

Quality Assurance Policy

Fermilab 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.

2. Scope

This policy applies to all Fermilab activities and operations carried out under the approved management systems on the Fermilab site and all leased spaces.

The Fermilab Software Quality Assurance (SQA) Program defines the minimum quality assurance requirements for applications developed and/or used by Fermilab.

3. Applicability

This policy excludes assessments performed by Fermilab Internal Audit Services (i.e. Financial assessments, Office of the Inspector General audits, etc.).

4. Effective date

This policy goes into effect on January 1, 2017 and replaces the September 2013 version.

5. Policy

Fermilab's Quality Assurance Program is detailed in the Quality Assurance Program document and is implemented by relevant procedures created by Divisions, Sections, and Projects (D/S/P) and Management System Owners (MSO). The QA Program provides a single, integrated approach for assuring quality throughout Fermilab.

The QA Program sets expectations for D/S/P's and MSO's to:

- develop implementing procedures
- establish and maintain a graded approach to define and integrate the appropriate level of quality controls based upon risk of the subject, initiative or operation
- perform audits and self-assessments
- provide tools for continuous process improvement and adoption of best practices, and
- develop guidelines for levels of inspection, documentation, and recordkeeping

Fermilab conducts a variety of risk-based assessments, audits, and reviews to identify and understand business risks (i.e. financial, regulatory, environmental, legal, safety & health, etc.) and to identify opportunities to continually improve processes throughout the Laboratory. This is accomplished through Self and Independent Assessments conducted at the Laboratory as evidence to ensure the assessed areas meet all applicable requirements. Issues discovered as a result of these assessments shall be documented in the Fermilab Issues Management Tracking System, commonly referred to as iTrack.

Self-Assessments shall be conducted by Divisions/Sections/Projects (D/S/P) or Management Systems Owners to evaluate their own specific internal procedures and performance. (See [QAM chapter 12080, *Self Assessments*](#)). These shall be planned and scheduled based on risk using a graded approach. If the topic being assessed has specific timeline requirements for assessment, these must be adhered to as well.

Independent assessments are conducted by external organizations, 3rd parties (e.g. DOE or registrar), or internal organizations independent from the area being assessed to ensure the laboratory's adherence to applicable requirements. These will be scheduled based on the requirements set by the external organizations or as requested by Fermilab.

Fermilab makes every reasonable effort to prevent the use of suspect/counterfeit items (S/CI) to safeguard personnel, the public, the environment, and the investments that affect the laboratory's mission. The S/CI Program at Fermilab is documented in [QAM chapter 12020](#). The S/CI program explains that each individual is expected to be vigilant to detect and report S/CI items. It is the responsibility of each individual to be aware of the consequences of incorporating S/CI items into operations. As appropriate for their job duties, all individuals shall make themselves aware of the various items that are likely to be S/CI.

To the extent reasonable and appropriate, quality assurance activities at all levels should systematically aim to:

- Build lasting customer relationships
- Earn customer and stakeholder trust
- Keep activities relevant with current research directions and customer expectations
- Choose partners 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
- Embed organizational and personal learning, and improvement into our processes
- Seek and accept complaints as opportunities to strengthen customer relationships
- Utilize national and international consensus standards where practical, consistent with contractual or regulatory requirements, or where a competitive advantage is achieved

6. Definitions

Assessment:

A review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively. (See [QAM chapter 12080, *Self Assessments*](#)).

Graded Approach:

The process of ensuring that the levels of analysis, documentation, and actions used to comply with requirements are commensurate with the relative importance to safety, safeguards, and security; the magnitude of hazard involved; the life-cycle stage of a facility or item; the programmatic mission of a facility; the particular characteristics of a facility or item; and the relative importance to radiological and non-radiological hazards.

Issue:

Findings, recommendations, and nonconformities that require action and are the result of reviews, tours, assessments, inspections, and audits conducted throughout the laboratory.

iTrack:

The mandatory laboratory-wide issues management system for documenting reviews, findings, recommendations, nonconformities, and other issues.

Quality Assurance:

Actions that provide confidence that quality and suitability for intended use is achieved.

Quality Assurance Program:

The overall program established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Risk-Based Planning:

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

Division, Section, and Project Heads/Management System Owners:

- Responsible for providing the resources necessary to schedule and conduct assessments within their organization according to this policy
- Identify necessary and appropriate assessments within Program Execution Plans (PEPs), which are developed as part of the annual budget/business planning process
- Ensure the D/S/P Quality Assurance Representative is informed of all assessments occurring and the results
- Ensure iTrack is utilized for all findings or nonconformities found during assessments, and ensure they are tracked through to completion

Environmental, Safety, Health, and Quality Section:

- Schedule and conduct Quality Assurance assessments
- Track assessment metrics and periodically report to the Assurance Council
- Review implemented corrective actions to evaluate the effectiveness of those actions
- Review, update and communicate changes to this policy

Quality Assurance Manager:

- Provide oversight to manage, improve and administer the Quality Assurance Program
- Maintain and improve the strategy for implementing graded quality assurance plans
- Work with D/S/P's to implement QA procedures
- Guide personnel in projects and operations to assist in quality assurance implementation
- Manage iTrack

Quality Assurance Representatives:

- Coordinate and assist with planning, scheduling, and execution of self-assessments in their division, section, or project
- Participate in DOE or 3rd party assessments representing their organization.
- Report assessment results for their D/S/P to the Quality Assurance Subcommittee
- Assist in verifying the effectiveness of completed corrective actions

8. References

[Quality Assurance Manual](#)

[Quality Assurance Program description](#)

[Software Quality Assurance Program description](#)

[iTrack Database](#)

9. Review cycle

This policy is to be reviewed at least every three years.