., Level 2 QA Plans).
- Reviewing implementing procedures as needed for the Project.
- Participating in reviews of collaborating institutions or vendors as required.

3.3 Quality Engineer or Quality Specialist

- Assisting in implementation of the QAP and Quality Control (QC) measures in specific aspects of the project.
- Supporting the development of QC processes and procedures as needed for the Project.
- Participating in revies of collaborating institutions or vendors as required.

3.4 Level 2, 3, and 4 Managers

- Developing and implementing system and component specific QA/QC plans, procedures, and guides that stipulate quality requirements.

4.0 QUALITY PROGRAM FOR PROJECTS

A Quality Assurance Plan is required for Projects that are required to follow the DOE O 413.3B, and is recommended for all other project types (e.g. GPP, AIP, etc.) as indicated in the Fermilab Conduct of Project Management Values and Standards. The Quality Assurance Plan for any Fermilab project shall adhere to the Fermilab Quality Assurance Program and Quality Assurance Manual.

4.1 Elements of a QA Plan

Elements of the QA Plan can include, but are not limited to, the following sections:

- Roles and Responsibilities
- Relationship between Fermlab, subcontractors, participating institutions and/or international partners
- Personnel Training and Qualifications
- Graded Approach
- Quality Improvement Processes
- Performance Criteria
- Procurement Quality
- Identification and Management of Suspect/Counterfeit Items (S/CI)
- Shipping Requirements for Components
- Inspection and Acceptance Testing
- Issues/Noncompliance Management
- Work Processes and Control
- Software Quality Assurance
- Construction Quality Management
- Assessments
- Risk Analysis/Mitigation
- Control of Documents and Records
- Lessons Learned

Requirements for the above elements may be found in the Fermilab Quality Assurance Manual.

A standardized template Project Quality Assurance Plan can be found on the Office of Project Support Services website.

It is important to ensure that all Project personnel are aware of the QA Plan, its key elements, and their specific roles and responsiblities. Quality Planning workshops are an effective way to ensure all stakeholders are aware of the QA Plan and provide useful input and feedback for continual improvement.

4.2 Quality Control Planning

Quality Control (QC) is a critical component of Quality Assurance. Quality Control Plans and supporting processes should be developed for areas with defined deliverables such as a device, component, software, or defined/measurable service. Integrating QC ensures that the proper checks and tests are identified and conducted (in process and at delivery) to verify that requirements will be met. It is strongly suggested that an approach to integrating quality control be identified and agreed upon with the individuals responsible for executing QC as early as possible.

Some effective key QC tools include:

- Quality Control Plans[1] (QCPs)
- Manufacturing & Inspection Plans (MIPs)
- Failure Modes and Effect Analysis (FMEA)
- Standard Operating Procedures/Work Instructions
- Training/Qualification Matrices
- Travelers[2]

The documentation of quality control results and data is required for records, verification, and traceability.

4.3 Documentation Requirements

The QA Plan, QC Plans, and any supporting QA/QC processes shall be filed with the respective project files and follow the applicable storage and retention schedule.

4.4 Procurement Quality and Vendor Qualifications

Project personnel with QA responsibilities shall participate in the technical evaluation of vendors, specifically supporting the review of vendor Quality-related documentation (e.g. Corporate QA Plans, QC Plans, Quality Reports). Designated quality personnel may assist with visits to vendors to examine the QA/QC programs if requested by the project management team.

4.5 Subcontractor QA Plan Review

Many projects will require subcontractors to submit Project Quality Assurance or Quality Control Plans for review. As with vendor visits, designated quality assurance personnel may assist with the review and acceptance of those plans prior to the subcontractor's start of work.

[1] Refer to QAM Chapter 12070 - Graded Approach Procedure, Appendix C – Quality Control Plan

[2] Note: the electronic traveler system, Vector, is available to all Fermilab projects/programs (see also section 5)

4.6 QA Requirements and Designated Hold Points

Quality Control requirements should be clearly understood at the outset of the project and coordinated with the subcontractor or collaborating institution. Some work activities will require testing and verification by an independent testing agency. Examples may include soil compaction, concrete sampling, leak testing, etc. This may be accomplished by the subcontractor, an independent testing agency under contract with that subcontractor, collaborating or Partner institution personnel, Fermilab personnel, or an independent testing agency retained by Fermilab. Whatever the case per the Project structure, these requirements should be understood early in the project with specific Hold Points identified and reflected in the project Resource Loaded Schedule to ensure proper awareness and timely completion.

4.7 Interface With Subcontractors During Project

Designated quality assurance personnel will be expected to participate in meetings where QA/QC requirements will be discussed. Examples would be Preparatory meetings with subcontractor personnel, routine site inspections, and final acceptance inspections.

5.0 LESSONS LEARNED

Historically, Projects have formally captured lessons learned near the end of the Project's lifecycle, such as at CD-4 for Projects that are required to follow DOE O 413.3B. However, it is important that all Projects formally capture lessons learned throughout the Project's lifecycle. This allows for the documentation, dissemination, and tracking of actions relating to the lessons learned that arise.

Projects are encouraged to capture lessons learned locally within their respective Project files, for immediate or future reference, as well as disseminate lessons learned more broadly (e.g., outside of the Project) when deemed valuable to do so. For the lessons learned that are deemed valuable to share more broadly during the Project lifecycle, the lessons learned should be entered into the Fermilab Lessons Learned Database in the Fermilab Quality Tool Suite. Entry into the Fermilab Lessons Learned Database creates the formal documentation and dissemination to subscribers. Despite how Projects decide to capture their lessons learned during the Project's lifecycle, all lessons learned should be uploaded to the Fermilab Lessons Learned database at the Project's completion. This preserves the information for future reference by all interested parties. Project personnel should contact the Office of Quality Assurance for assistance with this upload.

Project personnel can also leverage the Fermilab Lessons Learned Database to create specific actions for lessons learned that are being implemented. The system will allow for tracking the items through resolution in the issues management database, iTrack.

Refer to the QAM Chapter 12010 – *Fermilab Lessons Learned Program*.

6.0 SUPPORTING SYSTEMS AND DATABASES

The following lab supported systems and databases are typically used for FRA Project data. However, it should be noted that this list is not all-inclusive:

DocDB – the laboratory's Document Database system utilized by various Projects to store, manage, and control documentation. There are different instances across Projects.

iTrack – the laboratory's issues management system to track items from assessments, management walkthroughs, and reviews through resolution.

Lessons Learned Database – the laboratory's database used to capture and disseminate lessons learned across the laboratory.

Teamcenter – commercial database used to hold engineering documents, test results, etc.

Vector – a laboratory database used to create, facilitate, and store travelers.

7.0 REFERENCES

DOE O 413.3B – *Project and Project Management for the Acquisition of Capital Assets*
DOE G 413.3-2 – *Quality Assurance Guide for Project Management*
Fermilab Quality Assurance Manual (QAM)
Fermilab Quality Policy
Fermilab Engineering Manual
Fermilab Conduct of Project Management Values and Standards