SUBJECT:	Fermilab Integrated Contractor Assurance Program	**NUMBER:**	**3901**
RESPONSIBILITY:	Head, Office of Quality and Best Practices	**REVISION:**	000 B5
APPROVED BY:	FNAL Laboratory Director	**EFFECTIVE:**	

3901

Fermilab Integrated Contractor Assurance Program

Office of Quality and Best Practices

Fermi National Accelerator Laboratory

Batavia, IL

October 29, 2008

Reviewed By: _____

John Robert Grant

Head, Office of Quality and Best Practices
Fermi Research Alliance, LLC

Approved By: _____

Piermaria J. Oddone

Director, Fermi National Accelerator Laboratory
Fermi Research Alliance, LLC

TABLE OF CONTENTS

SUBJECT:	Fermilab Integrated Contractor Assurance Program	**NUMBER:**	**3901**
RESPONSIBILITY:	Head, Office of Quality and Best Practices	**REVISION:**	000 B5
APPROVED BY:	FNAL Laboratory Director	**EFFECTIVE:**	

Overview

INTRODUCTION

Fermilab's Contractor Assurance Program is required at the highest level by contract DE-AC02-07CH11359 between the Department of Energy (DOE) and the Fermi Research Alliance (FRA). The contract identifies DOE Order 226.1A, *Implementation of Department of Energy Oversight Policy,* as the requirements document for Fermilab's Contractor Assurance Program. The order requires contractors to document, effectively implement, and assess requirements, and ensure that systems are continually improved. DOE Order 226.1A also requires that Fermilab flow down its assurance requirements to subcontractors, to the extent necessary to ensure contractors' compliance with the requirements and the safe performance of work.

Oversight of implementation of DOE Order 226.1A is the responsibility of the Advisory Council on Integrated Assurance (AC, or Assurance Council). The AC is established within Fermilab's charter, which has been approved by the laboratory director.

The order and charter are implemented at the second level by this Fermilab Integrated Contractor Assurance Program and at subsequent levels by executing procedures necessary to ensure compliance and effectiveness.

The Fermilab Integrated Contractor Assurance Program (FICAP) describes the overarching institutional Contractor Assurance Program. It identifies the necessary requirements for implementing the DOE contract consistently throughout the laboratory's divisions/sections/centers, while ensuring quality, safety, and security are integrated into all work conducted under the contract.

This document describes the system of assessments, event reporting, worker feedback mechanisms, issues management, lessons learned, and performance measures that ensure the contractor systems are operating effectively and efficiently. It is designed to assist in identifying

opportunities for improvement and providing the means and requirements for identifying deficiencies and reporting them to responsible line management. Additionally, it establishes processes for effectively implementing corrective and preventive actions and sharing lessons learned across the laboratory and DOE complex.

This FICAP is a summary and refers to laboratory-wide manuals, policies, and procedures that detail the implementation the Fermilab contractor assurance system requirements. Currently, in the majority of cases, these activities are decentralized among the divisions/sections/centers. However, in the interest of standardizing and streamlining administrative functions, Fermilab is transitioning some to centralized management control. The first of these are Quality, Engineering, and Program/Project Mangement. In cases where the documents do not yet exist, full laboratory-wide implementations are being developed according to a schedule based on availability of resources and perceived benefits. When referring to those documents in this FICAP, the document name is enclosed in brackets ([ ]).

The minimum review cycle for this FICAP is annually and whenever new contractual requirements (e.g. DOE directives) affect the assurance programs. This plan is also modified if lessons learned throughout the laboratory indicate a need for revision.

The Office of Quality and Best Practices (OQBP) and the AC review all revisions other than minor editorial changes. If a review results in revisions, the OQBP will resubmit the revised FICAP 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 FICAP 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.

PURPOSE AND SCOPE

PURPOSE

The purpose of the Fermilab Integrated Contractor Assurance Plan (FICAP) is to ensure site management systems comply with DOE policies and orders specified in the prime contract.

SCOPE

The FICAP establishes the requirements necessary to comply with DOE Order 226.1A (under contract DE-AC02-07CH11359) and to implement the aforementioned DOE order and contract. Compliance with the is mandatory and applies to Fermi Research Alliance, LLC (including all legal entities under its exclusive control) and all its employees, contractors, subcontractors and Fermilab users when performing work that affects the laboratory.

Assurance processes encompass all of the various activities designed to do the following:

- identify deficiencies and opportunities for improvement
- report deficiencies to the responsible managers and authorities
- implement effective corrective actions

Assurance activities encompass quality, environment, safety, and health; safeguards and security; cyber security; and emergency management and include:

- assessments (including self-assessments, management assessments, and internal independent assessments as defined by laws, regulations, and DOE directives such as quality assurance program requirements) and other structured operational awareness activities (e.g., management walkthroughs);
- incident/event reporting processes, including accident investigations;
- worker feedback mechanisms;
- issues management, including causal analysis, identification of corrective actions and recurrence controls, corrective action tracking and monitoring, closure of corrective actions and verification of effectiveness, trend analysis, and identification of continuous improvement opportunities;
- lessons-learned programs; and
- performance indicators/measures.

ATTRIBUTES OF AN EFFECTIVE ASSURANCE PROGRAM

These are the guiding principles used and followed in this document.

Program Plan:

Program plans identify the areas to be reviewed, the periodicity of the reviews, the types of reviews necessary to maintain and improve the program, the sources of the review criteria, the methods and criteria to assess effectiveness, the qualifications of review personnel, and how the results of the various methods are integrated and considered as a whole to give an accurate picture.

Personnel Competence:

Personnel responsible for managing and performing assurance will possess experience, knowledge, skills, and abilities commensurate with their responsibilities.

Continual Improvement:

Assurance processes indentify ways to make programs more effective and efficient through improved performance and report such opportunities to line managers for their consideration. These processes must provide sufficient technical basis to allow managers to make informed decisions. Line management must have effective processes for communicating issues up the management chain to senior management. When disagreements exist in the results or communications of issues, processes for resolving disputes about findings and other significant factors in concerning issues are implemented and include provisions for independent reviews of issues having large consequential or meaningful effects internally or externally.

Requirement and Performance Objectives:

Assurance systems evaluate performance against requirements and performance objectives, which may include laws, regulations, national standards, DOE directives, DOE-approved plans

and program documents (e.g., security plans, authorization basis documents, and quality assurance plans), site-specific procedures/manuals, other contractually mandated requirements, and contractual performance objectives. Requirements and performance objectives are established and interpreted through approved processes so that they are relevant to the site and mission.

Priorities:

Site assurance systems are tailored to be effective and efficient and take into account hazards and risks (including risks associated with potentially hazardous activities and risks to DOE missions including schedule, cost, and scope uncertainties). Priorities are based on a systematic analysis of hazards, risks, and past performance organizations, programs, and facilities, including previous assessment results.

Performance Indicators and Measures:

Data is considered in a variety of management decisions, such as allocating resources, establishing goals, identifying performance trends, identifying potential problems, and applying lessons learned and good practices. Site performance criteria will focus on results and system-based metrics to drive improvements.

Assurance system data is documented and readily available. The results of assurance processes are periodically analyzed, compiled, reported and reviewed.

Assessments:

Line management must perform self-assessments of site assurance and mission activities.

The Contractor is responsible for complying with the terms of their contracts and providing adequate assurances.

DOE and the Contractor may perform some assessments jointly to increase efficiency and promote common understanding of processes and results. However, DOE is responsible and accountable for understanding and accepting the hazards and risks associated with activities.

The Contractor integrates processes for corporate audits, third-party certifications, or external reviews by experts in designing and implementing the contractor's assurance system.

Chapter 1. PROGRAM

1.1. INTRODUCTION

Fermilab views contractor assurance as a facility-wide initiative and the primary tool for demonstrating operations are complaint, safe, secure, efficient, and of the upmost quality when viewed from the customer's perspective. Contractor assurance activities cut across every function within the laboratory and the processes are used as a learning vehicle to highlight and facilitate change and continual improvement.

From an overall standpoint, contractor assurance activities occur in three major steps. The first step is collection of data, in which assurance information is gathered through assessments, metrics, and management reports. The second step is evaluation and improvement, which management monitors and reviews data from a central issues management system and a [management dashboard]. Management utilizes the analysis of this data to determine performance. Actions are taken towards improvement and are then analyzed for effectiveness. The third step is communication, which ensures that assurance information is provided to senior management, the DOE Site Office, and most importantly, the people doing the work.

The laboratory director is responsible for all programs and delegates to the OQBP the day-to-day management of the Contractor Assurance Program and the oversight of all management systems for compliance to the Assurance Council, as illustrated in Figure 1 in Appendix A. The head of this office reports directly to laboratory director in all matters concerning contractor assurance, lessons learned, and quality. The lessons learned coordinator is designated by the head of OQBP and is the central point of contact for Fermilab's Lessons Learned System.

Each management system, such as ES&H, Cyber Security, Safeguards and Security, has a Management System Owner (MSO), as illustrated in Figure 2 in Appendix A. Designated by and reporting to the MSOs are system experts who perform the role of Management System Coordinator (MSC).

Within the divisions/sections/centers, assurance representatives (ARs) are designated to support the MSCs. MSOs, MSCs, and ARs have responsibilities to support issues management, lessons learned, occurrence reporting, the Price-Anderson Accountability Program, compliance assurance, and management, independent and readiness assessments within their area. Additional information, outside the scope of Contractor Assurance Program, is provided through the independent Internal Audit Office, which administratively reports to the laboratory director, and functionally reports to the FRA Board of Directors Audit Committee.

Operation of the Contractor Assurance Program consists of several major components with clear, documented description of activities. Managers understand the description of their responsibilities, and a clear plan of key activities has been developed. OQBP coordinates site-wide assessment activities for the Contractor Assurance Program and validates each functional manager's annual assessment plan to assure the highest risk processes are included. Functional organizations provide assurance information in the form of assessment reports and metrics. Assessment completion is compared to established plans to ensure accountability. Assessment reports are reviewed for breadth, depth and consistency, and feedback is provided to the functional organizations.

The OQBP also provides feedback to functional managers through lessons learned, the Advisory Council on Integrated Assurance (AC) and direct communication.

Assessment and event information is collected and evaluated for trending; this includes internal, independent, and external assessment data. Assurance information is provided to the DOE Site Office in a variety of ways, including reports, presentations, and letters. Finally, Fermilab reviews the Contractor Assurance Plan annually and coordinates any changes with the Site Office in order to assurance compliance with DOE Order 226.1A.

DOE Order 226.1A has six components:

- Assessment
- Issues management
- Incident and event reporting
- Worker feedback
- Lessons learned
- Performance indicators/measures

The six components provide the programs and processes that work together to ensure that issues and improvement opportunities are identified, investigated, corrected, communicated and when appropriate (e.g., non-conforming hardware, equipment, material), dispositioned, verified, and validated).

The format of the FICAP and the assurance program it documents is based on DOE Order 226.1A and is structured in the following way:

- Program
- Personnel Training and Qualifications
- Documents and Records
- Assessment
- Performance
- Reporting
- Lessons Learned
- Worker Feedback
- Issues Management
- Dissenting Opinions

1.2. CONTRACTOR ASSURANCE AND MANAGEMENT SYSTEM INTEGRATION

Divisions/sections/centers participate in the development of institutional programs through the AC, management system integration support, and directly through development teams. Uniformity is imposed where implementation by one organization may have a negative impact on another or there is a gain in efficiency and/or effectiveness. There are distinct variations in implementation at the division/section/center level or activity level only when there is a need because of the nature of the operations.

Vertical integration is facilitated by the downward flow of information regarding expectations for management system and program implementation. Vertical integration begins with management and continues down through the organization lines to the individual worker. The downward flow of information takes on many forms ranging from very formal, such as contract, to informal exchanges, such as email. At the same time, vertical integration provides mechanisms for the upward flow of information, which includes requests for support and resources from the worker through the organization, to supervisors or senior management, as appropriate.

Horizontal integration provides parity and compatibility to avoid conflicting requirements among organizations and technical disciplines, standardization, efficiency, and assurance of similar levels of compliance. For example, coordination meetings and committee meetings not only provide for passing the information up and down the chain of responsibility, but also often provide opportunities for program comparisons across and within the organization.

Performance areas that cross functional, management system, or program lines, such as occupational injuries, radiation exposure, absenteeism or occurrence reports, are evaluated by the affected organization and the appropriate system or program experts.

Assurance systems are either part of management system or stand-alone programs and comply with the Fermilab Director's Policy Manual, policy number 39, Assurance Program. As noted in Appendix A, Figure 1, and policy 39, all assurance systems managed by Fermilab are reviewed by the AC.

All management system and program requirements are consistent with and complimentary to each other.

1.2.1. Integrated Safety Management System

Fermilab's integrated safety management system is documented in the Fermilab Environment, Safety and Health Manual (FESHM) in accordance with the requirements established in 10 CFR 851, *Worker Safety and Health Program;* the Integrated Safety Management System requirements prescribed in DOE Order 231.1A *Environmental, Safety and Health Reporting;* DOE Policy 450.4; and DOE M 450.4-1, *Integrated Safety Management Systems Manual.*

1.2.2. Emergency Management System

Fermilab's emergency management system is documented in the Fermilab Emergency Response Plan and is complimented by the Site Security Plan in accordance with DOE Order 151.1C, *Comprehensive Emergency Management System*.

1.2.3. Cyber Security Management Program

Fermilab's cyber security program is documented in the Cyber Security Program Plan in accordance with DOE Order 205.1A, *Department of Energy Cyber Security Management Program* and the Office of Science Program Cyber Security Plan (PCSP).

1.2.4. Quality Assurance Program

Fermilab's quality assurance program is documented in the [Fermilab Integrated Quality Management Program (FIQMP)] in accordance with DOE Order 414.1C, *Quality Assurance*.

1.3. ORGANIZATIONAL STRUCTURE

Users who require a more detailed view of Fermilab's directorate-level organization are directed to the Directorate Organization Chart posted on the Fermilab website.

DIRECTORATE

The Fermilab Directorate is made up of the laboratory director; the deputy director; the chief operating officer; the chief financial officer; the director of Environment, Safety and Health (ES&H); the head of the Office of Quality and Best Practices (OQBP); the associate director of Accelerators; the International Linear Collider Program director; the associate director for research; and the associate director for operations support. In addition, there are two assistant directors and a number of support offices, including the Fermilab Legal Office, the Office of Communications (formerly Public Affairs), the Office of Project Management Oversight (OPMO), and the Office of Research and Technology Applications.(ORTA)

DIVISIONS, SECTIONS AND CENTERS

Reporting to the associate director of accelerators are the Accelerator Division, the Technical Division, and the Accelerator Physics Center. Reporting to the associate director for research are the Particle Physics Division, Computing Division, the Fermilab Center for Particle Astrophysics, and the Compact Muon Solenoid Center. Reporting to the associate director for operations support are the Facilities Engineering Services Section, the Business Services Section, and the Workforce Development and Resources Section. Reporting to the chief financial officer are the Accounting, Budget, and Management Information Systems departments.

Within each division/section/center are the necessary line management and support organizations to ensure their missions are achieved safely, and within budget. , and the

Directorate each maintain organizational charts, which can be found online at their respective links.

INTERNAL AUDIT

FRA's accounts, records, and internal accounting policies and controls are subject to audit. Internal Audit is an independent office that regularly provides reports to Fermilab management, FRA, and 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.

ADVISORY COUNCIL ON INTEGRATED ASSURANCE

The Advisory Council on Integrated Assurance (AC) is an internal assurance council that reviews the overall management and operations (M&O), commitments, initiatives, 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 DOE Order 226.1A.

1.4. CONTRACTOR ASSURANCE PROGRAM AUTHORITY AND RESPONSIBILITIES

Although specific authority and responsibilities are allocated within Fermilab's organizational structure, all laboratory personnel, including employees, contractors at any level, users, and guests are responsible for safety, security, the quality of their work, and for being attentive to opportunities for continuous improvement. All personnel are responsible for stopping any activity that poses imminent danger to any individual, the Fermilab or local mission, or the environment. Employees must inform their immediate supervisors or Fermilab representative of any conditions that are noncompliant with Fermilab policies and requirements.

Additionally, authority and responsibility for Contractor Assurance Program development, implementation and maintenance resides with the following:

1.4.1. Laboratory Director

The director of Fermi National Accelerator Laboratory reports to the Chair of the Fermi Research Alliance Board of Directors, to the DOE Fermilab Site Office, and to the DOE Office of Science, and has ultimate responsibility and authority for management systems and programs at Fermilab. The director approves policies and substantive changes to them and is committed to and supportive of effective implementation of this FICAP. The laboratory director appoints associate directors and other key scientific personnel to perform selected functions described in this FICAP. The director authorizes this program via his signature.

1.4.2. Chief Operating Officer (COO)

The chief operating officer, who reports to the laboratory director, is designated as the chair of the Assurance Council and is responsible for the functioning of the council as specified in the Council's Charter (see Appendix A.3).

1.4.3. Office of Quality and Best Practices

The head of the Office of Quality and Best Practices, who reports to the laboratory director, is designated as the senior Fermilab official responsible for the development, implementation, assessment and improvement of the Contractor Assurance Program and Lessons Learned Program. The head of OQBP coordinates all substantive changes to it, advises and assists the laboratory director in providing continuity, completeness, and appropriate standardization in the overall program. This responsibility includes policymaking, planning, reporting, oversight, establishing program metrics to measure performance, evaluating the effectiveness of actions and other activities required to achieve an integrated and effective Contractor Assurance Program.

The head of OQBP similarly advises the Directorate, divisions/sections/centers, and AC on the FICAP and related procedures. OQBP is the point of contact for Contractor Assurance Program reviews, assessments within the scope of this document, and lessons learned.

The head of OQBP appoints the lessons learned coordinator to assist the MSCs and ARs.

Within the Fermilab organization, the Head of OQBP has several significant coordination roles:

- Facilitate establishment and maintenance of site-wide assessment activities including assessment system requirements; audit data archival and management; establishing, maintaining, and approving of audit plans; tracking and closure of findings; and ensuring effectiveness of the system and actions taken.
- Provide feedback through the DOE field element to the issuing authority for DOE corporate operating experience documents when specific implementation of lessons learned or corrective actions and a formal response are required.
- Serve as the enforcement coordinator of the system if required per 10-CFR-851 and the Office of Enforcement protocols and procedures.
- Maintain communication with the program office and the Office of Enforcement about safety, security, noncompliance conditions, and noncompliance report resolution when required.
- Facilitate coordination of actions and responses to any Office of Enforcement requests for information, onsite investigations, enforcement conferences, focused inspections, and investigations. Also, notify the chair of the AC.
- Facilitate coordination of investigation, planning, containment, long-term actions, and responses when notified by The Office of Independent Oversight and Performance Assurance (OA) of an imminent danger situation, a major safeguards and security or cyber security vulnerability, or an emergency management deficiency that presents an unacceptable immediate risk to workers, the public, the environment, or national security.

1.4.4. Programs, Divisions, Sections, and Centers

Associate laboratory directors and the heads of programs, divisions, sections, and centers are responsible for quality, safety, security, and operations in their respective organizations. As

appropriate for their areas of responsibility and using the graded approach, they establish additional or more specific performance requirements than those established by the ES&H, Cyber Security, Safeguards and Security, and/or Quality Assurance Program while avoiding any unnecessary duplication of documentation or effort. They are responsible for sponsoring and performing assessments to facilitate the organizational mission, objectives, and performance requirements.

Each division/section/center appoints an assurance representative (AR) to assist the coordinators and to act as a point-of-contact for implementing management systems and lessons learned. Additionally, subject matter experts (SMEs) are used as necessary to provide the appropriate level of knowledge dictated by the situation.

1.5. PERSONNEL RESPONSIBLE FOR MANAGEMENT AND ASSURANCE SYSTEMS

One of Fermilab's goals is to coordinate all management and assurance systems to the extent necessary and practical. Certain members of the Assurance Council have key roles and functions in this effort. All members of the AC share the responsibility of ensuring ongoing compatibility and integration of all systems within Fermilab.

1.5.1. 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.

1.5.2. Computing Division Head

Reporting to the associate director for research, the head of the Computing Division is responsible for developing and maintaining the Cyber Security Assurance System.

1.5.3. Business Services Section Head

Reporting to the associate director for Operations Support, the head of Business Services is responsible for developing and maintaining the Physical Security, Procurement, and Property Management assurance systems.

NOTE – The financial requirements from DEAR and FAR for Procurement, Finance, Project, and Property Systems are assessed by Internal Audit and are outside the scope of DOE O 226.1A. They are only mentioned here to record they have assurance systems and to denote process interactions exist.

1.5.4. Chief Financial Officer (CFO)

Reporting to the laboratory director, the CFO is responsible for developing and maintaining the Financial Assurance System.

1.5.5. Facilities Engineering Services Section Head

Reporting to the associate director for Operations Support, the FESS head is responsible for developing and maintaining the Real Property Assurance.

1.5.6. Office of Project Management Oversight Head

Reporting to the laboratory director, the head of the Office of Project Management Oversight is responsible for developing and maintaining the Project Management Assurance System.

1.5.7. Workforce Development and Resources Section Head

Reporting to the associate director for Operations Support, the WDRS head is responsible for developing and maintaining the Human Resource Asset Management Assurance System.

1.5.8. Office of Quality and Best Practices Head

Reporting to the laboratory director, the head of Office of Quality and Best Practices is responsible for developing and maintaining the Quality Assurance Program .

1.5.9. Lessons Learned Coordinator

Reporting to the head of the Office of Quality and Best Practices, the lessons learned coordinator manages lessons-learned activities across Fermilab, and in doing so performs the following functions:

- Screens DOE corporate operating experience documents and DOE lessons learned. Identifies operating-experience documents relevant to contractor operations by screening documents from United States and foreign government agencies, industry, professional societies, trade associations, national academies, and universities.

- Distributes corporate and external operating-experience documents to personnel for review, analysis, implementation of corrective actions, and routine use.

1.6. ROLE RESPONSIBILITIES

1.6.1. Management Systems Owner

NOTE - A management system is the framework of processes and procedures used to ensure that an organization can fulfill all tasks required to achieve its objectives. For example, an environmental management system enables organizations to improve their environmental performance through a process of continuous improvement. Thus, an example of a management system owner at Fermilab is the ES&H director.

A management systems owner must:

- Ensure that quality, safety and security are the primary concerns and are not trumped by strong contractual emphasis on program objectives and schedules.
- Regularly demonstrate emphasis on quality, safety and security performance; compliance with quality, safety and security requirements; positive quality, safety, and security cultures; and a practice of continuous improvement. Additionally, the MSO facilitates the transition from being event-driven to being an assessment-driven organization.
- Select and place the management system coordinator at a senior reporting level, demonstrate management commitment to the program, and provide access to senior management when necessary.
- Ensure that the individual(s) selected for the management system coordinator position has strong credibility within the organization and with senior management.
- Support and rely on the views of the management system coordinator.

- Support OQBP's coordination and scheduling of responses to any Office of Enforcement requests for information, onsite investigations, enforcement conferences, focused inspections, and investigations.
- Notifies external regulatory authorities as applicable. Also, notifies the head of OQBP and the chair of AC.

1.6.2. Management System Coordinator

NOTE - A management system coordinator is usually mid-level manager or specialist supporting portions or all of the framework of processes and procedures used to ensure that an organization can fulfill the requirements in the management system. This person's perspective is enterprise-wide.

For instance, the ES&H Management System has two management system coordinators, one focuses on radiological systems and one focuses on general ES&H. Both positions report to the ES&H MSO, the ES&H director.

Management system coordinators:

- Serve as the focal point for rule implementation and compliance, and champion excellence in the organization's compliance assurance and continuous improvement efforts.
- Utilize assurance representatives to drive management system policies, requirements and objectives to achieve performance improvement and both internal and external customer satisfaction.
- Through broad awareness of safety and information security issues and performance across the organization, identify and report areas of weakness or systemic problems not otherwise recognized.

- Participates in or performs primary assessment of operating-event trends to identify recurring issues and evaluate the root causes of the recurring issues.
- Assists in or performs primary investigation and identification of operating-event causes, especially for enterprise-wide ramifications.
- Develops, implements, and tracks enterprise-wide actions to correct problems identified in causal analysis of operating experience. Develops lessons learned on successes.
- Ensure managers are adequately trained in the regulatory screening and reporting program.
- Monitor assurance program effectiveness and progress toward an assessment driven, continuous-improvement focused organization.
- Manage or oversee the screening of problems, issues, findings, and conditions to identify non-compliances.
- Review data and systems for programmatic issues, negative trends, and repetitive issues; and publish findings.
- Ensure regular performance of assessments in order to evaluate implementation of processes for screening, Occurrence Reporting and Processing System (ORPS), Noncompliance Tracking System (NTS), Incident Tracking and Analysis Capability (ITAC) System, Safeguards and Security Information Management System (SSIMS), and internal reporting.
- Ensure timely screening of issues from a variety of sources for potential regulatory non-compliance. These sources include events, performance assessment reports, nonconformance reports, radiological assessment reports, ITAC reports, inspections, and audits.
- Ensure proper and timely reporting of non-compliances into ORPS, NTS, ITAC, and local tracking systems.

- Ensure validation of ORPS, NTS , ITAC, and SSIMS corrective actions prior to closure; verify corrective actions address the causes, are comprehensive, and have been completed; and mark ORPS, NTS, ITAC and SSIMS reports as "complete" only when all actions have been validated.
- Ensure that comprehensive effectiveness reviews are conducted for ORPS, NTS, ITAC and SSIMS issues when corrective actions have been completed.
- Participate in dialogue between DOE and Fermilab in any investigation, focused inspection, or compliance review to ensure that the facts and technical issues surrounding the noncompliance are explained and any actual or potential adverse impact on safety and security is properly considered.
- Regularly inform senior management of compliance issues, safety and security performance issues, enforcement actions elsewhere in the DOE complex, and the status of the regulatory screening and reporting program.

1.6.3. Assurance Representative

NOTE - An assurance representative is usually a manager or specialist supporting portions or all of the framework of processes and procedures used to ensure that an organization can fulfill the requirements in the management system. This person's perspective focuses on division/section/center implementation. Assurance representative role is identified for each management system in Section 1.5.

For instance, the ES&H Management System has senior safety officers within each division/section/center. These positions report direct-line to the division/section/center manager and dotted-line to the ES&H director.

Assurance representatives:

- Serve as the focal point for management system and maintenance implementation in the organization, under the jurisdiction of their head of the division/section/center.
- Coordinate reviews of management system revisions for their organizations.
- Act as local SME to interpret and apply basic requirements.
- Serve as a participant and point of contact for assessments and investigations.
- Assess operating-event trends to identify recurring issues and evaluate the root causes of the recurring issues.
- Investigate and identify operating-event causes.
- Develop, implement, and track actions to correct problems identified in causal analysis of operating experience. Develops lessons learned on successes.
- Identify opportunities for improvement.
- Assist in supplier evaluations.
- Serve as interface with other ARs, MSCs, and MSOs.
- Attend periodic meetings held to discuss institutional management issues and lessons learned. Communicate that information on to the appropriate people in their organization.

1.7. GRADED APPROACH

1.7.1. Graded Approach Process Principles

In accordance with DOE Order 226.1A, the Fermilab Integrated Contractor Assurance Program utilizes a graded approach to tailor the kinds and extent of controls applied to implement quality in fulfilling applicable requirements. Further explanation of the graded approach process principles and use is found in the Fermilab Integrated Quality Assurance Program and Graded Approach Procedure.

1.7.2. Responsibilities

The OQBP is responsible for documenting the graded approach used by Fermilab and for providing the training necessary to ensure its continued implementation and effectiveness.

All division/section/center heads ensure 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.

1.8. INTERNAL COMMUNICATIONS

Communication of policies and requirements is achieved through management meetings, team briefings, round table discussions, and new employee inductions. Employees are actively encouraged to participate in employee surveys and to make suggestions to aid improvement and self-recognition.

1.9. EXTERNAL COMMUNICATIONS

The COO and the head of OQBP review and approve all communication concerning the Fermilab Integrated Contractor Assurance Program including requests for information from organizations outside of FRA including site DOE and all DOE reports prior to response or submittal.

1.10. CRITERIA FOR PROGRAM CERTIFICATION

Annually, the laboratory director and chair of the FRA board of directors submit assurance letters to the Fermilab site DOE office. Each letter states that the systems of management controls, including all systems revised in accordance with the clause entitled, *Application of DOE Contractor Requirements Documents*, is adequate to assure that the objectives of the management system are being accomplished and that the system and controls are compliant.

1.11. POLICY AND PROGRAM DOCUMENTS

The following policies and procedures are accessible through the web for continued access and reference:

Fermilab Environment, Safety and Health Manual

Fermilab Integrated Quality Management Program

Fermilab Emergency Response Plan

Fermilab Cyber Security Program Plan

Fermilab Site Security Plan

Graded Approach Procedure

Fermilab Director's Policy Manual, policy number 39, Assurance Program

Chapter 2. PERSONNEL TRAINING & QUALIFICATION

See Appendix A4, Other Requirements, for explanation and reference to Fermilab document governing the requirements for this section.

Chapter 3. DOCUMENTS AND RECORDS

See Appendix A4, Other Requirements, for explanation and reference to Fermilab document governing the requirements for this section.

Chapter 4. ASSESSMENTS

See Appendix A4, Other Requirements, for explanation and reference to Fermilab document governing the requirements for this section.

Chapter 5. PERFORMANCE

5.1. INTRODUCTION

Performance is the result of the daily work, processes, and activities of the Line Managers, Supervisors and Staff using management systems and process controls to achieve the objectives set by laboratory management.

Performance metrics are a vital tool in quantifying performance and provide a basis for many Fermilab assessment processes. Performance metrics serve as organizational benchmarks and communicate effectively and efficiently laboratory organizations' progress in meeting mission requirements and standards to DOE and laboratory management.

Fermilab has identified and monitors the performance of programs and organizations through the use of performance measures in the prime contract. The data is used to demonstrate performance improvement (or deterioration) relative to identified goals. Fermilab has established a program that identifies, gathers, analyzes, trends, disseminates, and makes use of performance indicators.

Performance indicator data is considered in allocating resources, establishing goals, identifying performance trends, identifying potential problems, and applying lessons learned and good practices. Quantitative performance indicators/measures are also considered (in combination with other appraisal and operational awareness results) when evaluating personnel performance and establishing oversight priorities.

5.2. RESPONSIBILITIES

5.2.1. Office of Quality and Best Practices (OQBP)

The Office of Quality and Best Practices works with the Directorate to develop annual performance measures for inclusion in the contract between the DOE and FRA for operation

of the Fermilab. Measures are reviewed and approved by appropriate levels of Fermilab management.

5.2.2. Management Responsibilities

Senior laboratory management is responsible for ensuring objectives are established for relevant functions and levels within the organization using a graded approach. The objectives are required to be verifiable and consistent with the site plan, Performance Evaluation Measurement Plan, and the prime contract.

5.3. PLANNING

Strategic and tactical planning for Fermilab is conducted by the 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, and assessments, scientific peer reviews and DOE Office of Science program reviews.

Strategic planning for a specific year begins in a previous year with DOE Business Plan 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 plans 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.

Planning includes the creation of partnerships and alliances, selection of laboratory priorities and culture, educational programs, technology transfers, and developing a working relationship with the local community; responsiveness and accountability; and corporate involvement/ contributions including joint appointments, innovative financing proposals, infrastructure support and an overall investment in the success of the laboratory (i.e. all programs, issues and needs of Fermilab).

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.

5.4. MANAGEMENT REVIEW

The AC reviews the adequacy, suitability, and effectiveness of the management systems and the FICAP at least annually. Requirements from the PEMP are included in each management system or appropriate division/section/center processes and included as part of the reviews conducted by the AC. The council presents the status and any issues, changes, and proposed plans to the director for review and support documentation for the annual assurance letter. [Management Review Procedure]

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

Management and assurance system owners hold reviews based upon need and submit annual system review summaries to the Assurance Council.

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.

5.4.1. Assessing the Performance and Output

Management assesses performance via indicator data routinely and uses the outputs of the Management Review as a basis for process improvement. The performance indicator data is considered in allocating resources, establishing goals, identifying performance trends, identifying potential problems, and applying lessons learned and good practices. Problems with performance are identified and corrected at the earliest possible stage. Areas where performance excels are examined for potential application elsewhere.

5.4.2. Analysis and Use of DOE Level Data

Fermilab uses its performance data to benchmark against other sites within the DOE complex. The resultant benchmarking comparison, review and joint discussion with the other site(s) about improvement, and level of consequence and probability determine the necessity and extent or appropriateness of the actions taken.

5.4.3. Contract Review

PEMP and contractor assurance system data is documented and readily available to DOE. Results are periodically analyzed, compiled, and reported to DOE in support of the formal contract evaluation.

5.5. POLICY AND PROGRAM DOCUMENTS

[Management Review Procedure]

Chapter 6. REPORTING

6.1. INTRODUCTION

Fermilab policy requires that laboratory management and the DOE are notified of all events which may:

1) affect the safety and health of the public or workers;
2) seriously impact the intended purpose of the laboratory;
3) have an adverse effect on the environment; or
4) create publicity detrimental to the mission of the laboratory.

The procedures for reporting appropriate events are contained within the bounds of each management system or program. As an example, the FESHM outlines the internal roles and responsibilities for notification and categorization of events, and investigation of occurrence, generating and submitting reports.

Types of reportable occurrences involve, but are not limited to: facility conditions; environmental concerns; personnel safety, radiological protection, safeguards and security, transportation, loss or damage to DOE property, defective items or services; and cross-category items to include related occurrences, near miss events, and potential concerns.

6.2. RESPONSIBILITIES

CHIEF OPERATING OFFICER (COO) AND CHAIR OF THE AC

- Acts as the Facility Manager for the laboratory. This individual will make the final decision as to whether an incident is a reportable occurrence.
- Notifies the DOE-Fermi Site Office (FSO) of reportable occurrences and provides the FSO manager a copy of the notification report.
- Coordinates activities when multiple divisions/sections/centers are involved.
- Assures reports are placed into the DOE databases in a timely manner.

- Determines need for formal investigations and reports.
- Approves final investigation report.
- Reviews corrective action as reports are submitted to DOE.

  NOTE - Final ORPS reports may contain corrective actions that have not been completed. When the corrective action as been completed by the division/section/center, the ORPS Manager will need to access the Facility Manager portion of the DOE ORPS database to close out the corrective action.

HEAD OF OQBP

- OQBP is the point of contact for lessons learned, OA, Office of Enforcement, and DOE field office requests and reports.

PROGRAMS, DIVISIONS, SECTIONS, AND CENTERS

- Provides timely identification, categorization, and notification to the facility manager of a potential event or condition that may require categorization.
- Provides for the timely submittal of the Occurrence Reporting and Processing System (ORPS) report to the facility manager.
- Conducts investigation of incidents, utilizing subject matter experts as appropriate and completes necessary reports.
- Assures all corrective actions are documented and coordinates implementation of all corrective actions.
- Assures lessons learned are developed and submitted.
- Verifies on-site subcontractors are aware of contract requirement to report an occurrence and the process to do.

MSOs

- Notifies external regulatory authorities as applicable. Also, notifies the head of OQBP and the chair of AC.
- Assures system contains contract requirement to report an occurrence and a method to provide awareness to and ensure understanding by the subcontractors.

MSCs

- Ensures information is placed into the on-line DOE ORPS central occurrence report database that serves as the repository for all Laboratory occurrence reports.
- Disseminates lessons learned to Lesson Learned Coordinator for recording into the DOE system.
- Analyzes related occurrences in order to improve performance in environment, safety, health, security, or Laboratory operations.
- Performs analysis of reports for management systems as required by DOE orders.
- Assures consistency between different reporting systems required by DOE orders.

ARs

- Develops lessons learned documents and submits them to the MSCs to share within the laboratory.
- Develops, implements, and tracks enterprise-wide actions to correct problems identified in causal analysis of operating experience.
- Assures consistency between different reports required per DOE orders.

6.3. EVENT REPORTING

6.3.1. Occurrence Reporting

Fermilab adheres to standards and requirements of DOE occurrence reporting as described in DOE Manual 231.1-2, *Occurrence Reporting and Processing of Operations Information*. The occurrence reporting function lies within the ES&H, though responsibility is shared with the Operations Directorate. The complete ORPS program is described within FESHM.

Occurrence reporting covers primarily ES&H events but also includes certain events related to emergency management. Event reporting in the other assurance system programs (cyber security and physical security) are governed by specific DOE requirements in those programs and are addressed in the program-specific assurance systems.

6.3.2. Price-Anderson Act Reporting

To date, Price-Anderson Amendments Act (PAAA) reports are rarely generated for violations of 10 CFR 835, DOE's rule on Occupation Radiation Protection. Reporting thresholds are implemented which clarify when non-compliance tracking system reports are required. PAAA reporting is an ES&H function.

6.3.3. Lower-Level

Fermilab proactively attempts to preclude the advent of major issues through active awareness and prompt resolution of lower-level concerns as soon as possible after they are discovered.

NOTE – Lower-level items are non-reportable, have a lower consequence or probability of failure but are the "right" thing to do, and are items to attend in order to prevent from developing into a bigger issue. They, generally, can be handled on the spot or with a limited amount of resources in a follow-up action plan.

Awareness is a result of an open door policy with management and the requirement for management interaction with line personnel. Opportunities for interaction are created

through the use of formal inspections and self-assessments and informal management walk-arounds and manager/employee interaction.

Lower-level concerns are captured through various means throughout the laboratory outside of the mandated Fermilab/DOE systems (e.g., Issues Management and ESHTRAK Systems). Action items are assigned and tracked to completion by management. In addition, items are reviewed on a periodic basis to look for trends and series of near misses as an indicator of an area requiring management attention. Results, analysis for trends, types of issues encountered, and corrective actions are used to generate lessons learned as appropriate.

The purpose of these processes is to promote a culture of situational and operational awareness at all levels, to train personnel to not be complacent to day-to-day concerns, and to generate process ownership.

6.3.4. Closure

Fermilab tracks all reports within the DOE databases for closure by DOE and updates its systems accordingly.

6.4. DOE REQUESTS AND SUPPORT

When requested, Fermilab assists in the factual accuracy review of OA appraisal reports by completing the following actions.

- Review the preliminary draft appraisal report and provide a response through the responsible DOE field element as requested.
- Review the final draft report and provide comments through the responsible DOE field element within 10 working days of receiving the final draft report.

6.5. POLICY AND PROGRAM DOCUMENTS

Fermilab Environment, Safety and Health Manual

Chapter 7. LESSONS LEARNED

7.1. INTRODUCTION

The Lessons Learned Program is intended:

- to provide a program for the management of operating experience to prevent adverse or positive operating incidents and to expand the sharing of good work practices among DOE sites.
- to provide the systematic review, identification, collection, screening, evaluation, and dissemination of operating experience from U.S. and foreign government agencies and industry, professional societies, trade associations, national academies, universities, and DOE and its contractors.

Positive or negative learning is captured from multiples sources: corrective and preventive actions, project and program plan data capture and/or experience, performance reviews, assessments, and training feedback or other worker feedback. Lessons learned are recorded and shared, either through manual distribution, email, or communicated on a web site.

7.2. RESPONSIBILITIES

The head of OQBP, who reports to the laboratory director, is designated as the senior Fermilab official responsible for the development, implementation, assessment and improvement the Lessons Learned Program. **OQBP** coordinates all substantive changes to it, advises and assists the laboratory director in providing continuity, completeness, and appropriate standardization in the overall program. This responsibility includes policymaking, planning, reporting, oversight, establishing program metrics to measure performance, evaluating the effectiveness of actions and other activities required to achieve an integrated and effective Lessons Learned Program.

The head of OQBP similarly advises the Directorate, divisions/sections/centers, and AC on the Lessons Learned Program and related procedures

The head of OQBP appoints the lessons learned coordinator to assist the MSCs and ARs.

All personnel are expected to learn from the sharing of internal and external experience in order to prevent adverse operating incidents and to expand the sharing of good work practices.

Management is responsible for ensuring lessons learned from within their organization are actively solicited, reviewed and communicated.

The Lessons Learned Coordinator periodically scans for and coordinates the exchange of information, externally and internally.

7.3. GATHERING AND USE OF LESSONS LEARNED

Operating experience is collected, stored, and retrieved through a central clearinghouse, which allows ready access to and communication about collected information. Lessons learned are reviewed for similar issues or for the ability to use the information to improve processes or systems. Plans are created or adjusted and changes are implemented due to applicable lessons. The information considered is from internal and external sources.

The [Lessons Learned Program document] describes how lessons learned are integrated into the management systems at the laboratory.

7.4. POLICY AND PROGRAM DOCUMENTS

[Lesson Learned Program]

Chapter 8. WORKER FEEDBACK

8.1. INTRODUCTION

Fermilab promptly addresses employee concerns about environment, safety, health, security, fraud, waste, abuse, or mismanagement of DOE and Fermilab managed activities. Resolution of employee concerns/complaints about environment, safety and health issues is expected to occur at the lowest management level possible. However, if the issue cannot be resolved at this level, the employee may proceed within his/her management chain or report the problem using alternative resolution processes described in this chapter.

Any situation that presents an imminent danger to the safety of an employee, visiting scientist, member of the public, or the environment must be halted immediately. Once the imminent danger has been mitigated, the concern may be reported.

Management encourages a no-fault attitude, one in which individuals are empowered to identify opportunities for improvement and report problems so that deficiencies are identified and resolved. All individuals have the responsibility and obligation to inform management when there is evidence of non-compliance. This can be done in conjunction with other managers and departments. Also, any issue may be elevated from any level. The management team reviews and determines the appropriate path forward including actions for rectifying and improving such non-compliance. This constitutes the initiation of issues management and continual improvement philosophy employed at Fermilab and are the necessary practices for successful feedback mechanisms.

A variety of worker feedback mechanisms are in place at Fermilab to facilitate the reporting of concerns and to proactively gather inputs. Each management system and program has system requiring or requesting input by workers, including employees, experimenters, and subcontractors. Employees are informed of the mechanisms during new employee orientation,

performance review, meetings, training, and written documentation such as emails or Fermilab-wide postings.

Worker feedback mechanisms are described within the Employee Concerns Process for documenting concerns or suggestions that would not ordinarily be raised verbally through the line management and there are provisions to allow the author to remain anonymous .

8.2. RESPONSIBILITIES

PROGRAMS, DIVISIONS, SECTIONS, AND CENTERS

Program and division/section/center heads are responsible for ensuring that concerns brought to their attention are promptly addressed and when appropriate, corrected. In situations where permanent corrective actions cannot be immediately implemented, administrative or other temporary measures to mitigate the concern shall be implemented in the interim, where appropriate. Corrective actions are tracked using the [Personnel Management System] for confidential items covered by labor regulations, Issues Management System for issues concerning significant items requiring the Directorate's involvement (typically lab-wide policy, system, and/or structure), and local processes for items restricted to the program/division/section/center until the issue is resolved.

SUPERVISORS

Supervisors shall ensure that concerns brought to their attention are evaluated and addressed.

LABORATORY EMPLOYEES, SUBCONTRACTORS, USERS, AND GUESTS

These individuals are responsible for abiding by all laboratory requirements and for reporting unsafe conditions or acts to their supervisors for correction. They are encouraged to utilize the other avenues of this concerns system in situations where their concerns have not been

adequately addressed by their supervisors, contact persons, or other appropriate personnel. Subcontractor employees may be subject to separate reporting requirements in accordance with their own employers' requirements and as specified by their subcontract with Fermilab. However, the procedures described below are available for the use of subcontractor employees.

8.3. EMPLOYEE CONCERNS SYSTEM

The Employee Concerns System is for both DOE federal and contractor employees to report concerns associated with environment, safety, health, security, fraud, waste, abuse, or mismanagement of DOE and contractor managed activities, or reprisal for having reported such concerns.

8.3.1. Policy

DOE recognizes that free and open expression of employee concerns is essential to safe and efficient accomplishment of the Department's missions. Employees of DOE and any DOE contractors and subcontractors have the right and responsibility to report concerns relating to the environment, safety, health, and management of DOE-related activities and for identifying and preventing the harassment and intimidation of co-workers. DOE encourages open communication between management and employees and has a zero tolerance policy for reprisals against those who raise concerns.

8.3.2. Employee Concerns Process

There are three avenues in the process:

Fermilab and the DOE encourages all employees to attempt resolution through the immediate supervisor or management prior to using this program or call the Fermilab Action Line (extension 4000, or 630-840-4000 from offsite). A report to the Fermilab Action Line may be anonymous. If a resolution cannot be achieved through these channels, individuals can call or write to an office listed in section 8.4.

The Fermilab Internal Complaint Procedures (Administrative Grievance) provides employees to a internal process to use as a tool to facilitate resolution of their concerns, complaints, and disputes quickly, satisfactorily, and cost effectively.

The Fermilab Whistle Blower Protection Policy communicates the expectation for employees to report issues or concerns relating to the safe operations of DOE facilities and the efficient administration of DOE programs and confirms employees' expectations that all concerns will be addressed.

8.4. OTHER RESOURCES

The DOE Office of Inspector General (OIG) maintains a hotline to facilitate the reporting of allegations of fraud, waste, abuse, or mismanagement in U.S. Department of Energy (DOE) programs or operations. Allegations may be reported by DOE employees, contractors, and the general public.

To report an allegation of fraud, waste, abuse, or mismanagement at the U.S. Department of Energy, contact the OIG through one of the following methods:

1. Call 1-800-541-1625 (toll free) or 202-586-4073 (toll).
2. Write your concerns to:

   U.S. Department of Energy

   Office of Inspector General

   ATTN: IG Hotline

   1000 Independence Avenue, SW

   Mail Stop 5D-031

   Washington, DC 20585
3. Fax your concerns to 202-586-4902.
4. E-mail your concerns to ighotline@hq.doe.gov

8.5. POLICY AND PROGRAM DOCUMENTS

Fermilab Whistle Blower Protection Policy

Fermilab Internal Complaint Procedures (Administrative Grievance) Procedure

[Personnel Management System]

Chapter 9. ISSUES MANAGEMENT

9.1. INTRODUCTION

DOE Order 414.1C and DOE Order 226.1A establish requirements for assurance and quality improvement processes. Fermilab issues management processes are aimed at meeting the requirements of these rules and orders, as well as other customer and regulatory drivers.

Issues management is utilized to ensure that significant items requiring the Directorate's involvement and/or commitment on resources, problems, trends, and issues are identified, documented, analyzed, and prioritized to promote effective resolution in a timely manner.

Issues management applies to issues identified through contractual obligations, corrective actions, assessments, lessons learned, and worker feedback, as well as injury, incident, and event (mishap) reporting which tend to be of major consequence, need lab-wide attention, and/or need senior management involvement. Fermilab's Issues Management System (IMS) utilizes a centralized database to track, manage, and report the status of identified issues. IMS use is detailed in the [IMS Issues Tracking Procedure].

Causal analysis is an essential element of issues management. Issues, events, and incidents are categorized by significance and importance using a graded approach. This categorization drives the performance of causal analysis, including the depth and breadth of investigation necessary to complete the analysis and identify causes. Significant issues, events, and incidents require formal root cause analysis and documentation per the Corrective and Preventive Action Procedure unless entered into the IMS to track a commitment made as part of the prime contract.

9.2. RESPONSIBILITIES

The head of OQBP reviews issues for appropriateness of inclusion, ensures entry, assigns ownership of individual items, and ensures follow-up within the Issues Management System. OQBP also assesses plans and actions taken for evaluating the effectiveness.

Individuals assigned are required to ensure actions are taken until item is reviewed and closure accepted.

Management is responsible for ensuring issues are indentified, raised to the appropriate level for consideration, reviewed for internal and external application, necessary actions determined, and communicated to others.

9.3. ISSUE IDENTIFICATION

Methods of identifying issues include, but are not limited to

- Internal review processes: These include receipt inspection, maintenance and surveillance activities, and vendor surveillances.
- Worker identification: In an organization that promotes compliance and safety-consciousness, when workers observe abnormal conditions or potential deficiencies, they report them through a defined process. Ultimately, these observations are reported to management and entered into the appropriate problem resolution process.
- Internal assessments: Problems may be identified during internal management or independent assessments.
- External assessments: Problems may be identified during the course of external assessments; surveillances; inspections; and visits conducted by DOE headquarters oversight, field, site, and Operations Office personnel; employees of a state or the federal government, such as the Environmental Protection Agency, Department of

Transportation, Inspector General, General Accounting Office, or Occupational Safety and Health Administration (OSHA).

- Data review: Trending and evaluation of operational data and issues management databases to identify adverse trends, dominant problem areas, and potential repetitive events or conditions.
- Employee concerns: An additional source for the identification of safety or security problems may be concerns reported into the employee concerns program.
- Event-related: Problems may be identified during the evaluation of an undesirable event, such as Occurrence Reporting and Processing System (ORPS) or a Security Incident Notification Report

9.4. ROOT CAUSE AND CORRECTIVE ACTION

Root cause analysis indentifies the primary event, other events directly relating or contributing to the situation, sequence of events, event and/or control relationships and dependencies, failed controls, and causes. The results of this analysis are categorized in line with DOE reporting requirements. A graded approach is used in determining the level of application rigor in the root cause analysis and correction action processes.

Corrective action investigation, analysis, plan development, actions and closure uses a structured approach which contains the following:

- identifying a condition adverse to the requirement,
- 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

9.5. ISSUE MANAGEMENT

Issues are analyzed individually and collectively to identify systemic problems, trends and opportunities for process improvement.

Issues identified are evaluated, controlled, and corrected using a graded approach based on issue risk ranking.

Issues are reviewed for event reportability under applicable requirements.

Issues elevated to the OQBP and/or the Fermilab Assurance Council are subject to an initial review to determine if the issue is relevant to Fermilab's issue tracking system or if the issue should be managed through other Fermilab channels. While doing this review, the issue's scope and extent of the condition or deficiency is examined. When deemed necessary or appropriate, the AC or OQBP may raise the issues to the laboratory director and/or DOE.

9.5.1. Imminent Risk Management

When notified by The Office of Independent Oversight and Performance Assurance (OA) of an imminent danger situation, a major safeguards and security or cyber security vulnerability, or an emergency management deficiency that presents an unacceptable immediate risk to workers, the public, the environment, or national security, Fermilab shall take the following actions in coordination with DOE line management:

- promptly identify and implement immediate compensatory actions to mitigate the condition,
- within 10 working days, notify the Cognizant Secretarial Officer and OA of actions or compensatory measures planned, and
- develop and implement long-term actions (including determining costs and identifying funds) to eliminate the vulnerability or reduce the level of risk to an acceptable level as soon as possible.

9.6. POLICY AND PROGRAM DOCUMENTS

Significant and Reportable Occurrences FESHM 3010

IMS Issues Tracking Procedure

Chapter 10. DISSENTING OPINIONS

10.1. DISSENTING OPINIONS

If an assessment or investigation team member holds a dissenting opinion, a minority report is to be created and submitted up the line management chain, along with the final report. A copy of both reports shall be submitted to AC as well. The division/section/center head and the appropriate MSO will review and attempt to resolve any dispute with the team members. If the author of the minority report believes the issues are still in dispute, he/she may refer the issue to the AC. The AC's decision is binding.

APPENDIX A

A.1 Figure 1

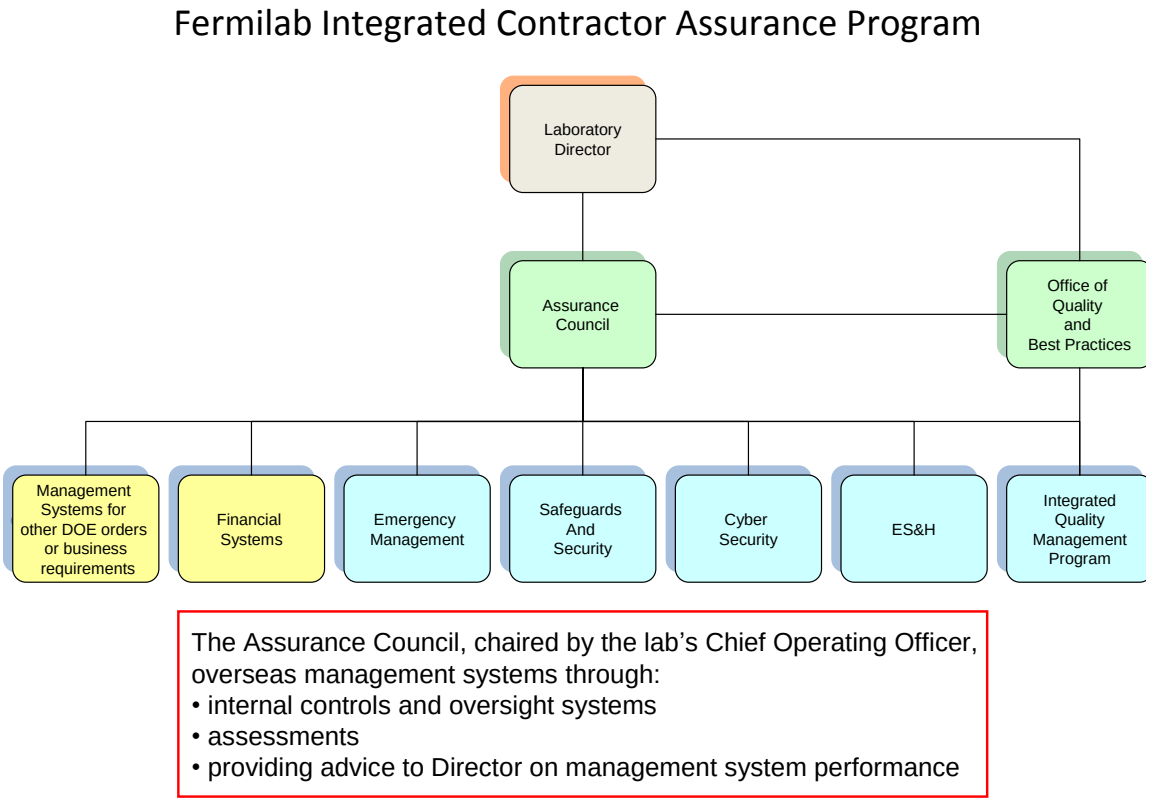

Figure 1. Fermilab Integrated Contractor Assurance Program reporting structure.

A.2 Figure 2

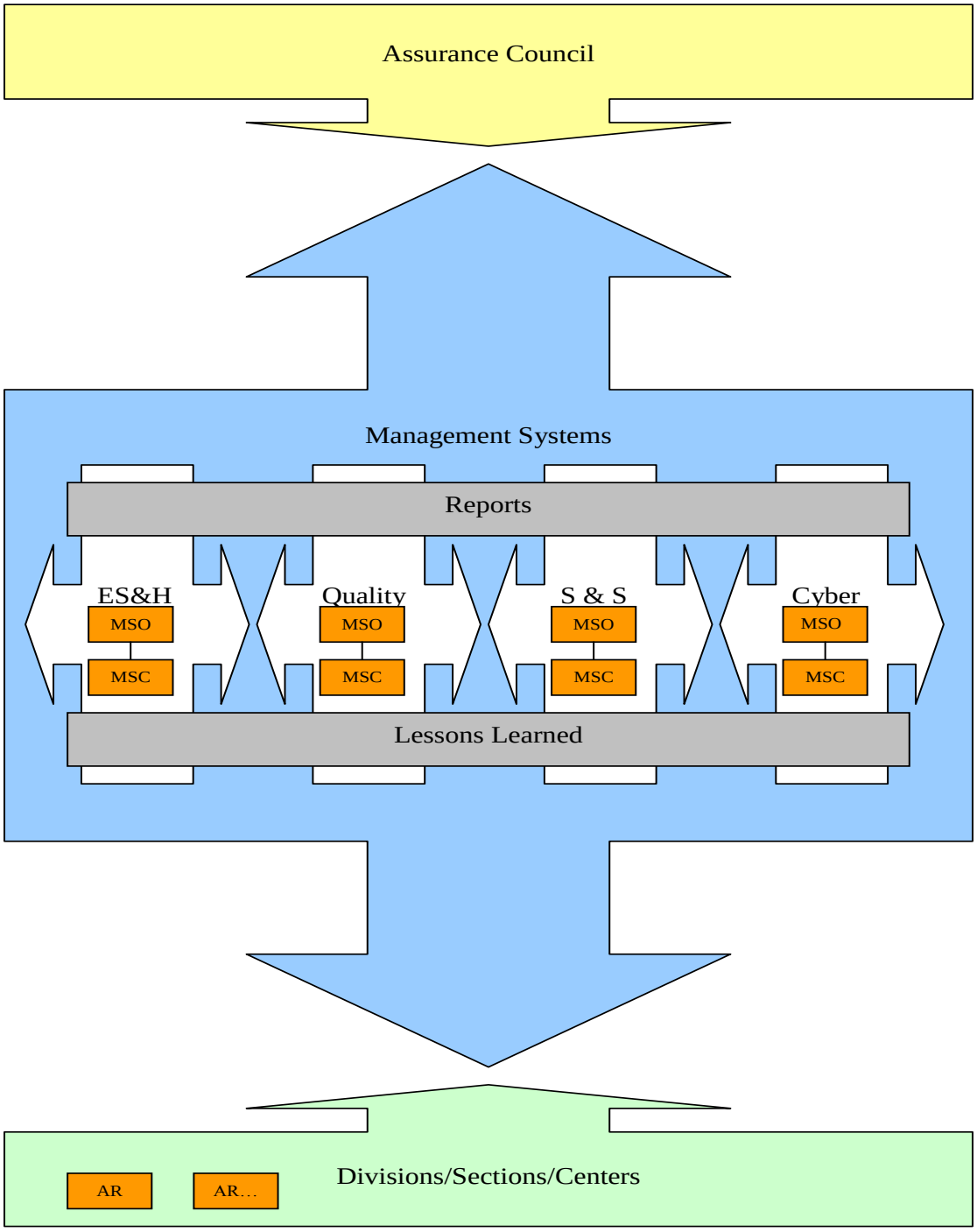

Figure 2. Major roles and communication flow within contractor assurance activities.

A.3 Advisory Council on Integrated Assurance Charter

CHARTER

Laboratory Director's Advisory Council

on Integrated Assurance

Fermi National Accelerator Laboratory

1.0 *Introduction*

In its proposal for the contract to manage and operate Fermi National Accelerator Laboratory (Fermilab), Fermi Research Alliance, LLC (FRA) proposed to the U.S. Department of Energy (DOE) that the Laboratory Director would establish an "Advisory Council on Integrated Assurance"(AC) representing a broad spectrum of senior Laboratory management experience and expertise to advise and assist the Director on the full range of integrated assurance matters involving FRA's performance of the Fermilab contract, including Laboratory compliance with the requirements of DOE Order 226.1A, "Implementation of Department of Energy Oversight Policy", and Director's Policy, Assurance Program – No. 39, Revision 000.

2.0 *Purpose*

The purpose of the AC is to serve as a mechanism to assure the Laboratory Director, and in turn to allow the Laboratory Director to provide comprehensive assurances to DOE and to the FRA Board of Directors, that sufficient internal control and oversight systems are in place and are operating properly with respect to the management and operation of Fermilab to enable the

prompt identification of deficiencies and opportunities for improvement, the prompt and accurate reporting of deficiencies to the responsible Laboratory managers and to DOE and other authorities, and the timely and effective implementation of corrective actions. This will be accomplished by such activities as the performance by the AC of regular assessments of the sufficiency of, and Laboratory compliance with, assurance and oversight systems and policies developed by the Laboratory, and by the providing of advice by the AC to the Director on the status of all programs that require submission of assurance reporting to DOE.

3.0 *Membership*

The Fermilab Chief Operating Officer (COO) shall be a member and shall serve as the Chairperson of the AC. The Head of the Office of Quality and Best Practices (OQBP) shall also be a member and serve as the AC Secretary, and shall provide or arrange for administrative and, as necessary, technical support for the AC. The COO may also appoint, with the approval of the Laboratory Director, additional members of the AC in order to provide a broad range of management, technical, and quality assurance perspectives and expertise. The COO may also establish committees or working groups from the membership of the AC, and may task others who are not members of the AC to provide support to the AC or its committees and working groups.

4.0 *Responsibilities and Duties*

4.1 It is the responsibility of each AC member to become familiar with the policies and requirements set forth in DOE Order 226.1A, "Implementation of Department of Energy Oversight Policy"), in the Fermilab prime contract clause entitled "Management Controls" (clause I.87), and in such other directives and authorities as may be identified by the Chairperson or the Secretary of the AC. See list in Appendix 1.

4.2 The AC shall provide advice to the Laboratory Director as to the sufficiency of Laboratory assurance systems and reporting processes in connection with the preparation of formal assurance statements that the Director must provide to DOE or such other matters as the Director may request.

4.3 Using the assistance of the OQBP provided technical or quality specialists where necessary, the AC shall undertake an ongoing program designed to identify adequacy of and deficiencies in existing assurance processes as well as evolving "best practices," and work with Laboratory organizations to incorporate necessary changes in the processes.

4.4 In connection with the conduct of its business, the AC shall meet regularly (normally once a month, and more frequently if determined necessary by the Chairperson) for the primary purposes of discussing the progress of ongoing AC work, of reaching agreement or consensus on final reviews or recommendations by the AC, and of planning for future AC activities. Members may assign a designee to attend meetings that they are unable to attend due to illness or schedule conflicts. The Laboratory Director and Deputy Director shall serve as advisors to the AC, and may attend such meetings and participate in other AC activities and discussions at their discretion. Attendance at AC meetings by other than members, their designees, the Laboratory Director, or the Deputy Director will be by invitation of the Chairperson or the Laboratory Director only.

5.0 Procedures

5.1 The AC shall develop and have OQBP regularly update a list of matters to be tracked by the AC (e.g., audit/review findings and resulting action plans, status of performance measures, assurance reporting requirements to DOE, etc.).

5.2 The AC shall adopt a uniform tracking application to be used across the Laboratory for entering information to be reviewed by the AC.

5.3 The AC shall regularly review the information on tracked matters and promptly advise the Laboratory Director on significant adverse developments such as failure to enter necessary information or documentation, failure to meet schedules or milestones, or trends or patterns of poor performance or other deficiencies, including an assessment of the risk to the successful performance of Laboratory missions which such adverse developments present.

5.4 The Chairperson of the AC shall consult with the Laboratory Director with respect to such matters as when reviews or other activities of the AC are to be completed, in what format a particular AC work product should be prepared, and whether a particular AC work product is to reflect a consensus position, the view of a simple majority of AC members, or some other method of ascertaining the AC position. Unless the Laboratory Director has otherwise advised the Chairperson, the method of ascertaining the AC position on a particular matter must involve the participation of at least two-thirds of the AC membership (members or designees) at the time of deliberations.

5.5 The AC shall develop a process to document the reviews and other work performed by the AC and the corrective actions taken as a result of AC reviews so that such may be readily and easily audited by DOE and other reviewers.

6.0 Changes to the Charter

This Charter shall be periodically reviewed by the Laboratory Director and by the AC to ensure its provisions comport with applicable or evolving policies and requirements. The AC may recommend that changes be made to this Charter, but only the Laboratory Director has authority to direct or approve changes to this Charter.

7.0 Appendix 1: Reference DOE Orders and CFRs

- DOE Order 151.1C, Comprehensive Emergency Management System
- DOE Order 205.1A, Department of Energy Cyber Security Management Program
- 10 CFR 851, Worker Safety and Health Program; the Integrated Safety Management System requirements prescribed in DOE Order 231.1A Environmental, Safety and Health Reporting; DOE Policy 450.4; and DOE M 450.4-1, Integrated Safety Management Systems Manual
- DOE O 470.2B, Independent Oversight and Performance Assurance Program, Attachment 2, dated 10-31-02
- DOE O 413.1A, Management Control Program, dated 04-18-02
- DOE Order 414.1C, Quality Assurance

A.4 Other Requirements

Chapters 2 through 4 are contained in the Fermilab Integrated Quality Management Program, which can be downloaded from the Fermilab website.

These chapters were referenced to avoid duplication of requirements.

A.5 References

(1) DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide for Use with* 10 CFR 830, Subpart A, *and* DOE O 414.1A, *Attachment 2* DOE O 414.1C, *Quality Assurance*, dated 6-17-05*; DOE P 450.4, Safety Management System Policy; and* DOE P 450.5, *Line ES&H Oversight Policy,* dated 5-31-01.

(2) DOE G 414.1-2A, *Quality Assurance Management System Guide* for Use with 10 CFR 830 *Subpart A Quality Assurance Requirements and* DOE O 414.1C, *Quality Assurance,* dated 6-17-05.

(3) DOE Order 151.1C, *Comprehensive Emergency Management System*

(4) DOE Order 205.1A, *Department of Energy Cyber Security Management Program*

(5) 10 CFR 851, *Worker Safety and Health Program;* the Integrated Safety Management System requirements prescribed in DOE Order 231.1A *Environmental, Safety and Health Reporting;* DOE Policy 450.4; and DOE M 450.4-1, *Integrated Safety Management Systems Manual*

(6) DOE O 470.2B, *Independent Oversight and Performance Assurance Program, Attachment 2,* dated 10-31-02

(7) Fermilab Integrated Quality Management Program

(8) Fermilab Director's Policy Manual, policy number 39, Assurance Program

SUBJECT:	Fermilab Integrated Contractor Assurance Program	**NUMBER:**	**3901**
RESPONSIBILITY:	Head, Office of Quality and Best Practices	**REVISION:**	000 B5
APPROVED BY:	FNAL Laboratory Director	**EFFECTIVE:**	

TABLE OF REVISIONS

Author(s)	Description	Revision	Date
Ed Vokoun	Draft A8.6 – Assurance Council review	000	04/09/08
Ed Vokoun	Draft A8.7 – Revised from AC feedback.	000	04/21/08
Ed Vokoun	Draft B1 – Technical Review	000	04/30/08
Ed Vokoun	Draft B2 – Change title to indicate "Integrated"	000	05/05/08
Ed Vokoun	Draft B3 – Clarify and edit based upon 000B2 feedback	000	06/03/08
Ed Vokoun	Draft B4 – Added Section 5.5	000	07/03/08
Ed Vokoun	Draft B5 – Updated with current revision of Assurance Council Charter	000	10/29/08