

Quality Policy

1. Purpose

Quality Assurance at Fermilab is implemented through the Quality Management System to maintain a high state of readiness, reliability, and sustainability of programs that support the Nation's efforts of using high energy physics to advance our understanding of the fundamental nature of matter and energy. This Policy establishes the Quality Assurance Program.

2. Scope

This Policy applies to all Fermilab activities and operations carried out under Division, Sections, Projects, and Management Systems on the Fermilab site and all leased spaces.

3. Applicability

This Policy applies to Fermi Research Alliance, LLC and all its employees, Fermilab users, and subcontractors.

4. Effective Date and Date Reviewed/Updated

This Policy went into effect on January 1, 2017 and its update was effective on 14 February 2020.

5. Policy

- a. Fermilab's Quality Assurance Program (QA Program) is detailed in the Quality Assurance Manual (See [Quality Assurance Manual](#) and [QAM 12002, Fermilab Quality Assurance Program](#)) and is implemented by relevant procedures created by Line Management and Management System Owners (MSO). The QA Program provides a single, integrated approach for assuring quality throughout Fermilab.
- b. The QA Program sets expectations for Line Management and MSOs to:
 - develop and document implementing procedures
 - establish and maintain a graded approach to identify the appropriate level of quality controls
 - perform management assessments and actively participate in assessment activities
 - provide tools for continuous process improvement and adoption of best practices
 - develop guidelines for levels of inspection, documentation, and recordkeeping
 - integrate use of quality tools (e.g. iTrack, HPI) into processes
 - identify, analyze, and apply lessons learned
 - detect and report Suspect/Counterfeit Items
- c. To the extent reasonable and appropriate, quality assurance activities at all levels should systematically aim to:
 - build lasting relationships
 - earn partner, collaborator, and stakeholder trust

- keep activities relevant with current research directions and stakeholder expectations
- choose partners, collaborators, and suppliers that share Fermilab's commitment to safety and quality
- reduce process complexity, variation, and cost, and foster organizational flexibility
- focus on preventive versus corrective actions
- actively capture and apply lessons learned by embedding organizational and personal learning and improvement into our processes
- seek and accept feedback as opportunities to strengthen relationships and processes
- employ national and international consensus standards where practical, consistent with contractual requirements or where a competitive advantage is achieved

6. Definitions

Assessment: A review, evaluation, inspection, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively. There are two main types of assessments: independent and management assessments. (See [QAM Chapter 12080, Fermilab Assessment Program](#))

Graded Approach: The process of ensuring that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with: the relative importance to safety, safeguards, and security; the magnitude of any hazard involved; the life-cycle stage of a facility or item; the programmatic mission of the facility. (See [QAM Chapter 12070, Graded Approach Procedure](#))

Item: A non-conformance, management concern, opportunity for improvement, or recommendation, that is the output of an assessment, a review, tour, inspection, or audit conducted throughout the Laboratory. (See QAM Chapter 12002, *Fermilab Quality Assurance Program*)

Suspect/Counterfeit Item – An item identified through visual inspection, testing, or other means that does not appear to conform to established Government or industry-accepted specifications or national consensus standards. An item whose documentation, appearance, performance, material, or other characteristics may have been knowingly misrepresented by the vendor, supplier, distributor, or manufacturer. An item that has been copied or substituted without legal right or authority to do so. (See [QAM Chapter 12020, Suspect/Counterfeit Item \(S/CI\) Program](#))

iTrack: (Issues Management Tracking System) A database used to document and facilitate the resolution of items of any nature arising from formalized activities where reports are typically generated.

Line Management – Chiefs, Division Heads, Section Heads, Project Directors, Project Managers

Management System Owner (MSO) – Appointed owners of the management systems who are responsible for ensuring FNAL policies and procedures related to their managements systems are developed, implemented, monitored, maintained, evaluated, and improved; as such they apply across the laboratory.

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

Risk-Based Planning: Focuses on the strategic, regulatory, financial, and business risks to which the Laboratory has exposure. The goal is to customize a dynamic, defensible assessment plan that addresses the unique needs and risks of the work being performed.

7. Responsibilities

Line Management and Management System Owners:

- Responsible for ensuring all employees, users, and subcontractors performing work for or within their areas of responsibility are aware of this Policy.
- Responsible for ensuring the requirements established in this Policy and Fermilab Quality Manual are effectively integrated in programs, processes, and procedures and implemented.

Head of Quality Assurance:

- Provides oversight to manage, improve and administer the Quality Assurance Policy and the Fermilab QA Program.
- Maintains and improves the implementation strategy for program-specific QA plans.
- Provides input, support, and feedback to the Line Management and MSOs on their QA procedures and processes.
- Guides personnel in Projects and operations with QA implementation.
- Manages Fermilab Quality Program tools (e.g. iTrack, Lessons Learned database).
- Manages, directs, and supports Quality Section Liaisons and responsibilities assigned as it relates to this policy.

Quality Section Liaisons:

- Support Line Management and MSOs with the understanding and implementation of this Policy within their respective areas.
- Serve as the primary contacts for Line Management and MSOs for Fermilab Quality Policy and Fermilab Quality Program related matters.

8. Authorities

Prime Contract No. DE-AC02-07CH11359 Clauses H.13 (Contractor Assurance System) and I.87 (Management Controls)

9. Owner

The Head of Quality Assurance owns this Policy.

10. Review Cycle

This Policy shall be reviewed every three years.

11. Communication Plan

The requirements of this Policy shall be communicated to all employees, and periodic training shall be provided to MSOs and Line Management. This policy shall be available online in the Fermilab policy database. The Head of Quality Assurance is responsible for the communication of this Policy.