

1001

Integrated Quality Assurance

**Office of Quality and Best Practices
Fermi National Accelerator Laboratory
Batavia, IL**

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OVERVIEW

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INTRODUCTION

The U.S. Department of Energy's (DOE) Office of Science is the steward of a system of 10 world-class national laboratories. These laboratories perform basic research and research and development that is not well suited to university or private sector research because of its scope, infrastructure, or multidisciplinary nature. These laboratories collaborate not only with each other for an effective synergy, but also with international teams of scientists and engineers. Five of these laboratories are multi-program facilities, while the other five are single-program facilities. The Fermi National Accelerator Laboratory (FNAL), also known as Fermilab, is located in Batavia, Illinois and is one of the five single-program labs supported by the DOE. In line with the DOE's strategic goals, Fermilab's scientists advance the understanding of the fundamental nature of matter and energy by conducting basic research at the frontiers of high energy physics and related disciplines.

In the late 1960's, the U.S. Atomic Energy Commission acquired the 6,800-acre Fermilab site from the State of Illinois. The laboratory was managed and operated by the Universities Research Association (URA) from the time of its inception until 2007. In January 2007, the Fermi Research Alliance, LLC (FRA), formed through a partnership between the URA and the University of Chicago, contracted with the DOE to perform prime management and operating functions at Fermilab. URS Corporation is a subcontractor to FRA. Both URS and FRA are committed to executing plans, processes, and procedures that implement, institutionalize, and continually improve Fermilab's Integrated Quality Assurance program, (IQA).

At the highest level, Fermilab's Integrated Quality Assurance program is required by contract DE-AC02-07CH11359 between DOE and FRA. The contract identifies DOE Order 414.1C, *Quality Assurance* as the requirements document for Fermilab's IQA. In accordance with this order Fermilab has adopted a national consensus standard ANSI/ASQ Z1.13-1999 to ensure the application of Quality Assurance to scientific research.

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.

Implementation of Order 414.1C is documented at the first level in the Laboratory Director's Policy Manual, Policy 10: *Quality Assurance*. The policy establishes principles for the laboratory's Integrated Quality Assurance program and provides a link between the DOE order and the requirements for work conducted by Fermilab. The order and policy are implemented at the second level with this Integrated Quality Assurance program and at subsequent levels with procedures that ensure compliance and effectiveness.

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Quality assurance applies to all work conducted at Fermilab, in accordance with the principles of the quality program listed in this overview. This IQA describes the overarching institutional Integrated Quality Assurance 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 the quality requirements necessary to consistently meet the DOE contract obligations throughout the laboratory's divisions/sections/centers 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.

This IQA refers to laboratory-wide manuals, policies, and procedures that detail the activities which execute the Fermilab QA requirements. In cases where this IQA refers to a document under development the document name is enclosed in brackets ([]).

In accordance with requirements of DOE O 414.1C, the IQA is reviewed annually. If a review results in revisions, the Office of Quality & Best Practices (OQBP) will resubmit the revised IQA to the DOE for review and approval. Any changes will be identified and explained, and the OQBP will provide the basis for concluding that the revised IQA continues to satisfy requirements. If no revisions are made, the DOE will be notified that the review was conducted and that no revisions were necessary.

DEFINITION OF IQA

INTEGRATED QUALITY ASSURANCE

Integrated Quality Assurance (IQA) – The foundation of integrated 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 of the work that they do. Line responsibility for quality assurance is woven into the organizational structure, as well as all aspects of the IQA program at Fermilab.

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 Director delegates the QA responsibility to the line managers (division/section/center heads) assigned to carry out the work. The responsibility is further delegated to line supervisors and ultimately to the workers.

PURPOSE AND SCOPE

PURPOSE

The purpose of Integrated Quality Assurance is to implement DOE Order 414.1C and the Fermilab Director's Policy 10, *Quality Assurance*, and to improve Fermilab's overall performance at meeting or exceeding customer expectations. Additionally, this program

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will help sustain Fermilab's legacy and heritage of success and will demonstrate FRA's and URS's value as trusted, consistent and dependable partners with DOE.

The aim of the IQA is to

- define a QA program which ensures that Fermilab's products and services meet or exceed customers' expectations,
- provide the laboratory with requirements for the purpose of implementing and maintaining an Integrated Quality Assurance program throughout the laboratory, and
- provide a quality assurance system capable of monitoring, controlling, and continually improving the program's activities, processes, and systems.

SCOPE

The IQA establishes the requirements necessary to implement the Fermilab Director's Policy 10 and comply with DOE Order 414.1C (under prime contract DE-AC02-07CH11359). This IQA 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. Compliance is mandatory.

PRINCIPLES OF THE QUALITY PROGRAM

Quality assurance will be achieved for all work, based on the following principles.

- Quality is assured and maintained through a single, integrated, effective QA Program.
The quality program is maintained through a single Integrated Quality Assurance program. To limit duplication of effort and ensure both integration and consistent application throughout the laboratory, a single lab-wide implementing procedure (e.g. corrective and preventive actions, graded approach) is used whenever that procedure can be extended beyond individual divisions/sections/centers without detriment to its intention, compliance, or effectiveness.
- Management support for planning, organization, resources, direction, and control is essential to QA.
Fermilab's Director and the heads of each division/section/center will provide sufficient resources for implementing the QA Program to the areas under their control and will ensure effective compliance with its requirements.
- Performance and quality improvement require thorough, rigorous assessment and corrective action.

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Reviews and assessments are a welcome part of conducting business at Fermilab. These include self-assessments; management assessments within divisions/sections/centers; and independent assessments and reviews conducted by or for the OQBP, the Fermilab Assurance Council, the Laboratory Director, the FRA, or the DOE. The QA Program augments the laboratory's ability to conduct rigorous assessments and provide effective corrective actions, by providing training and support to representatives of each division/section/center while ensuring consistent conduct and visible assessment planning and outcome.

- Workers are responsible for achieving and maintaining quality.

While the ultimate responsibility for ensuring an effective Integrated Quality Assurance program lies with the Laboratory Director, the responsibility for full and effective implementation of the QA Program is delegated to every employee, user, and subcontractor while conducting work for Fermilab or its customers. Management, from line management to the heads of each division/section/center, is responsible for overseeing these individuals and ensuring compliance. The Director has delegated responsibility for the administration, maintenance, and continued improvement of the QA Program to the Head of OQBP. All employees are required to take the course Introduction to Integrated Quality Assurance, (FN000446).
- Environment, safety, and health risks, as well as impacts associated with work processes, can be minimized.

The QA Program at Fermilab is implemented in conjunction with all relevant operational and scientific programs (see section 1.2), including Environmental Safety and Health (ES&H) programs, to ensure that all work is conducted correctly, and in a safe and responsible manner.
- Suspect/counterfeit items (S/CI) and safety software can be controlled.

The QA Program requires the establishment and implementation of quality process requirements in order to control safety software and suspect/counterfeit items. The IQA extends beyond acting on customer issues; it includes proactively engaging in controlling incoming, in-process, and final materials, products, parts, etc.

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Chapter 1. PROGRAM

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1.1 INTRODUCTION

Fermilab's mission is defined as follows:

Fermi National Accelerator Laboratory advances the understanding of the fundamental nature of matter and energy by providing leadership and resources for qualified researchers to conduct basic research at the frontiers of high energy physics and related disciplines.

Fermilab strives to meet this mission within the context of a safe and respectful workplace.

The primary function of Fermilab is scientific research. By reference under DOE Order 414, quality assurance 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 DOE O 414.1C and control of suspect/counterfeit items.

The format of the IQA is as follows:

Management

- Criterion 1 Program
- Criterion 2 Personnel Training and Qualifications
- Criterion 3 Quality Improvement
- Criterion 4 Documents and Records

Performance

- Criterion 5 Work Processes
- Criterion 6 Design
- Criterion 7 Procurement
- Criterion 8 Inspection and Acceptance Testing

Assessment

- Criterion 9 Management Assessment
- Criterion 10 Independent Assessment

Suspect/Counterfeit Items (S/CI)

Scientific Research (ANSI/ASQ Z1.13-1999)

Each criterion and the S/CI requirement are addressed by separate chapters, with the exception of criteria 9 and 10, which are combined. A number of national and international consensus standards were considered for use. Fermilab has adopted ANSI/ASQ Z1.13-1999 as the consensus standard most appropriate to Fermilab's mission of fundamental scientific research.

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1.1.1 *Integrated safety management system*

Fermilab's integrated safety management system is documented in the Fermilab Environment, Safety and Health Manual (FESHM) as required by 10 CFR 851: Worker Safety and Health Program and the following DOE policy, manual, and order: Integrated Safety Management System policy (DOE P 450.1);

Integrated Safety Management Systems Manual (DOE M 450.4); and DOE Order 231.1A Environmental, Safety and Health Reporting.

This IQA is consistent with and complimentary to the Fermilab Integrated Safety Management Program delineated in FESHM.

1.1.2 *Integrated contractor assurance program*

Fermilab's Contractor Assurance Program is documented in the Fermilab Integrated Contractor Assurance Program in accordance with the H13 clause of the prime contract between DOE and FRA. This IQA is consistent with and complimentary to the Fermilab Integrated Contractor Assurance Program.

1.2 RESPONSIBILITIES

1.2.1 *Organization*

DIRECTORATE

Fermilab's organization at the directorate level is depicted in the Fermilab directorate-level organization chart (Fig. 1), current at the time of this writing. The Fermilab Directorate is made up of the Laboratory Director; the Deputy Director; the Chief Operating Officer (COO); the Chief Financial Officer (CFO); the Director of Environment, Safety and Health (ES&H); the Associate Laboratory Director of the Computing Sector and Chief Information Officer (CIO); the Associate Laboratory Director of the Accelerators Sector; the Associate Laboratory Director of the Particle Physics Sector; the Associate Laboratory Director for the Operations Sector and COO and the Program Managers for major initiatives and large projects.

In addition, there are two assistant directors and a number of support offices, including the Fermilab Legal Office, the Office of Communication, the Office of Program and Project Support (OPPS), and the Office of Research and Technology Applications (ORTA).

INTERNAL AUDIT

FRA's accounts, records, and internal accounting policies and controls, located at the FRA Corporate Office and at Fermilab, are subject to audit. Internal Audit is an independent office that regularly provides reports to Fermilab Management, FRA, and

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the Board of Directors Audit Committee. This process monitors the adequacy, effectiveness, and performance of the internal controls, ensures prudent business practices, and verifies compliance with the prime contract between FRA and the DOE

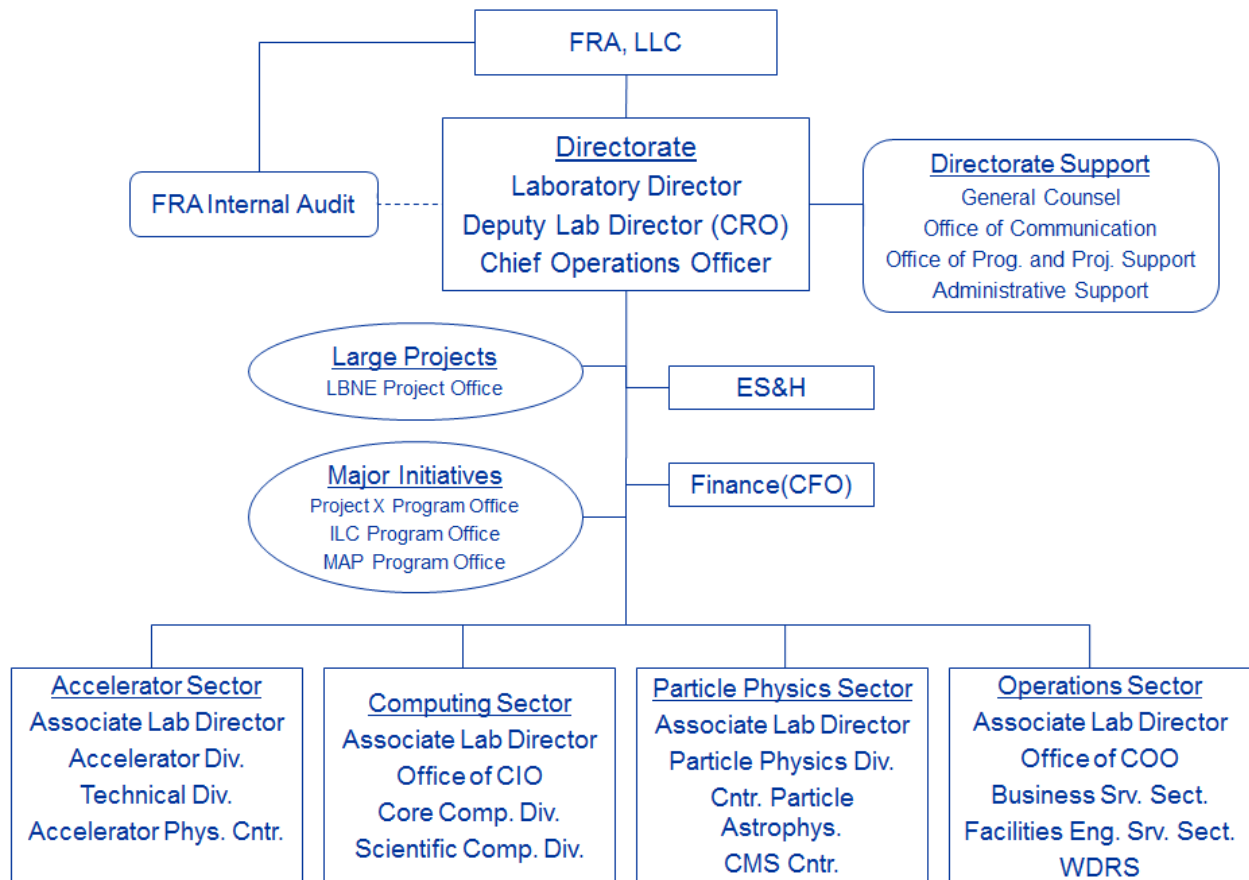


Figure 1 Fermilab Directorate Organization Chart

SECTORS, DIVISIONS/SECTIONS/CENTERS

Reporting to the Associate Laboratory Director of the Accelerator Sector are the Accelerator Division, the Technical Division, and the Accelerator Physics Center. Reporting to the Associate Laboratory Director of the Particle Physics Sector are the Particle Physics Division, the Center for Particle Astrophysics, and the Compact Muon Solenoid Center. Reporting to the Associate Laboratory Director for the Operations Sector are the Facilities Engineering Services Section, the

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Business Services Section, and the Workforce Development and Resources Section. Reporting to the Associate Laboratory Director for the Computing Sector are the Scientific Computing Division and the Core Computing Division. Reporting to the Chief Financial Officer are the Accounting, Budget, and Management Information Systems departments.

Within each sector, division/section/center are the necessary line management and support organizations to ensure their missions are achieved safely, and within budget. Sectors, divisions/sections/centers, and the Directorate each maintain organizational charts, which can be found online at their respective links.

OFFICE OF PROGRAM & PROJECT SUPPORT

Reporting to the Head of the Office of Program and Project Support (OPPS) are the Head of the Office of Project Management Oversight (OPMO), the Head of the Office of Integrated Planning (OIP), and the Head of the Office of Quality & Best Practices (OQBP) as shown in Figure 2.

Office of Program and Project Support (OPPS)

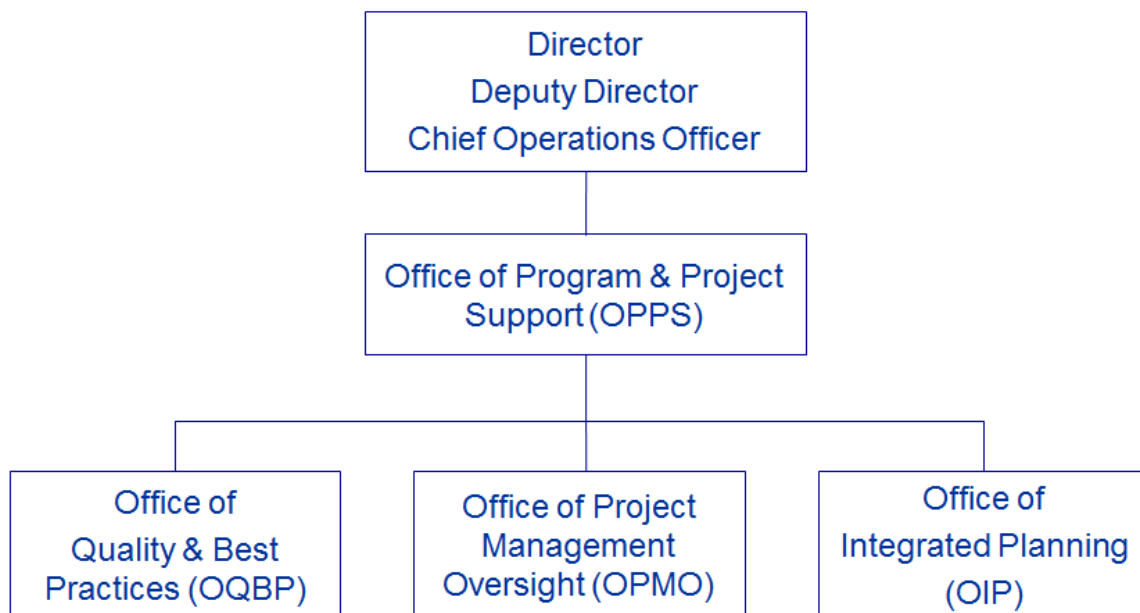


Figure 2 Fermilab Office of Program & Project Support Organization Chart

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ADVISORY COUNCILS

The Laboratory Director receives input, advice and recommendations from a number of advisory councils on matters relating to science and operations.

- **Physics Advisory Committee (PAC)**
 Composed of members from various laboratories and universities, the PAC considers proposals for current and future scientific research and development (R&D) programs in both particle physics and particle astrophysics. This committee advises the Director on strategic approaches to supporting such proposals. Typically serving four year terms, PAC participants are experienced and well respected in the high energy physics community.
- **Accelerator Advisory Committee (AAC)**
 Composed of members from various laboratories and universities, the AAC advises the Fermilab Director on accelerator upgrade plans, accelerator R&D, and associated strategic approaches aimed towards the development of future accelerator facilities. The AAC typically meets for two and a half days at a time, in the spring and fall, at Fermilab.
- **Advisory Council on Integrated Assurance (AC)**
 This internal assurance council reviews the overall management and operations, commitments, initiatives, and laboratory improvement efforts and advises the Laboratory Director regarding the level of compliance of these activities. The council pays special attention to the requirements denoted in the H13 clause of the prime contract, *Contractor Assurance*.
- **Diversity Council**
 The Diversity Council fosters organizational equity through programs designed to increase the diversity of the laboratory. Employee participation is encouraged through teams, which are organized to develop the initiatives of the Council. The Council, a task force for change, develops, implements, and maintains strategic programs with established goals for the laboratory.
- **Laboratory Collaboration Council (LCC)**
 Established by FRA and UChicago/Argonne, LLC, the Laboratory Collaboration Council is chaired on a rotating basis by the directors of FNAL and Argonne National Laboratory. The LCC explores ways in which both laboratories can promote efficiency, best practices, synergy, and cost savings in support of research programs. It creates working groups chartered by joint action of the laboratory directors, which provides critical support for R&D,

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technology transfer, and experiments at the Large Hadron Collider at Europe's treaty-based particle physics laboratory (CERN).

1.2.2 *Authority and responsibilities*

LABORATORY DIRECTOR

The Director of Fermi National Accelerator Laboratory reports to the Chairman of the Board of Directors of Fermi Research Alliance, to the DOE Fermilab Site Office, and to the DOE Office of Science. With ultimate responsibility and authority for quality at Fermilab, the Director approves the QA Policy and all substantive changes to it and is committed to and supportive of its effective implementation. The Director appoints Associate Laboratory Directors and other key scientific and management staff, including the Head of the Office of Program and Project Support (OPPS), the Head of the Office of Integrated Planning (OIP), the Head of the Office of Project Management Oversight (OPMO) and the Head of Quality and Best Practices (OQBP).

OFFICE OF PROGRAM AND PROJECT SUPPORT

The Head of OPPS reports to the Laboratory Director and is responsible for supporting the sectors and the directorate across a broad front that includes strategic planning, project and program planning from construction through operation of facilities, human resources planning, integration of the site development plan with the strategic plan and the support of laboratory systems and standards such as the Organization Human Assets Plan (OHAP), the Earned Value Management System (EVMS) and the Engineering Manual.

OFFICE OF INTEGRATED PLANNING

The Head of OIP reports to the Head of OPPS who in turn reports to the Laboratory Director. The Head of OIP supports the directorate and sectors in maintaining the strategic plan and acting as a technical interface between sectors and the CFO in developing budget plans for the laboratory.

OFFICE OF PROJECT MANAGEMENT OVERSIGHT

The Head of OPMO reports to the Head of OPPS who in turn reports to the Laboratory Director. The Head of OPMO is responsible for providing assistance in the planning, preparation, execution, monitoring, review, assessment, and management of large projects (>\$5M) within the laboratory.

OPMO provides advice and counsel on strategic planning, scheduling and budgeting for new projects, guidance to new project teams in the formation stages in the development of project management skills, project culture, documentation,

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and tools required for the execution of projects consistent with Fermilab and DOE requirements in Working Group Meetings (WGMs).

The Head of OPMO monitors and assesses project performance through attendance and participation in Project Management Group (PMG) meetings, periodic project reports, in-depth Directors' reviews and DOE reviews, which address the technical, cost, schedule, and management of projects. OPMO has the primary responsibility for maintaining project management procedures and a website with resources for project teams.

The OPMO maintains a DOE certified FRA Earned Value Management System (EVMS) with interfaces to existing Fermilab business and management systems and provides training to personnel required to use and understand the EVMS system. The Head of OPMO ensures that all DOE projects requiring use of earned value management will have, as part of their Fermilab Director's CD-2 Director's Review, a review of the project's implementation of the FRA EVMS to establish that the project is compliant with DOE and ANSI requirements. Issue resolution is coordinated by the OPMO if the issue involves changes to the FRA Earned Value Management System Description or supporting Fermilab procedures.

OFFICE OF QUALITY AND BEST PRACTICES

The Head of QQBP reports to the Head of OPPS who in turn reports to the Laboratory Director. The Head of QQBP is designated as the senior Fermilab official responsible for the development, implementation, assessment, and improvement of Integrated Quality Assurance. QQBP provides dedicated quality management and quality engineering resources to support QA implementation by D/S/Cs and to assess the level of compliance and effectiveness of QA implementation by D/S/Cs. QQBP leads periodic meetings with Quality Assurance Representatives (QARs) from each D/S/Cs and QQBP QA staff.

The Head of QQBP approves the IQA and all substantive changes to it, advises and assists the Laboratory Director in providing continuity, completeness, and appropriate standardization in the overall quality program, and is committed to and supportive of the quality programs. This responsibility includes policymaking, planning, reporting, oversight, and other activities required to achieve an integrated and effective QA Program. The QQBP ensures quality-related training is provided. The Head of QQBP also advises the Directorate and divisions/sections/centers on QA matters, while line management within each division/section/center implements the QA policy, this IQA, and related procedures. QQBP is the point of contact for quality reviews.

The Head of QQBP is the owner of the IQA and by policy, administers and is the point of contact for the program. Other than minor editorial changes, all revisions are reviewed by the QQBP and by each division/section/center. Comments are adjudicated prior to issue of the approved revisions. All revisions (other than minor

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revisions) are denoted by a change in the integer portion of the document's revision number, and after review by the OQBP, are submitted to the Director for approval. Minor editorial changes, those that do not add, diminish, or otherwise change requirements, are approved by OQBP or an authorized designee. Minor changes are denoted by decimal values in the revision number and their approval is documented in the table of revisions only.

The minimum review cycle for this IQA is annually. To ensure all mandatory revisions are accommodated, the IQA is also reviewed whenever new contractual requirements (e.g. DOE directives) affect the Quality Program.

PROGRAMS, DIVISIONS, SECTIONS AND CENTERS

Associate Laboratory Directors and the heads of each program and divisions/sections/centers are responsible for quality in their respective organizations. As appropriate for their areas of responsibility, they use the graded approach to establish additional or more specific performance quality requirements than those established in the IQA, while avoiding any unnecessary duplication of documentation or 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 division's/section's/center's activities are conducted in accordance with the principles and requirements of the IQA.

Each division/section/center appoints a QAR as a point of contact for implementation of the QA Program.

Each large project appoints an embedded Project Quality Assurance Manager as shown in the generic organization chart in Figure 3. In addition OQBP maintains resources dedicated to supporting and assessing the implementation of QA in scientific research projects.

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Organization of Large Projects

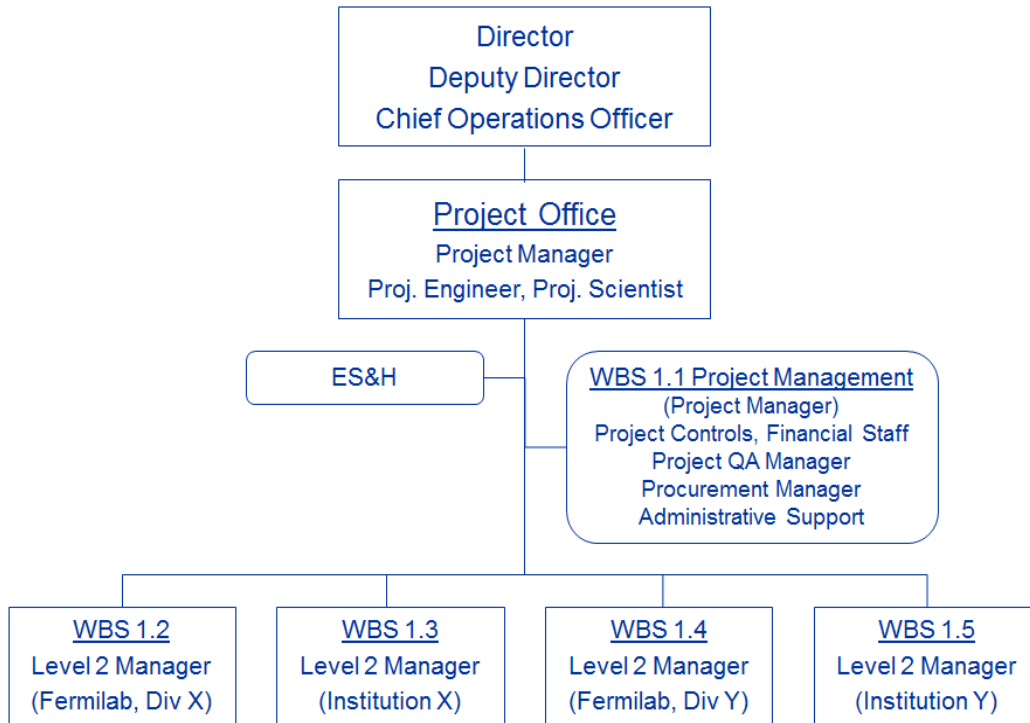


Figure 3 Organization of Large Projects at Fermilab Includes Embedded QA Manager

STAFF RESPONSIBLE FOR ASSURANCE SYSTEMS

One of Fermilab's goals is to coordinate all assurance systems to the extent necessary and practicable. Certain members of the Assurance Council have key roles in this effort.

- **ES&H DIRECTOR**

Reporting to the Laboratory Director, the ES&H Director is responsible for developing and maintaining assurance systems for the ES&H and emergency management programs, and with the Head of OQBP, is responsible for ensuring ongoing compatibility and integration with the QA Program.

- **BUSINESS SERVICES SECTION HEAD**

Reporting to the Associate Laboratory Director for the Operations Sector, the Head of Business Services is responsible for developing and maintaining the physical security assurance system, the emergency services assurance system, and procurement assurance systems and with the Head of OQBP for ensuring ongoing compatibility and integration with the QA Program.

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- **HEADS OF THE SCIENTIFIC COMPUTING DIVISION AND THE CORE COMPUTING DIVISION**

Reporting to the Associate Laboratory Director for the Computing Sector and the CIO, the Heads of the Scientific Computing Division and Core Computing Division are responsible for developing and maintaining the Cyber Security Assurance System and with the Head of OQBP, ensure ongoing compatibility and integration with the QA Program.

- **CHIEF FINANCIAL OFFICER (CFO)**

Reporting to the Laboratory Director, the CFO is responsible for developing and maintaining the financial assurance system. The CFO and the Head of OQBP are responsible for ensuring ongoing compatibility and integration with the QA Program.

- **WORKFORCE DEVELOPMENT AND RESOURCES SECTION (WDRS) HEAD**

The WDRS Head reports to the Associate Laboratory Director for the Operations Sector and is responsible for developing and maintaining the Human Resource Asset Management Assurance System. With the Head of OQBP, the WDRS Head is responsible for ensuring ongoing compatibility and integration with the QA Program.

- **FACILITIES ENGINEERING SERVICES SECTION (FESS) HEAD**

Reporting to the Associate Laboratory Director for the Operations Sector, the FESS Head is responsible for developing and maintaining the real property assurance system and with the Head of OQBP, is responsible for ensuring ongoing compatibility and integration with the QA Program.

- **OFFICE OF PROJECT MANAGEMENT OVERSIGHT HEAD**

Reporting to the Head of OPPS, the Head of Office of Project Management Oversight is responsible for developing and maintaining the program and Project Management Assurance System and, with the Head of OQBP, ensures ongoing compatibility and integration with the QA Program.

ALL EMPLOYEES, CONTRACTORS, USERS, AND VISITORS

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. Employees are required to inform their immediate supervisors of any conditions that are noncompliant with Fermilab policies and requirements.

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1.3 GRADED APPROACH

1.3.1 *Graded approach process principles*

In accordance with DOE order 414.1C, Integrated Quality Assurance utilizes a graded approach to tailor the kinds and extent of controls applied to implement quality in fulfilling applicable requirements. The graded approach complies with DOE requirements and regulations and is implemented without adversely impacting the environment or compromising the safety of the public, employees, or facilities. The graded approach is applied based on prudent management, planning, and cost. Risks related to each function are evaluated, as are the consequences poor outcomes may have on the customer, the workers, the community, and the environment. Application of the graded approach entails: identification of activities which present significant quality risk, defining the activity, evaluating risk and control choice, 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. See 1002.1000 Graded Approach Procedure for details.

1.3.2 *Responsibilities*

The OQBP is responsible for documenting the graded approach used by Fermilab's Quality Assurance management system and for providing the training necessary to ensure its continued implementation and effectiveness. All division/section/center heads shall ensure that a graded approach to quality requirements is used in accordance with this section for products, projects, and services under their control. All department heads and managers use a graded approach when establishing the level of control for accomplishing quality program elements within their functional areas.

1.4 POLICY AND PROGRAM DOCUMENTS

Director's Policy 10 Quality Assurance
Fermilab Environment, Safety and Health Manual (FESHM)
3901 Fermilab Integrated Contractor Assurance Program (FICAP)
1002.1000 Graded Approach Procedure

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Chapter 2. PERSONNEL TRAINING & QUALIFICATION

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2.1 INTRODUCTION

All Fermilab employees, regardless of their working location, and personnel working on site at Fermilab, are required to have the necessary experience, knowledge, skills, and abilities to perform their jobs. Personnel are qualified to perform their job based on one or more of the following:

- previous experience, education, and training;
- performance demonstrations or tests to verify previously acquired skills;
- completion of training courses or qualification programs;
- on-the-job training.

Initial employee qualification is ensured by the hiring process. This process is administered by the Workforce Development and Resources Section (WDRS). Individuals are hired to meet established position requirements as specified by job descriptions and skills, as defined by line managers. Line managers also ensure that job candidates meet specified requirements.

Training assists personnel in acquiring knowledge of the correct and current processes and methods to accomplish assigned tasks. It enables personnel to understand the fundamentals of the work, the associated hazards, the context within which the work is performed, and the reasons for any special work requirements. Types of 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 site/facility. This includes site-specific access requirements and regulatory based training. Management is responsible for defining training requirements and ensuring that the training is completed as required.
- **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. Project/task-specific training requirements are defined by project managers and workers. This category includes experimental operations, accelerator and beam-line operations, R&D and test facility operations.

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Administrative controls are placed on new employees prior to their completing certain training. Such controls, administered by the first-line supervisors, ensure that employees do not work in areas or on tasks until they have received the minimum required level of training and can adequately and safely perform the assigned tasks without direct supervision.

Individuals, including new or less senior scientific staff, may receive mentoring by subject matter experts or more senior staff to enhance their abilities and their knowledge or skills.

The process for determining qualifications and developing and providing training is determined by division/section/center heads and WDRS.

2.2 RESPONSIBILITIES

Fermilab line managers are required to ensure personnel possess the experience, knowledge, skills, and abilities necessary to fulfill their responsibilities. This is accomplished by using the graded approach to define the necessary training, and records of training, for each individual. This work 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. Project/task-specific training emphasizes correct performance of work, personal accountability and responsibility, and where appropriate, provides an understanding of QA principles and the relevant management procedures.
- Maintaining appropriate records of training, as defined by the graded approach. The TRAIN database documents institutional and site-specific training. This database also contains training plans and history reports to assist line management and employees manage their training progress.
- Utilizing position descriptions, hazard analyses, new employee requisitions, and/or the Medical Department's 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.

Administrative controls are used until personnel complete the training required for their assignments.

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2.3 CONTINUING TRAINING

Personnel are provided continuing training as appropriate to ensure that job competency and compliance are maintained. Continuing training includes awareness and updates on lessons learned, equipment changes, procedure changes, and changes in technology. Fermilab professionals, such as scientists; engineers; business, finance, and project management personnel maintain current knowledge in their fields by a variety of means which may include: working in collaboration with other scientists, participating in symposia, colloquia, seminars or conferences, participating in professional organizations, publications and peer reviews. For all recurring training which is tracked by TRAIN, automatic notifications are sent to affected employees and their supervisors.

2.4 POLICY AND PROGRAM DOCUMENTS

Laboratory Director Policy 19 Training
WDRS Policy and Procedures Manual
FESHM 5310, Occupational Medicine
FESHM 2060 Work Planning and Hazard Analysis
FESHM 4010, Training
FESHM 7010 ES&H Program for Construction – Fixed Price
FESHM 7020 Subcontractor Safety - Other Than Construction

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Chapter 3. QUALITY IMPROVEMENT

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3.1 INTRODUCTION

Quality improvement demands awareness and constant examination of all activities, processes, systems, projects, and programs. As such, individuals are responsible for the quality of all aspects of their job, especially in a constantly changing environment, and for reporting issues. Therefore, the improvement process includes provisions for individual feedback and mechanisms to identify, analyze, and resolve quality issues, in order to prevent their occurrence or recurrence.

Management encourages a no-fault attitude, where individuals are empowered to identify opportunities for improvement and report problems so that deficiencies are identified and resolved. Even when individuals are reluctant to share concerns with their line management, Fermilab offers ways to elevate concerns and to communicate anonymously.

Fermilab maintains continuous quality improvement through a variety of activities, including training, design, assessments, and observation by walk-through, inspections, tests, monitoring, reviews, and analysis. Issues and improvement opportunities are documented and managed utilizing corrective action tracking and lessons learned systems.

The lessons learned process is an integral part of continuous quality improvement through the sharing of relevant best practices throughout Fermilab and the DOE complex.

3.2 RESPONSIBILITIES

3.2.1 *Management responsibilities*

Senior laboratory management is responsible for ensuring quality objectives are established for relevant functions and levels within the organization using a graded approach. The quality objectives are required to be verifiable and consistent with the quality policy. Senior management also ensures that systems are created to facilitate the quality improvement functions described below.

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,

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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.

The Office of Quality and Best Practices (OQBP) verifies that major program and project plans include quality plans. OQBP verifies that corrective actions elevated to the Directorate have been implemented, are effective, and are examined for application within Fermilab and/or other organizations.

3.3 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.

3.3.1 *Planning*

Strategic planning for Fermilab is conducted by the Head of the Office of Integrated Planning (OIP) in conjunction with the Deputy Director, with advice from off-site advisors, including the Director's Physics Advisory Committee and internal bodies, such as the Fermilab Assurance Council and Directorate. The goal is to position Fermilab on the forefront of scientific discovery and to maximize the effectiveness of its physical and intellectual assets.

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.

Strategic planning for a specific year begins in a previous year with Fermilab's preparation of the Annual Laboratory Fermilab Planning Fiscal Year 20xx (previously referred to as the Fermilab Business Plan) requested by the DOE Office of Science, while the tactical planning is accomplished through the fiscal Performance Evaluation Measurement Plan (PEMP). The PEMP is negotiated with DOE at the start of the year and used for monitoring progress throughout the year until the year's end. As funding levels are set, the Fermilab Director assigns priorities for the main programs at Fermilab.

Fermilab's Strategic Plan is in alignment with the Fermilab Laboratory (Fiscal) Plan. These are developed with the DOE at the beginning of each financial year in order to highlight the unique roles the laboratory fills, propose work that will advance DOE's mission objectives, and assure work is aligned to laboratory capabilities.

Each division/section/center develops 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.

3.3.2 *Management review*

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The Assurance Council reviews the adequacy, suitability, and effectiveness of the Integrated Quality Assurance program at least annually as described in the [3904.1000 Management Review Procedure].

Note – The “Management Review” can be a combination of reviews throughout the fiscal year.

Division/section/center, 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), be proactive in problem prevention, and to get the work accomplished. Programs and projects are managed per DOE Order 413.3B, *Program and Project Management for the Acquisition of Capital Assets* and implemented in accordance with requirements provided by the Office of Project Management Oversight.

3.3.3 *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

3.3.4 *Root cause assessment and corrective action*

Issues elevated to the Directorate through the OQBP and/or the Fermilab Assurance Council are subject to an initial review to determine if the issue should be tracked by the Assurance Council or if the issue should be managed through other Fermilab channels. Depth of root cause assessment is applied using a graded approach based on risk as described in Fermilab’s Root Cause Procedure. Where deemed necessary

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or appropriate, the AC or OQBP may raise the issues to the director of Fermilab and/or DOE.

Quality problems are analyzed individually and collectively to identify systemic quality problems, trends and opportunities for process improvement. See also Fermilab Corrective & Preventive Action Procedure.

3.4 POLICY AND PROGRAM DOCUMENTS

FESHM 3010 Significant and Reportable Occurrences
FESHM 1040 ES&H Assurance Program
1004.1002 Root Cause Procedure
1004.1001 Fermilab Corrective & Preventive Action Procedure
[Management Review Procedure]

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Chapter 4. DOCUMENTS & RECORDS

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4.1 INTRODUCTION

Fermilab documents specifying policies, prescribing processes, or establishing design specifications and requirements are controlled to ensure that the direction they provide is accurate, current, and approved by authorized individuals. Fermilab's 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 Program. Implementation assistance for all employees is found in the Employee Records Handbook.

4.2 RESPONSIBILITIES

Responsibility for lab-wide policies and procedures is shared between the Directorate and the originating divisions/sections/centers, as assigned by the Directorate. Divisions/sections/centers establish methods to control procedural requirements, design, and other quality management documents and records used solely within their division. Management is responsible for providing the resources necessary to fulfill the document control and records management requirements.

Fermilab employees, users, and contractors 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. Using the graded approach, 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.

In accordance with Fermilab Director's Policy 13, Document Control, 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 maintained by Records Management and are described in more detail in the Records Management Program. The program includes provisions for specifying, preparing, reviewing, approving, disposing, and maintaining records and

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references, applicable rules, regulations, and directives governing how the laboratory is to manage records.

4.5 POLICY AND PROGRAM DOCUMENTS

Directors Policy 1, Policy on Policies
Directors Policy 13, Document Control
Fermilab Records Management Program
Employee Records Management Handbook

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Chapter 5. WORK PROCESSES

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5.1 INTRODUCTION

Work includes the design, operation, maintenance, modification, and construction of experiments, accelerators, systems, and procedures by Fermilab employees, regardless of location, and any personnel working on site at Fermilab. A graded approach is used to determine the level of controls applied to work performed at Fermilab.

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
- specific provisions for activities not otherwise covered in this document, including facilities management, maintenance, materials management and shipping & receiving

As described in Chapter 3: Quality Improvement, Fermilab works to mutually agreed upon goals from the DOE and other stakeholders. Progress toward goals is monitored.

Clear lines of responsibility have been established for normal and emergency conditions.

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. Control of scientific research is described in Chapter 11.

All work is performed in compliance with applicable DOE and/or legal requirements.

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.

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.

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5.2.2 *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.

5.2.3 *Functional responsibilities*

The following laboratory organizations have institutional responsibility for work processes.

FACILITIES MANAGEMENT

Management and maintenance of the facilities and facility's equipment is distributed between Fermilab Facilities Engineering Services Section (FESS) and the division/section/center in charge (landlord) of each facility. In general, FESS is responsible for the laboratory's utility infrastructure, roads and grounds, and Wilson Hall. Divisions/sections/centers are responsible for management and maintenance of systems unique to their facilities to carry out specific functions. Subtleties within this general framework are negotiated and agreed upon between FESS and divisions/sections/centers. The Condition Assessment Program and all Real Property reporting including administration of the DOE facility information management system is centrally managed by FESS for the laboratory. Director's policies 5, 18, and 36 provide additional detail on facility management responsibilities.

INVENTORY CONTROL

Management of inventory control is distributed among Business Services Section (BSS) and the division /sections/centers. The BSS Inventory Control functions are described in the Property/Inventory Control Policy and Procedures Manual and include provisions for audits, turnover ratio, stock rotation and just-in-time procurements of common use items.

Division/sections/centers are responsible for special process spares, normal spares, and other specialized inventories.

SHIPPING AND RECEIVING

The BSS shipping function ensures proper labelling, packaging and tracking of outgoing materials. The BSS receiving function is responsible for ensuring that products are properly received, accounted for, delivered on-site and dispatched. Some direct shipments are received by division/section/center facilities.

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5.3 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.

Emphasis in defining work process controls is placed upon prevention. Records of quality checks are used as the basis of feedback for process quality improvement.

ES&H requirements and controls for work processes are defined in FESHM.

5.4 SPECIFIC PROVISIONS FOR PROCESSES NOT ALREADY DESCRIBED

Controls are established for the procurement and acceptance of items and services and are addressed in Chapter 7: Procurement.

Measuring and Test Equipment Control are designed to meet requirements identified in Chapter 8: Inspection and Acceptance Testing.

5.4.1 *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 follow DOE Order 430.1B, *Real Property Asset Management*.

Personal property is controlled according to the Property/Inventory Control Policy & Procedure Manual.

Chapter 10 describes the control of Suspect/Counterfeit Items.

5.4.2 *Maintenance*

Divisions/sections/centers are responsible for ensuring maintenance is performed on facilities and equipment under their care. FESS is the primary maintenance service provider for facilities and the laboratory's infrastructure and these services are agreed upon between FESS and the divisions/sections/centers. Maintenance plans are documented by divisions/sections/centers. The organization coordinating or performing the maintenance is responsible for ensuring that records of maintenance are kept.

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5.4.3 *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 ES&H approval to operate accelerator facilities are required to follow FESHM 2010. Divisions/Sections/Centers document readiness reviews for specific activities performed in their respective areas. In addition certain research projects are required by orders other than DOE O 414.1C to perform readiness reviews at specified intervals.

5.4.4 *Calibration of process equipment*

It is the responsibility of each division/section/center to identify, monitor and maintain key process equipment that requires calibration or verification. Results are maintained. (See also: Chapter 8 Inspection and Acceptance Testing.)

5.4.5 *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.

5.4.6 *Transferring the results of research*

Essentially all of Fermilab's work is published in open literature. Pursuant to presidential memorandum -- Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses, Fermilab is continuously assessing technology transfer activities. The main scientific output, technical papers, are published in peer reviewed journals and conference proceedings. The Fermilab Office of Research and Technology Applications (ORTA) manages technology transfer, and as appropriate, in coordination with the Laboratory Collaboration Council (LCC), utilizes ANL Technology Transfer resources.

5.5 SOFTWARE

5.5.1 *Safety software*

Fermilab does not employ safety software under the definition of safety software in DOE Order 414.1C Quality Assurance.

5.5.2 *Policy on computing*

The governing policy is available on the Computing Sector web site.

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5.6 POLICY AND PROGRAM DOCUMENTS

FESHM Fermilab Environment Safety & Health Manual
Property/Inventory Control Policy & Procedure Manual
Fermilab Policy on Computing

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Chapter 6. DESIGN

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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 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 chapter.

6.2 RESPONSIBILITIES

6.2.1 *Head of the Office of Program & Project Support*

The Fermilab Engineering Manual is managed by the Head of OPPS.

6.2.2 *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 Lead Engineer is designated.

6.2.3 *Lead Engineer*

Generally, any engineering effort defined by a set of specifications requires the participation of a lead engineer, the engineer responsible for ensuring that the design meets project specifications. The lead engineer has overall responsibility for the efforts of all engineers working on a single project. The lead engineer is responsible for organizing overall project documentation. He or she provides technical leadership and ensures that all engineering, including system integration, is performed according to the provisions of the Engineering Manual.

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6.3 DESIGN PROCESS STEPS

The following controls are applied as appropriate, using a graded approach as defined and described in Chapter 2 “Engineering Risk Assessment” of the Fermilab Engineering Manual

6.3.1 *Planning*

The requirements, including acceptance criteria, are understood by all relevant divisions/sections/centers and departments. These requirements are documented and updated accordingly. All parties agree on the organizational and technical interfaces and arrange information and communication channels. After sufficient design iteration, requirements, plans, cost, and schedule estimates are established as the baseline. From this stage forward changes are managed in accordance with the project’s configuration management plan and implementing procedures. Planning is described in Chapters 1, 2 and 3 of the Fermilab Engineering Manual.

6.3.2 *Inputs*

Design inputs and constraints, including applicable orders, codes, standards, policies, and procedures, etc., are identified. Design inputs are reviewed for accuracy and completeness and to identify any ambiguity or conflict. Design inputs are described in Chapter 3 “Requirements and Specifications Review” of the Fermilab Engineering Manual.

6.3.3 *Process*

The design process translates inputs into design output documents and actions that are technically correct and compliant with requirements.

The design process is managed by the assigned lead engineer. The design process controls are applicable to in-house, contracted, and collaborative design activities and services. Those providing contracted design services are evaluated and selected based on their ability to meet specified requirements demonstrated by equivalency of their programs or adherence to Fermilab processes. Collaborative design activities are generally governed by Memoranda of Understanding (MOU) and/or Statements of Work (SOW).

Design processes apply to original design and design modifications.

Design efforts undergo risk evaluation by the assigned lead engineer to define the level of steps / level of rigor of controls prior to commencement of work. When applied to research and development activities, design processes are tailored to meet the controls necessary for successful outcomes. As appropriate, R&D / experimental plans specify the necessary controls and documentation contained in the activity’s / project’s Project Execution Plan and are approved by the assigned lead engineer.

The entire Fermilab engineering process is described in Chapters 1 through 9 of the Fermilab Engineering Manual and system design is described in Chapter 4 “System Design”.

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6.3.4 *Outputs*

The completed design is recorded in design output documents such as drawings, specifications, test/inspection/acceptance plans, fabrication/assembly procedures, maintenance requirements, and reports. As-built drawings and fabrication/assembly procedures are maintained after production or construction to show actual configuration.

A documentation package, including qualification test results, final revisions of fabrication drawings, marked as-built drawings, proof-tests, operational readiness review/readiness assessments, etc., is assembled and retained as the final design closeout package. Design outputs including: mechanical and electrical documents, calculations, drawings, software, design notes, operator instructions, system and software maintenance plans, and interlock safety systems are described in Chapters 4 and 9 “Final Documentation” of the Fermilab Engineering Manual.

6.3.5 *Review*

Reviews are conducted at a level commensurate to the scope and complexity of the design to ensure conformance to requirements. As appropriate, design reviews may be formal, structured, documented, and are comprehensive and objective.

Design reviews are performed by technically knowledgeable persons and may include technical experts from outside the design team and in certain cases, outside of the laboratory. Engineering design reviews are described in Chapters 3 “Requirements and Specification Review” and 5 “Engineering Design Review” of the Fermilab Engineering Manual.

VERIFICATION AND VALIDATION

Fermilab has a documented verification process that reviews design outputs against their ability to meet requirements.

Design validation is accomplished through the use of the construction or assembly or by testing the complete prototype system (or subsystem) during and after assembly. Results of validation tests are documented and maintained. Testing and validation is described in Chapter 7 of the Fermilab Engineering Manual.

6.3.6 *CHANGES*

A design change is defined as one that alters a component or system function, method of performing the function, or design configuration.

Levels of change control vary with the magnitude of the proposed change. Proposed changes are reviewed by the same organizations that reviewed and approved the original design. This ensures that changes do not inadvertently challenge or violate safety or operational boundaries or conditions set by the original design.

Temporary modifications receive the same levels of control as permanent modifications. Clients inform the assigned lead engineer of any new requirements/changes to specifications or acceptance methods via established

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communication channels. The assigned lead engineer reviews changes to the functional requirements and specifications against their ability to meet requirements. Changes to requirements are documented and all relevant divisions/sections/centers and departments are made aware of the changes involved.

CONFIGURATION MANAGEMENT

Configuration control includes plans, specifications, analyses, design and basis for design. They provide an accessible, archived history of initial baseline, modifications, and changes.

Changes, additions, and modifications to the design processes are controlled in accordance with the activity's or project's configuration management plan and implementing procedures. Closeout documentation is inspected, reviewed, and accepted by the assigned lead engineer. Final documentation, archiving and control are described in Chapter 9 of the Fermilab Engineering Manual.

6.4 POLICY AND PROGRAM DOCUMENTS

Fermilab Engineering Manual

Director's Policy #8 Design

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Chapter 7. PROCUREMENT

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7.1 INTRODUCTION

This section establishes the QA requirements for the Fermilab procurement process. The process expectations are as follows

- items and services provided by suppliers meet or exceed the contractual requirements;
- requirements are accurately, completely, and clearly communicated; and
- proper product or service is delivered on time.

Fermilab management controls exist for procurements 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).

All controls discussed below are applied using a graded approach.

All materials and services are purchased from technically acceptable and responsible suppliers and approved per procedures in the Procurement Manual. Fermilab practices environmentally preferable purchasing as described in FESHM 5011. Suppliers are required to comply with all specifications and terms and conditions, as incorporated into the purchase order.

Fermilab suppliers are required to provide goods and services which are in conformity with purchase order requirements. Fermilab may, in accordance with purchase order terms and conditions, perform site audits, require suppliers to perform self-assessments, and control plans and data or other reports to ensure compliance.

Note - Changes to purchase order requirements may be made only by written agreement of the parties.

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 Chapter 10: Suspect and Counterfeit Items.

7.2 RESPONSIBILITIES

The procurement of all goods and services is under the control of the Business Services Section (BSS), except where delegated by the Head of the Business Services Section.

7.2.1 *BSS procurement department*

The Procurement Department is responsible for the coordination of all procurement issues. This responsibility includes acquisition planning in association with engineering, quality and other functions as necessary, generating and verifying

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solicitation and purchase documents, negotiating terms and conditions, and performing subcontract administration.

All procurements using Procards are restricted to dollar value maximums and item or service type as described in the Procurement Manual. The Procurement Department reviews all Procard purchases to ensure such purchase transactions are properly authorized and to detect any abuse. All unauthorized use of the Procard system is referred to the appropriate management authority.

7.2.2 Requestor

The requestor is responsible for providing complete specifications, statements of work, drawings, and/or other pertinent technical data in support of the purchase requisition to Procurement. Documentation that pertains to purchase order requirements, such as certifications and supplier's data, source inspection, vendor qualification or certification, lot traceability, material safety data sheet (MSDS) requirement, industry standards, and acceptance sampling is included in the purchase requisition if required. The requestor is responsible for verifying that all documentation and product is received per purchase order. The requestor is also responsible for assuring incoming technical inspections or tests are performed and/or vendor supplied data is analyzed for purchase order requirements prior to final acceptance.

7.2.3 Shipping and receiving

Shipping and Receiving responsibilities are described in Chapter 5.

7.3 PROCUREMENT DOCUMENTS

Fermilab procurement documents are generated and managed in accordance with the Procurement Manual. These documents include specifications, standards, and other applicable documents referenced in the purchase requisition and are incorporated into the purchase order.

7.4 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. A graded approach is used to determine the level of evaluation and controls. Potential suppliers should be identified early in the design and procurement process to allow sufficient time to evaluate their capabilities. The supplier evaluation process is the joint responsibility of Procurement and the requestor when technical expertise is necessary.

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

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requirements. Corrective actions in accordance with purchase order terms and conditions are implemented should suppliers not perform as required.

Flow down of requirements to subcontractors at any tier is assured through terms and conditions of the purchase order.

The supplier evaluation and monitoring process is addressed in the Procurement Manual.

7.5 PURCHASE REQUISITION REVIEW

The purchase requisition is created, owned, and processed by the requestor and division/section/center or area requisition preparer. Responsibility for the accuracy of purchase requisition data and requirements resides with the requestor. Requisitions are reviewed and approved by the requisitioning organization prior to being processed by BSS Procurement.

Controls are applied based on purchase categories, dollar value and ES&H impact. Procurement may return incorrect or incomplete purchase requisitions. A history of issues and revision is maintained within the financial system.

7.6 POLICY AND PROGRAM DOCUMENTS

Procurement Policies and Procedures Manual
FESHM 5010 ES&H and National Environmental Policy Act (NEPA) Procurement Review
FESHM 5011 Sustainable Acquisition

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Chapter 8. INSPECTION AND ACCEPTANCE TESTING

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8.1 INTRODUCTION

This section 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. The graded approach is used to determine the level of controls applied to specific activities by division/section/center heads or project managers.

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 AND 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 (Fermilab Corrective & Preventive Action Procedure). 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. Divisions/sections/centers are responsible for control of nonconforming items. Controls include identification, documentation, evaluation, segregation (when practical), item disposition (reject, repair, rework, use-as-is), and notification to affected organizations.

FESHM manual 3010, Significant and Reportable Occurrences, is consulted to determine if the nonconformance is reportable.

8.4 INSPECTION AND 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

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the inspection/test, the inspection/test data, the inspection/test criteria, and the inspection/test results.

8.5 CONTROL OF MEASURING AND 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 divisions/sections/centers 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.

The process of calibration compares an unknown, a test item, or an instrument with reference standards according to a specific procedure. Calibration standards are traceable to the National Institute of Standards and Technology or equivalent. Where no recognized standard exists, the basis for calibration is defined and documented. 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.

8.6 POLICY AND PROGRAM DOCUMENTS

FESHM 3010 Significant and Reportable Occurrences
1004.1001 Fermilab Corrective & Preventive Action Procedure

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Chapter 9. ASSESSMENTS

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9.1 INTRODUCTION

This chapter describes the program used to assess the adequacy, implementation, and effectiveness of Fermilab processes and systems. This program includes internal assessments used as part of the laboratory management process (both management and independent assessments), and externally imposed audits and reviews (independent assessments).

Internal 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 Fermilab requirements, the regulatory environment, and the mission. This includes both management assessments of an organization by its own personnel, and independent assessments, using peers or another organization's personnel. Internal Fermilab assessments are conducted in accordance with the Fermilab Assessments Manual (FAM). An external assessment is an independent assessment that may include an audit, surveillance, incident-based review, or inspection conducted by individuals who are not laboratory employees.

Scientific work is assessed by a peer review process. Scientists determine the extent and adequacy of this process.

9.2 RESPONSIBILITIES

Integrated Quality Assurance requires that managers assess their processes to identify and correct problems that hinder the organization from achieving its objectives. These assessments include personnel assessing their own work processes and independent assessments using other laboratory personnel or outside sources. Personnel performing independent assessments are appropriately qualified and have sufficient authority and freedom from line management to allow for an unbiased assessment. Each division/section/center implements assessments in accordance with Fermilab Assessments Manual. The heads of divisions/sections/centers and ES&H and QA representatives monitor the progress of actions in their organizations on a periodic basis and ensure that the actions are finalized with appropriate objective evidence.

OQBP monitors the adequacy of the assessments and the progress of corrective actions. OQBP sponsors or conducts periodic assessments of the effectiveness of the implementation of IQA throughout the laboratory including assessments of scientific research projects.

The coordination of external QA assessments is performed by the OQBP.

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9.3 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. Findings are reported for failure to comply with requirements. They require a corrective action plan, disposition, follow-up, verification and validation. The degree of validation is commensurate with the identified risks. Corrective actions are recorded and tracked to closure in accordance with the Fermilab Corrective & Preventive Action Procedure. Results from assessments are evaluated for reportability. OQBP ensures that issues with laboratory-wide implications are identified, escalated to the Assurance Council, and corrective actions are implemented.

9.4 PROVISIONS FOR DOE AND OTHER EXTERNAL ASSESSMENTS

Fermilab provides accommodations (i.e., access, administrative support, facility space) for DOE and other external assessment teams. Findings and corrective actions for DOE assessments are administered in accordance with the Contractor Requirements Document of DOE O 470.2B, *Independent Oversight and Performance Assurance Program*. Findings and corrective actions for other external assessment teams (i.e., IEPA, sponsor audits) are discussed and agreed upon among the external assessment team, OQBP, and the assessed organization.

9.5 POLICY AND PROGRAM DOCUMENTS

1004.1001 Fermilab Corrective & Preventive Action Procedure
3902 Fermilab Assessment Manual

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Chapter 10. SUSPECT/COUNTERFEIT ITEMS

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10.1 INTRODUCTION

In accordance with DOE O 414.1C and DOE G 414.1-3, 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 Suspect/Counterfeit Items Program and supporting procedures. Fermilab provides training on S/CI processes and controls (including prevention, detection and disposition of S/CIs).

10.2 RESPONSIBILITIES

The OQBP 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.

Division/Section/Center S/CI Coordinators receive S/CI notifications from OQBP and other sources and determine dissemination of this information within their D/S/Cs. They respond to notifications from OQBP when requested and send notifications to OQBP in accordance with the Controlling Suspect/Counterfeit Items Procedure.

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 risks associated with S/CI and the S/CI reporting process.

10.3 PREVENTION

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

10.4 DETECTION

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

10.5 REPORTING

If S/CIs are discovered, the reporting process follows the Suspect/Counterfeit Items Program and supporting procedures. 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 reportability category.

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10.6 CONTROL OF NONCONFORMING ITEMS

The control of nonconforming items is discussed in Chapter 8: Inspection and Acceptance Testing.

10.7 POLICY AND PROGRAM DOCUMENTS

FESHM 3010 Significant & Reportable Occurrences
1006 Suspect/Counterfeit Items Program
1006.1001 Controlling Suspect/Counterfeit Items Procedure

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Chapter 11. SCIENTIFIC RESEARCH

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11.1 INTRODUCTION

Research includes activities where the output is knowledge, information, data, or proof-of-concept, but not product or service design or development. Fermilab uses particle accelerators and detectors to allow scientists to examine the most basic building blocks of matter, and the forces acting on them. Fermilab scientists also contribute to theoretical physics and particle astrophysics.

Fermilab has adopted the standard, ANSI/ASQ Z1.13-1999 Quality Guidelines for Research, which describes recommended quality assurance activities for research. As each type of research is unique in its approach and application, each requires varying levels of controls to produce the desired results. Fermilab describes the application of these controls in the Quality Assurance Guidelines for Scientific Research at Fermilab.

Current research conducted at Fermilab focuses on:

- Experiments of varying size and complexity
- Theoretical Explorations in Physics
- Development of Other Supporting Technologies (e.g. accelerator elements and systems, cryogenics, material science, detector development, computing, etc.)

11.2 RESPONSIBILITIES

Many of these elements are described in more detail in the Procedures for Researchers (PFX)

- a. The laboratory Director, Deputy Director, and Associate Directors are responsible for:
 - Setting the strategy for science at Fermilab
 - 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 such as the High Energy Physics Advisory Panel (HEPAP) and its subpanels, various reviews, and the Fermilab Accelerator and Physics Advisory Committees
- b. The Principal Investigator(s) (Experiment Spokesperson(s)) is(are) responsible for:
 - Formally proposing the planned research, including technical approach, schedule and deliverables, and facility requirements
 - Developing memoranda of understanding (MOU) between the collaboration and Fermilab for the implementation of experiments and other projects
 - Overseeing the performing and documentation of the research of their collaboration

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- Assisting in the assessment of the research performed by their collaboration
- Ensuring the appropriate publication of research results
- c. 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
- d. 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.

11.3 MANAGEMENT OF RESEARCH PROJECTS

Fermilab's Quality Assurance 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 occasional public reporting (e.g., at All Experimenters' Meetings) to more formal peer and other review formats appropriate for the conduct of research. Each large project appoints an embedded Project Quality Assurance Manager and OQBP maintains resources dedicated to supporting and assessing the implementation of QA in scientific research projects.

11.4 POLICY AND PROGRAM DOCUMENTS

Directors Policy 42 Scientific Research
4200 Quality Assurance Guidelines for Scientific Research at Fermilab

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TABLE OF REVISIONS

Author(s)	Description	Revision	Date
QDT	Draft A11 – last QDT meeting of 2007	000 A11	12/19/07
Jed Heyes	Draft A12-1 Clean up per action items from QDT for submittal to QQBP including updated org chart, corrected TOC errors and date on cover page	000 A12-1	12/21/07
Technical Editor, Jed Heyes	Draft A13-0 editorial clean up – created comparison with version A12-1 for review.	000 A13	01/10/07
Jed Heyes	Draft A13-1 removed Appendix per QDT	000 A13-1	01/11/08
QDT	Draft A13-2 and B	000 B	01/14/08
Jed Heyes	Draft B1 updated org chart page 12	000 B1	01/15/08
QQBP	Draft B2 updated based on input from division/section heads – name change from FQAP to FIQMP per QDT	000 B2	01/31/08
QDT	Draft B3 Updates to B4-1 from QDT based on division/section comments and replaced all instances of QAP with FIQMP and the full name change throughout the document. Changed date on cover to February, 2008	000 B4-1	02/08/08
Jed Heyes	Updated B5 to reconcile comments from DOE-CH including the addition of new To Be document references, explicit mention of the scientific activities, and clarifications. B6 Additional changes based on DOE-CH, corrections, document number was changed from 10.01 to 1001 to align with a proposed new QQBP document schema. Removed document hyperlinks. Clarified 3.3.1 to be consistent with FICAP. B7 changed the name of FEMP to Fermilab Design & Engineering Processes Manual (FDEPM).	000 B7	06/04/08
Jed Heyes	Draft B7 to B8. Answered draft comments resolution from QQBP.	000 B8	06/17/08
Jed Heyes	B8 to B9. Updates from QA PMP review for consistent use of terms in both documents. Removed to be []	000 B9	07/09/08

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	from Fermilab Integrated Contractor Assurance Program and Suspect/Counterfeit Items Program. Control of M&TE promoted from 8.3.2 to 8.5 and renamed Control of Measuring and Test Equipment Program, Changed Process Improvement Procedure to Process Improvement Program, changed Project Management Procedure to Project Management Planning Manual		
Jed Heyes	B9 to B10 Updated references to Inspection & Acceptance Test Program, updated [Material Control] to [Material Control Program]	000 B10	07/29/08
Jed Heyes	B11 – Updates (including name change to IQA) based on senior management discussion and recommendations from the FRA Visiting Committee regarding scope of work	000 B11	09/10/08
Jed Heyes	Added definition of IQA in Overview	000 B12	09/17/08
Jed Heyes	Revised to address comments from DOE review and incorporate reference to the ANSI/ASQ Z1.13 standard for scientific research	000 B13	10/07/08
Jed Heyes	Added Chapter 11, Scientific Research and updated formatting, page numbering	000 B14	10/16/08
Jed Heyes	Minor changes to make references to steps ex: A-E versus 1-5 and the same document consistent ex: Corrective / Preventive Action	000 B15	10/17/08
Jed Heyes	Created sections 5.1 and 5.2 to distinguish between the meaning of their content to address comments from DOE	000 B16	10/21/08
Jed Heyes	Spelling correction page 6, refreshed Table of Contents to the above change.	000 B17	10/22/08
Jed Heyes	Minor revision approval by OQBP only. Replaced all instances referring to the [Corrective / Preventive Action] or [Corrective Action / Preventive Action	000.1 B17	02/27/09

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	Procedure] with Fermilab Corrective & Preventive Action Procedure consistent to the latest Graded Approach procedure. Removing the To-Be status.		
Jed Heyes	Minor revision to correct typographical error in the header from B18 to B17 which is the same revision number in the file name. No other changes made.	000.2 B17	08/18/09
Jed Heyes	Annual review and updates. Changed references from EG&G to URS on pages 6 & 7. Added All employees are required to take the course Introduction to Integrated Quality Assurance, (FN000446) to page 9. Updated the Organization Chart on page 13. Updated reference to records management program documents on pages 29 & 30. Removed To-Be brackets and corrected title on Quality Assurance Guidelines for Scientific Research at Fermilab. Added reference to Management Review Procedure on page 27 Added reference to Fermilab Management Assessment Procedure on pages 49 & 50. Updated title of former PFX document on page 54. Promoted to Rev001	001	12/22/2009
Mari Nichols Jed Heyes,	Annual review. Minor edit clean-up to remove hidden field codes, convert to standard stylized template, and fix headings, spacing, Minor grammatical edits & clarifications throughout. Standardize references to Policy & Procedure documents in each chapter, removed To Be brackets [] on Fermilab Assessment Manual, Corrective & Preventive Action Procedure,	001 B1- B3	12/01/2011

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RESPONSIBILITY:	Head, Office of Quality and Best Practices	REVISION:	002
APPROVED BY:	FNAL Laboratory Director	EFFECTIVE:	01/20/2012

	<p>Engineering Manual and Root Cause Analysis Procedure, updated name of Fermilab Engineering Manual - corrected numbering in chapter 11. Replaced DOE Order 226.1A with H13 clause in 1.1.2 and any subsequent references, Updated section 1.2 to the latest Fermilab organizational structure including reference to Sectors, and the new Offices of Program & Project Support (OPPS) and of Integrated Planning (OIP), updated figure 1 directorate and inserted figure 2 office of program & project support including section 1.2.2 where these changes and the addition of a statement on QA in projects and Figure 3 to support it. Replaced Fermilab Issues Management system with Tracked by the Assurance council in 3.3.4 and any subsequent references, corrected reference to Fermilab Records Management Program in 4.4, updated the name of the Engineering Manual in 6.1 and 6.2.1 and replaced Chief Engineer with Head of OPPS in 6.2.1, 6.3.3 replaced DA with lead engineer, minor clarifications in 9.2 & reference to scientific research project assessments, added reference to embedded QA and OQBP support and assessment in scientific projects in 11.3. Clarified S/CI reporting roles in 10.5.</p> <p>Additional minor edits based on input from the Fermilab Site Office QA staff</p>		
Jed Heyes	Promoted for submittal to DOE	Rev 002	01/20/2012