

## Quality Assurance Policy

Management System: Quality

### Revision History

<b>Author</b>	<b>Description of Change</b>	<b>Revision No. &amp; Date</b>
T.J. Sarlina	Revision 004, initial re-release of the Quality Assurance Policy. Reformatted policy template and content.	Revision 4 September 2013

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## 1.0 INTRODUCTION

This document establishes Fermilab's Quality Assurance policy that is in compliance with all quality requirements applicable to the Laboratory. Quality assurance at the Laboratory is used 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.

## 2.0 DEFINITIONS

### 2.1 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. (DOE O 414.1)

### 2.2 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 any 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.

### 2.3 Quality Assurance:

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

### 2.4 Quality Assurance Program:

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

## 3.0 RESPONSIBILITIES

### 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 Division/Section/Center Heads and Project Managers to build and implement graded quality assurance plans and procedures
- Guides personnel in programs and operations to assist in quality assurance implementation

## 4.0 POLICY

### 4.1 Quality Assurance Program

Fermilab's Quality Assurance Program is composed of the Integrated Quality Assurance (IQA) program document, programmatic implementing procedures, and D/S/C's and project's implementing procedures. The IQA program provides a single, integrated approach for assuring quality throughout Fermilab and ensures adherence to DOE O 414.1 Quality Assurance requirements.

The IQA program and programmatic procedures implement this policy; set expectations for D/S/C's and projects to develop implementing procedures; establish and maintain a graded approach; perform audits and self-assessments; provide tools for continuous / process improvement and adoption of best practices; and provide guidelines for levels of inspection, documentation, and recordkeeping.

### 4.2 Graded Approach

Fermilab uses a graded approach to define and integrate the appropriate level of quality controls based upon risk of the subject, initiative or operation.

### 4.3 Suspect/Counterfeit Items

It is Fermilab's policy to make every reasonable effort to prevent the use of suspect/counterfeit items (S/CI) to ensure personnel and public safety, and environmental integrity, while safeguarding investments that affect the Laboratory's mission.

The S/CI Program at Fermilab is documented in the FESHM chapter 12020. The S/CI program shall explain how 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.

### 4.4 Expectations

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 encourage 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

## 5.0 REFERENCES

- 5.1 DOE O 414.1, Quality Assurance - <https://www.directives.doe.gov/directives/0414.1-BOrder-dadmchg1/view>
- 5.2 FESHM - <http://esh.fnal.gov/xms/FESHM>
- 5.3 Integrated Quality Assurance Program document - <https://esh-docdb.fnal.gov:440/cgi-bin/ShowDocument?docid=2469>

