

ESE Integrated Quality Assurance

Electronic Systems Engineering Department

Computing Division

Fermi National Accelerator Laboratory

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OVERVIEW

INTRODUCTION

The Electronic Systems Engineering Department (ESE) of the Computing Division at Fermilab is dedicated to providing high quality design, implementation, maintenance and project management support for hardware systems for HEP and Astrophysics experimentalists and phenomenologists. Hardware systems include board and system level hardware and firmware, and infrastructure electronics. The department upholds the principles of Integrated Quality Assurance as defined in the Fermilab Integrated Quality Assurance (IQA) Program Document and the Director's Policy 10. The line management of the ESE Department and the Computing Division support and propagate IQA authority and responsibility throughout the organizational structure as delegated by the Director. All members of the ESE department are included and compliance is mandatory.

The aim of the ESE IQA program:

- Ensure that ESE products and services meet or exceed customers' expectations
- Support the process of implementing and maintaining an Integrated Quality Assurance program throughout the laboratory
- Utilize the laboratory quality assurance system for monitoring, controlling, and continually improving the department's activities, processes, and systems

PRINCIPLES OF THE QUALITY PROGRAM

Quality assurance is defined in the IQA program document and is summarized by these principles.

- Quality is assured and maintained through a single, integrated, effective QA Program.
- Management support for planning, organization, resources, direction, and control is essential to QA.
- Performance and quality improvement require thorough, rigorous assessment and corrective action.
- Workers are responsible for achieving and maintaining quality.
- Environment, safety, and health risks, as well as impacts associated with work processes, can be minimized.
- Suspect/counterfeit items (S/CI) and safety software can be controlled.

This document is based on the Fermilab IQA Program Document and highlights the details of how IQA is implemented in the ESE Department. The laboratory IQA document is the next document that department members should refer to and is the default document in all of the following POLICY AND PROGRAM DOCUMENTS sections.

Chapter One: PROGRAM

INTRODUCTION

The ESE Department supports the laboratory mission and strives to meet this mission within the context of a safe and respectful workplace. ESE activities follow the ten criteria of DOE Order 414.1C and control of suspect/counterfeit items. The details of those criteria will not be presented here. This document presents information where ESE has specific local modifications to the laboratory IQA policy or to emphasize policy for department members.

This document will follow the format of the IQA which is organized by criteria.

RESPONSIBILITIES

Organization

The ESE Department head reports to the Computing Division, then to the Associate Director for Computing & CIO. Within the department and the division are the necessary line management and support organizations to ensure that their missions are achieved safely, within budget and on schedule.

Authority & Responsibilities

All Fermilab personnel, including employees, contractors at any level, users, and visitors, are responsible for safety, the quality of their work, and for being attentive to opportunities for continuous improvement. They are responsible for stopping any activity that poses imminent danger to any individual, the Fermilab or local mission, or to the environment. ESE employees are required to inform their immediate supervisors promptly of any conditions that are noncompliant with Fermilab policies and requirements.

GRADED APPROACH

ESE applies a graded approach to IQA as defined in 1002.1000 Graded Approach Procedure.

POLICY AND PROGRAM DOCUMENTS

Director's Policy 10 Quality Assurance

Fermilab Environment, Safety and Health Manual

1002.1000 Graded Approach Procedure

Chapter Two: PERSONNEL TRAINING & QUALIFICATION

INTRODUCTION

ESE IQA policy follows the Fermilab IQA policy on personnel training and qualification.

ESE line managers ensure that personnel possess the training, experience, knowledge, skills, and abilities necessary to fulfill their responsibilities.

ESE department strongly supports continuing education so that our engineers and technicians can maintain their job competency and existing skills, keep up to date in a rapidly changing field, and explore new areas of electronics to the benefit of the laboratory, the science program and their careers.

POLICY AND PROGRAM DOCUMENTS

ESE has local policy and safety documents on the department web site at <http://cdorg.fnal.gov/eese/esetemplate.html> under Safety and IQA

ESE will maintain the following documents:

- ESE Department Safety Manual
- Operational Readiness forms for local testing.
- Job Hazard Analysis forms specific to the ESE work area.

Chapter Three: QUALITY IMPROVEMENT

INTRODUCTION

The ESE Department supports Quality improvement through awareness and constant examination of all activities, processes, systems, projects, and programs. ESE individuals are responsible for the quality of all aspects of their job, especially in a constantly changing environment, and for reporting issues. The improvement process includes provisions for individual feedback, a no-fault attitude and mechanisms to identify, analyze, and resolve quality issues, in order to prevent their occurrence or recurrence. The department uses the lessons learned process as an integral part of continuous quality improvement through the sharing of relevant best practices throughout Fermilab.

RESPONSIBILITIES

Management

Management at all levels is responsible for encouraging and enabling all individuals under their supervision to participate in the following quality improvement activities:

- Identifying and analyzing opportunities for improvement.
- Responding to discovery of quality-related issues and following up on any required actions.
- Documenting any failures and non-conformances identified from these efforts.
- Ensuring that significant problems are reported to the appropriate and potentially affected management levels (program, facility, division/section/center manager, and/or Directorate) and that causes are identified and corrected.

The degree of these efforts is commensurate with the degree of programmatic significance, financial impact, compliance, public relations, or environment, safety, and health risks associated with the problems.

QUALITY IMPROVEMENT PROGRAM COMPONENTS

Quality improvement is implemented throughout the organization using a structured, graded approach, including the elements of planning, measuring, analyzing and improving.

Planning

The ESE Department supports the Computing Division plans to support the needs of the Fermilab Strategic Plan. These plans include responsibilities, schedules, resources required and defined processes for carrying out intended work.

MANAGEMENT REVIEW

The ESE Department, program, and project 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), to be proactive in problem prevention, and to get the work accomplished within the budget and schedule.

QUALITY PROBLEM RESOLUTION ANALYSIS

The process of resolving quality problems involves:

- identifying a condition adverse to quality,
- evaluating its significance and extent,
- 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,
- replicating the actions where appropriate,
- verifying implementation,
- documenting closure, and
- determining effectiveness of the corrective and preventive actions for significant problems

POLICY AND PROGRAM DOCUMENTS

Significant and Reportable Occurrences FESHM 3010

Issues Tracking Procedure

ES&H Assurance Program FESHM 1040

[Corrective / Preventive Action Procedure]

Chapter Four: DOCUMENTS & RECORDS

INTRODUCTION

The ESE Department supports the Laboratory system for managing laboratory-wide policies and documents is described in the Director's Policy Manual. Additional document control requirements may be imposed by outside customers/sponsors, or be required for certain specific activities. Records are managed in accordance with Fermilab's Records Management Policies and Procedures.

RESPONSIBILITIES

Fermilab employees, users, and contractors are required to comply with the document control and records management policies and procedures in place at Fermilab.

DOCUMENTS

Using the graded approach, ESE management identifies those documents which are required in order to safely and effectively manage, perform, and assess work and determines the level of control required. Controls include activities such as preparation, review, approval, distribution, usage, availability, revision, and disposal of documents.

RECORDS MANAGEMENT

The ESE Department uses the Computing Division Document Database for department related documents and the CD web servers and Computer Server disc spaces for project and experiment documentation where ESE is the issuing organization. The Computing Division maintains and supports these services.

POLICY AND PROGRAM DOCUMENTS

Directors Policy 1, Policy on Policies

Directors Policy 13, Document Control

Records Management Policies and Procedures

Chapter Five: WORK PROCESSES

INTRODUCTION

The ESE Department uses a graded approach to determine the level of controls applied to work performed at Fermilab. Work includes the design, operation, maintenance, modification, and construction of experiments, accelerators, systems, and procedures by ESE employees, regardless of location. 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

Clear lines of responsibility have been established for normal and emergency conditions and all work is performed in compliance with applicable DOE and/or legal requirements.

Scientific research is performed in accordance with generally accepted scientific methods and controlled by scientific collaboration, publication in peer reviewed journals and review by DOE.

RESPONSIBILITIES

Management

ESE line management is required to evaluate and ensure that people performing work have the appropriate skills, background, and academic qualification or professional certification, and area or task specific training necessary to carry out the work per Chapter 2: Personnel Training and Qualification. Management is responsible for ensuring work controls are in place and effective.

All Personnel

Each person is responsible for the quality of their work, reporting issues, and contributing to the integration of environment, safety, and health and productivity goals. All personnel are responsible for maintaining items to prevent damage, loss or deterioration and ensuring proper use. Personnel are expected to make every attempt do their work correctly the first time, in accordance with established procedures and work instructions.

WORK PROCESS CONTROL

Work at Fermilab covers a wide range of complexity. Processes can range from straightforward and prescriptive to dynamic and non-prescriptive. Line management is responsible for applying the graded approach to determine the appropriate level of work process controls, including which activities require written procedures and which procedures can be augmented through the appropriate personnel

training and qualifications. Management defines workmanship standards, equipment to be used, and specification for materials, process measurement points, and measurement standards. ES&H requirements and controls for work processes are defined in FESHM.

ITEM CONTROL

Using a graded approach, 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 divisions/sections/centers. The requirements for controlling and maintaining property, equipment, items, and the site infrastructure are defined in the Fermilab IQA Program Document.

READINESS REVIEWS

ESE supports readiness reviews 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. The ESE Department controls and document readiness reviews for specific activities including unattended operation of equipment performed in their areas.

CALIBRATION OF M&TE EQUIPMENT

ESE Department will identify, monitor and maintain key controlled Measurement and Test Equipment (M&TE) equipment, which is equipment that requires calibration or verification. Results are maintained. It is the policy of the ESE Department that only M&TE equipment so identified will be calibrated. This policy does not apply to research apparatus/equipment unique to an experiment, which is set up and calibrated by researchers using procedures or processes which have been reviewed and accepted by the experiments appropriate scientific managers. A graded approach is applied to M&TE control and calibration whereby process equipment needs to be calibrated only to the extent and intervals necessary to adequately perform the measurement involved. At this time no ESE instrumentation is involved with critical safety or laboratory processes.

The ESE Department has two instruments that currently have a calibration responsibility; one for traceability reasons and one as directed by the ES&H office. The first is the calibration service that we offer to the laboratory with our Fluke 5520A commercial calibration system. It is calibrated yearly to NIST standards as our responsibility to our users. The second is the compact X-Ray system that is also available to the laboratory as a service but only as operated by our ES&H trained operators and only as long as we maintain yearly safety and calibration inspection by the manufacturer. The operators for both of these instruments are informed of the calibration requirements and the need to quickly detect and address out-of-normal operations for these systems.

All other ESE Department instruments are individually evaluated to determine the need for calibration. The graded approach is applied so that only activities with required measurement accuracy necessitate instrument calibration. A portion of the Department uses a dedicated subset of electronic instruments for repair of modules in the PREP pool. These instruments are identified and tracked in the Computing Division equipment database and calibrated yearly or biennially depending on manufacturer recommendations and past performance. The report of equipment to be calibrated is generated automatically monthly and the calibration technician updates the list as calibrations are performed. Additionally the repair technicians can request calibrations at any time for their instruments.

The rest of the ESE Department instrumentation is considered to be un-calibrated unless it has a valid calibration sticker attached. The most frequent use of the Department instrumentation is for module and system diagnostics and debugging and these activities do not require absolute measurement accuracies. The level of accuracy needed for diagnostics and debugging is easily determined using simple measurements with a known source or by a comparison measurement with one or two other instruments. Therefore the Department has determined that it is the responsibility of each user to: 1) evaluate the use and accuracy needs for each instrument he is using, 2) make validation measurements as appropriate and 3) request calibration where it is necessary or indicated. These are basic skills for all department engineers and techs and they can be taught to our students and co-ops during the introduction to instruments and measurements for the project task they are assigned to.

(See also: Chapter 8 Inspection and Acceptance Testing.)

POLICY AND PROGRAM DOCUMENTS

Fermilab Environment Safety & Health Manual FESHM

Fermilab Policy on Computing.

Current list of Instruments requiring calibration verification:

1. FLUKE 5520A MultiProduct Calibrator System with MetCal software. (used for local calibration)
2. Glenbrook Technologies Jewel Box 90C X-Ray System Serial #A0108-789K (ES&H requires yearly inspection).

Chapter Six: DESIGN

INTRODUCTION

The ESE Department 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.

The controls and implementing procedures are contained in the [Fermilab Design & Engineering Processes Manual, FDEPM].

RESPONSIBILITIES

Division/Section/Center/Program Management

Management authorizes resources, provides resources, assigns engineering oversight, and ensures functional requirements are established. For projects of sufficient complexity, size, or risk, a Design Authority (DA) is designated.

Design Authority

The DA responsibilities are defined in the Fermilab IQA Program Document and the FDEPM.

DESIGN PROCESS STEPS

The design process is defined in the Fermilab IQA Program Document and the FDEPM.

POLICY AND PROGRAM DOCUMENTS

Fermilab Design & Engineering Processes Manual [FDEPM].

Chapter Seven: PROCUREMENT

INTRODUCTION

The ESE Department makes all purchases through the Procurement Department as managed through the FRA prime contract and Procurement Policies, and Procurement Manual. All purchased materials and services are acquired by purchase order or procurement credit card (Procard).

The procurement and receipt inspection processes supports the identification and prevention of the introduction of suspect and counterfeit items (S/CI). The system for S/CI detection, prior to release for use, is detailed in Fermilab IQA Program Document. Requestor responsibilities are defined in the same document.

The members of the ESE department should understand the laboratory S/CI procedures and when making purchases via requisitions or Procard they should 1) use detailed part numbers and/or performance specifications in order to ensure the parts received perform the function required, 2) order from known manufacturers or their authorized distributors, and 3) check the items soon after reception either as an item or as a component of an assembled module.

POLICY AND PROGRAM DOCUMENTS

Procurement Policies and Procedures Manual

ES&H and National Environmental Policy Act (NEPA) Procurement Review FESHM 5010

Chapter Eight: INSPECTION AND ACCEPTANCE TESTING

INTRODUCTION

The ESE Department follows the process for the inspections and acceptance tests performed at Fermilab as defined in the Fermilab IQA Program Document. The material purchased and received by the ESE department can be divided into three general categories; components, assembled modules and departmental infrastructure. The I&AT process for these are different and detailed below.

RESPONSIBILITIES

All department personnel that receive material for the department are required to inspect that material on receipt to verify that it appears to be as ordered and that the condition is as expected. Following that:

Components are purchased by the ESE Department to satisfy a construction task for an experiment or laboratory department. That task will have functional testing at the module level, the components have defined functionality within the design and are purchased for that module and so individual component testing is rarely necessary. A small fraction of the components purchased by the department are stored for the PREP module repair process. These parts are specific part numbers from the module or component Original Equipment Manufacturer where there is a history of purchases and the risk of not testing individual components before using them is considered extremely low.

Assembled modules are built or repaired to satisfy a construction task for an experiment or laboratory department. The I&AT process varies for each specific module but can be generalized into these steps.

- Inspect the module for obvious problems; material flaws, mechanical problems, or missing components.
- Power the device as it will be used monitoring closely for overloads and observing such activity indicators included in the design.
- Run functional tests as defined for the module. These usually progress from simple basic functionality tests up to complex function tests and integration with other system modules.

Material received as ESE departmental infrastructure are test equipment or instruments used to perform general departmental functions. Initial acceptance is the responsibility of the member that placed the order. That person should follow the general process of:

- Perform the initial visual inspection of the material for correct condition.
- Learn the operation of the equipment either from the OEM manuals, the manufacturer's representative or other appropriate source.

- Follow the manufactures recommended procedure for initial operation.
- Test the functionality as recommended by the manufacturer and as required in order to satisfy the department needs that lead to the purchase of the equipment.
- Notify the department of the new instrument its capabilities and where the department can get more information about the instrument.

POLICY AND PROGRAM DOCUMENTS

FESHM 3010 Significant and Reportable Occurrences

[Corrective Action / Preventive Action]

Chapter Nine: ASSESSMENTS

INTRODUCTION

The ESE Department follows the Fermilab program used to assess the adequacy, implementation, and effectiveness of Laboratory processes and systems as defined in the Fermilab IQA Program Document.

POLICY AND PROGRAM DOCUMENTS

[Corrective Action / Preventive Action]

[Fermilab Assessments Manual]

Chapter Ten: SUSPECT/COUNTERFEIT ITEMS

INTRODUCTION

The ESE Department follows the Fermilab process for the identification, control, and disposition of suspect/counterfeit items (S/CI) defined in the Fermilab IQA Program Document.

RESPONSIBILITIES

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

All requestors and ProCard holders are made aware of the need to purchase from reputable suppliers and distributors using detailed part numbers and functional requirements if appropriate.. All personnel are informed of the risks associated with S/CI and of the laboratory S/CI reporting process.

DETECTION

The primary means of detecting S/CIs is through inspection. Some S/CI can be detected when components do not meet operational specifications.

REPORTING

If S/CIs are discovered, the reporting process follows the Suspect/Counterfeit Items Program and supporting procedures. This includes notifying the area supervisor, senior safety officer, and quality assurance representative. FESHM manual 3010 is consulted to determine the appropriate reporting category.

CONTROL OF NONCONFORMING ITEMS

The control of nonconforming items is discussed in the Fermilab IQA Program Document.

POLICY AND PROGRAM DOCUMENTS

FESHM 3010 Significant & Reportable Occurrences

1006 Suspect/Counterfeit Items Program

Chapter Eleven: SCIENTIFIC RESEARCH

INTRODUCTION

ESE Department supports scientific research by following the adopted standard, ANSI/ASQ Z1.13-1999 *Quality Guidelines for Research* and the local responsibilities that are described in more detail in the Procedures for Experimenters (PFX)

Current research conducted in the department focuses on development of Other Supporting Technologies (e.g. accelerator elements and systems, cryogenics, material science, detector development, computing, etc.).

RESPONSIBILITIES

Local responsibilities are described in more detail in the Procedures for Experimenters (PFX)

Scientific Collaborators are responsible for:

- Identification of spokesperson(s) and/or principal investigator(s)
- Participation in the conduct of research
- Securing funding as agreed in applicable MOU

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 external, e.g. DOE, review committees, and by submission of publications to refereed journals.

POLICY AND PROGRAM DOCUMENTS

[Directors Policy on Scientific Research]

[Quality Guidelines for Scientific Research at Fermilab]

[Procedures for Experimenters (PFX)]

TABLE OF REVISIONS

Author(s)	Description	Revision	Date
Vince Pavlicek	Draft V1 – create doc from FNAL IQA, not released	1	30 Apr 09
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Vince Pavlicek	Version 3 with updated I&AT section and other small edits	3	29 Jan 11