Assessments Policy

Management System: Quality

Revision History

Author	Description of Change	Revision No. & Date
T.J. Sarlina	Revision 001, initial re-release of the Assessments Policy. Reformatted policy template and content.	Revision 001 October 2013

WARNING: This policy is subject to change. The current version is maintained on the Directorate website.
[Using a search engine on the internet such as Google could produce an outdated/unsupported document]

TABLE OF CONTENTS

1.0 INTRODUCTION 3

2.0 DEFINITIONS 3
- **2.1** Assessment 3
- **2.2** Division/Section/Center/Project (D/S/C/P) Self-Assessment 3
- **2.3** DOE Assessments 3
- **2.4** ISO/OHSAS Assessments 3
- **2.5** Environment, Health & Safety (ES&H) Self-Assessment 4
- **2.6** Management Assessments 4
- **2.7** Quality Assessments 4
- **2.8** Risk-Based Planning 4

3.0 RESPONSIBLILITIES 4
- **3.1** Division, Section, Center, and Project (D/S/C/P) Heads / Management System Owners 4
- **3.2** Quality Assurance Representative (QAR) 4
- **3.3** Environmental, Safety, Health & Quality (ESH&Q) 4

4.0 POLICY 5
- **4.1** Assessments 5
  - **4.1.1.** Self-Assessments 5
  - **4.1.2.** Independent Assessments 5
- **4.2** Scheduling 5
- **4.3** Reporting 5
- **4.4** Corrective & Preventive Actions 5
- **4.5** Review 6

5.0 REFERENCES 6

WARNING: This policy is subject to change. The current version is maintained on the Directorate website.
[Using a search engine on the internet such as Google could produce an outdated/unsupported document]

1.0 INTRODUCTION

Fermilab is required to conduct assessments per the Quality Assurance DOE Order 414.1D, to identify and understand business risks and to identify opportunities to continually improve processes throughout the Laboratory. This is accomplished through Self and Independent Assessments conducted at the Laboratory as evidence to ensure the assessed areas meet all applicable requirements.

It is Fermilab policy to use a risk-based approach for planning and performing these assessments, focusing our limited resources on those systems, processes, and procedures that represent the greatest business risks to continued operations. Such business risks may include but are not limited to financial risks, regulatory risks, legal risks, and environment, safety, and health risks.

Exclusion:
This policy excludes assessments performed at Fermilab by Internal Audit Services (Financial assessments).

2.0 DEFINITIONS

2.1 Assessment
A review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.

2.2 Division/Section/Center/Project (D/S/C/P) Self-Assessment
Self-Assessments performed by D/S/C/P's to determine their compliance to Fermilab Policies and Procedures and other applicable Laboratory requirements.

2.3 DOE Assessments
DOE assessments are independent assessments that are conducted specifically by the Department of Energy (DOE) and measure Fermilab's compliance against requirements set forth in applicable DOE Orders.

2.4 ISO/OHSAS Assessments
ISO/OHSAS assessments are independent assessments that are conducted by a 3rd party registrar that specifically measures Fermilab's compliance against a written standard. For example: ISO 14001 assessments verify compliance to environmental management requirements; and OHSAS 18001 assessments verify compliance to occupational, health and safety requirements. In the case of ISO and OHSAS successful completion of the assessments results in continuation (or reissue) of Fermilab's certification.

WARNING: This policy is subject to change. The current version is maintained on the Directorate website.
[Using a search engine on the internet such as Google could produce an outdated/unsupported document]

2.5 Environment, Health & Safety (ES&H) Self-Assessment

Self-Assessments performed by Divisions and Sections to determine their own adherence to the ES&H Program and requirements (see FESHM chapter on ES&H Self-Assessment Program).

2.6 Management Assessments

Self-Assessments conducted by Fermilab Management System Owners to assess the performance of their own organizations and to identify and correct problems that will hinder their organization from achieving their mission, objectives, and performance requirements

2.7 Quality Assessments

Quality Assessments are a type of independent assessment conducted by ESH&Q on specific areas (D/S/C/P's, Management System, process, etc…) and shall verify the quality management system is implemented effectively laboratory-wide and verify adherence to applicable requirements. (See FESHM chapter on Quality Assessments).

2.8 Risk-Based Planning

Risk-based planning focuses on the strategic, regulatory, financial, and business risks to which the laboratory has exposure. The goal is to customize a dynamic, defensible assessment plan that addresses the unique needs and risks of the work that is being performed.

3.0 RESPONSIBLILITIES

3.1 Division, Section, Center, and Project (D/S/C/P) Heads / Management System Owners

- Responsible for providing the resources necessary to conduct and schedule assessments within their organization according to this policy.
- Identify necessary (and appropriate) assessments within Program Execution Plans (PEPs), which are developed as part of the annual budget/business planning process.
- Ensure the D/S/C/P Quality Assurance Representative is informed of all assessments occurring and the result.
- Ensure iTrack is utilized for all findings or nonconformities found during assessments, and ensure they are tracked through to completion.

3.2 Quality Assurance Representative (QAR)

- Report assessment results for their D/S/C/P to the QA Subcommittee.

3.3 Environmental, Safety, Health & Quality (ESH&Q)

- Schedule and conduct Quality assessments.
- Compile and report assessments results to the Assurance Council annually.
- Review and ensure the effectiveness of implemented corrective action plans.

4.0 POLICY

4.1 Assessments

4.1.1. Self-Assessments

Self-Assessments shall be conducted by Divisions/Sections/Centers/Projects (D/S/C/P) or Management Systems Owners to evaluate their own specific internal procedures and performance. Self-assessments include but are not limited to D/S/C/P Self-Assessments, Management Assessments, and Environment, Safety & Health Self-Assessments. (See FESHM).

4.1.2. Independent Assessments

Independent Assessments are assessments conducted by external organizations, 3rd parties (e.g. DOE or registrar), or internal organizations independent from the area being assessed to ensure the Laboratory's adherence to applicable requirements. Independent assessments include but are not limited to Quality Assessments, ISO/OHSAS Assessments, and DOE Assessments.

4.2 Scheduling

Self-Assessments:

Self-Assessments including Management assessments and self-assessments conducted by D/S/C/P's shall be documented and scheduled based on risk using a graded approach. Other self-assessments such as ES&H self-assessments shall be scheduled based on the requirements of the topic being assessed – e.g. ES&H self-assessments are to be scheduled and completed annually per FESHM.

Independent Assessments:

Shall be scheduled based on the requirements set by the external 3rd party which are typically at set intervals, or as requested by independent internal organizations.

4.3 Reporting

Reports shall be distributed to the management of the assessed area, to those who participated in the assessment, and ESH&Q if applicable. Further distribution shall be determined by management. All assessments, regardless of type, are required to be reported through designated QARs to the QA Subcommittee.

4.4 Corrective & Preventive Actions

Nonconformities or issues found from all assessments shall be recorded and tracked through to closure using the iTrack system, and shall follow iTrack Procedures and the Fermilab Corrective & Preventive Action Procedure documented in FESHM. Nonconformities assigned by any external 3rd party shall follow their requirements if applicable (i.e. specific DOE or registrar requirements).

4.5 Review

Reports from assessments shall be compiled by ESH&Q and reported to the Assurance Council on an annual basis to review the results, identify trends, and make continual improvement recommendations to the Laboratory.

On a periodic basis implemented corrective action plans shall be reviewed by ESH&Q to ensure implementation was effective.

5.0 REFERENCES

FESHM
http://esh.fnal.gov/xms/FESHM

DOE O 414.1D Quality Assurance
https://www.directives.doe.gov/directives/0414.1-BOrder-dadmchg1/view