Fermilab Integrated Quality Assurance Program

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I. EXECUTIVE SUMMARY

At the highest level, Fermilab's Integrated Quality Assurance (IQA) program is required by contract between DOE and FRA. DOE Order 414.1D, *Quality Assurance* is the required document for Fermilab's IQA program. Fermilab has adopted the national consensus standard ANSI/ASQ Z1.13-1999 to ensure the application of Quality Assurance to scientific research, and uses ANSI/ISO/ASQ Q9001-2008 to ensure the application of Quality Assurance to non-research activities and management systems.

The order requires Fermilab to flow down its Quality Assurance (QA) requirements to subcontractors at any tier to the extent necessary to ensure contractors' compliance with the requirements and the safe performance of work.

Quality Assurance applies to all work conducted at Fermilab, in accordance with the principles of the quality program listed in this overview. This IQA program describes the overarching institutional integrated QA program for Fermilab. It is implemented using a graded approach to the application of controls, based on the analysis of risks identified in areas where work is to be performed. It identifies quality requirements necessary to consistently meet the DOE contract obligations throughout the laboratory's divisions/sections/centers/projects (D/S/C/P) and ensures that quality, safety, health, security, cyber-security, environmental, facilities/infrastructure maintenance and performance of research are integrated into all work conducted under the contract.

The IQA program is reviewed at least annually. All revisions to the IQA program will be submitted to the DOE for review and approval. If no revisions are necessary the DOE will be notified that a review has occurred and resulted in no changes.

II. DEFINITION, PURPOSE, AND SCOPE

The foundation of QA management is a line responsibility; i.e. the line organization must have the authority, responsibility, and be held accountable for integrating QA into, and as a part of, all work that they do. Line responsibility for QA is woven into the organizational culture at Fermilab.

The purpose of the IQA program is to define a QA program which ensures that Fermilab's products and services meet or exceed customer expectations; provide the lab with requirements for the purpose of implementing and maintaining a QA program throughout the lab; and to provide a QA system capable of monitoring, controlling, and continually improving the program's activities, processes, and systems.

The scope of the IQA program applies to Fermi Research Alliance, LLC (including all legal entities under its exclusive control) and all employees, contractors, subcontractors, and Fermilab users when performing work that affects the laboratory.

III. REQUIREMENTS

The primary function of Fermilab is scientific research. By reference under DOE O 414.1D, QA for scientific research is controlled exclusively by ANSI/ASQ Z1.13-1999 *Quality Guidelines for Research.* All other activities at Fermilab follow the ten criteria of the DOE O 414.1D as outlined in the following criteria.

Integrated safety management system as required by the Work Smart Set (WSS) of ESH&Q standards attached to the DOE contract, and other laws and regulations is documented in the Fermilab Environmental, Safety and Health Manual (FESHM). This IQA program is consistent with and complimentary to the Fermilab Integrated Safety Management program delineated in FESHM.

The Contractor Assurance System, in accordance with the prime contract between the DOE and FRA, is documented in the Contractor Assurance System Description. This IQA program is consistent and complimentary to the Contractor Assurance System.

IV. QUALITY ASSURANCE PROGRAM

Management

Criterion 1: Program

1.1 Introduction

Fermilab has established an organizational structure along with responsibilities, authority, and written procedures that ensure successful implementation and maintenance of the IQA program.

1.2 Organization & Responsibilities

The Laboratory Director has ultimate responsibility for all aspects of QA for all work done under the FRA/DOE contract on the Fermilab site.

The Laboratory Director and the heads of each D/S/C/P ensure that responsibilities and authorities are defined and communicated within the organization. Responsibilities and authorities are recorded as part of employee job descriptions and within council, and committee charters.

To see the organization at Fermilab at a high-level and for each division, section, center, and project reference the most recent version of the Organizational Chart.
http://www.fnal.gov/pub/about/organization/index.html

Associate Laboratory Directors and the heads of each D/S/C/P are responsible for providing plans, schedules, and resources for work, and for implementing quality in their respective organizations. As appropriate for their areas of responsibility, they establish additional performance requirements above and beyond those established in the IQA

program, while avoiding any unnecessary duplication of effort. They are responsible for the performance and sponsoring of assessments to facilitate the achievement of the organizational mission, objectives, and performance requirements. They ensure that their D/S/C/P activities are conducted in accordance with the principles and requirements of the IQA program.

1.3 Quality Assurance (QA) Subcommittee

The Fermilab ES&H Committee (FESHCom) charges the QA Subcommittee with oversight and implementation of the IQA program at Fermilab. The QA Subcommittee provides guidance to the laboratory and has authority over QA decisions concerning the IQA program, and monitors implementation, maintenance, and continual improvement of the program. Issues discovered that require more resources than what is available through the QA Subcommittee, and issues that require laboratory-wide visibility and management support are escalated up through FESHCom for resolution. FESHCom further decides if matters require escalation to the Assurance Council (AC) for even higher visibility, senior management support and resolution.

Members of the subcommittee consist of the appointed QA Subcommittee Chair, Deputy and Quality Assurance Representatives (QARs) from each organization. The Chair and Deputy are responsible for ensuring the goals and responsibilities of the QA Subcommittee are met, and that issues are appropriately escalated. The QARs are responsible for IQA program implementation within their organization, and serve as participants and points of contact for maintenance of the program, assessments of compliance and effectiveness of the program, and quality investigations.

1.4 Graded Approach

1.4.1 Graded Approach Process Principles

The IQA program utilizes a graded approach to tailor the kinds 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 approving 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.

1.4.2 Responsibilities

All D/S/C/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.

Criterion 2: Personnel Training & Qualifications:

2.1 Introduction

All Fermilab employees and personnel, 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.

2.2 Qualifications

Initial employee qualification is ensured by 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 also ensure that job candidates meet specified requirements.

2.3 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 (OTJ) 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:

- Developing an Individual Training Needs Assessment (ITNA) 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 (OTJ) training. OTJ 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 OTJ are qualified.

- Maintaining appropriate records of training.
- Utilizing position descriptions, hazard analyses, new employee requisitions, and/or the Work Activities Analysis Form 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.

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.

Management is also responsible for reviewing the effectiveness of its training programs. Results from these reviews shall be used as inputs for continual improvement.

Criterion 3: Quality Improvement:

3.1 Introduction

Fermilab maintains continuous quality improvement through a variety of activities, including training, design, assessments, observation by walk-through, inspections, tests, monitoring, reviews, and analysis.

3.2 Quality Improvement Program

Issues, improvement opportunities, corrective actions, and lessons learned generated from the activities listed in the introduction are documented and tracked in iTrack; the laboratory-wide mandatory issues management system per the Issues Management Directorate Policy. Procedures for documenting and tracking these items are documented in the Fermilab Environmental, Safety & Health Manual (FESHM), and include the iTrack Procedure, Corrective and Preventive Action Procedure, and the Contractor Assurance/Lessons Learned Program and Procedures.

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

Quality improvement is implemented throughout the organization including the elements of planning, measuring, and analyzing.

Planning:

Strategic planning for Fermilab is conducted by the Head of the Office of Integrated Program Planning Management (IPPM) in conjunction with the Deputy Director. Input to the planning process includes feedback from management reviews, problem resolution, root cause analysis, lessons learned, assessments, scientific peer reviews and DOE Office of Science program reviews.

Measuring:
The Assurance Council reviews the adequacy, suitability, and effectiveness of the IQA program on an annual basis. The AC is charged by the Laboratory Director to provide assurance that sufficient internal controls and oversight systems are in place and are operating properly to maintain Fermilab's Contractor Assurance System (CAS). The AC consists of senior management team members and CAS Management System Owners that have the authority to make decisions pertaining to issues management.

D/S/C/P managers hold reviews based upon need. The frequency is adjusted to adequately manage all aspects of the activity, process, or system, to satisfy the customer (internal or external), be proactive in problem prevention, and to accomplish the work.

Analysis:
The process of resolving quality problems includes resolution analysis. Problems are analyzed to determine cause(s), suitable corrective and preventive actions, and verify that the correct actions were taken to satisfy the root cause of the original quality problem found. The process of resolving quality problems involves:

- Identifying a condition adverse to quality, and evaluating its significance
- Analyzing the problem and determining its causes
- Reporting the planned actions to the organization identifying the problem
- Assigning responsibility for correcting the problem
- Taking prompt containment action and documenting that action
- Examining training processes, procedures, or management systems
- Determining corrective action and documenting that action
- Taking steps to prevent recurrence and replicating the actions where appropriate
- Verifying implementation, and documenting closure
- Determining effectiveness of the corrective and preventive actions

In addition, issues elevated to the Directorate and/or the Fermilab AC are subject to an initial review to determine if the issue should be tracked by the AC or managed through other Fermilab channels. Where deemed necessary or appropriate, the AC may raise the issues to the Director of Fermilab and/or DOE. Quality problems, including those brought by the QA Subcommittee, are analyzed individually and collectively to identify systemic quality problems, trends and opportunities for process improvement.

Criterion 4: Documents & Records

4.1 Introduction

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

4.2 Responsibilities
Responsibility for lab-wide policies and procedures is shared between the Directorate and the originating D/S/C/P's. D/S/C/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 in place at Fermilab.

4.3 Documents
Documents are required in order 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.

4.4 Records Management
Records are necessary to provide evidence of process effectiveness and conformity with requirements. Fermilab's policies and procedures for a centralized records management program are described in more detail in the Records Management Program. The program includes provisions for specifying, preparing, reviewing, approving, disposing, and maintaining records and references, applicable rules, regulations, and directives governing how the laboratory is to manage records.

Performance

Criterion 5: Work Processes
5.1 Introduction
Work includes the design, operation, maintenance, modification, and construction of experiments, accelerators, systems, and procedures performed by Fermilab employees, regardless of location. In addition to Fermilab employees this also applies to users, contractors, and collaborators. The set of controls applied to work processes includes written procedures for activities of sufficient complexity or potential hazard; periodically monitoring and assessing performance; personal accountability; and specific provisions for activities not otherwise covered in this document.

Control of scientific research is described in Criterion 12.

5.2 Responsibilities

5.2.1 Management

Management is responsible for ensuring sufficient resources are available and given to facilities, plant and equipment, processes, personnel, health and safety needs, and support services to maintain the site in an operational state. Management is responsible for ensuring work controls are in place and effective. Line management is required to evaluate and ensure that people performing work have the appropriate skills, background, education, and training necessary to carry out the work per Criteria 2: Personnel Training and Qualification.

5.2.2 All Personnel

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

5.3 Work Process Control

Line management determines the appropriate level of work process controls, including which activities require written procedures and which procedures must be augmented through personnel training and qualifications. Management defines workmanship standards, equipment to be used, specifications for materials, process measurement points, and measurement standards. ESH&Q requirements and controls for work processes are defined in FESHM.

Controls are established for the procurement and acceptance of items and services and are addressed in Criterion 7: Procurement. Measuring and Test Equipment Control are designed to meet requirements identified in Criterion 8: Inspection and Acceptance Testing.

5.3.1 Item Control

Items are identified and controlled, with their traceability maintained during receipt, shipping, storage, handling, installation, use, and disposal. These controls are commensurate with the item's application, usage, and associated risk and are managed by D/S/C/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.

5.3.2 Maintenance

D/S/C/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 and these services are agreed upon between FESS and the D/S/C/P's. Maintenance plans are documented by D/S/C/P's. The organization coordinating or performing the maintenance is responsible for ensuring that records of maintenance are kept.

5.3.3 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 ESH&Q approval to operate accelerator facilities are required to follow FESHM 2010. D/S/C/P's are required to document any readiness reviews performed in their respective areas. In addition, certain research projects are required by orders other than DOE O 414.1D to perform readiness reviews at specified intervals.

5.3.4 Calibration of Process Equipment
It is the responsibility of each D/S/C/P to identify, monitor and maintain key process equipment that requires calibration or verification. Results are maintained. (See also: Criterion 8: Inspection and Acceptance Testing.) Process equipment examples include buildings, pumps, water supply systems, building air supply systems, experimental apparatuses, etc… which are then calibrated by using measuring & test equipment (section 8.5 Control of Measuring & Test Equipment).

5.3.5 Work Environment
All facilities are to be maintained in a state of order, cleanliness, and repair, as appropriate for accomplishing 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.

5.4 Software

5.4.1 Safety Software
Fermilab does not employ safety software under the definition of safety software in DOE Order 414.1D Quality Assurance.

5.4.2 Software Quality Assurance
Quality assurance requirements for software used at Fermilab to support the laboratory's program and mission is described in the Fermilab Software Quality Assurance Program.

Criterion 6: Design

6.1 Introduction

Fermilab's design process provides appropriate 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 judgment, scientific principles, and applicable codes and standards and applies to research/experimental equipment including accelerator components, and detectors as well as to conventional facilities, structures and equipment. The Lead Engineer has overall responsibility for the efforts of all engineers working on a single project. The controls and implementing procedures are contained 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 (hereafter referred to as design elements). Note - Software design is outside the scope of the IQA program.

6.2 Responsibilities
Responsibility and effectiveness of the design and engineering process lies primarily with line management. Line management includes D/S/C/P heads, their deputies, department heads and supervisors. Members of line management are responsible for adding additional requirements to the engineering process as they see fit to ensure the success and quality of projects executed under their supervision. Other functions with responsibilities within the execution of the design and engineering process includes Project and System Managers, Department Heads, Lead Engineers, and Engineers. Their responsibilities are outlined within the Fermilab Engineering Manual.

6.3 Design Process Steps
The Fermilab Engineering Manual describes in detail the design and engineering process steps: 1) Requirements and Specifications – defines objectives; 2) Engineering Risk Assessment – determines level of documentation and review required; 3) Requirements and Specifications Review; 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.

Criterion 7: Procurement

7.1 Introduction
This criterion establishes the QA requirements for the Fermilab procurement process. Fermilab procurement documents are generated and managed in accordance with the Procurement Manual.

All materials and services are purchased from technically 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 conformity with purchase order requirements. 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 and data or other reports to ensure compliance.

The procurement and receipt inspection processes supports the identification and prevention of the introduction of suspect and counterfeit items (S/CI), and shall occur whether materials were purchased through purchase order or using the ProCard. 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 Criterion 11: Suspect and Counterfeit Items.

7.2 Responsibilities
The procurement of all goods and services is under the control of the Business Services Section (BSS) Procurement Department, except where delegated by the Head of the BSS. The Procurement Department is responsible for the coordination of all procurement requests received from laboratory D/S/C/P's. This responsibility includes acquisition planning in association with engineering, quality and other functions as necessary, generating and verifying solicitation and purchase documents, negotiating terms and conditions, performing subcontract administration, and closeout.

7.3 Supplier Evaluation
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.

Criterion 8: Inspection & Acceptance Testing

8.1 Introduction
This criterion establishes the process for the inspections and tests performed at Fermilab that 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.

8.2 Responsibilities
Line management is responsible for specifying when and what type of inspection is required. Additionally, line management is responsible for ensuring that adequate inspections are performed.

8.3 Inspection & Testing Process
Inspection and acceptance testing plans, where applicable, identify item characteristics and processes to be inspected/acceptance tested, inspection techniques, acceptance criteria, hold points, and the organization responsible for performing the inspection. Where deficiencies are identified appropriate corrective and/or preventative actions are taken.

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

8.3.1 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/C/P's are responsible for control of nonconforming items. Controls include identification, documentation, evaluation, segregation (when practical), item disposition (reject, repair, rework, use-basis), and notification to affected organizations. FESHM 3010, Significant and Reportable Occurrences, is consulted to determine if the nonconformance is reportable.

8.4 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 M&TE used to perform the inspection or test, the inspection/test data, the inspection/test criteria, and the inspection/test results.

8.5 Control of Measuring & Test Equipment
The measuring and test equipment (M&TE) used for inspection and acceptance tests are identified, calibrated, maintained, and controlled commensurate with their intended use. Procedures are established by D/S/C/P's for testing, retesting, adjusting, and recalibrating 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. 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.

When M&TE or standards are found to be out of tolerance, appropriate evaluations are performed to assess any adverse impact on previous inspection, testing, data collected or calibration using that equipment and to determine the acceptability of items previously inspected or tested and appropriate notifications made. The evaluation, including conclusions, is documented.

All M&TE equipment not operating to specifications is identified and pulled from service or locked out and are not returned to service until passing calibration requirements. Consideration is given to computer programs that are part of the calibration of the equipment when calibrating and/or checking the equipment for use.

Assessment
Reviews and assessments are a welcome part of conducting business at Fermilab. These include self-assessments; management assessments within D/S/C/P's; and independent assessments and reviews conducted by ESH&Q, the AC, the Laboratory Director, the FRA, or the DOE. The IQA program augments the laboratory's ability to conduct rigorous assessments and provide effective corrective actions, by providing training and support to

representatives of each D/S/C/P while ensuring consistent conduct and visible assessment planning and outcome.

Criterion 9: Management Assessments

9.1 Introduction

This criterion describes the program used to assess the adequacy, implementation, and effectiveness of Fermilab's management processes per the Assessments Director's Policy, and FESHM.

Management assessments are used by an organization to evaluate its own management processes and their implementation in an effort to identify good and noteworthy practices, uncover issues, identify corrective actions, and ensure that the work being performed is satisfactory and in accordance with requirements. Scientific work is assessed by a peer review process. Scientists determine the extent and adequacy of this process.

9.2 Responsibilities

The IQA program requires that managers assess their processes to identify and correct problems that hinder the organization from achieving its objectives. The heads of D/S/C/P's monitor the progress of actions in their organizations on a periodic basis and ensure that the actions are finalized with appropriate objective evidence. ESH&Q 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 IQA program throughout the laboratory.

9.3 Assessment Results

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. Findings are reported for failure to comply with requirements. Corrective actions are recorded and tracked to closure through the iTrack database per the Issues Management Director's Policy, and the Corrective and Preventive Action and iTrack procedures in FESHM. Laboratory-wide implications are identified, escalated to the QA Subcommittee, and corrective actions are implemented.

Criterion 10: Independent Assessments

10.1 Introduction

Independent assessments are conducted on a periodic basis to ensure the adequacy of the implementation of the IQA program. These assessments compliment the Management Assessments described in Criterion 9. Fermilab management and ESH&Q have the responsibility and authority for planning internal independent 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, and environmental, health, safety, and quality related external independent assessments are coordinated by the ESH&Q Section.

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

10.3 Assessment Results
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. Laboratory-wide implications are identified, escalated to the QA Subcommittee, and corrective actions are implemented.

10.4 Provisions for DOE and Other External Assessments
Findings and corrective actions for DOE assessments are administered in accordance with the Contractor Requirements Document of DOE O 227.1, *Independent Oversight Program*. Findings and corrective actions for other external assessment teams are entered into iTrack and tracked to completion per the Issues Management Director's Policy, and the Corrective and Preventive Action and iTrack procedures in FESHM.

11. Suspect/Counterfeit Items Prevention

11.1 Introduction
Fermilab has established a process for the identification, control, and disposition of suspect/counterfeit items (S/CI). Implementation of the S/CI program can be found in FESHM. Fermilab provides training on S/CI processes and controls (including prevention, detection and disposition of S/CIs).

11.2 Responsibilities
The QA Manager is responsible for ensuring that S/CI training is available. Line management is responsible for identifying individuals requiring S/CI training, ensuring they receive this training, and providing necessary resources for implementing the S/CI program.

Designers provide appropriate specifications and controls to safeguard the laboratory against the introduction of S/CI.

Procurement is responsible for selecting technically 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.

11.3 Prevention
Methods to prevent the purchase of S/CIs are based on making all purchases from reputable suppliers and distributors.

11.4 Detection
The primary means of detecting S/CIs is through inspection.

11.5 Reporting
If S/CIs are discovered, the reporting process follows the S/CI procedure as outlined in FESHM. This includes notifying the area supervisor, the S/CI coordinator, and may include the senior safety officer. FESHM 3010 is consulted to determine the appropriate reportable category.

12. Scientific Research

12.1 Introduction
Current research conducted at Fermilab focuses on experiments of varying size and complexity, Theoretical Explorations in Physics, and Development of Other 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.

12.2 Responsibilities
These elements are described in more detail in the Procedures for Researchers (PFX)

12.2.1 The laboratory Director, Deputy Director, and Associate Directors 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.

12.2.2 The Principal Investigator(s) and/or Experiment Spokesperson(s) is (are) responsible for formally proposing the planned research, including technical approach, schedule and deliverables, and facility requirements; developing the contractual documentation between the collaboration and Fermilab for the implementation of experiments and other projects; overseeing the performing and documentation of the research of their collaboration; assisting in the assessment of the research performed by their collaboration, and ensuring the appropriate publication of research results.

12.2.3 Scientific Collaborators are responsible for identification of spokesperson(s) and/or principal investigator(s), participation in the conduct of research, and securing funding as agreed in applicable contractual documents.

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

12.3 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. 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 large project appoints an embedded Project Quality Assurance Manager that maintains resources dedicated to supporting and assessing the implementation of QA in scientific research projects.

13. Revision History

Author(s)	Description	Revision #	Date
T.J. Sarlina, Kathy Zappia	Revision 001, initial re-release of the Integrated Quality Assurance Program. This revision is a complete overhaul of the IQA program from the last released version 002 dated 01/20/2012 created by OQBP. This document has been updated to reflect the current working status of the IQA program at Fermilab.	001	September 2013