

## QAM 12080: Fermilab Assessment Program

### Revision History

Author	Description of Change	Revision Date
Mary Curtis	<ul style="list-style-type: none"><li>Added instruction to upload reports directly into appropriate database (Section 5.2.7 and Checklist in Appendix B)</li></ul>	January 2021
Mary Curtis	<ul style="list-style-type: none"><li>Updated document to reference new database, Fermilab Quality Tool Suite, and changes to assessor program.</li></ul>	August 2020
Mary Curtis	<ul style="list-style-type: none"><li>Updated to reflect changes to QAM 12002.</li><li>Enhance definition of "Recommendation."</li></ul>	September 2019
Kathy Vuletich	<ul style="list-style-type: none"><li>Removed reference to iTrack item type "Finding." This term is identical to a "Non-conformity" and is no longer used in iTrack.</li><li>New requirement - Assessors take Internal Assessor Training.</li><li>Added self-assessment criteria for MSOs.</li><li>Added Effectiveness Reviews by responsible parties.</li></ul>	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	<ul style="list-style-type: none"><li>Added verbiage to some of the terms in the acronyms &amp; definitions section to enhance robustness</li><li>Statements of clarification added to the responsibilities section (no change in responsibilities)</li><li>ESH&amp;Q Section Head to Assistant Director for ESH&amp;Q</li></ul>	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 aligns with requirements set in DOE O 414.1D and consists of Independent Assessments and Management Assessments at both the Laboratory and functional levels. Assessment topics are identified and planned by Fermilab employees. 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 and 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

**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 actions adequately address the problem.

**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 Quality Tool Suite (FQTS)** – A system that contains three interrelated databases: iTrack, Lessons Learned and Assessment Schedule.

**Independent Assessment** – An assessment conducted by external or internal parties unrelated to the work or processes being evaluated.

**Item** – A non-conformance, management concern, opportunity for improvement, recommendation, best practice, or lesson learned that is the output of an assessment and tracked in iTrack.

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**iTrack** – (Issues Management Tracking System) A database used to document and facilitate the resolution of items of any nature arising from formalized activities where reports are typically generated.

**Lead Assessor** – A member of the assessment team who organizes and manages assessment activities including team selection, schedule, interviews, interviewees, lines of inquiry and final report. The lead assessor may delegate to assessment team members.

**Lead-in-Training** – A member of the assessment team who is acting in the role of lead but has not met the requirements of a lead assessor. See Appendix A for requirements.

**Management Assessment** – An assessment performed by an organization on its own processes and programs. (May be a Self-assessment, Triennial ES&H assessment, FESHCom Subcommittee assessment, Tripartite assessment, Management Field Observation, or ES&H Inspection and Walkthrough.)

**Mentor** – A member of the assessment team who guides the Lead-in-Training.

**Observer** – A member of the assessment team who does not have an active role in the assessment but may provide their observations of the assessed area to the other members of the team.

**Preventive Action** - A proactive action taken to eliminate the cause of a potential nonconformance or another undesirable situation.

*Note: There can be more than one cause for a potential nonconformance. Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.*

**Review** – An iTrack-designated term for activities that generate items. An **assessment** is a type of review in iTrack.

**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**)

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### 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.
- 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 assessment results (items) are entered into iTrack database and assessment records are sent to Quality Section for entry into Directorate DocDB. Ensures items are tracked to completion and properly closed.

#### 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 Quality Section Head. This rolling three-year assessment Plan shall include both independent and management assessment activities with at least one Management assessment per year and at least one independent external assessment per three-year cycle.
- Advises Quality Section 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.
- 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 assessment results (items) are entered into iTrack database and assessment records are sent to Quality Section for entry into Directorate DocDB. Ensures items are tracked to completion and properly closed.

### 3.3 Quality Section Head

*These responsibilities may be delegated to other members of the Quality Section as deemed necessary.*

- Provides support to management within the scope of this procedure.
- Coordinates yearly Tripartite assessment, Management assessment, and QA assessment planning.
- 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).

### 3.4 Lead Assessor (see Appendix A for qualifications)

- Ensures compliance with this procedure.
- Completes Internal 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 (if necessary).
- Creates assessment plan and schedule with assessment team.
- Conducts optional opening and closing meetings with management, interviewees, and assessment team. Conducts assessment.
- 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 Quality Section and entering the items identified to iTrack (refer to QAM 12030).
- Responsible for mentoring assessors to be lead assessors as requested by the Quality Section Head.

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### 3.5 Assessment Team Member (Assessor, Lead, Lead-in-Training, Mentor)

(see Appendix A for qualifications)

- Ensures compliance with this procedure.
- Completes Internal Assessor Training – FN000557 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
  - Lead – manages the overall assessment, from planning to final report.
  - Lead-in-Training – manages the assessment with a Mentor’s guidance.
  - Mentor – 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 Observer. This function does not play an active role in assessment activities but may share relevant observations with the other members of the team.*

### 3.6 Quality Section 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.

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#### 4.1 Independent Assessments

Independent Assessments are conducted by external organizations, third parties (e.g., DOE or registrar), or internal Fermilab organizations with responsibilities outside of the assessed area. These assessments complement the Management assessments conducted by Line Management and MSO personnel. The Quality Section 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.** Coordination of external independent assessments is performed by management of the assessed organization with support from the Quality Section as requested or required. ES&H and the Quality Section 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 Assurance Council. All completed Management System Management assessments shall be reported and communicated, and corrective actions tracked per procedures listed in this document.

### 4.3 Other Management Assessments

#### 4.3.1 Triennial ES&H Assessments

Certain federal regulations, such as 10CFR835 “Occupational Radiation Program,” mandate program reviews on a triennial basis (i.e., every three years). These reviews 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. 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 Fermilab’s Worker Safety & Health Program.

#### 4.3.5.1. OSHA-style Inspections

The frequency of OSHA-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 [Chapter 6015](#), "Highly Protected Risk Inspection Program," explains the program in detail. For efficiency, line managers and FSO are encouraged to participate.

## 5.0 PROCEDURES

This section details the procedures for the Internal Assessment Program, from preparing the annual Assessment Plan through conducting the assessment and documenting the results. Appendix A contains definitions of assessment activity terms and Appendix B contains an Assessment Checklist for reference when conducting an assessment.

### 5.1 Fermilab Annual Assessment Plan

#### 5.1.1 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 Quality Section who shall add them to the Assessment Schedule in FQTS.

##### 5.1.1.1 Independent (External) Assessments

Independent external assessments are those conducted by entities outside of Fermilab, such as: DOE, third party assessors, other industry experts, or peer reviewers. MSOs shall schedule at least one independent external assessment

every three-year cycle and notify the Quality Section who shall add it to the Assessment Schedule in FQTS.

#### **5.1.1.2 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.

QA Assessments are determined using risk-based planning by the Quality Section with agreement from Line Management/MSOs. Risk-based planning shall consider the following inputs:

- Reorganization of line organization.
- 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**.)

#### **5.1.2 Management Assessments (Self-Assessments)**

Line Management shall schedule Management assessments each fiscal year and document them in the FQTS Assessment Plan.

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

Management shall determine Management 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 Tripartite Assessment

The Quality Section Head shall schedule and lead a planning meeting every year with representatives from DOE-FSO, 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 Assessment Plan database and communicated to DOE-FSO, D/S ES&H representatives, DSOs,. Changes to the Tripartite Assessment Schedule shall be agreed upon by all three entities. Final assessment reports shall be made available on the ES&H DocDB website.

## 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 shall 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 forward it to the Quality Section for entry into Directorate DocDB.

At the same time, if necessary, 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 forwarded to the Quality Section for entry into Directorate DocDB.

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 Quality Section Head shall be informed and shall resolve.

Upon completion of the assessment, the lead assessor shall draft an Assessment Report using the Assessment Report Template. 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)
- 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
  - Management Concern
  - Recommendation
  - Opportunity for Improvement
  - Best Practice
  - Lessons Learned
- List of documents reviewed

The lead assessor shall distribute the draft Report to interviewees for review and comment. If there are dissenting opinions, the Quality Section Head 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 Section 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 Report, shall be entered to iTrack by uploading the document(s) directly to the Review. See Fermilab Quality Tool Suite User Guide or QAM 12030 for additional information on how to upload the documents. .

## 5.3 Conducting Inspections, Walkthroughs, and Management Field Observations

### 5.3.1. 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.

### 5.3.2 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 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.

### 5.3.3. 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.

### 5.3.4. 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).

## 5.4 Assessment of Corrective and Preventive Actions

### 5.4.1 Effectiveness Reviews

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 [QAM 12030](#) "Fermilab Quality Tool Suite Procedures and Risk Assignment" for additional information.

### 5.4.2 Outcome of an Effectiveness Review

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.*

## 6.0 REFERENCES

[Assessment Plan Database](#)

[Communication Memo Template](#)

[Planning Template](#)

[Assessment Report Template](#)

[Fermilab Quality Tool Suite User Guide](#)

[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](#)

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[QAM 12030](#) – Fermilab Quality Tool Suite Procedures and Risk Assignment

[QAM 12040](#) - Corrective and Preventive Actions

## 7.0 APPENDIX A – Assessment Activity Terminology

**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.

**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 identification of corrective or preventive actions.

**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 identification of corrective or preventive actions.

Requirements in iTrack:

- Perform Risk Analysis
- Identify root cause (through Causal Analysis or HPI)
- Corrective or Preventive Actions identified

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

Requirements in iTrack:

- Response is required
- Risk Analysis is Optional
- Does not require a root cause to be identified

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

Requirements in iTrack:

- Response is required
- Risk Analysis is Optional
- Does not require a root cause be identified

**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 Quality Section. 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 IA training and prior assessment shadowing (participation in two or more assessments) or experience or subject matter expertise.

**Lead Assessor** - Completion of IA training, prior assessment experience, professional certification or training, prior qualifications (as determined by Quality Section). 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 and with a qualified lead assessor as a mentor.

**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 with a mentor on the team, he/she 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 and has been recognized by the Quality Section Head as someone who will expertly advise and train assessors.

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**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	<input type="checkbox"/>
2. At meeting, create Assessment plan and, if necessary, draft a Communication Memo. ( <i>Use Memo and Plan Templates.</i> )	Assessment Team	<input type="checkbox"/>
3. Distribute Communication Memo notifying assessed area management, interviewees, assessment team and other stakeholders of assessment.	Lead Assessor	<input type="checkbox"/>
4. Distribute final plan to team.	Lead Assessor	<input type="checkbox"/>
5. Conduct assessment.	Assessment Team	<input type="checkbox"/>
6. Draft report and send out to interviewees for factual accuracy. Incorporate comments as necessary. ( <i>Use Report Template.</i> )	Assessment Team	<input type="checkbox"/>
7. Enter items into iTrack and assign responsible parties.	Lead Assessor/delegate	<input type="checkbox"/>
8. Distribute final report to assessed area management, interviewees, team, Quality Section, and other stakeholders.	Lead Assessor	<input type="checkbox"/>
9. Upload all assessment documents into FQTS.	Lead Assessor	<input type="checkbox"/>
10. Conduct closeout meeting with management of assessed area if necessary.	Lead Assessor	<input type="checkbox"/>