QAM 12002: The Fermilab Quality Assurance Program

Revision History

Author	Description of Change	Revision Date
Jemila Adetunji	Updates throughout the document to reflect alignment with organizational and functional changes. Updates made to hyperlinks throughout the document.	June 2020
Jemila Adetunji	Major update to each section in the document to provide further clarity and direction for enhanced implementation of the QA Program requirements.	February 2019
Dave Baird	Removed reference to Improvements Database and replaced with ESH&Q Section's Quarterly Summaries	August 2018
Kathy Vuletich	• Removed reference to issues management item type "Finding." The definition is identical to a "Non-conformity." The item type "Finding" has been removed from use in iTrack and applicable documentation. • Updated references to Fermilab Policies.	January 2018
T.J. Sarlina	Removed references to DOE Order 414.1D, *Quality Assurance,* as per guidance from the Secretary of Energy Advisory Board (SEAB). Also updated Section 5.5.1, Calibration of Equipment.	November 2016
Kathy Zappia/ T.J. Sarlina	Periodic review of program with minor editorial changes, new graphic standards, updated hyperlinks.	March 2016
Jemila Adetunji / Kathy Zappia	Minor editorial changes, formatting for inclusion in the QAM, and updated hyperlinks.	December 2014
T.J. Sarlina / Kathy Zappia	Initial release of the Integrated Quality Assurance Program. Replaces OQBP QA program of 01/20/2012	September 2013

TABLE OF CONTENTS

1.0 INTRODUCTION

The Fermilab Quality Assurance (QA) Program is a vital element of the Quality Management System. The Quality Management System is one of the Management Systems that constitute the Fermilab Contractor Assurance System (CAS) required by the Prime Contract between the Department of Energy (DOE) and the Fermilab Research Association (FRA). The Fermilab Quality Policy establishes the quality-related goals and expectations for programs and personnel across the laboratory. This document describes the overarching QA Program for the laboratory and addresses how the expectations of the Fermilab Quality Policy shall be met. The primary objective of the Fermilab Quality Assurance Program is to establish a framework for the laboratory to provide reasonable assurance to the DOE, FRA, collaborating institutions/Partners, as well as internal and external customers/suppliers that expectations will be met. This quality framework shall be implemented to guide the laboratory leadership, management system owners, and project/program/process owners in establishing the necessary processes that provide constant, consistent, predictive, and effective assurance. With effective implementation of the requirements established in this QA Program document, the laboratory will be able to:

- consistently meet or exceed customer expectations, applicable regulatory, and Prime Contract requirements;
- implement appropriate quality planning using a graded approach;
- define appropriate measurement systems for critical processes;
- effectively identify and actively address risks and opportunities;
- integrate safety, quality, predictability, and reliability into processes;
- establish effective processes in partnerships and collaborations;
- provide reasonable assurance;
- and continually improve.

The Fermilab Quality Assurance Program applies to all work conducted at Fermilab, other Fermilab-managed facilities and resources, and other sites where work for Fermilab is being performed. It is implemented using a graded approach to the application of controls based on the analysis of risks identified where work is to be performed. It identifies requirements necessary to consistently meet the DOE Prime Contract obligations throughout the laboratory and ensures that essential aspects of quality, safety, health, security/cyber-security, environmental, facilities/infrastructure maintenance, and robust performance of research are integrated into all work conducted under the contract.

Fermilab flows down the QA Program requirements to subcontractors at any tier to the extent necessary to ensure subcontractors' compliance with the requirements and the safe performance of work. Subcontractors performing work for or in conjunction with Fermilab who have an established quality assurance program are also required to meet Fermilab requirements for that particular scope of work. The Fermilab QA Program has aligned with the applicable requirements established in the DOE O 414.1 – *Quality Assurance*; as well as both, the national consensus standard ANSI/ASQ Z1.13-1999 to ensure the application of Quality Assurance to scientific research, and ASQ/ANSI/ISO 9001:2015 standard to ensure the application of Quality Assurance to business processes that support research activities.

Fermilab establishes different types of agreements with other DOE laboratories, researchers, institutions or other entities for various types of research, project, and experiment-related activities. Fermilab's Office of Partnerships and Technology Transfer (OPTT) defines the processes and parameters for the various agreements. The Fermilab liaison, technical contact, or primary responsible person for the research, project, or experiment-related activity is responsible for ensuring adequate programs, processes, resources, training, and capabilities are in place to meet the requirements established in this document as well other Fermilab policies for deliverables in the scope of the associated agreement.

The Fermilab QA Program is continually reviewed for improvement opportunities and the QA Program document is reviewed as necessary, or at a minimum of every 3 years.

2.0 DEFINITIONS

Corrective Action – An action to eliminate the cause of a detected nonconformity or other undesirable situation.
***Note**: There can be more than one cause for a nonconformance. Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.*

Human Performance Improvement (HPI) – A set of concepts and principles associated with a performance model that illustrates the organizational context of human performance. The model contends that human performance is a system that comprises a network of elements that work together to produce repeatable outcomes. The system encompasses organizational factors, job-site conditions, individual behavior, and results.

Lessons Learned (LL) – A best proactive or innovative approach that is captured and shared to promote repeat application; and may also be an adverse work practice or experience that is captured and shared to avoid recurrence.

Preventive Action – A proactive action taken to eliminate the cause of a potential nonconformity or other undesirable situation.
Note*: There can be more than one cause for a potential nonconformity. Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.*

Quality Assurance Manual (QAM) – A living set of procedures established to provide guidance and communicate critical quality program requirements.

3.0 RESPONSIBILITIES

3.1 Laboratory Director

- Aligns with, supports, and promotes the Fermilab QA Program; has ultimate accountability for all aspects of Quality for all work done under the FRA/DOE contract.
- Holds management accountable for the implementation of and compliance with this QA program as well as for its effectiveness.
- Appoints the Head of Quality Assurance as the Quality Management System Owner and the Fermilab QA Program owner.

3.2 Chiefs, Deputy Directors, Division/Section Heads, and Project Directors/Managers

- Ensure compliance with the requirements in this document for their areas of responsibility including the flow down of requirements and awareness.
- Ensure integration of the QA Program requirements into Business, Project, Experimental, and Operational programs/processes.
- Responsible for appropriate quality planning, allocating adequate resources for work, and for implementing quality requirements in their respective organizations.
- Establish adequate and transparent performance metrics to monitor the performance and health of the organization, business processes, experiment or Project.
- Ensure line management has the authority, responsibility, and is held accountable for integrating quality into processes and programs.
- Responsible for assessing the efficacy and robustness of processes within areas of responsibility and resolving gaps to prevent substandard performance or achievement of goals/objectives.

- Responsible for the effectiveness of this QA Program by establishing adequate assurance processes and practices in their areas of responsibility.

3.3 Line Management / Supervisors / Group Leaders

- Ensure compliance with the requirements in this document for their areas of responsibility including the flow down of requirements and awareness.
- Ensure integration of QA Program requirements in processes and procedures.
- Ensure processes and procedures in areas of responsibility are assessed to evaluate effectiveness and robustness.
- Ensure the appropriate resources are allocated and assigned to perform tasks and quality requirements are met.
- Complete required Fermilab Quality Program Training modules and ensure completion of training by staff.
- Maintain familiarity with the chapters of the Quality Assurance Manual to ensure adequate flow down to staff and areas of responsibility.

3.4 Management System Owners (MSOs)

- Ensure compliance with this procedure within their respective management systems.
- Ensure integration of the QA Program requirements into Management System programs/processes.
- Establish specific Management System framework upon which D/S Heads, Project Managers, and line managers shall implement their processes and allocate/direct resources. This framework shall include policies, programs, processes, and requirements which must be adhered to and flowed down to all individuals executing work.
- Establish adequate and transparent performance metrics to monitor the performance and health of the management system.
- Responsible for assessing the efficacy and robustness of their respective Management Systems and implementation in Divisions, Sections, and Projects and resolving any gaps to prevent the laboratory's exposure to loss or failure.
- Responsible for the effectiveness of this QA Program by establishing adequate assurance processes and practices for their respective management systems.

3.5 Quality Management System Owner

- Possesses the authority to direct and oversee the Fermilab QA Program.
- Establishes, maintains, communicates, and verifies compliance to the Fermilab Quality Policy.

- Ensures that assessments, using a graded approach to determine necessary rigor, are conducted to evaluate compliance with this procedure and the effectiveness of implementation.
- Ensures that appropriate training to identify and handle Suspect/Counterfeit Items (S/CI) is available.
- Ensures that training is available on the Fermilab Quality Program.
- Communicates, and escalates when necessary, programmatic gaps, trends, and nonconformances that indicate noncompliance to the QA Program requirements.
- Assumes responsibility for the content and maintenance of this procedure, the Quality Assurance Manual, and the continuous improvement of the Fermilab QA Program.

3.6 Quality Section Liaisons (QSLs)

- Members of the Quality Section designated as Fermilab Quality Program points of contact for D/S Leadership and Management System Owners.
- Proactively support D/S Heads, Project Managers, Line Managers, and Management System Owners with the implementation, maintenance, and continuous improvement of the QA Program requirements in their respective areas.
- Perform data analysis and use other applicable quality tools to help D/S Heads and Management System Owners identify independent or management assessment opportunities in their areas of responsibility to promote continual improvement. QSLs may also facilitate or participate in these assessment activities.
- Work closely with other Laboratory leadership, Division Safety Officers (DSOs), and D/S Risk Officers to identify areas of opportunity for improvement and self-assessment over the course of the year or, multi-year, and verify completion.
- Support the monitoring, tracking, and trending of issues in iTrack for timely and effective resolution and/or escalation.
- Effectively identify and capture lessons learned by consistently following the Lessons Learned process documented in QAM Chapter 12010 – Fermilab Lessons Learned Program and Procedures.
- Continuously improve the quality tools to support D/S/P.
- Monitor the implementation, maintenance, and continual improvement of the Fermilab QA Program.

3.7 Project Quality Community of Practice (PQCP)

- Consists of Fermilab employees who are Quality Assurance Managers, Quality Coordinators, Quality Engineers, Quality Engineering Specialist or designated

quality representatives for Fermilab Projects and Experiments. Other members of the Quality Section are invited per the discretion of the Quality Section Head.

- Works collaboratively to ensure consistent implementation of the Fermilab Quality Assurance Program requirements within and between Projects.
- Identifies new and emerging quality issues in Projects represented in the PQCP; and collaborates on solutions.
- Provides input for the changes/updates/improvements to the Fermilab QA Program that may impact the QA Program implementation in Projects or Experiments.
- Provides input for potential improvements to the processes owned by the Office of the Chief Project Office.
- Shares and discusses lessons learned; monitors implementation of lessons learned across Projects.

4.0 PROGRAM DESCRIPTION

The foundation of Quality management is line responsibility. The line organization must have the authority, responsibility, and be held accountable for integrating quality assurance into all work performed in their areas of responsibility. Line responsibility for QA is woven into the organizational culture at Fermilab for sustainability.

The QA Program ensures that Fermilab's products and services meet or exceed customer expectations; outlines the requirements for implementing and maintaining a QA program throughout the lab; and provides a system capable of monitoring, controlling, and continually improving the laboratory's activities, processes, and systems.

The scope of the QA program applies to Fermi Research Alliance, LLC including all legal entities under its exclusive control (e.g. leased spaces in Sanford Underground Research Lab (SURF)) and all employees, subcontractors, and users when performing work that affects the laboratory's resources.

5.0 PROCEDURES

5.1 Program

Fermilab has established an organizational structure along with responsibilities, authority, and procedures that ensure effective implementation and maintenance of the QA Program.

The Laboratory Director, Chiefs, MSOs, and Heads of each D/S/P ensure that responsibilities and authorities are defined and communicated within the management system or organization. Responsibilities and authorities are recorded as part of employee job descriptions as well as within council and committee charters.

Fermilab is organized in Offices, Divisions, Sections, and Projects led by Chiefs, Deputy Directors, Project Directors, and Heads. To view the organization at Fermilab at a high-level and for each division, section, and project reference the most recent version of the Organizational Chart.

The Management System Owners are responsible for defining Management System descriptions as per Contractor Assurance System (CAS) requirements. MSOs are also required to establish foundational programs/processes upon which D/S/P Heads shall establish their programs/processes. MSOs shall monitor and evaluate the implementation and performance of those programs/processes and seek ways to continuously improve. Gaps and issues identified relating to program implementation or performance shall be recorded in iTrack and tracked through resolution. The Quality team shall evaluate the efficacy of the Management Systems and help the MSOs identify opportunities for improvement.

The Heads of each D/S/P are responsible for adhering to the requirements set forth in this QA Program document and for ensuring adequate and effective processes are in place to implement the requirements in their respective areas of responsibility. D/S/P are responsible for ensuring alignment with the foundational processes established by the Management System Owners, as applicable, within their respective areas. They are responsible for providing adequate quality planning, schedules, and adequate resources for work. As appropriate for their areas of responsibility, they establish additional performance requirements above and beyond those established in the QA Program, while avoiding any unnecessary duplication of effort. They are responsible for the performance and sponsoring of assessment activities to facilitate the achievement of the organizational mission and objectives. They ensure that their D/S/P activities are conducted in accordance with the principles and requirements of this Fermilab QA Program document.

5.1.1. Contractor Assurance System

The Contractor Assurance System (CAS) is established to provide reasonable assurance that the objectives of the management systems are accomplished and the systems and controls which have been instituted are effective and efficient. CAS

covers all work activities and all personnel performing work at Fermilab including subcontractors and users. The CAS structure encompasses all aspects of the cross-cutting management systems which are essential to the laboratory's success.

5.1.2. Contractor Assurance

The Assurance Council (AC) is charged by the Laboratory Director and chaired by the Chief Operating Officer to serve as a forum to evaluate, monitor, and improve compliance with the Prime Contract Clause H.13 – Contractor Assurance System (CAS) requirements. The AC provides reasonable assurance to the Laboratory Director that the objectives of the CAS are accomplished, risks to achieving compliance to the clause are identified and mitigated, and the systems and controls are effective and efficient. The Assurance Council reviews performance via metrics and key performance indicators that includes, but not limited to:

- PEMP Status updates and other lab initiatives
- Prime Contract deliverable status
- Risk management data
- Management System Assessment results and trends
- Safety and Security data
- Management concerns/emerging issues
- Changes that could impact Fermilab's CAS
- Input/feedback/directives received from DOE

The Assurance Council serves as the body to continual review the efficacy of the management systems and the CAS as an entirety.

5.1.3. Quality Management System (QMS)

The Quality Management System is one of the laboratory's management systems. It is a set of interrelated or interacting elements that Fermilab uses to plan, direct, control, coordinate, assure and improve how quality policies, objectives, processes, and procedures are established, implemented, monitored, and achieved. The system is intended to establish confidence and assurance that requirements of the Fermilab QA Program and customer expectations for quality are met or exceeded via proactive management of processes, tasks, and activities.

5.1.4. Graded Approach

The Fermilab QA program utilizes a graded approach, defined within QAM Chapter 12070, to tailor the types and extent of controls applied to implement quality in fulfilling applicable requirements. The graded approach is applied

based on prudent management, planning, and cost. Application of the graded approach entails:

- Identification of activities which present significant quality risk,
- Defining the activity,
- Evaluating risk and control choice, and
- Documenting and reaching concurrence on the application of the graded approach.

This process supports the laboratory's responsibility to prioritize resource usage in areas where the activities have been identified as requiring the most control and oversight. All D/S/P Heads shall ensure that a graded approach to quality requirements is applied in accordance with this section for products, projects, and services under their control, and is used when establishing levels of control.

5.2 Personnel Training & Qualifications

All Fermilab employees and personnel (e.g. users, subcontractors), regardless of their working location, are required to have the necessary experience, knowledge, and skills to perform their jobs. Personnel are qualified to perform their job based on previous experience, education, and training; on-the-job training; and completion of training courses or qualification programs. Line management is required to evaluate and ensure that individuals assigned to perform the work have the appropriate skills, background, education, and training necessary to carry out the work. Line managers are also responsible for ensuring adequate and qualified resources are allocated to fulfill the requirements of the Fermilab Quality Assurance Program.

5.2.1. Qualifications

Initial employee qualification is part of the hiring process administered by the Workforce Development and Resources Section (WDRS). Individuals are hired to meet established position requirements specified by job descriptions and skills as defined by line managers. Line managers ensure that job candidates meet specified requirements.

5.2.2. Personnel Training

Types of personnel training may include:

- Institutional training – conveys general information about the organization's mission, vision, goals, and management system. It may also include general knowledge or skills training.

- Site/facility-specific training – conveys emergency plans and the environmental, safety, security, and operational information necessary for personnel to prepare for and perform their assigned duties in the facility. This includes site-specific access requirements and regulatory based training.
- Project/task-specific training – imparts the knowledge required for personnel to perform their assigned duties safely and successfully. This training may include project/task goals and schedules, implementing procedures, safety and hazard controls, methods, requirements, process metrics, and skills.
- On-The-Job (OJT) training – enables personnel to learn their assigned duties while actually performing work. This training may include instruction from a senior-level employee or mentor.

Personnel are also provided with continuing training as appropriate to ensure that job competency and compliance are maintained.

Fermilab line managers are required to ensure personnel possess the experience, knowledge, skills, and abilities necessary to fulfill their responsibilities. This includes:

- Completing an Individual Training Needs Assessment (ITNA) to develop an Individual Training Plan (ITP) for their employees and revising it as job requirements change The ITNA covers institutional and site-specific training.
- Identifying and providing required project/task-specific training.
- Identifying and providing required On-The-Job (OJT) training. OJT can be mentor based where an expert is assigned by line management to train personnel. It is line management's responsibility to ensure mentors assigned to conduct OJT are qualified.
- Maintaining appropriate records of training.
- Utilizing position descriptions, hazard analyses, new employee requisitions, and/or the Work Activities Analysis Form (WAAF) to identify the functional requirements and any physical limitations. This ensures that a continuous match exists between the capabilities of the employee and the physical requirements and/or mental demands of the current assignment.

The TRAIN database is the official repository for training provided by the laboratory. Each employee is responsible for participating with their

supervisor in defining the necessary training, successfully completing all required training, and applying training on the job. For laboratory training, requirements may be defined by subcommittees and presented by relevant subject matter experts. For training not provided by the laboratory, subsequent records shall be kept in personnel files as appropriate.

Management and training points of contact are responsible for reviewing the effectiveness of its training programs. Results from these reviews shall be used as inputs for continual improvement.

5.3 Quality Improvement

Fermilab maintains continuous quality improvement through a variety of activities, including training, design, assessments, walk-throughs, inspections, tests, monitoring, reviews, data analysis, and communication/feedback.

5.3.1. Quality Improvement Program

Issues, improvement opportunities, and corrective actions, generated from the activities listed above are documented and tracked in Fermilab's Issues Management Tracking System, iTrack which resides in the Fermilab Quality Tools Suite (FQTS) Procedures for documenting and tracking these items are documented in the Quality Assurance Manual Chapters 12030 and 12040.

Management at all levels is responsible for supporting and enabling individuals under their supervision to participate in identifying and analyzing opportunities for improvement; responding to discovery of quality-related and program/process issues; following up on required actions; documenting failures and non-conformances; ensuring that significant problems are reported to the appropriate management levels (program, facility, D/S/P manager, supervisor, or group leader, and Directorate/Chiefs); establishing and measuring performance; and ensure root causes are identified and resolved.

All line managers are responsible for encouraging the reporting of improvement opportunities and lessons that have been learned from activities across the laboratory. These items shall be documented in iTrack and tracked if there are corresponding actions. All employees planning work activities/task are encouraged to review lessons learned to incorporate relevant aspects to prevent repeating mistakes. Procedures for documenting

Lessons Learned are available in the QAM Chapter 12010 - Fermilab Lessons Learned Program.

Communication is a critical component for ensuring expectations are understood by all levels of stakeholders, suppliers, customers, and staff. Chiefs, Deputy Directors, D/S Heads, Project Directors/Managers, and Management System Owners are responsible for appropriate communication planning and the effective implementation of those plans. Communication methods include verbal, written, listening, and feedback. Effective and timely communication can result in the following:

- Calibrated understanding of laboratory and organizational strategies, goals, and objectives; and the role all levels of staff have in meeting them.
- Early insight to risks, issues, and gaps that could preclude the achievement of goals, objectives, and deliverables.
- Empowered staff that embraces change.

It is the expectation that all levels of management establish effective communication strategies and plans for their areas of responsibility and continually evaluate these strategies and plans for efficacy, then adjust as necessary. Effective communication strategies and planning with collaborating institutions, partners, and vendors is also critical to the success of research, experiments, Projects, and other collaborative efforts.

Obtaining feedback is another method of communication and an important mechanism for identifying opportunities for improvement. Feedback can be obtained from internal and external sources. Process owners should clearly understand the customers and suppliers of their processes which can be identified by tools such as process maps and workflow diagrams such as a SIPOC (supplier, input, process, output, and customer) that explicitly highlights the function and flow of each aspect of that particular process. Understanding customers and suppliers (internal and external) allows for the establishment of deliverables/goals as well as the inputs required to achieve the deliverables/goals. Customer feedback can be used to improve the processes relating to a particular deliverable. D/S/P leadership should clearly define methods for obtaining feedback from their staff and use that feedback to address concerns, resolve issues, and improve processes.

5.3.2. Quality Improvement Support

It is the responsibility for all levels of management and staff to support, promote, and actively engage in the laboratory's continuous improvement efforts.

- Fermilab Senior Management members are responsible for supporting the continuous improvement of the Fermilab Quality Management System and QA Program. Senior management shall demonstrate commitment to the Fermilab QA Program and its continuous improvement by promoting this commitment to the individuals in their areas of responsibility as well as to users, collaborators, vendors, and partners. They are responsible for ensuring adequate resources are allocated to implement the requirements established in this program document, monitor implementation, plan and complete self-assessments, address corrective actions, implement preventive actions, and continuously improve by instituting lessons learned.
- Management System Owners (MSOs) are responsible for the maintenance and improvement of their management system. MSOs identify opportunities for improvement via the issues management process, risk analysis, supplier/customer feedback, annual PEMP results, contract deliverable completion, and other means. There is an expectation for MSOs to continually improve the framework comprised of policies and procedures by actively measuring performance against goals/objectives and seeking input from D/S/P who implement abide by the policies and implement processes as well as the Assurance Council.
- The Office of Integrated Planning and Performance Management supports quality improvement by leading the Laboratory's strategic planning process, goal setting, and performance planning and oversight processes. Input to the planning process includes feedback from management reviews, issue resolution, root cause analysis, lessons learned, assessments, scientific peer reviews and DOE Office of Science program reviews.
- Quality issues are analyzed individually and collectively to identify systemic quality issues, trends and opportunities for process improvement. Refer to QAM Chapter 12050 on Root Cause Analysis and the FESHM Chapter 3020 on Incident Investigation and Analysis for the procedure relating to incident investigation and analysis.
- The process of resolving quality issues involves:
    - Identifying a condition adverse to quality and evaluating its significance.

  - Analyzing the problem and determining its causes.
  - Taking prompt containment action and documenting that action.
  - Developing or verifying planned actions with the organization resolving the problem.
  - Assigning responsibility for correcting the problem.
  - Examining training processes, procedures, or management systems.
  - Determining corrective action and documenting that action.
  - Taking steps to prevent recurrence.
  - Verifying implementation, and documenting closure.
  - Determining effectiveness of the corrective and preventive actions.

- The Incident Analysis Team (IAT) has been established to facilitate continual improvement of the HPI Program. Human Performance Improvement (HPI) supports resolution of quality issues through analyzing problems to determine cause(s), suitable corrective and preventive actions, and verifying that the correct actions were taken to satisfy the root cause of the original problem(s).
- Fermilab has an Enterprise Risk Management process to address major, cross-cutting risks that potentially jeopardize the overall goals of the lab. An Enterprise Risk Management Board has been established to identify, categorize, evaluate, monitor, and report significant institutional risks that have the potential to affect the achievement of the laboratory mission and performance objectives. . Fermilab has an established Risk Management procedure for Projects. Identifying and planning for potential risks is imperative for quality, reliability, customer satisfaction, and sustainability. Risk management is a key component of continuous improvement.
- Assessments also support the resolution of quality problems by taking the proactive approach to reviewing a program or process to identify opportunities for improvement or identify preventive actions through discovery. Refer to the QAM Chapter 12080 – Fermilab Assessment Program.

5.4 Documents & Records

Fermilab documents specifying policies, prescribing processes, or establishing design specifications and requirements are controlled per the Document Management and Control Policy. Additional document control requirements may be required by outside customers/sponsors or be required for certain specific activities.

Responsibility for lab-wide policies and procedures is shared between the Directorate and the originating D/S/P's. D/S/P's establish methods to control procedural requirements, design, and other quality management documents and records used solely within their organization. Management is responsible for providing the resources necessary to fulfill the document control and records management requirements. Fermilab employees, contractors, users, and collaborators are required to comply with the document control and records management policies and procedures. Project or experiment contacts to collaborating institutions/partners are responsible for ensuring adequate processes are in place to adhere to the requirements set forth in this section.

Documents are required to safely and effectively manage, perform, and assess work. Management identifies those documents needed to accomplish these objectives and determine the level of control required. Controls include activities such as preparation, review, approval, distribution, usage, availability, revision, and disposal of documents. All policies, program documents, program implementation plans, and procedures are controlled by the issuing organization, which schedules reviews and updates for each document under its control as prescribed by that document.

Records are necessary to provide evidence of process effectiveness and conformity with requirements. For more information on the policies and procedures for Fermilab's records management program, refer to the Records Management Policy and the Records Management Program. The program includes provisions for specifying, preparing, reviewing, approving, maintaining, and disposing of records. Disposition of records shall follow the approved DOE records retention schedules.

5.5 Work Processes

Line management ensures sufficient resources are available and provided to maintain the site in an operational state and that work controls are in place and effective. Work includes the agreements, procurement, accounting, research, design, fabrication/construction, assembly, storage, transportation, delivery, installation, operation, support, maintenance, modification, and decommissioning of experiments, accelerators, facilities, business systems, and otherwise performed by Fermilab employees, subcontractors, users and partners regardless of location. The set of controls applied to work processes includes written procedures for activities of sufficient complexity or potential hazard; monitoring and assessing performance; personal accountability (roles and responsibilities); incorporating quality and reliability, and specific provisions for activities not otherwise covered in this document. The control of scientific research is described in Section 5.12 – Scientific Research.

Each person is responsible for the quality of their work, reporting issues, contributing to the incorporation of environment, safety, health, and productivity goals, and for maintaining items to prevent damage, loss or deterioration.

5.5.1. Work Process Control

Using a graded approach, line management is responsible for determining the appropriate level of work process controls, including which activities require written procedures and which procedures must be augmented through personnel training and qualifications. Evidence the analysis for work controls shall be provided and maintained. Management defines workmanship standards, equipment to be used, specifications for materials, process measurement points, and measurement standards. ES&H and Quality requirements and controls for work processes are defined in FESHM, FRCM, and QAM.

Controls are established for the procurement and acceptance of items and services. Controls on Measuring and Test Equipment are designed to meet requirements identified in Section 5.8.4 - Inspection and Acceptance Testing. Controls for preservation of equipment, devices, tools, components, products, and services are implemented by the organization responsible for them. Controls include traveler processes for accompanying components and products through assembly processes; databases for tracking equipment, devices, tools, and services; and response plans for preserving services and equipment when natural phenomenon's or other incidents occur.

For work performed by vendors and collaborating institutions/partners, work process controls are established by that particular vendor or institution. Fermilab has a responsibility to verify adequate work process controls are established and implemented at the collaborating institution for work performed for Fermilab to ensure requirements can be effectively and consistently met.

Item Control

Items are identified and controlled, with their traceability maintained during receipt, shipping/transportation, storage, handling, installation, use, and disposal. These controls are commensurate with the item's application, usage, cost, and/or associated risk and are managed by D/S/P's. The requirements for controlling and maintaining property, equipment, items, and the site

infrastructure follow DOE Order 430.1, *Real Property and Asset Management*. Personal property is controlled according to Property/Inventory Policies. Fermilab shall have policies and procedures in place for the management and protection of property belonging to other institutions, organizations, or external parties. These policies and procedures shall be maintained by the Management System Owner of the Property and Infrastructure Management System.

For items procured, fabricated, assembled, and/or shipped by vendors and collaborating institutions/partners for Fermilab, Fermilab has the responsibility to ensure adequate item control processes are established and implemented.

Maintenance

D/S/P's are responsible for ensuring maintenance is performed on facilities and equipment under their care. Facilities Engineering Services Section (FESS) is the primary maintenance service provider for facilities and the laboratory's infrastructure. These services are agreed upon between FESS and the D/S/P's. Maintenance plans are documented by D/S/P's. The organization coordinating or performing the maintenance is responsible for ensuring that records of maintenance are kept.

Readiness Reviews

Readiness reviews are conducted prior to the start of operations that are new or have been significantly changed. The extent and detail of the reviews are commensurate with the scale, cost, complexity, hazards, and programmatic significance. Reviews which require ES&H approval to operate accelerator facilities are required to follow the FESHM Chapter 2010 - Planning and Review of Accelerator Facilities and their Operations. D/S/P's are required to document any readiness reviews performed in their respective areas. In addition, certain research projects are required by applicable DOE Orders to perform readiness reviews at specified intervals.

Calibration of Equipment

Calibration is a critical step in any process that utilizes measurement or diagnostic tools to ensure success. Improper calibration can result in injury to workers, damage to equipment and/or a reduction in efficiency, reliability, or quality. It is the responsibility of each D/S/P to identify, monitor and maintain key process equipment that requires calibration or

verification. Any equipment used to test or calibrate devices that have safety or scientific significance shall be considered for inclusion in the calibration program. Results shall be documented and retained.

Process requirements and criticality shall be considered during the evaluation. Where possible, each item requiring calibration shall be clearly labeled identifying the item as requiring calibration, the department or person responsible for the item, the calibration due date, and a unique identification number. (See also: Section 5.8.4 – Control of Measuring & Test Equipment (M&TE). When labeling the item is not possible, another form of identification must be identified to ensure adequate traceability and ability to meeting calibration and verification requirements.

D/S/P personnel are responsible for ensuring vendors, partners, or collaborating institutions performing work for or in conjunction with Fermilab have processes in place that align with these requirements

Work Environment

All facilities are to be maintained in a state of order, cleanliness, and repair, as appropriate to accomplish their missions. It is everyone's responsibility to maintain the integrity and cleanliness of their work area, assure they understand and meet the requirements at each building location, and follow the general expectation for Fermilab. It is the responsibility of Fermilab building/facilities management to ensure Fermilab facilities are adequate and do not negatively impact the safety, health, environment, or quality of personnel, parts, equipment, or components. D/S/P are responsible for ensuring vendors, partners, or collaborating institutions performing work for or in collaborations with Fermilab have processes in place to assure adequate work environments where work for Fermilab is being performed align with these requirements.

Change Management

The management of change is a critical component of any established process or program. Process owners shall establish appropriate methods for evaluating, initiating, communicating, and implementing changes. This can include changes to procedures, designs, processes, and resources. Common tools used to evaluate changes include Failure Modes and Effects Analysis (FMEA), process maps/flow charts, and Strengths, Weaknesses, Opportunities, and Threats (SWOT) analyses. Management System Owners

are responsible for ensuring high-level expectations are set for change management in their management system. Line management is responsible for ensuring the appropriate tools are employed for all aspects of change management in their areas of responsibility. Project/Experiment personnel are responsible for ensuring the appropriate processes are established and followed for changes in design, in-process activities, and delivery.

Organizational Knowledge

Organizational knowledge is information used and shared to achieve Fermilab's mission and objectives. It comprises of work process documentation necessary to ensure requirements are met. Fermilab has several methods for communicating and managing information and processes for use by individuals performing work. Several platforms such as Document Database (DocDB), Fermipoint, and Teamcenter are employed to share and manage information. These platforms allow for the appropriate maintenance and version control necessary to provide current information when needed. Lessons learned and information gathered from external sources such as collaborating institutions and suppliers also serve as inputs to organizational knowledge.

5.5.2. Software

- **Safety Software**
  Fermilab does not employ safety software under the definition of safety software as described within DOE Order 414.1D *Quality Assurance*.
- **Software Quality Assurance**
  QA requirements for software used at Fermilab to support the laboratory's program and mission is described in the Fermilab Software Quality Assurance Program.

5.6 Systems Engineering

Fermilab's technical management and engineering processes prescribe the need for adequate control of planning, design inputs, outputs, verification and validation, configuration and design changes, and technical and administrative interfaces. Design work is based on sound engineering and scientific principles and judgment and applicable codes and standards. It applies to research/experimental equipment including accelerator components, detectors, software, hardware, as well as to conventional facilities, structures and equipment. Projects and Experiments designate a system manager or responsible engineer who has the overall responsibility for the efforts of all engineers working on a particular Project or Experiment and ensures effective

implementation of engineering processes and procedures. The controls and implementing procedures are established in the Fermilab Engineering Manual.

The Fermilab Engineering Manual defines a graded approach to engineering controls and configuration management that couples the applicable rigor of management controls to the risk posed by the structures, systems, components, software for engineering design, or construction and manufacturing processes under development.

The Engineering Management System Owner is responsible for ensuring design and engineering processes are established, documented, communicated, and flowed down to the D/S/Ps. Technical management and engineering processes include requirements management, design, interface control, configuration management/change control, value engineering, and technical reviews. Line or systems management or the responsible engineer is responsible for implementing and evaluating the effectiveness of the design and engineering processes. Members of line/system management are responsible for identifying opportunities to improve design and engineering processes appropriately enhancing requirements to the engineering process to ensure the quality and success of experiments and projects executed under their supervision. Other functions having accountability for the successful execution of the technical management and engineering process includes Project and System Directors/Managers, Department Heads, Lead Engineers, and Engineers. Their responsibilities are outlined in the Fermilab Engineering Manual

The Fermilab Engineering Manual describes, in detail, the design and engineering process steps:

1) Requirements and Specifications – defines objectives;
2) Engineering Risk Analysis – determines level of documentation and review required;
3) Requirements and Specifications and Engineering Risk Reviews;
4) System Design – steps of design phase;
5) Engineering Design Review – defines required design reviews;
6) Procurement & Implementation;
7) Testing & Validation;
8) Release to Operations; and
9) Final Documentation – defines documentation requirements for completion of the project.

Engineering processes should include the end-to-end management of products, components, and systems. A critical component of the engineering function includes the

implementation of effective and efficient change management processes. Refer to Section 5.5.1.

5.7 Procurement & Procurement Assurance

All materials and services are purchased from acceptable and responsible suppliers including distributors authorized by the manufacturer. Materials and services are acquired by purchase order or use of the procurement credit card (ProCard) and approved per procedures in the Procurement Manual. All requestors and ProCard holders are made aware of the need to purchase from reputable suppliers and distributors. Fermilab suppliers are required to provide goods and services which are in conformance with purchase order requirements or signed subcontracts. Responsibility for the accuracy of purchase requisition data and requirements resides with the requestor. Fermilab may, in accordance with purchase order terms and conditions, perform site audits, require suppliers to perform self-assessments, and provide control plans, manufacturing inspection plans, and data or other reports to ensure compliance. Fermilab provides a necessary and sufficient level of oversight of subcontractors to verify that Fermilab and subcontract requirements are being met.

The procurement and receipt inspection processes support the identification, and prevents the introduction, of suspect and counterfeit items (S/CI), refer to QAM Chapter 12020 – *Suspect/Counterfeit Items (S/CI) Program*. Inspection receipt shall occur whether materials were purchased through purchase order or via the ProCard, see section 5.8 in this document. Personnel are informed of the S/CI reporting process and the risks associated with S/CI. The system for S/CI detection, prior to release for use, is detailed in Section 5.11 - Suspect and Counterfeit Items. Suspect or counterfeit items must be reported to Procurement for inclusion in vendor files as appropriate.

The procurement of all goods and services is under the control of the Procurement Department. Procurement coordinates all procurement requests received from laboratory D/S/P's. This includes acquisition planning related to engineering, quality, and other functions as necessary, generating and verifying solicitation and purchase documents, negotiating terms and conditions, performing subcontract administration, and closeout. Procurement processes shall also establish applicable requirements for any necessary post-delivery activities associated with procured items or services.

All purchase orders, subcontracts, and agreements established per the appropriate Procurement processes shall have a Fermilab contact (person requesting the Procurement action) responsible for ensuring the following elements are established:

- Ensure all applicable ES&H, quality, and technical requirements are adequately specified.
- Quality requirements such as Quality Assurance Plans as applicable, and Quality Control Plans which includes elements such as, but not limited to, incoming and in-process inspection criteria, material certification requirements, acceptance criteria, witness/hold points, packaging, storage, transportation/shipping requirements.
- Ensure subcontractor or supplier can consistently and effectively meet identified requirements.
- Submit Subcontractor or Supplier's Quality Plans to the Fermilab Quality Assurance Section for review for adequacy.
- Submit ES&H related documentation to the ES&H Section and/or appropriate FESHCom Subcommittee for review for adequacy where necessary.
- Personnel responsible for oversight of the subcontractor activities are aware of the subcontract or agreement to ensure adequate resources are allocated to oversee subcontractor activities and verify implementation of requirements throughout the duration of the work.
- Ensure all obligations to the subcontractor are met.
- Ensure specified deliverables are completed/received and meet requirements.
- Notify Procurement and the individuals responsible for the work of any issues with the subcontractor or supplier that would negatively impact, ES&H, quality, reliability, costs, or timely delivery/completion.
- Provide feedback to Procurement on the performance of the subcontractor or supplier as input to Procurement Supplier Evaluation processes.

Prospective suppliers are evaluated based upon their ability to meet quality, technical, and financial performance criteria, and to operate in a safe and environmentally compliant manner as outlined in the Procurement Manual. Evaluation and monitoring of supplier's performance during the life cycle of the purchase order are performed to ensure that technically acceptable items are produced and services continue to meet the quality, technical, delivery, and other performance requirements. Corrective actions in accordance with purchase order terms and conditions are implemented should suppliers not perform as required. The Procurement Management System Owner is responsible for ensuring appropropriate processes are established and effectively flowed down to D/S/Ps. The Procurment Management System Owner is responsible for assuring the Procurement processes are effective and continously improved.

5.8 Inspection & Acceptance Testing

Inspections and tests are performed in order to verify that the physical and functional aspects of items, services, and processes meet requirements and are fit for use. The performance expectations, inspections, and tests are considered during the design phase and, where appropriate, are specified in the design output and/or procurement documents. Line management is responsible for specifying when/what type of inspection is required and for ensuring that adequate inspections are performed and documented.

5.8.1. Inspection & Testing Process

Inspection and acceptance testing plans identify item characteristics and processes to be inspected/acceptance tested, inspection techniques, acceptance criteria, hold points, and the individuals or organization responsible for performing the inspection. Appropriate corrective actions shall be taken where deficiencies are identified accompanied by the appropriate follow-up to ensure effectiveness.

When appropriate, inspections and tests are performed by personnel who are independent of the activities being inspected.

For instances where inspection and testing processes are performed by collaborating institutions/partners performing work under an agreement with Fermilab, the Fermilab responsible person or technical contact is responsible for ensuring adequate processes are established to meet the requirements in this section. The Fermilab responsible person or technical contact is also responsible for verifying consistent implementation of inspection and acceptance testing and obtaining related records, data, and results. Collaborating institutions/partners are required to report inspection and testing that fail to meet requirements/standards. Refer to QAM Chapter 120100 – Incoming Inspection and Acceptance.

5.8.2. Control of Nonconforming Items

Items that do not conform to specified requirements are subject to controls to prevent their inadvertent installation or use. D/S/P's are responsible for control of nonconforming items. Projects and experiments working with collaborating institutions/partners are responsible for ensuring adequate controls and processes are established for managing nonconformances that occur within the institution or partnering agreement. Controls include

identification, documentation, evaluation, segregation (when practical), item disposition (reject, repair, rework, use-basis), and notification to affected organizations. The FESHM Chapter for Significant and Reportable Occurrences is consulted to determine if the nonconformance should be considered reportable.

5.8.3. Inspection & Test Records

Inspection and test results are documented and preserved. The inspection and test status of items or processes requiring examination are clearly identified to ensure that only those with acceptable results are used. At a minimum, inspection/test records identify the following: item(s) inspected, the inspection/test procedure used, who performed the inspection/test, the identification number(s) of the measuring & test equipment (M&TE) used to perform the inspection or test, the inspection/test data, the inspection/test criteria, and the inspection/test results.

5.8.4. Control of Measuring & Test Equipment (M&TE)

The measuring and test equipment used for inspection and acceptance tests are identified, calibrated, maintained, and controlled commensurate with their intended use. Procedures are established by D/S/P's for testing, retesting, adjusting, and recalibrating M&TE. It is the responsibility of line management to ensure established procedures are implemented and followed, and that the appropriate monitoring, measuring, and testing resources are available to employees performing these procedures. It is the responsibility of the Fermilab contact or technical contact to collaborating institutions/partners to ensure adequate processes are in place at the institution or partner for the control of M&TE.

Equipment is checked to ensure it is the proper type, range, accuracy, and precision and is uniquely identified and traceable to its calibration records. Each D/S/P is responsible for ensuring calibration of equipment per section 5.5.1 in this document. Calibration standards are traceable to the National Institute of Standards and Technology or equivalent. M&TE examples include scales, radiation survey instruments, pH monitors, and voltage meters.

If any M&TE is found to be out of tolerance, then appropriate evaluations shall be performed to assess any adverse impact on previous inspection, testing, collected data, or calibration using that equipment. The evaluation, including conclusions, should be documented and appropriate notifications

made. When M&TE equipment or associated computer programs are identified as not operating to specifications, they shall be removed from service or locked out and not returned to service until passing calibration requirements.

Traceability of measuring and test equipment is the responsibility of each D/S/P. Documentation and tracking of calibration, evaluations, inspection, testing, and collected data is tracked by methods meeting the unique needs of each D/S/P including the use of online databases and tracking spreadsheets. The method selected for traceability shall be reviewed and verified on a predetermined basis.

5.9 Management Assessments

Management assessments are performed, as described in the Fermilab Quality Policy and QAM, by an organization to evaluate its own management processes (self-assessment) and their implementation to identify noteworthy practices, uncover issues, identify corrective actions, verify meeting of Prime Contract deliverables, PEMP objectives, and ensure that the work being performed is satisfactory and according to requirements. The performance of management assessments is a critical assurance activity.

Line managers are required to assess their processes to identify and correct problems that hinder the organization from achieving its objectives. The Heads of D/S/P's monitor the progress of objectives and goals in their organizations to ensure work is performed and resources are allocated to meet those objectives and goals. The D/S/P Heads are responsible for monitoring the resolution of items identified from assessments, assigning responsibility for resolution, identifying an appropriate timeframe for resolution, ensuring the actions are finalized with appropriate objective evidence, and documented in iTrack. Management System Owners assess the effectiveness of their respective management systems and identify opportunities to improve or evolve. The QA Section monitors the adequacy of the assessments, the progress of corrective actions, and sponsors or conducts periodic assessments of the effectiveness of the implementation of the QA program throughout the laboratory. Scientific work is assessed by a peer review process. Scientists determine the extent and adequacy of this process.

Issues and opportunities for improvements identified as the result of an assessment are presented to the organization that was assessed, provided to the appropriate levels of management for review, and evaluated to determine the level of follow-up required. Non-conformances are reported for failure to comply with requirements. Corrective

actions are recorded and tracked to closure through the iTrack database per the Quality Policy and the appropriate chapters in the QA Manual. Items having Lab-wide impact are identified and reported at the Assurance Council and other senior management team meetings for awareness and action.

5.10 Independent Assessments

Independent assessments are conducted on a periodic basis to verify adequate implementation of the Fermilab QA program and other established programs and processes across the laboratory. These assessments complement the Management Assessments described in the section above. Fermilab management in conjunction with the Quality Section has the responsibility and authority for planning internal independent assessments, such as QA Assessments, and for providing the necessary resources to conduct them. The coordination of external independent assessments is performed by the management of the assessed organization with assistance from the Quality Section if required. Environmental, health, safety, security, and quality related external independent assessments shall be coordinated by the ES&H and Quality Sections.

D/S/P Heads are responsible for providing resources for assessments, implementing any identified corrective actions, tracking/reporting the status of Corrective Action Plans, and improving processes to prevent recurrence. Personnel planning the assessments are responsible for ensuring personnel performing the independent assessment do not have direct responsibilities in the area they are assessing.

Issues and opportunities for improvement identified as the result of an assessment are presented to the organization that was assessed, provided to the appropriate levels of management for review, and evaluated to determine the level of follow-up required. Corrective actions are recorded and tracked to closure through the iTrack database. Items having Lab-wide impact are identified and reported to the Assurance Council and senior management team for action.

Nonconformances and corrective actions for DOE assessments are administered in accordance with the Contractor Requirements Document of DOE O 227.1, *Independent Oversight Program*. Nonconformances and corrective actions for other external assessment teams are entered into iTrack and tracked to completion per the Quality Policy, and relevant chapters in the QAM.

5.11 Suspect/Counterfeit Items Prevention

Fermilab has established a process for the identification, control, and disposition of suspect/counterfeit items (S/CI) detailed in the QAM Chapter 12020. Fermilab provides training on S/CI processes and controls (including prevention, detection and disposition of S/CI's). Line managers shall identify individuals requiring S/CI training, ensure they receive this training, and provide necessary resources for maintaining the S/CI program.

Designers provide appropriate specifications and controls to safeguard the laboratory against the introduction of S/CI. The Procurement Department is responsible for selecting acceptable and responsible suppliers including distributors authorized by the manufacturer. All requestors and ProCard holders are made aware of the need to purchase from reputable suppliers and distributors. Personnel are informed of the S/CI reporting procedures and the risks associated with S/CI. Suspect or counterfeit items should be reported to Procurement for inclusion in vendor files as appropriate.

5.11.1. Prevention

Methods to prevent the purchase of S/CI's are based on making all purchases from reputable suppliers and distributors.

5.11.2. Detection

The primary means of detecting S/CI's is through inspection.

5.11.3. Reporting

If S/CI's are discovered, the reporting process follows the S/CI procedure as outlined in QAM. This includes notifying the area supervisor, the S/CI coordinator, and may include the Division Safety Officer. The FESHM Chapter for Significant and Reportable Occurrences is consulted to determine the appropriate reportable category.

5.12 Scientific Research

Current research at Fermilab involves experiments of varying size and complexity, theoretical explorations in physics, and development of supporting technologies (e.g. accelerator elements and systems, cryogenics, material science, detector development, and computing). Fermilab has adopted the standard, ANSI/ASQ Z1.13-1999 *Quality Guidelines for Research*, which describes recommended quality assurance activities for research. Each type of research is unique in its approach and application and requires varying levels of controls to produce the desired results.

5.12.1. Responsibilities

- The Fermilab Director, Deputy Directors, Chief Officers, D/S Heads, and Management System Owners are responsible for setting the strategy for science at Fermilab and approving expenditures of funds for scientific proposals and establishment of projects. In performing these actions, they rely on the advice and recommendation of scientific committees.

- Principal Investigators and/or Experiment Spokespersons are responsible for formally proposing the planned research, including technical approach, schedule, deliverables, and facility requirements; developing the contractual documentation between the collaboration and Fermilab for the implementation of experiments and other projects; overseeing the execution and documentation of the research by their collaboration; assisting in the assessment of the research performed by their collaboration; and ensuring the appropriate publication of research results.

- Scientific Collaborators are responsible for identification of spokespersons and/or principal investigators, participation in the conduct of research, and securing funding as agreed in applicable contractual agreements.

- Partnering or Collaborating Institutions are responsible for identifying adequate Technical Coordinators and/or Institutional liaisons for research conducted with Fermilab per partnering agreements.

- Scientific Peers are responsible for reviewing results of scientific research at various stages of completion. Reviews include examination and testing of data, methods, results, and conclusions to ensure they are properly applied and supported. This can be internal to the collaboration, by Fermilab or external (e.g. DOE) review committees, and by submission of publications to refereed journals.

5.12.2. Management of Research Projects

Fermilab's *QA Guidelines for Scientific Research at Fermilab* applies the controls for scientific research described in ANSI/ASQ Z1.13-1999. Fermilab uses a graded approach to ensure only the controls appropriate to the activity are applied and range from Subject Matter Expert reviews to more formal peer review and other formats appropriate for the conduct of research.

Each Fermilab Project shall appoint a Project QA Manager/Coordinator responsible to established quality requirements for the Project in alignment with the requirements established in this Fermilab QA Program document. This alignment includes quality requirements established for collaborating institutions or partners performing work for or in collaboration with Fermilab per established agreements.

6.0 REFERENCES

Fermilab Contractor Assurance System
Fermilab Quality Policy
Quality Assurance Manual (QAM)
FESHM
Engineering Manual
ANSI/ASQ Z1.13-1999, Quality Guidelines for Research
ASQ/ANSI/ISO 9001:2015, Quality Management Systems – Requirements

Fermilab Training Program
Software Quality Assurance Program
Procurement Manual
DOE O 414.1D – *Quality Assurance*
DOE O 227.1A – *Independent Oversight Program*
DOE O 430.1C – *Real Property Asset Management*