QAM 12002: Fermilab Quality Assurance Program

Revision History

Author	Description of Change	Revision Date
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 v002 of the OQBP QA program dated 01/20/2012.	September 2013

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1.0 INTRODUCTION

The Fermilab Quality Assurance (QA) Program is a key component of the Quality Management System supporting the Fermilab Contractor Assurance System (CAS) required by the prime contract between the Department of Energy and the Fermilab Research Association. The QA program is reviewed as necessary but at least every 3 years.

Quality Assurance applies to all work conducted at Fermilab and other Fermilab-managed sites. This document describes the overarching QA program for the laboratory. 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 quality requirements necessary to consistently meet the DOE contract obligations throughout the laboratory's divisions/sections/projects (D/S/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.

Fermilab flows down the QA program requirements to subcontractors at any tier to the extent necessary to ensure contractors' compliance with the requirements and the safe performance of work. Fermilab has aligned with both the national consensus standard ANSI/ASQ Z1.13-1999 to ensure the application of Quality Assurance to scientific research, and ANSI/ISO/ASQ Q9001-2015 standard to ensure the application of Quality Assurance to non-research activities.

2.0 DEFINITIONS

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 "good work practice" or innovative approach that is captured and shared to promote repeat application; A lesson learned may also be an adverse work practice or experience that is captured and shared to avoid recurrence.

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.*

Preventive Action – An action to eliminate the cause of a potential nonconformity or other undesirable potential 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 document that contains Fermilab's policies and procedures designed to manage quality.

3.0 RESPONSIBILITIES

3.1 Laboratory Director

- Approves the QA Program and has ultimate responsibility for all aspects of QA for all work done under the FRA/DOE contract.
- Holds management accountable for implementation of and compliance with this program.
- Appoints the Quality Assurance Manager as the Fermilab QA Program owner.

3.2 Division/Section Heads and Project Managers

- Ensure compliance with this procedure for their areas of responsibility including flow down of requirements and awareness.
- Responsible for providing plans, schedules, and resources for work, and for implementing quality in their respective organizations.
- Ensure that line management has the authority, responsibility and be held accountable for integrating Quality Assurance into processes and programs.

3.3 Quality Assurance Manager

- Ensures that assessments 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.
- Assumes responsibility for the content and maintenance of this procedure.

3.4 QA Subcommittee

- Provides guidance to the laboratory and has authority over QA decisions concerning the Fermilab QA program.
- Monitors the implementation, maintenance, and continual improvement of the QA program.

4.0 PROGRAM DESCRIPTION

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

The Quality Assurance 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) and all employees, contractors, subcontractors, and Fermilab users when performing work that affects the laboratory.

5.0 PROCEDURES

5.1 Program

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

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

To see 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 Heads of each D/S/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 QA 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, and objectives. They ensure that their D/S/P activities are conducted in accordance with the principles and requirements of the QA program.

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 being accomplished and that the systems and controls which have been put into place are effective and efficient. CAS covers all work activities and all personnel performing work at Fermilab including subcontractors and guests. The CAS process encompasses all aspects of the sixteen cross-cutting management systems which are essential to the laboratory's success.

5.1.2. Quality Management System

The Quality Management System is one of sixteen management systems and 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.

5.1.3. Quality Assurance (QA) Subcommittee

The Fermilab ES&H Committee (FESHCom) charges the QA Subcommittee with oversight and implementation of the QA Program at Fermilab. The QA Subcommittee

provides guidance to the laboratory and monitors implementation, maintenance, and continual improvement of the program. Issues discovered that require more resources than what is available through the QA Subcommittee as well as 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 for senior management support and resolution.

Members of the subcommittee consist of the appointed QA Subcommittee Chair, Deputy, and Quality Assurance Representatives (QAR's) from each organization. The QAS Chair and Deputy Chair direct the activities of the Subcommittee and ensure that issues are appropriately escalated. The QAR's serve as points of contact for implementation and maintenance of the QA Program within their organizations; coordinate and assist with assessments of compliance and effectiveness of the program, including quality investigations when necessary; and participate in reviewing revisions to this document and other lab-wide QA programs, policies and procedures.

5.1.4. Graded Approach

The Fermilab QA program utilizes a graded approach, defined within QAM Chapter 12070, 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. 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, 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 people performing work have the appropriate skills, background, education, and training necessary to carry out the work.

5.2.1. Qualifications

Initial employee qualification is part of the hiring process administered by the Workforce Development and Resources Section. 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:

- 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 (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 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, records should be kept in personnel files if appropriate.

Management is 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, and analysis.

5.3.1. Quality Improvement Program

Issues, improvement opportunities, and corrective actions, generated from the activities listed above are documented and tracked in the laboratory's Issues Management Tracking System, iTrack. Procedures for documenting and tracking these items are documented in the Quality Assurance Manual.

Management at all levels is responsible for encouraging and enabling individuals under their supervision 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 appropriate management levels (program, facility, D/S/P manager and/or Directorate); and ensure root causes are identified and corrected.

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 are tracked in the ESH&Q Section's Improvements Database, and also the Lessons Learned Database. Procedures for documenting Lessons learned are available in the QAM chapter on Contractor Assurance/Lessons Learned Program and Procedures.

5.3.2. Quality Improvement Support

- The Office of Integrated Planning and Performance Management supports quality improvement by leading the Laboratory's strategic planning process, goal setting, project and program oversight, 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.
- The Assurance Council (AC) is charged by the 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. The AC consists of senior management team members and CAS Management System Owners that have the authority to make decisions pertaining to continual improvement activities and issues management. Issues elevated to the 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 and/or DOE.
- Quality issues are analyzed individually and collectively to identify systemic quality issues, trends and opportunities for process improvement. Refer to the

FESHM chapter on Incident Investigation and Analysis for the procedure relating to incident investigation and analysis.

- Human Performance Improvement (HPI) supports resolution of quality issues through analyzing problems 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
  - Verifying implementation, and documenting closure
  - Determining effectiveness of the corrective and preventive actions

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.

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.

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 design, construction, operation, support, maintenance, modification, and decommissioning of experiments, accelerators, facilities, and systems performed by Fermilab employees, regardless of location. In addition to Fermilab employees, this 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. 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

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. Controls on Measuring and Test Equipment are designed to meet requirements identified in Section 5.8 - Inspection and Acceptance Testing.

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, 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.

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 ESH&Q approval to operate accelerator facilities are required to follow the FESHM Chapter for 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 an important 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 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 should be considered for inclusion in the calibration program. Results are documented and retained.

Process requirements and criticality shall be taken into account 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 - Inspection and Acceptance Testing.)

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.

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 Design

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. It 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 this document*

Responsibility and effectiveness of the design and engineering process lies primarily with line management. Members of line management are responsible for adding additional requirements to the engineering process as they see fit to ensure the quality and success of projects executed under their supervision. Other functions having responsibilities for the successful execution of the design and engineering process includes Project and System 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 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.

5.7 Procurement

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 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 prevents the introduction, of suspect and counterfeit items (S/CI). Inspection receipt shall occur whether materials were purchased through purchase order or via 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 Section 11 - Suspect and Counterfeit Items. Suspect or counterfeit items should 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.

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.

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.

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 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.

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. 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 is 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

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. 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.

If any M&TE is found to be out of tolerance, 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.

5.9 Management Assessments

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

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 actions in their organizations on a periodic basis and ensure that the actions are finalized with appropriate objective evidence. The 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 QA program throughout the laboratory.

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-conformities 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 QAM. Items having Lab-wide impact are identified and reported to the senior management team for action.

5.10 Independent Assessments

Independent assessments are conducted on a periodic basis to ensure adequate implementation of the Fermilab QA program. These assessments compliment the Management Assessments described in the Management Assessments section. 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.

D/S/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 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 senior management team for action.

Non-conformities and corrective actions for DOE assessments are administered in accordance with the Contractor Requirements Document of DOE O 227.1, *Independent Oversight Program*. Non-conformities 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. 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. Procurement 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, Chief Officers, 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 documents.

- 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 large project appoints a Project QA Manager/Coordinator responsible to support and assess the implementation of QA activities for the project.

6.0 REFERENCES

- Fermilab Contractor Assurance System
- Quality Assurance Manual (QAM)
- FESHM
- Engineering Manual
- ANSI/ASQ Z1.13-1999, Quality Guidelines for Research
- Fermilab Training Program
- Software Quality Assurance Program
- Procurement Manual