QAM 12080: FERMILAB ESH&Q SELF-ASSESSMENT and INSPECTION PROGRAM

Revision History

Author	Description of Change	Revision Date
T.J. Sarlina	Merged QAM 12080 (Self-Assessments) and FESHM 1010.1 (ES&H Self-Assessments) into one program document and cancelled FESHM 1010.1.	January 2016
Kathy Zappia / Jemila Adetunji	- Additional verbiage some of the terms within the acronyms & definitions section – to enhance robustness - Statements of clarification added to the responsibilities section (no change in responsibilities) - Update of title – ESH&Q Section Head to Assistant Director for ESH&Q - Rewording for clarification but no changes	July 2014
Kathy Zappia	Initial release of QAM chapter 12080. This replaces and cancels OQBP Self-Assessments Procedure 3902.1003.	December 2013

TABLE OF CONTENTS

1.0 INTRODUCTION

This document describes the elements that constitute Fermilab's Self-assessment and Inspection Program. The program consists of Self-Assessments at both the laboratory and functional level, Tripartite Assessments, Management Field Observations, and ES&H Inspections and Walkthroughs. Each element of the program is considered to be an internal activity planned and executed by Fermilab employees but may also include participation by Department of Energy (DOE) Fermi Site Office (FSO) personnel. The identification of assessment topics is guided by an evaluation of risks using a graded approach, and conducted in accordance with applicable requirements. All assessments and subsequent findings included in this program are required to be recorded and tracked to completion in the iTrack database.

2.0 DEFINITIONS

- **Assessment** - A review, evaluation, surveillance, or audit where a systematic approach is used to evaluate processes, systems or services to determine compliance to specified requirements and effectiveness; with the goal of identifying best practices and areas of non-compliance. An assessment usually results in corrective actions where appropriate resolution is required.
- **Assessment Plan** - Description of the activities and arrangements for an assessment.
- **Assessment Scope** - Extent and boundaries of an assessment.
- **Assessor** - A person with the competence to conduct an assessment.
- **Audit Criteria** - Specific endpoints that delineate the desired state of the function to be audited. These often are contained in policies, procedures and requirements.
- **Corrective Action** - Action to eliminate the cause of a detected nonconformity or other undesirable situation in order to prevent recurrence. It is a reactive, long-term solution to prevent the same problem from happening again by removing its source.
  Note: *There can be more than one cause for nonconformity. Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.*
- **Preventive Action** - Action to eliminate the cause(s) of a potential nonconformity or other potential negative outcome in order to prevent occurrence. It is a proactive action.
  Note: *There can be more than one cause for a potential nonconformity. Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence*
- **Risk-Based Planning** – This 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 being performed.
- **Self-Assessment** – A review of one's own processes, organization, etc. to determine whether specific requirements are being met, and if improvement opportunities are present.

3.0 RESPONSIBILITIES

3.1 Divisions/Sections Heads, Management System Owners & Project Managers

- Ensure compliance with this procedure for their areas including flow down of requirements and awareness.
- Document and schedule self-assessments based on risk using a graded approach.
- Provide the necessary resources to implement this procedure and complete self-assessments.
- Ensure that their organization and all stakeholders are informed of self-assessments.
- Ensure that the self-assessment activities and results are entered into the iTrack database; including implementation of corrective and preventive actions for all findings, non-conformances, opportunities for improvement, best practices, and recommendations, and for ensuring they are tracked to completion, and properly closed.

3.2 Quality Assurance Manager

- Provide support to management within the scope of this procedure.
- Coordinate yearly Tripartite Assessment and self-assessment planning.
- Review periodic trending and analyses of self-assessment items to verify that root causes are being adequately identified and to determine if items are appropriately and effectively addressed.
- Ensure that the effectiveness reviews of actions are conducted and that the results of effectiveness reviews are incorporated when planning future assessments.

3.3 Assessors

- Ensure compliance with this procedure.
- Report the results of assessments to participants, management, management system owners, and respective stakeholders.
- Consult QAM 12030 to determine the risk level of the area(s) to be assessed and perform risk-based planning.

3.4 Quality Assurance Representatives

- Quality Assurance Representatives (QAR) have the responsibility to communicate the assessment plans and results of their D/S/P to the QA Subcommittee.

4.0 PROGRAM DESCRIPTION

4.1 Fermilab Programmatic Assessments

The ESH&Q-Quality Assurance (QA) group plans and conducts system or program-level independent assessments in various areas within the Divisions, Sections, Management Systems, and Projects across the Laboratory. These assessments are conducted to evaluate process or system implementation and effectiveness; and ultimately drive improvement.

4.1.1. Scheduling

QA assessment plans are determined by ESH&Q Quality Assurance group with agreement from management (D/S/P's or Management System Owners), and are based on requirements

and risks using a graded approach. A risk-based planning approach should consider the following inputs:

- Reorganization of D/S/P.
- Changes in Management System responsibilities or of Management System ownership.
- Other audits that have highlighted a particular problem, area of concern or elevated risk.
- Recurring incidents or non-conformances.
- Policy, process, or procedure changes.
- Requirement changes (i.e. DOE Order updates, Project scope changes).
- Events or incidents, both internal and external to Fermilab.
- Assurance Council or senior management requests.
- Unidentified processes or procedures.

QA assessment plans will be updated each fiscal year. The schedule shall be posted and communicated so that the organization is aware of the schedule for the upcoming year.
QA assessment plans and schedules are meant to be working documents, and should be revised as changes occur. If a QA assessment is postponed or canceled a rationale should be provided and documented.

A notification memo will be sent to the participants and stakeholders to provide awareness of the upcoming assessment. This memo should contain the participants, timeline, scope and expected actions. Alternate means to notify stakeholders may be used at the discretion of the Fermilab QA Manager.

4.2 Self-Assessments

Divisions, Sections, Management Systems, and Projects plan and conduct self-assessments that review their organization's responsibilities, processes, and programs to identify and correct situations that hinder the achievement of their mission, objectives, and performance requirements, and to identify improvement opportunities and lessons learned. Self-Assessments are conducted on any topic affecting a Division, Section, Management System, or Project.

4.2.1. Requirements

Divisions/Sections are required to conduct self-assessments per fiscal year that are Environment, Safety, Health, or Quality related, and based upon risk using the graded approach. Regardless of the number of self-assessments executed by a Division/Section, all self-assessments completed are required to be reported, communicated, and tracked per procedures listed within this document.

Management System self-assessments follow a 3-year planning cycle in which 4 management systems are chosen each year by the Assurance Council to complete a self-assessment. All Management System self-assessments completed are required to be reported, communicated, and tracked per procedures listed within this document. Management Systems currently exempt from the 3-year self-assessment planning cycle include:

- Governance – FRA Board oversight
- Finance – Mandatory regulatory audits are performed by outside organizations
- Information – ISO 20000 certification will suffice

- Projects – DOE reviews and audits are performed

Exempt management systems may vary as programmatic changes occur.

4.2.2. Scheduling

Self-assessment schedules are determined by management and are based on requirements and risks using a graded approach. A risk-based planning approach should consider the following inputs:

- Reorganization of D/S/P.
- Other assessments that have highlighted a particular problem, area of concern or elevated risk.
- Recurring incidents or non-conformances.
- Policy, process, or procedure changes.
- Requirement changes (i.e. DOE Order updates, Project scope changes).
- Events or incidents, both internal and external to the organization.
- Assurance Council or senior management requests.

Self-assessment schedules must be updated each fiscal year. The schedule shall be posted and communicated so that the organization is aware of the schedule for the upcoming year, and it shall be communicated to the organization's QAR. The QAR shall then communicate the self-assessment schedule to the QA Subcommittee. Schedules are meant to be working documents, and should be revised as changes occur. If a self-assessment is postponed or canceled a rationale should be provided in the schedule.

4.2.3. Special ES&H Assessments

Certain federal regulations, such as 10CFR835, mandate program reviews on a triennial basis (i.e. every three years). These reviews shall cover the entire program during the three year span and are to be documented, communicated and tracked per requirements listed in this document.

4.2.4. FESHCom Subcommittee Self-Assessments

On an as needed basis, FESHCom Subcommittees may determine a self-assessment is necessary on a particular laboratory policy, process, program, or in response to an incident. The Subcommittee identifying the need to conduct the self-assessment is responsible for coordinating, executing, and reporting the self-assessment per requirements listed in this document.

4.3 Tripartite Assessments

Tripartite assessments involve the partnering of ESH&Q, Division Safety Officers (DSOs), and the Fermilab Site Office. Planning and execution of tripartite assessments occurs on an annual basis and they are used to evaluate aspects of the ES&H Management System within the Divisions and Sections. In order for an assessment to be classified as a Tripartite Assessment, participation is obligatory from all three entities (i.e. ESH&Q, a Division/Section, and DOE-FSO). Divisions/Sections are required to conduct or participate in Tripartite Assessments on an as-needed basis, and topics shall be based on risk using the graded approach.

The Quality Assurance Manager will schedule and lead a planning meeting every year with representatives from DOE-FSO, D/S ES&H representative or DSO, and the ESH&Q Section to discuss assessment topics, assign participants and tentative timeframes for completion. Each representative should come prepared to present focused topics with assessment scope, audit criteria and tentative start dates that will be agreed upon at this meeting.

Note: *Assumption of a global topic from DOE-FSO is encouraged to fulfill their requirements as well as Fermilab requirements. This will eliminate a separate audit from DOE-FSO.*

The finalized Tripartite Assessment Schedule is communicated to DOE-FSO, D/S ES&H representatives, DSOs and others as required. Finalized assessment reports are made available on the ESH&Q website.

4.4 Management Field Observations

Management field observations are a unique blend of assessment and walkthrough where a D/S head, department head, or project manager may periodically review the areas under their control for various reasons. Reasons can include but are not limited to the verification that policies, procedures, and programs have been implemented properly. Management field observations should be scheduled on an as needed basis as management deems they are necessary.

4.5 Inspections and Walkthroughs

Inspections and Walkthroughs are planned and conducted by Division/Section qualified personnel, and are a means of collecting information about ES&H program performance. Elements of Inspections and Walkthroughs include OHSA-style inspections, and Highly Protected Risk (HPR) inspections. Frequency of inspections and walkthroughs are determined by the requirements listed in Fermilab's Worker Safety & Health Program.

4.5.1. OSHA-style Inspections

The frequency of OHSA-style inspections shall be tailored to the level of risk. "Office" areas, industrial and other technical areas should be inspected on an as needed basis. For optimum efficiency they should be conducted during regularly scheduled HPR inspections.

4.5.2. Highly Protected Risk Inspections

The HPR program is scheduled and implemented by the ESH&Q Fire Protection Engineer, and encompasses all aspects of fire protection at the Laboratory. The program requires inspection of fire prevention practices and procedures, quality construction, fire detection and suppression systems, verification of testing and maintenance of fire protection systems and equipment, and general review of processes and activities occurring within the building including basic housekeeping. FESHM Chapter 6015, "Highly Protected Risk Inspection," explains the program in detail. For efficiency, D/S Heads, department heads and FSO are encouraged to participate.

5.0 PROCEDURES

The following section outlines the proper steps to take when executing assessments and walkthroughs

5.1 QA Assessments, Self-Assessments and Tripartite Assessments

5.1.1. Planning

Those employees selected to be assessors are responsible for planning the assessment. If desired, complete the Assessment Plan Template. The template includes the following:

- Organization assessed – this should include their organization's name, and/or any specific processes that are to be assessed.
- Purpose & Scope of Assessment – This is the rationale for the assessment, why the assessment is needed (e.g. requirement, DOE order, previous nonconformity, lessons learned, etc.).
- Assessment Agenda/Schedule – the tentative schedule that has been agreed upon with the participants of the assessment.
- Criteria & Requirements to be assessed – this section should list the specific requirements or criteria that are to be assessed.

Distribute the Assessment Plan to all participants of the assessment to ensure their awareness and agreement. Distribute the Communication Memo to all participants and their management. Assessors conducting QA Assessments, Self-Assessments, and Tripartites are encouraged to utilize the Communication Memo Template.

5.1.2. Conduct Assessment Interviews and Review Documents

The assessment is conducted in accordance with the assessment plan and schedule. Assessors obtain the documentation and evidence necessary to verify compliance to the requirements outlined in the Assessment Plan. Activities performed during the assessment can include (but are not limited to):

- Scheduling and conducting interviews
- Reviewing and examining documents and records
- Inspection of facilities or observing work activities

5.1.3. Document Results

The individuals performing the assessment should log any documents or records reviewed, list all personnel interviewed, and document any findings, nonconformities, management concerns, recommendations, opportunities for improvement, or best practices found.

All findings, nonconformities, management concerns, recommendations, opportunities for improvement, and best practices found during the assessment should be agreed upon by the participants of the assessment and management before they are documented in iTrack.

5.1.4. Enter Items In iTrack

All findings, nonconformities, management concerns, recommendations, opportunities for improvement and best practices (defined in QAM 12030, "iTrack Procedures & Risk Assignment") discovered during the assessment shall be entered into iTrack by the assessor (or designated iTrack data entry individual) and assigned an owner. (Refer to the iTrack webpage for the iTrack User Guides). The owner of the item is responsible for delegating corrective actions and other activities necessary to properly close out the item in accordance with Fermilab's Corrective & Preventive Action Procedure (see QAM 12040).

5.1.5. Reporting

The assessor shall complete an Assessment Report once the audit has concluded and all of the items have been agreed upon by all parties. If a dissenting opinion is held by a team member, a minority report can be filed as per FESHM 1010. An Assessment Report Template is available and is the preferred way to document the assessment. The Assessment Report should include the following information:

- Date(s) of assessment – actual dates of the assessment
- Organization assessed – organization name
- List of participants – who was assessed
- List of assessors – who were the assessors
- Scope – what processes were reviewed, what work sites were inspected, etc.
  Criteria/Requirements – what criteria and requirements were used as input to the self-assessment
- Interviews – short synapsis of any interviews that took place, this may be not applicable (N/A) if the QA assessment was inspection based
- List of documents reviewed
- Report – summary of what took place during the QA assessment and the results
- Opportunities for Improvement
- Recommendations
- Best Practices Observed – list any best practices seen during the QA assessment
- Lessons Learned – identify any lessons learned reviewed during the QA assessment, but also any identified as a result of the assessment
- Findings / Nonconformities – details of the actual nonconformities found

5.1.6. Distribution

The Assessment Report shall be distributed to all of the assessment participants, management of the organization, and others as determined by the D/S Head or Management System owner. The results will also be shared with the QA Subcommittee so that lessons learned, issues found, and other best practices can be shared more broadly.

5.1.7. Records

The original Assessment Report and iTrack Review ID shall be sent to ESH&Q QA for record keeping purposes. All records that were generated by the assessment, including the Assessment Plan, Assessment Report, checklists created, other planning documents, etc., shall be kept in a location accessible by the assessed organization. Accessible locations can be a FermiPoint site, DocDB, or similar collection point.

5.2 Inspections, Walkthroughs, or Field Observations

5.2.1. Conduct Inspection, Walkthrough, or Field Observation

Designated personnel shall direct the activities of the inspection or walkthrough and also serve as the direct point of contact with the organization's management and all participating staff members. See FESHM Chapter 6015, "Highly Protected Risk Inspection" for details.

The inspection or walkthrough is conducted in accordance with the plan and schedule. Personnel obtain the documentation and evidence necessary to verify compliance to ES&H or

other requirements. Activities performed during the inspection can include (but are not limited to):

- Reviewing and examining documents and records
- Inspection of facilities
- Observing work activities
- Discussing procedures with employees involved in work activities

5.2.2. Document Results

The personnel performing the inspection should log any documents or records reviewed, list all personnel interviewed, and document any findings, nonconformities, management concerns, recommendations, opportunities for improvement, or best practices found during the inspection as necessary.

5.2.3. Enter Items In iTrack

All findings, nonconformities, management concerns, recommendations, opportunities for improvement and best practices (defined in QAM 12030, "iTrack Procedures & Risk Assignment") documented during the inspection shall be entered into iTrack by the D/S personnel (or designated iTrack data entry individual) and assigned an owner. (See the iTrack webpage for the iTrack User Guides). The owner of the issue is responsible for delegating corrective actions and other activities necessary to properly close out the item in accordance with Fermilab's Corrective & Preventive Action Procedure (QAM 12040).

5.3 Effectiveness Reviews of Corrective and Preventive Actions

A randomly selected number of Corrective and Preventive actions associated with findings/nonconformities will be evaluated via the Quarterly Verification Review Process in iTrack to determine whether or not the actions taken to resolve the original issue were effective. For specific details of the verification process, see QAM 12030, "iTrack Procedures & Risk Assignment."

Each quarter, the ESH&Q QA group and DSOs will review the effectiveness of the root cause analyses and corrective/preventive actions taken. ESH&Q-QA is responsible for reviewing items from QA Assessments, Self-Assessments, and Tripartites. DSO's are responsible for reviewing items from Inspections and Walkthroughs, and Self-Assessments that are ES&H based.

Review can include the following actions (but are not limited to):

- Review of the evidence of the implemented actions.
- Follow-up interviews with parties involved in the implementation of the corrective/preventive actions.
- Follow-up interviews with parties impacted by the implementation of the corrective/preventive actions.

Disposition of the initial executed corrective/preventive action plan is determined based on the review, and can result in one of the following outcomes:

- Corrective/preventive action plan implementation was effective, thus no further actions are necessary.

- Corrective/preventive action plan implementation was ineffective. If this is the case, the item should be reopened in iTrack, the owner of the nonconformance shall be contacted, and a new plan developed.

6.0 REFERENCES

FESHM 6015 – Highly Protected Risk Inspection

QAM 12030 – iTrack Procedures & Risk Assignment

QAM 12040 - Corrective & Preventive Action

ESH&Q iTrack Webpage

iTrack Database

Assessment Report Template

Assessment Plan Template

Assessment Communication Memo Template

Fermilab Worker Safety & Health Program