QAM 12080: Fermilab Assessment Program

Revision History

Author	Description of Change	Revision Date
Mary Curtis	• Add information about Charge Memos.	November 2022
Mary Curtis	• Clarify required actions for Independent (external) assessments.	October 2022
Mary Curtis	• Described new process for creating the annual Enterprise Integrated Assessment Plan. • Added new requirement about evaluating effectiveness of root cause methods used. • Update definitions to align with recent changes.	February 2022
Mary Curtis	• Added instruction to upload reports directly into appropriate database (Section 5.2.7 and Checklist in Appendix B)	January 2021
Mary Curtis	• Updated document to reference new database, Fermilab Quality Tool Suite, and changes to assessor program.	August 2020
Mary Curtis	• Updated to reflect changes to QAM 12002. • Enhance definition of "Recommendation."	September 2019
Kathy Vuletich	• Removed reference to iTrack item type "Finding." This term is identical to a "Non-conformity" and is no longer used in iTrack. • New requirement - Assessors take Internal Assessor Training. • Added self-assessment criteria for MSOs. • Added Effectiveness Reviews by responsible parties.	January 2018
T.J. Sarlina	Merged QAM 12080 (Self-Assessments) and FESHM 1010.1 (ES&H Self-Assessments) and cancelled FESHM 1010.1.	January 2016
Kathy Zappia / Jemila Adetunji	- Added verbiage to some of the terms in the acronyms & definitions section to enhance robustness - Statements of clarification added to the responsibilities section (no change in responsibilities) - ESH&Q Section Head to Assistant Director for ESH&Q	July 2014
Kathy Zappia	Initial release of QAM chapter 12080. This replaces and cancels OQBP Self-Assessments Procedure 3902.1003.	December 2013

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1.0   INTRODUCTION

The Fermilab Assessment Program consists of Independent Assessments and Management Assessments at both the Laboratory and functional levels. Assessment topics are identified and planned by Fermilab employees and recorded and managed in the Integrated Assessment Plan (IAP); a fraction of these topics comprise the Enterprise Integrated Assessment Plan (E-IAP). Assessments are conducted by Fermilab staff, other external parties, or members of the Department of Energy (DOE). The identification of assessment topics is guided by an evaluation of risks using a graded approach and conducted in accordance with applicable requirements. All assessment activities' resulting items shall be recorded and tracked to completion in the Fermilab Quality Tool Suite (FQTS) - iTrack database (Issues Management Tracking System). Subsequent reviews of completed corrective and preventive actions for specific items shall be conducted in a timely fashion and results recorded in iTrack database.

2.0   DEFINITIONS

AOC – Area of Concern

Assessment – A review, evaluation, inspection, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively. There are two main types of assessments: independent and management assessments.

Assessor – A person with the training, experience and/or expertise to conduct an assessment.

Corrective Action – An action to eliminate the cause of a detected nonconformance or another undesirable situation.

Note: There can be more than one cause for a nonconformance. Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

Effectiveness Review – A formal review of closed corrective actions of a nonconformance or management concern to determine if the causal analyses adequately identified the causes of the issue, including the root cause methodology; as well as if the corrective actions adequately address the issue.

Enterprise Integrated Assessment Plan (E-IAP) – A subset of the annual Integrated Assessment Plan selected by the Office of Quality Assurance Head and SOG Chair after evaluating the priority and risk level of each topic.

Graded Approach – The process of ensuring that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with the relative importance to safety, safeguards, and security; the magnitude of any hazard involved; the life-cycle stage of a facility or item; the programmatic mission of the facility.

Fermilab Contact or Representative – The Fermilab employee who is the liaison between the lab and the external assessment team.

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Risk – A fundamental consideration in determining the extent to which controls should be applied at the facility level.

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 being performed.

Self-assessment – An evaluation of a program or process conducted by members of the organization being evaluated. (See **Management Assessment.**)

SOG – Services Oversight Group

3.0   RESPONSIBILITIES

3.1   Line Management (Chiefs, Divisions/Sections/Department Heads, Supervisors, Group Leads, Project Heads)
- Responsible for assessing the efficacy and robustness of processes within areas of responsibility and resolving gaps to prevent substandard performance or achievement of goals/objectives.
- Ensures compliance with this procedure for their areas including flow down of requirements and awareness.
- Schedules assessment activities based on risk using the graded approach. Documents details of scheduled activities in Fermilab Assessment Schedule (in FQTS).
- Provides the necessary resources to implement this procedure and complete assessments.
- Ensures that their organization and all stakeholders are informed of assessments.
- Names the lead assessor for the assessment.
- Works with the lead assessor to identify interviewees for assessed area.
- Works with the lead assessor to determine responsible parties to address items identified through the course of the assessment.
- Ensures that assessments topics are included in the Integrated Assessment Plan in the Assessment database and results (items) from assessments are entered into iTrack database including assessment records. Ensures items are tracked to completion and properly closed.
- Designates an Assessment Point of Contact to liaise with the D/S Quality Assurance Liaison on assessment-related tasks and activities.
- Designates a Fermilab Contact or Representative to liaise with the external assessment team and manage compliance with applicable requirements.

3.2   Management System Owner (MSOs)
- Responsible for assessing the efficacy and robustness of their management system across Line Management Organizations and resolving gaps to prevent substandard performance or achievement of goals/objectives.
- Responsible for creating a Management System assessment plan and submitting it to the Office of Quality Assurance Head. This rolling three-year assessment Plan shall include both independent and management assessment activities with at least <u>one</u> Management assessment <u>per year</u> and at least <u>one</u> independent <u>external</u> assessment <u>per three-year cycle.</u>

- Advises Office of Quality Assurance on scheduling independent (QA Assessments) in their area of responsibility.
- Provides the necessary resources to implement this procedure and complete assessments.
- Ensures that their organization and all stakeholders are informed of assessments.
- Names the lead assessor for the assessment.
- Works with lead assessor to identify interviewees for assessed area.
- Works with the lead assessor to determine responsible parties to address items identified through the course of the assessment.
- Ensures that assessments are entered in the Assessment database and results (items)from assessments are entered into iTrack database including assessment records. Ensures items are tracked to completion and properly closed.

3.3 Head of the Office of Quality Assurance

These responsibilities may be delegated to other members of the Office of Quality Assurance as deemed necessary.

- Provides support to management within the scope of this procedure.
- Coordinates yearly Management Assessments and QA assessment planning - to incorporate into the Integrated Assessment Plan.
- Compiles selected assessment topics proposed by Line Management and MSOs into a proposed E-IAP for the SOG's subsequent review at the August meeting.
- Meets with FSO to obtain feedback on the IAP and opportunities for additional assessments by August 15.
- Presents the proposed E-IAP to the SOG each fiscal year and integrating agreed upon feedback.
- Ensures that the final, approved E-IAP is entered into the database.
- Manages requests for Independent assessments from management.
- Manages the Integrated Assessment Plan, including the assessments on the E-IAP, in the Assessment database.
- Maintains the FQTS-Assessment Database.
- Communicates issues relating to the completion of assessments, specifically highlighting issues relating to the completion of assessments on the E-IAP.
- Reviews periodic trending and analyses of Management assessment items to verify that root causes are being adequately identified and to determine if items are appropriately and effectively addressed.
- Resolves disputes that arise over items discovered during assessment activity.
- Establishes the criteria for assessment roles (lead assessors, leads-in-training and mentors).
- Approves the list of mentors.

3.4 Laboratory Director

- Reviews and approves the Enterprise Integrated Assessment Plan on an annual basis.

3.5 The Enterprise Risk Management Board Chair or Laboratory Risk Manager

- Communicates laboratory areas of concern relating to Enterprise risks that could be assessed to the SOG.

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3.6   The HPI Subcommittee Chair
- Communicates laboratory areas of concern identified from the HPI Subcommittee that could be assessed to the SOG.

3.7   Chief Safety Officer
- Coordinates yearly Tripartite assessment planning and communicates results to Office of Quality Assurance for entry into the FQTS – Assessments Database.
- Communicates laboratory areas of concern identified from FESHCom or otherwise that could be assessed to the SOG.

3.8   Services Oversight Group (SOG)
- Provides input on potential assessment topics to the SOG Chair throughout the fiscal year.
- Reviews the Enterprise Integrated Assessment Plan to determine if the Laboratory's Areas of Concern (AOC) are being assessed.
- Stays abreast of top or emerging enterprise risks that should be considered for assessment.
- Provides input based on the feedback from the PEMP (midyear and annual).
- Provides input based on informal feedback provided by the FRA Board, DOE-Fermi Site Office (FSO), FRA Consultants, or otherwise.
- Identifies resources to complete assessments identified based on areas of concerns.
- Submits the E-IAP to the Laboratory Director for approval by September 15.
- Reviews the outcomes from the assessments on the E-IAP to understand the outcomes, ensure concerns will be addressed, and to ensure the appropriate responsible parties are assigned to address issues identified.

3.9   Lead Assessor, Lead-In-Training (see Appendix A for qualifications)
- Ensures compliance with this procedure.
- Completes Fermilab Lead Assessor Training – FN000557 prior to the start of the assessment.
- Selects the assessment team and confirms that all team members meet assessor qualifications.
- Notifies the management and participants of the organization to be assessed of the assessment.
- Creates assessment plan and schedule with assessment team.
- Conducts optional opening and closing meetings with management, interviewees, and assessment team.
- Drafts reports with the assistance of the assessment team. Provides a draft to the interviewees and management for factual accuracy. Incorporates comments and prepares the final report for distribution to participants, management, management system owners, and other stakeholders.
- Works with management of assessed area to name responsible parties for corrective actions in iTrack.
- Manages the assessment records by sending the report, plan, memo, etc. to the Office of Quality Assurance and entering the items identified to iTrack (refer to QAM 12030).
- Responsible for mentoring assessors to be lead assessors as requested by the Office of Quality Assurance Head.

3.10   Assessment Team Member (Assessor, Lead, Lead-in-Training, Mentor)
(see Appendix A for qualifications)
- Ensures compliance with this procedure.
- Completes <u>Internal Assessor Training – FN000557</u> prior to the start of the assessment.
- Assists with planning and conducting the assessment.
- Works with lead assessor to report the results of assessments to interviewees, management, management system owners, and other stakeholders.
- Specific responsibilities
    - <u>Lead</u> – manages the overall assessment, from planning to final report.
    - <u>Lead-in-Training</u> – manages the assessment with a Mentor's guidance.
    - <u>Mentor</u> – guides the Lead-in-Training as they manage all steps of the assessment. Participates as a member of the assessment team.

Note – The assessment team may have an <u>Observer</u>. This function does not play an active role in assessment activities but may share relevant observations with the other members of the team.

3.11   Quality Assurance Liaison
- Supports Line Management with identifying, planning, or participating in assessment activities to promote continual improvement.
- Supports MSOs with identifying, planning, or participating in assessment activities to promote continual improvement.
- Works closely with other Laboratory leadership, Division Safety Officers (DSOs), and Risk Officers to establish assessment plans over the course of the year or, multi-year, and verifies completion.
- Supports the monitoring, tracking, and trending of issues in iTrack for timely and effective resolution and/or escalation.
- Completes the Assessment record in the FQTS Assessment Plan database, linking the assessment record to the appropriate iTrack review.

4.0   PROGRAM DESCRIPTION

Fermilab conducts a variety of risk-based assessments, audits, and reviews to identify and understand business risks (e.g., financial, regulatory, environmental, legal, safety & health) and to identify opportunities to continually improve programs and processes. This is accomplished through Independent and Management Assessments of Laboratory areas to gather evidence to confirm all applicable requirements are being met. Issues discovered during these assessments shall be documented in iTrack. Depending on the issue, a corrective action or response shall be determined and documented in iTrack.

4.1   Independent Assessments
Independent Assessments are conducted by external organizations, third parties (e.g., DOE or registrar), or internal Fermilab organizations with responsibilities <u>outside</u> of the assessed area. These assessments complement the Management assessments conducted by Line Management and MSO personnel. The Office of Quality Assurance plans and conducts system or program-level independent

assessments (QA Assessments) on a periodic basis to verify adequate implementation of the Fermilab Quality Assurance (QA) program and other established programs and processes across the Laboratory.

Fermilab management has the responsibility to identify independent assessment topics to provide input into the Fermilab Annual Assessment Plan and to provide the necessary resources to support internal independent assessment activity.

Personnel planning the assessment activity are responsible for confirming that assessment team members do not have direct responsibilities for the assessed area. In addition to the independence, the assessment team shall contain members who are technically qualified and knowledgeable in the areas being assessed. Coordination of external independent assessments is performed by management of the assessed organization with support from the Office of Quality Assurance as requested or required. ES&H and the Office of Quality Assurance coordinate environmental, health, safety, security, and quality related external independent assessments.

4.2   Management Assessments (Self-assessments)

Line Managers and MSOs plan and conduct Management assessments that review their organization's responsibilities, processes, and programs to identify and correct situations that may hinder the achievement of their mission, objectives, and performance requirements, and to identify improvement opportunities and lessons learned. Management assessments are conducted on any topic affecting a line management organization or MSO.

4.2.1   Requirements

Line managers shall conduct Management assessments per fiscal year based upon risk using the graded approach. Regardless of the number of Management assessments executed by a line management organization, all completed Management assessments shall be reported and communicated, and corrective actions tracked per procedures listed in this document.

MSOs shall conduct Management assessments on a regular basis as determined by the MSO and on an as-needed basis as determined by the SOG shall cover the entire program during this timeframe and shall be reported, communicated, and tracked per requirements listed in this document.

4.3.2   FESHCom Subcommittee Management assessments

FESHCom Subcommittees may determine management assessments are necessary on a particular Laboratory policy, process, program, or in response to an incident. The Subcommittee that recognizes this need is responsible for coordinating, executing, and reporting the management assessment activity per requirements listed in this document.

4.3.3   Tripartite Assessments

Tripartite assessments involve the partnering of the ES&H Section, Division/Section, and the DOE-FSO, and are used to evaluate aspects of the ES&H Management System within the line management organization. Planning and execution of Tripartite assessments occur on an annual basis. To be classified as a Tripartite Assessment, all three entities (ES&H, line management organization, and DOE-FSO) must participate.

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Topics shall be risk-based using the graded approach. Tripartite assessments shall be reported, communicated, and tracked per requirements listed in this document.

4.3.4 Management Field Observations

Management field observations are a unique blend of assessment and walkthrough where a line manager (e.g., department head, project manager) may periodically review the areas under their control for various reasons including but not limited to verifying implementation of policies, procedures, and programs. Management field observations shall be scheduled on an as needed basis by management and reported, communicated, and tracked per requirements listed in this document.

4.3.5 ES&H Inspections and Walkthroughs

Inspections and Walkthroughs are planned and conducted by qualified line management personnel and are a means of collecting information about ES&H program performance. Frequency of inspections and walkthroughs are determined by the requirements listed in <u>Fermilab's Worker Safety & Health Program</u>.

4.3.5.1 OSHA-style Inspections

The frequency of OHSA-style inspections (e.g., Construction walkthroughs) 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 Highly Protected Risk (HPR) inspections.

4.3.5.2 Highly Protected Risk Inspections

The HPR program is scheduled and implemented by the ES&H Section 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 <u>Chapter 6015,</u> "Highly Protected Risk Inspection Program," explains the program in detail. For efficiency, line managers and FSO are encouraged to participate.

5.0   PROCEDURE

This section details the processes for the Internal Assessment Program, from preparing the annual Fermilab Integrated Assessment Plan (IAP) and related Enterprise IAP, through conducting the assessments, documenting the results, and evaluating the effectiveness of the response. Appendix A contains definitions of assessment activity terms and Appendix B contains an Assessment Checklist for reference when conducting an assessment.

5.1   Fermilab Integrated Assessment Plan

Line management and MSOs will identify self-assessments (management assessments) or independent assessment topics in July for the upcoming fiscal year. The QSL will work with the Line Organization's Assessment Program Point of Contact to identify topics and enter them in the database.

The Head of the Office of Quality Assurance and SOG Chair will analyze the list of assessment topics and from these, narrow the list of topics for the E-IAP. The topics included in the E-IAP will be determined using the Assessment Hierarchy Criteria (Table 1) and IAP Priority Levels (Table 2).

Table 1 – Assessment Hierarchy Criteria

Driver/Requirement Type	Flexibility	IAP Status	SOG Role Review performance information from assessments and:
(1) Contractual/Regulatory • Prime or other contracts • Legal • Regulatory	Must conduct these assessments unless laws/regulations change, or contract is re-negotiated	Included annually, unless there are changes in contract and/or applicable laws, and regulations	Consider other assessments in IAP and identify those with overlap or similarity in order to address lab-wide issues, identify/develop trends, and reduce overall discretionary assessments workload.
(2) Executive or FRA LLC Board	Discretionary	Included in a single year's IAP	Collaborate annually with FSO, ERMB, and senior management to identify critical targeted assessments for inclusion in IAP.
(3) Laboratory • Laboratory internal requirements/guidance • Risks (e.g., risk register) • Management Systems	Conduct is discretionary in the sense that the laboratory can change its own systems. Changes could require consultation with FSO, depending on informal commitments.	Included annually unless MS systems requiring them are changed	Collaborate with MSOs and identify changes to MSs as appropriate in order to optimize lab performance and the value of the assessments
(4) Management • Management direction/discretion (e.g., self-assessments)	Conduct is discretionary; assessments focus on issues where management deems additional insight or monitoring is required.	Included annually unless changed by management direction	Collaborate with managers to optimize value of assessments
(5) Standard Requirements • Best practices • Process improvements • Normal work actions			

Table 2 – IAP Priority Levels

Priority Level	Definition
1	High risk or top area of concern of the Services Oversight Group.
2	Not a high risk or top area of concern, but a topic to be kept on the radar based on issues, trends, or emerging discussions.
3	Low risk topic, not of immediate concern but required to be performed based on driver.

The Assessment Hierarchy describes five levels of assessments based on their drivers or requirements, where levels 1-3 are deemed to be of higher priority. The IAP Priority Levels describe three priority levels to be applied to IAP assessments, where levels 1-2 are deemed to be of higher priority. After applying the Assessment Hierarchy Criteria and the IAP Priority levels, any assessment topic assigned with a combination of criteria levels 1-3 and priority level of 1-2, will be included on the proposed E-IAP. See matrix in Table 3.

Table 3 E-IAP Decision Matrix

Assessment Hierarchy Criteria	Priority Level		
	1	2	3
1	E-IAP	E-IAP	
2	E-IAP	E-IAP	
3	E-IAP	E-IAP	
4			
5			

5.1.2 Management Assessments (Self-Assessments)
Line Management shall schedule self-assessments each fiscal year and log them in the FQTS Assessment database.

On a three-year cycle, MSOs shall schedule and conduct both independent and self-assessment activities to gauge the health of their management system processes. They shall schedule and conduct at least <u>one</u> Management System assessment <u>per year</u> and shall notify the Office of Quality Assurance who will add them to the Assessment Plan in FQTS.

Management shall determine self-assessment plans based on requirements and risks using a graded approach. A risk-based planning approach shall consider the following inputs:

- Reorganization of line management organization.
- 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 (e.g., DOE Order updates, Project scope changes).
- Events or incidents, both internal and external to the organization.

- Assurance Council or senior management requests.
- Corrective actions from previous assessments that failed to address underlying issue. (Corrective actions that were deemed **not effective**.)

The Assessment Plan shall be communicated to all stakeholders and may be accessed through the FQTS. The Plan is a working database and shall be revised as changes occur. If a Management assessment is postponed or canceled a rationale shall be provided in the Assessment record.

5.1.3 Independent Assessments

The schedule for Independent assessments shall be updated each fiscal year in the FQTS Assessment Schedule. Organizations may view the Schedule through FQTS.

On a three-year cycle, MSOs are responsible for planning, scheduling, and conducting/facilitating both independent and management assessment activities to gauge the health of their management system processes. MSOs shall notify the Office of Quality Assurance who shall add them to the Assessment Schedule in FQTS.

5.1.3.1 Independent (External) Assessments

Independent external assessments are those conducted by entities outside of Fermilab, such as: DOE, Office of Enterprise Assessment (EA), third party assessors, other industry experts, or peer reviewers. The Fermilab contact or representative of the external assessment shall add the assessment information (topic, scope, dates, assessors) to the Assessment Schedule in FQTS. MSOs shall schedule at least one independent external assessment every three-year cycle and notify the Office of Quality Assurance who shall add it to the Assessment Schedule in FQTS.

For assessments conducted by the EA, the requirements of DOE O 227.1 shall be integrated into the assessment plan and management of the outcomes.

5.1.3.2 Independent (Internal) Assessments

QA assessments are a type of Independent internal assessment. QA assessment plans and schedules are working documents and shall be revised as changes occur. If a QA assessment is postponed or canceled, a rationale shall be provided and documented.

When requesting an Independent Assessment from the Office of Quality Assurance, managers should use the Charge memo for an Assessment template to record the purpose and scope of the assessment, and submit it to the Head of the Office of Quality Assurance.

QA Assessments are determined using risk-based planning by the Office of Quality Assurance with agreement from Line Management/MSOs. Risk-based planning shall consider the following inputs:
- Reorganization of line organization.

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- Changes in Management System scope or of Management System ownership.
- Other audits that have highlighted a problem, area of concern, or elevated risk.
- DOE review results
- Recurring incidents or non-conformances.
- Policy, process, or procedure changes.
- Requirement changes (e.g., 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.
- Corrective actions from previous assessments that failed to address underlying issue. (Corrective actions that were deemed **not effective**.)

5.1.4 Tripartite Assessment

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

Note: Including a global topic from DOE-FSO is encouraged to fulfill their requirements as well as Fermilab requirements. This minimizes the need for a separate audit from DOE-FSO.

The final Tripartite Assessment Schedule shall be recorded in the FQTS Assessment Plan database and communicated to DOE-FSO, DSOs, and D/S ES&H representatives. Changes to the Tripartite Assessment Schedule shall be agreed upon by all three entities. Final assessment reports shall be made available in the Assessment database or iTrack.

5.2 Conducting QA Assessments, Management Assessments and Tripartite Assessments
5.2.1 Assembling an Assessment Team

The lead assessor selects the members of the assessment team, confirming that all assessors have completed Internal Assessor Training (FN000057). **If the named lead assessor has not met the requirements, they shall be considered a lead-in-training on the team and a mentor shall be named to the assessment team to guide the lead-in-training.**

The number of assessors depends on the size and scope of the assessment. The lead assessor should consider subject matter expertise and assessment experience when selecting assessors.

5.2.2 Plan Assessment and Notify Stakeholders

The assessment team is responsible for planning the assessment. The lead assessor schedules a kick-off meeting with the team to create the Assessment Plan.

The Assessment Plan shall include the following information:
- Assessment Type
- Area to be assessed (name of line organization, management system, process, etc.)
- Purpose (Why is this assessment occurring?)
- Objective (Why is this value added to the Laboratory?)
- Scope (The extent and boundaries of the assessment.)
- Criteria (The standards or requirements that the assessment is based on.)
- Timeline
- Assessment Team with roles identified (lead/lead-in-training, assessor, mentor, observer)
- Assessment Activity Schedule (with interviewees)
- Lines of Inquiry (when applicable)

The lead assessor may capture planning details in the Assessment Plan Template.
Upon completion of the Assessment Plan, the lead assessor shall distribute it to the assessment team and upload a copy or a hyperlink to the Assessment record or iTrack record.

At the same time, the lead assessor shall create and distribute an Assessment Communication Memo to management of the assessed area, interviewees, assessment team and other stakeholders notifying them of the upcoming assessment. (This may not be necessary for Management assessments.)

For Independent assessments the lead assessor shall notify the organization's management, participants, and other stakeholders of the upcoming assessment using the Assessment Communication Memo Template. This Communication memo shall contain the interviewees, assessment team, scope, objective(s), and estimated timeline and shall be distributed once the Assessment date has been determined. The Communication Memo shall be uploaded to the Assessment record in the Assessment database.

Independent (external) assessment activities, including planning and communication, shall be conducted by the external entity according to their established processes and procedures.

5.2.3 Conduct Interviews and Review Documents

The assessment is conducted in accordance with the assessment plan. Assessors obtain documentation and evidence necessary to verify compliance to requirements outlined in the assessment plan. Activities performed during the assessment may include (but are not limited to):
- Conducting interviews
- Reviewing and examining documents and records
- Inspection of facilities
- Observing work activities

5.2.4 Document Results

The assessors shall log any documents or records reviewed, list all interviewees, and document any items found (i.e., nonconformances, management concerns, recommendations, opportunities for improvement, best practices or lessons learned). All items found during the assessment shall be agreed upon by interviewees and management before they are recorded in iTrack. If there are dissenting opinions, the Head of the Office of Quality Assurance shall be informed and shall resolve.

Upon completion of the assessment, the lead assessor shall draft an Assessment Report using the <u>Assessment Report Template</u>. The Report shall include the following information:

- Date(s) of assessment
- Area assessed (name of line organization, management system, process, etc.)
- Assessment team with roles identified (lead, assessor, observer, mentor)
- List of interviewees
- Assessment type
- Scope
- Criteria
- Interviews – short synopsis of any interviews that took place, if applicable
- Report – summary of what took place during the assessment
- Results – description of items identified
    - Nonconformance (NC)
    - Management Concern (MC)
    - Recommendation
    - Opportunity for Improvement (OFI)
    - Best Practice
    - Lessons Learned (LL)
- List of documents reviewed

The lead assessor shall distribute the <u>draft</u> Report to interviewees for review and comment. Typically, the lead assessor would allow two weeks for review and comment.

The lead assessor shall also discuss the specific findings from the assessment activity (OFIs, NCs, MCs, etc.) with those to whom the items may be assigned or stakeholders of areas that will be impacted. This discussion should occur **prior** to entering the items into iTrack to ensure that there is adequate awareness of the identified items, that the appropriate responsible parties have been identified, and corrective action planning can commence (this is especially important for NCs and MCs). Once adequate awareness has been made and consensus on the path forward has been met, then the items shall be entered into iTrack and managed through resolution (see Section 5.2.6).

If there are dissenting opinions, the Head of the Office of Quality Assurance shall be informed and shall resolve.

5.2.5 Distribute Report

After obtaining agreement from interviewees on the assessment results and making the necessary changes, the lead assessor shall distribute the Assessment Report to all management

of the assessed area, interviewees, the assessment team, and other stakeholders as determined by management. The results shall also be shared with the Quality Assurance Liaison so lessons learned, issues found, and other best practices can be shared more broadly.

5.2.6   Enter Items into iTrack

The lead assessor (or designated iTrack data entry individual) shall enter all nonconformances, management concerns, opportunities for improvement, best practices, and lessons learned (defined in Appendix A) into iTrack and assign each an owner (see   Fermilab Quality Tool Suite User Guide). The owner (the responsible party) 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 & Preventative Action Procedure (see QAM 12040).

5.2.7   Manage Records

All records generated during the assessment, including the Assessment Plan, Communication Memo, and Assessment Final Report, shall be uploaded to FQTS to the Assessment database or the related iTrack review. See Fermilab Quality Tool Suite User Guide or QAM 12030 for additional information on how to upload the documents.

5.3   Conducting Independent (External) Assessments

5.3.1   Planning

The external team will plan the assessment activities. They should notify the Fermilab contact or representative of the topic, scope, schedule, and purpose of the assessment. The Fermilab contact shall confirm this information is entered in the Assessment database in FQTS.

5.3.2   Conduct the Independent Assessment

The external team will conduct their independent assessment according to their plan and schedule. The team may interview personnel, request documentation and records, and observe activities.

5.3.3   Document Results

The lead reviewer of the external team will share the results of the assessment with the Fermilab contact or representative and other relevant personnel.

5.3.4   Enter Items In iTrack

The Fermilab contact or representative for the external assessment is responsible for identifying owners of the identified issues. The owners are responsible for delegating responses to appropriate responsible parties and determining due dates for addressing the items. The Fermilab contact or representative is responsible for seeing that all items are entered in iTrack.

5.3.5   Communication

The Fermilab contact or representative for the external assessment shall communicate the final report and items with stakeholders and interested parties upon completion."

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5.4 Conducting Inspections, Walkthroughs, and Management Field Observations

5.4.1 Planning
See Fermilab Worker Safety & Health Program for requirements.
Designated personnel shall direct the activities of the inspection or walkthrough and 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 Program, " FESHM Chapter 7005 "Facility Construction, Modification & Inspection," FESHM Chapter 9100 "Fermilab Electrical Safety Program" for details.

5.4.2 Conduct Inspections, Walkthroughs, or Field Observations
The inspection or walkthrough is conducted according to the plan and schedule. Personnel obtain the documentation and evidence necessary to verify compliance to ES&H, Security, 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

During an inspection or walkthrough, results are captured in Predictive Solutions, a database used by ES&H team members to capture observations in the field for construction safety and facility safety. Issues categorized as "critical" shall be entered into iTrack.

5.4.3 Document Results
The personnel performing the inspection shall log any documents or records reviewed, list all personnel interviewed, and document any nonconformances, management concerns, recommendations, opportunities for improvement, best practices or lessons learned found during the inspection.

5.4.4 Enter Items In iTrack
Issues categorized as "critical" in Predictive Solutions shall be entered into iTrack by the personnel conducting the inspection/walkthrough and assigned an owner. (See Fermilab Quality Tool Suite User Guide). 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).

5.5 Assessment of Corrective and Preventive Actions

5.5.1 Effectiveness Reviews
a. The Responsible Party (RP) for a nonconformance or management concern will name an Effectiveness Reviewer when closing a Corrective Action Plan (CAP). The Effectiveness Reviewer should be someone from the RP's organization who has familiarity with the process but is unaffiliated with the CAP. iTrack will send the Effectiveness Reviewer a notification email 90 days after the item is closed.

The email will contain a link to the iTrack Effectiveness Review's webpage where the results of the effectiveness review shall be entered. See <u>QAM 12030</u> "Fermilab Quality Tool Suite Procedures and Risk Assignment" for additional information.

b. Causal Analysis and RCA methods - The Office of Quality Assurance will review a sample of the causal analysis and root cause methods recorded in iTrack for closed CAPs related to Nonconformances and Management Concerns. The database will tally the number of methods identified in iTrack for closed Nonconformance and Management Concern-related CAPS and apply programmed logic to determine when the system will notify the Office of Quality Assurance that a causal analysis is available for review. Using their skills and expertise, a member of the Office of Quality Assurance will evaluate the use of the method and the outcome to confirm the method and analysis were effective in getting to the root cause.

5.5.2 Outcome of Effectiveness Reviews

a. Disposition of the original executed corrective/preventive action plan is determined based on the review and may result in one of the following outcomes:
- Corrective/preventive action plan implementation was **effective**. No further action is necessary.
- Corrective/preventive action plan implementation was **not effective**. If this is the case, the item shall be reopened in iTrack, the owner of the item shall be contacted, and a new corrective action plan shall be developed. *Actions identified as **not effective** may serve as inputs to consider in future assessments.*

b. Causal Analysis and root cause methods outcome
- If the method and analysis were deemed to be adequate, the Office of Quality Assurance will record this in iTrack and close this effectiveness review of the causal analysis and root cause methods.
- If the method and analysis require a follow up, a member of the Office of Quality Assurance will record this in iTrack, and the database will notify the Responsible Party that further action with the Causal analysis or method is required.
- After a satisfactory resolution has been determined, the Office of Quality Assurance will record this in iTrack, and the effectiveness review of the causal analysis and root cause methods will be closed.

6.0   REFERENCES

<u>Assessment Plan Database</u>
<u>Templates</u>
- <u>Communication Memo Template</u>
- <u>Planning Template</u>
- <u>Assessment Report Template</u>
- <u>Charge memo for an assessment Template</u>

<u>DOE Order 227.1A - *Independent Oversight Program*</u>
<u>Fermilab Quality Tool Suite User Guide</u>

Fermilab Worker Safety & Health Program
FESHM 6015 – *Highly Protected Risk Inspection Program*
FESHM Chapter 7005 – Facility Construction, Modification, & Inspection
FESHM Chapter 9100 – *Fermilab Electrical Safety Program (Work Smarts Standard)*
Internal Assessor Training Matrix
Internal Assessor Training Course FN000557
iTrack Database
Predictive Solutions - Safety Procedures
QAM 12030 – *Fermilab Quality Tool Suite Procedures and Risk Assignment*
QAM 12040 - *Corrective and Preventive Actions*

7.0   APPENDIX A – Assessment Activity Terminology

Appraisal –An Independent Oversight activity conducted by the Office of Enterprise Assessments to evaluate the effectiveness of line management performance and risk management or the adequacy of DOE policies and requirements. Fermilab identifies appraisals as EAs.

Criteria – The standards or requirements from policies or procedures that the assessment will be based on.

Department of Energy (DOE) Headquarters Reviews – Reviews conducted by DOE organizations at the headquarters level (e.g., Office of Science). Methods for conducting these reviews and the response to any corrective or preventive actions that result are established by the sponsoring Office.

EA – Office of Enterprise Assessments. The acronym is also used for the appraisal activity that the EA conducts.

Inspection/Walkthrough – An examination of a work area for the purposes of determining compliance to a specified requirement or standard. These usually result in simple corrections or remedial actions for identified items although corrective actions may result from these activities.

Interviewee – A person who will be interviewed during the assessment.

Item Types
>   **Best Practice** – A positive example of a work process or innovative approach with the potential to be the basis for significant operational improvements or cost savings.
>
>   **Lessons Learned** – A best practice that is captured and shared to promote repeat application, or an adverse work practice or experience that is captured and shared to prevent recurrence.
>
>   **Management Concern** – An issue management has identified that requires action to mitigate associated risk. Requires performance of a risk analysis, identification of a root cause and method used, and identification of corrective or preventive actions.
>
>   Requirements in iTrack:
>   - Perform Risk Analysis

- Identify root cause (through Causal Analysis or HPI)
- Identify root cause analysis method(s) used
- Corrective or Preventive Actions identified
- Effectiveness Review of Corrective or Preventive Action

Non-Conformance – The nonfulfillment of a specified requirement. A nonconformance can be found in a service, product, process, from a supplier, policy, or system. The specified requirements can be identified from a regulatory body or internal policy or procedure. Requires performance of a risk analysis, identification of a root cause and method used, and identification of corrective or preventive actions.
Requirements in iTrack:
- Perform Risk Analysis
- Identify root cause (through Causal Analysis or HPI)
- Identify root cause analysis method(s) used
- Corrective or Preventive Actions identified
- Effectiveness Review of Corrective or Preventive Action

Opportunity for Improvement – Suggestions on how to improve the identified topic.

Requirements in iTrack:
- Response is required
- Risk Analysis is Optional
- Causal Analysis is not required.

Recommendation – A suggestion or proposal from the Reviewer as to the best course of action to take on the identified topic. *This term is reserved for DOE or Project Reviews.*

Requirements in iTrack:
- Response
- Risk Analysis is optional
- Causal Analysis is not required.

Line of Inquiry (LOI) – An ordering of questions to gain an understanding of the process or system.

QA Assessment – A system or program-level independent assessment conducted in various areas within the Line Management organizations and MSOs by the Office of Quality Assurance. Their purpose is to evaluate process or system implementation and effectiveness and ultimately drive improvement.

Qualifications – The required training, experience, or expertise to participate on an assessment team.
    Assessor - Completion of the Office of Quality Assurance's *Internal Assessor* training <u>and</u> prior assessment shadowing (participation in two or more assessments) or experience or subject matter expertise. Assessors participating in **Independent** assessments must be technically qualified.

Lead Assessor – Completion of the Office of Quality Assurance's *Internal Assessor* training module and the *Lead Assessor Training* module (in TRAIN), prior assessment experience, professional certification or training, prior qualifications (as determined by Office of Quality Assurance). If professional certification or prior qualifications are not held, an alternative method to become a lead assessor is to participate in 3 or more assessments within a 3-year period with a designated mentor. (See **Lead-in-Training** below.)

To maintain the lead assessor designation, the employee must lead one assessment within a two-year period. If this is not achieved, the designation will revert to "Assessor." To obtain lead assessor status again, the employee is required to retake the *Lead Assessor Training* module and lead another assessment within a two-year period.

Lead- in-Training – An experienced assessor who has not yet qualified to be a lead assessor and is leading an assessment with a mentor. After the lead-in-training has satisfactorily completed 3 assessments as the lead-in-training with their designated assessment mentor on the team, they will be added to the list of lead assessors in the Assessor database in FQTS.

Mentor – A qualified lead assessor who has completed 5 or more assessments <u>and</u> has been recognized by the Head of the Office of Quality Assurance as someone who will expertly advise and train assessors.

Observer – Completion of IA training.

Objective – The goal of the assessment. Answers the question: why is this value added to the Laboratory?

Plan – Description of the activities (e.g., schedule, interviewees, LOIs) of an assessment.

Scope – The extent and boundaries of an assessment.

Third Party Audits/Assessment – Audit or assessment performed on the organization by agencies external to Fermilab.

Triennial ES&H (Environment, Safety & Health) Assessment – Assessment whose purpose is to determine if the Laboratory complies with a specific DOE Order or contract requirement. Conducted on a three-year cycle.

Tripartite Assessment – A major component of Fermilab's Quality assessment program. The Tripartite assessment is planned and performed jointly by a D/S, the ES&H Section, and DOE-FSO and led by a member of the organization being assessed.

8.0 APPENDIX B – Assessment Checklist

Task	Responsibility	Complete
1. Select Assessment Team. Schedule team kick-off meeting.	Lead Assessor or Lead-in-training(LIT) with mentor	☐
2. At meeting, create Assessment plan and, if necessary, draft a Communication Memo. *(Use Memo and Plan Templates.)*	Assessment Team	☐
3. Distribute Communication Memo notifying assessed area management, interviewees, assessment team and other stakeholders of assessment.	Lead Assessor or LIT with mentor	☐
4. Distribute final plan to team.	Lead Assessor or LIT with mentor	☐
5. Conduct assessment.	Assessment Team	☐
6. Draft report and send out to interviewees for factual accuracy. Incorporate comments as necessary. (*Use Report Template.)*	Assessment Team	☐
7. Create a Review record in iTrack to enter items. Assign responsible parties.	Lead Assessor/delegate or LIT with mentor	☐
Distribute final report to assessed area management, interviewees, team, Office of Quality Assurance, and other stakeholders.	Lead Assessor	☐
Upload all assessment documents to FQTS.	Lead Assessor or LIT with mentor	☐
8. Conduct closeout meeting with management of assessed area if necessary.	Lead Assessor or LIT with mentor	☐

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