QAM 12030: FERMILAB QUALITY TOOL SUITE PROCEDURES AND RISK ASSIGNMENT

Revision History

Author	Description of Change	Revision Date
Mary Curtis	Add access instructions for Federated Users.	December 2022
Mary Curtis	Added requirement about recording Root Cause Analysis method and reviewing a sample for effectiveness. Added new timeframe requirement for entering CAPs for specific item types.	February 2022
Mary Curtis	Added requirement to upload report to the appropriate database such as iTrack or Lessons Learned (Section 5.3.1) Updated definitions to align with those in QAM Chapter 12080. Added Section 9, *Guidance for selecting Item Category*	January 2021
Mary Curtis	Procedure updated to include requirements for Effectiveness Reviewer assignment.	August 2020
Mary Curtis	Procedure updated to reflect changes to iTrack. The changes include moving it to a different platform (Apex) and incorporating the Lessons Learned database. The system was renamed "Fermilab Quality Tool Suite" since it includes iTrack, Lessons Learned, and the Assessment Plan.	July 2020
Jemila Adetunji Kathy Vuletich T.J. Sarlina	1. Procedure updated to reflect upgrades to iTrack including a new Effectiveness Review process completed by responsible parties, and the incorporation of an Escalation Process. 2. Procedure also updated to reflect the change in how ES&H Walkthroughs/Inspections, like HPR inspections, are captured in iTrack. 3. Removed iTrack Item Type "Finding" in order to streamline the process within iTrack.	September 2017
Jemila Adetunji Kathy Vuletich	Procedure updated to reflect upgrades to the iTrack system, updated risk assignment tables, and clarification of iTrack usage.	January 2015
Rafael Coll	This chapter combines and cancels FESHM 1010.2 & 1010.3 and replaces frESHTRK with iTrack as the sole issues management system for Fermilab.	November 2013

TABLE OF CONTENTS

Fermilab Quality Assurance Manual   12030-2

*WARNING: This manual is subject to change. The current version is maintained on the Office of Quality Assurance website.*Rev. 12/2022

1.0   INTRODUCTION

Fermilab Quality Tool Suite is a compilation of three databases used to document and track issues identified (iTrack), Lessons Learned (Lessons Learned), and Fermilab's Assessment plan (Assessment Database). The iTrack database facilitates the resolution of items arising from formalized activities where reports are typically generated, however, informal assessments are also entered into iTrack for record and management. The Lessons Learned database provides a repository for internal or external Lessons Learned. The Assessment database maintains the current schedule of planned assessments across the lab. The Lessons Learned and Assessment databases, along with the HPI database, are integrated with iTrack in FQTS and easily accessed from the navigation bar. This integration provides the user a seamless transition between the different data.

Issues Management is a vital component of the Fermilab Quality Assurance Program. Effectively managing issues prevents the recurrence of problems and minimizes the impact of similar problems which may occur. Issues may arise from incidents, injuries, events, unwanted outcomes, or near misses, or proactively from inspection activities, assessments, audits, and review activities. Issues may range in complexity, severity, and impact; therefore, it is imperative that issues are effectively managed to identify the appropriate level of management and action. The laboratory has many ways to address issues via formal or informal investigations, HPI Reviews, or various root cause/causal analyses techniques. Regardless of the way selected, the expectation is for these issues to be properly managed where iTrack is used to facilitate the resolution of issues that are not easily resolved or cannot be addressed quickly. The Issues Management Lifecycle consists of the following elements:

- The issue is identified or detected.
- The appropriate risk level/significance is assigned.
- Causal analysis is performed to identify causal factors.
- The appropriate assignment of the issue is done to ensure resolution is adequately prioritized.
- Corrective/Preventive Action Planning is performed to ensure plans are identified to address the causal factors identified via the causal analysis.
- Corrective/Preventive Action Plan implementation is done to ensure the plans identified are effectively implemented in a timely manner.
- The Effectiveness Review is performed to determine whether the implementation of the plan will prevent recurrence or occurrence in another area.

Experience has shown that items found cannot all be rapidly and completely addressed using available resources; therefore, it is prudent first to address those presenting the greatest risk. This chapter describes the uses for iTrack and Lessons Learned, the procedures for using each, the procedures to determine effectiveness of implemented corrective actions with iTrack, and the procedures for assigning risk values to items entered into iTrack. This chapter does not cover the Assessment Plan aspect of the Fermilab Quality Tool Suite, see QAM Chapter 12080 – Fermilab Assessment Program. This chapter follows Fermilab's Quality Policy.

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.

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.

Hazard Severity – An assessment of the potential consequences, defined by degree of injury, occupational illness, environmental impact, property damage, or project impact that is likely to occur as the result of a deficiency. This determination is subjective in nature.

Item - A nonconformance, management concern, opportunity for improvement, recommendation, best practice, or lesson learned that is the output of an assessment or other review activity and tracked in iTrack. (See section 4.1 for individual item definitions.)

Lesson Learned (LL) – 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.

Lesson Learned Report – In the LL database, the record for capturing an LL that was not discovered as part of a planned activity.

Mishap Probability – The probability that a hazard will result in an incident based on an assessment of such factors as location, exposure, and affected population. The determination is subjective in nature.

Preventive Action – A proactive action taken to eliminate the cause of a potential nonconformance or other undesirable potential 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 – In iTrack, an activity that has the potential to generate an item.

Risk Assessment Code – The degree of risk associated with a deficiency that combines the elements of hazard severity and mishap probability.

Root Cause – An identified reason for the presence of a defect or problem. The most basic reason which, if eliminated, would prevent recurrence. The source or origin of an event. There may be more than one root cause for an event.

3.0   RESPONSIBILITIES

3.1   Office of Quality Assurance Head
- Manages the Fermilab Quality Tool Suite databases and provides training for its use.
- Ensures the results of assessments conducted by external organizations are entered.
- Performs periodic review of the contents of iTrack to check on the appropriateness and status of follow-up actions and to identify trends and lessons learned.
- Reviews periodic trending and analyses to determine if associated programs need to be redirected, to verify that root causes are being adequately addressed, and lessons learned generated.
- Ensures that the effectiveness of implemented corrective and preventive actions is reviewed and documented within iTrack.
- Verifies that all Items with a Risk Code of 1 or 2 have their corrective or preventive actions verified within 90 days of reported closure.
- Ensures that 10% of non-ES&H Items with a Risk Code of 3 have their corrective or preventive actions verified on a quarterly basis via iTrack processes.
- Identifies where issues management related training may be necessary.

3.2   Line Management (Chiefs, Division/Section/Department Heads, Supervisors, Group Leads, Project Heads, Management System Owners)
- Ensures results of internal and external assessments or reviews, reviews using Human Performance Improvement (HPI) principles, , project-specific reviews, and Tripartites, including all nonconformances, management concerns, opportunities for improvement, recommendations, best practices (open and closed), and LL are entered into iTrack.
- Ensures the appropriate responsible parties are identified in iTrack to address the issue in a timely manner.
- Ensures timely implementation of corrective or preventive actions for issues and their closure in iTrack.
- Periodically reviews the contents of iTrack to check on the appropriateness and status of follow-up actions, and to identify trends.
- Ensures effectiveness of implemented corrective or preventive actions.
- Proactively follows up on iTrack notifications received highlighting items assigned to individuals in their organization or relating to their Management System.

3.3   Division Safety Officers (DSO)
- Ensure execution of the Verification Process detailed in section 5.3.11.

3.4   Effectiveness Reviewer

- Conducts the effectiveness review for a closed Corrective Action Plans (CAPs) for nonconformances and management concerns.
- Engages the iTrack assigned responsible party of the respective causal analyses and corrective actions plans when necessary.

3.5   iTrack Assigned Responsible Parties

- Conducts causal analyses where required and when appropriate.
- Ensures adequate corrective action plans are identified in a timely manner to address the issue. This may require consultation from management, stakeholders, or subject matter experts.
- Ensures assigned items in iTrack are addressed appropriately, including providing detailed information of actions taken or decisions made, and provide evidence where applicable.
- Assigns the responsibility of the Effectiveness Review to another party.
- Provides sufficient awareness to their management and other stakeholders when there are issues or roadblocks to implementing a corrective action plan in a timely manner.

3.6   Quality Assurance Liaison (QAL)

- Assists Division/Section/Projects (D/S/P) by monitoring open items in iTrack, assisting with causal analysis and item resolution if necessary, and escalating overdue items.
- Actively reviews iTrack metrics and identifies necessary actions to resolve negative trends in D/S/Ps.
- Reviews a sample of Root Cause Analyses identified by Responsible Parties in iTrack to determine if the causes of issues have been adequately determined.

3.7   Project Manager

- Reviews requests for iTrack access for Federated iTrack Users.
- Conducts due diligence when evaluating requests, considering the information the Federated User will have unfettered access to. All issues, investigations, action plans, lessons learned, assessments, and results currently managed in FQTS will be available to view. Thus, access should only be granted to individuals who have an established relationship with Fermilab and the associated Project.
- Grants access as appropriate.

4.0   PROGRAM DESCRIPTION

In the Fermilab Quality Tool Suite, iTrack and Lessons Learned are two databases that are used at Fermilab to support process performance, monitoring, and follow up of associated items regardless of discipline.

For consistency, iTrack calls activities that generate items "Reviews." "Item" refers to nonconformances, management concerns, recommendations, opportunities for improvement, best practices, and lessons learned that are the output of these Reviews. Lessons Learned Reviews differ from Lessons Learned Items in that the former is a Lessons Learned that has been identified on its

own and not as an Item in a broader activity. When a Lessons Learned is identified in this manner, the new Lessons Learned database is used to capture it as its own Review. A Lessons Learned Item type is generated from a formal activity such as an internal assessment and is captured as part of that Review in the iTrack database. Definitions and requirements for iTrack item types are listed below.

4.1   Item Type Definitions

<u>Nonconformance</u> - 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.
Requirements in iTrack:
- Risk Analysis
- Causal Analysis
- Record root cause method(s) used
- Corrective or Preventive Actions
- Effectiveness Review of Corrective or Preventive Action

<u>Management Concern</u> **-** An issue identified by management that requires action to mitigate associated risk.
Requirements in iTrack:
- Risk Analysis
- Causal Analysis
- Record root cause method(s) used
- Corrective or Preventive Actions
- Effectiveness Review of Corrective or Preventive Action

<u>Recommendation</u> **-** A suggestion or proposal from the Reviewer as to the best course of action to be taken on an identified issue.   *This term is reserved for DOE or Project-related Reviews.*
 Requirements in iTrack:
- Response
- Risk Analysis is optional.
- Does not require identification of the root cause.
- Verification may be required.

<u>Opportunity for Improvement</u> **-** Suggestions on how to improve the identified issue.
Requirements in iTrack:
- Response
- Risk Analysis is optional.
- Does not require identification of the root cause.

<u>Best Practice</u> **-** A positive example of a work process or innovative approach with the potential to be the basis for significant operational improvements or cost savings.
Requirement in iTrack:
- Record in iTrack for informational purposes only.

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.
Requirement in iTrack:

- Response and Preventive Actions Plans are optional.

5.0 PROCEDURES

5.1 iTrack database and LL database: Uses

5.1.1 Reviews and Items tracked in iTrack

iTrack is used to track items from reviews where reports are typically issued and can include the following. (For definitions of review types listed, see Appendix B.)

- DOE Activities
- Triennial assessments
- External Reviews (ISO/OHSAS, IEPA, USDOT, etc.)
- Incidents or Events (CAIRS, ORPS, Near Miss, etc.)
- Critical items and trends identified during Formal ES&H Inspections and Walkthroughs, such as HPR Inspections
- Planned Management Assessments (Quality, D/S/P, Tripartite, Management Systems, etc.)
- Fermilab Internal Reviews (Director's Reviews, FRA / CAS Reviews, Internal Audits, etc.)
- Projects managed by other institutions where Fermilab is a collaborator
- Project reviews conducted by DOE
- Laboratory program reviews conducted by DOE or other external body
- Lessons Learned (Depending on the source of the Lesson Learned, it may be entered in one of two ways: as a Lessons Learned Review or a Lessons Learned Item as part of a different Review type.) It is tracked in both iTrack and Lessons Learned databases.

5.1.2 Reports tracked in LL database

LL database is used to capture and share lessons learned from internal and external sources that are not part of a formal Review activity.

5.1.3 Reviews and Items NOT tracked in iTrack and LL databases

Items resulting from activities where information is sensitive, another formal process exists, or no formal reports are issued, and issues are tracked by individual organizational databases or spreadsheets. These may include:

- Fire Department inspections (extinguishers, fire hoses, etc.),
- Non-critical or routine items found during Formal ES&H Inspections and Walkthroughs, such as Construction Walkthroughs and Highly Protected Risk (HPR) Inspections (a separate ES&H database has been implemented that is

tracking non-critical items found during these types of walkthroughs and inspections that allows for better trending and analysis of this type of data),

- FESS inspections,
- Items corrected by work orders (emergency or exit lights not working, etc.),
- Routine equipment inspections (eyewash and showers, machinery, etc.),
- Action items or task lists from meetings,
- New employee orientation tours,
- Items found randomly while performing normal work activities. These items should be reported through the normal management chain,
- Personnel related issues such as attendance or annual reviews,
- Internal Audit or Financial Reviews where there is sensitive financial information. The Audit or Review information may be entered in iTrack but results are tracked in different databases because of the sensitive nature of these review types.

5.2   iTrack database and LL database: Users

iTrack and LL databases have 3 levels of user: Administrator, Data Entry User, Responsible Party/General User. Each level has unique privileges within the system.

5.2.1   Administrator

An Administrator in iTrack and LL ensures the system is operating properly for Data Entry and General Users.

- Ability to assign Data Entry rights to General Users Ability to enter and update reviews, reports, and items for any D/S/P or Management System
- Maintains nomenclature in Oracle Apex
- Maintains Oracle Apex iTrack data specific to:
  o   Action Plan/Response Types
  o   External Agencies
  o   Item Types
  o   Hazard Severities & Mishap Probability – Risk Code Map
  o   Project List
  o   Review Categories
  o   Unsafe Codes
- Maintains iTrack email distribution for
  o   High Risk Code notification
  o   Corrective Action Verification
  o   Effectiveness Reviews

5.2.2   Data Entry User

A Data Entry User has data entry privileges in iTrack and LL specific to their assigned organization. Some Data Entry Users may be assigned to multiple organizations (D/S/P or Management System). A Data Entry User is authorized to:

- View all open Reviews performed on their D/S/P or Management System
- Create Reviews

- Create LL reports
- Enter new Items
- Edit Reviews
- Edit Lessons Learned
- Edit items (including adding Responsible parties, causal analyses, root cause analysis methods, milestones, Corrective Action Plans)
- Close Items
- Run reports
- Query the database
- Extract data to Excel

5.2.3 Responsible Party/General User

A Responsible Party is someone who has been assigned responsibility for an Item in iTrack. They have limited privileges in iTrack that include:

- Query the database
- Extract data to Excel
- Responsible Party - delegate responsibility to other parties
- Responsible Party - create action plans and milestones, update, and close items assigned to them

5.2.4 Federated iTrack User

A Federated iTrack User is a scientific collaborator from a partner institution who has been assigned responsibility for an Item in iTrack. Before they can view or edit the information in the database, they are required to request and receive access.

Access Request

1. Go to https://www-esh.fnal.gov/pls/apex/f?p=127
2. Below the text "Please select an authentication system to verify your identity" select your external authority from the list provided.
3. Enter your credentials that are required by the system.

After gaining access to the Fermilab system, you will be directed to iTrack.

4. Complete the request form that appears, selecting applicable project(s).
5. Click "Submit Request."
6. The Fermilab iTrack Project Manager will receive an email with the request and conduct their due diligence when evaluating it, considering the information the Federated User will have unfettered access to. Access should only be granted to individuals who have an established relationship with Fermilab and the associated Project.
7. The Project Manager will either approve access or ask for additional information, recording the result on the form from the database.
8. Once approved, the Federated iTrack User will receive an email with instructions to log into iTrack.

After receiving access, the Federated iTrack User's privileges in iTrack will be the same as those of the Responsible Party/General User described in **Section 5.2.3**.

5.3 iTrack database and LL database: Procedures

Please refer to the *Fermilab Quality Tool Suite User Guide* which can be found on the Office of Quality Assurance Website or from the Fermilab Quality Tool Suite for detailed instructions on how to enter Reviews and Items into iTrack and create LL reports, descriptions of the data entry fields, and information on required and optional fields.

Note: Items that cross D/S/P organizational lines shall be negotiated with all applicable D/S/P line management in advance of entering data into iTrack.

There are 7 main Review Categories in iTrack:
- Assessments
- ES&H Activities
- External Reviews
- Incidents or Events
- Internal Laboratory Activities
- PEMP (Performance Evaluation and Measurement Plan)
- Project Activities

Who is responsible for iTrack entries, what action they will take, and how the action is communicated are described below.
- RESPONSIBLE: This is the person responsible for executing the step in iTrack.
- ACTION: Detailed actions taken by the responsible person to complete the step in iTrack.
- COMMUNICATION: Explanation of the automatic communication iTrack or LL sends when action has been taken, including the recipients.

Information for these three topics for each key record-creating step in iTrack or LL follows.

5.3.1 Review complete. Create a Review Record in iTrack.
a) RESPONSIBLE: Person or Organization that performed or sponsored the Review – **the Review Owner**.

b) ACTION: Gather the Review information and "Create a Review" in iTrack. This Review information includes:
- Review category, title, and description,
- Dates the Review occurred,
- Who led the Review and what was reviewed,
- Related documents or reports (Upload directly to the Review record in iTrack)

c) COMMUNICATION: Non

5.3.2   **Create a Lessons Learned Report**
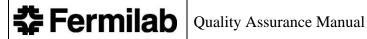There are two ways LLs are entered in the Fermilab Quality Tool Suite. One way is directly through the LL database.

a) RESPONSIBLE: The individual who identified the LL is responsible for creating the LL Review in the LL database of the Fermilab Quality Tool Suite.

b) ACTION: The Responsible Party completes the data entry requirements including but not limited to:
   •   Report title, originator/organization
   •   Management System
   •   Source of Lessons Learned
   •   Lesson Date
   •   Lessons Learned Topic and Work/Process Description

c) COMMUNICATION: The database will email the new LL information to subscribers.

Note: As part of the LL Review creation, iTrack will automatically create an LL **Item** in the LL Review.

The second way an LL can be entered into the Fermilab Quality Tool Suite is through the iTrack database when an LL is entered as an Item Type as part of a Review. (See section 5.3.3)

5.3.3   **Enter Items into iTrack**
a) RESPONSIBLE: Person or Organization that performed or sponsored the Review – the designated Data Entry User (identified in iTrack as the Review Owner).

b) ACTION: Items that are the output of the Review are entered into iTrack and assigned to the appropriate person responsible for resolving the Item – also known as the Responsible Party. Information in iTrack about the Items includes:
   •   Title and description of the Item
   •   Item type (see section 4.1 for definitions)
      o   Nonconformance
      o   Management Concern
      o   Opportunity for Improvement
      o   Recommendation – This term is restricted to DOE or Project-related reviews.
      o   Best Practice
      o   Lesson Learned

- Item Category – Select the category of the issue from the list iTrack provides. This is **not** the root cause of the item but a general category the issue falls under. For additional guidance see Technical Appendix C.
- Where and when the Item was found
- Risk associated with that Item if applicable (See section 4.1 for a list of Items this applies to, and Technical Appendix A for how to perform a Risk Analysis.)
- The associated Management System related to the Item.
- Responsible Party assigned to the Item
- Date found and Due date

c) COMMUNICATION: Responsible Party, CC direct manager, and CC Distribution List
- Once the Item has been submitted to iTrack, an email confirmation will be sent automatically to the Responsible Party, with CC to their direct Manager, and anyone listed in the Distribution List section of the data entry form.
- The Responsible Party, direct Manager, and the Distribution List will receive email notification of any updates made to the item including updated due dates.
- The email notification will also include instructions and references to help guide the Responsible Party in updating Items assigned to them.

5.3.4 Delegate Responsibility
a) RESPONSIBLE: Responsible Party assigned to the Item.

b) ACTION: The Responsible Party has 3 options to assign the action (delegate responsibility):
1. solely to one other person,
2. to multiple people, or
3. keep responsibility with themselves and not delegate responsibility.

c) COMMUNICATION: Any new Responsible Parties and their direct Managers will be sent an email notification notifying them of their newly assigned responsibility just as in step 5.3.3.

5.3.5 Determine Root Cause with Causal Analysis, if required.
a) RESPONSIBLE: Responsible Parties (and identified team to assist with the task if applicable - external to iTrack).

b) ACTION: **Nonconformances** and **Management Concerns** require a Causal Analysis to determine the actual root cause of the original issue found. See QAM 12050 – Root Cause Analysis for guidelines on how to complete this step.
- Choose the applicable HPI Causal Code, and
- Record the method chosen to determine the root cause.

Note: Identifying a cause and the method(s) used are required before the Item can be closed.

c) COMMUNICATION: None

5.3.6 Determine Corrective or Preventive Action Plan or Response
a) RESPONSIBLE: All Responsible Parties assigned to an item.

b) ACTION: Depending on the type of item entered, either an Action Plan or Response should be entered into iTrack. Each Responsible Party determines what Action Plan or Response is appropriate to resolve their portion of the item.
- **Nonconformances and Management Concerns**: CORRECTIVE or PREVENTIVE ACTION PLANS must be determined and entered into iTrack. This must be submitted within **15* days** of the item's creation.
- **Opportunities for Improvement or Recommendations:** A RESPONSE must be determined and entered into iTrack. The response for an OFI must be submitted within **30* days** of the item's creation.
- *Note: if the NC, MC, or OFI is a Risk Level 1 or 2, the CAP must be submitted within **10 days** of the item's creation.

c) COMMUNICATION: Responsible Party and direct manager
- The Responsible Party and their direct manager are automatically notified by iTrack that a new Action Plan or Response has been added in iTrack.
- If the CAP or Response has not been submitted within the required timeframe (see section 5.3.6.b), iTrack will remind the RP of the omission weekly until a CAP or Response is entered.

5.3.7 Complete and Close Action Plan or Response
a) RESPONSIBLE: All Responsible Parties assigned to an Item

b) ACTION: Responsible Parties complete all actions required and enter this information into iTrack.
- **Action Plans Only**: To close the Action Plan evidence of what actions were taken needs to be entered into iTrack. This can include brief descriptions of the actions taken and hyperlinks to completed documents of evidence.
- **Responses Only**: For responses, a justification response needs to be entered into iTrack on either what was done to respond to the Opportunity for Improvement (OFI) or Recommendation, or justify why the OFI or Recommendation will not be acted upon at this time
- **Nonconformances and Management Concerns**: Assign an Effectiveness Reviewer for the CAP. The Effectiveness Reviewer should be someone from the Responsible Party's organization who has familiarity with the process (including Subject Matter Experts) but is unaffiliated with the CAP. The

Quality Assurance Liaisons can assist with the selection of the Effectiveness Reviewer.

c) COMMUNICATION: Responsible Party and direct manager
   • Once the ACTION PLANS or RESPONSES have been closed in iTrack, the Responsible Party and direct Manager will receive an automatic notification email notifying them of the closure.
   • Once ALL ACTION PLANS/RESPONSES have been closed by ALL Responsible Parties associated with an item, personnel on the Distribution List of the original item will receive automatic email notification, including parties on the CC Distribution List.

5.3.8 Closing a Review or Lessons Learned Report

a) RESPONSIBLE: iTrack System

b) ACTION: The Review or LL review will automatically close after ALL Items have been closed. This includes any associated Corrective or Preventive Actions, Milestones, or Responses, and any Responsible Parties that were added in the hierarchy chain as an Approver.

c) COMMUNICATION: All Responsible Parties, direct managers, and participants listed on the Review Distribution List will be notified automatically via email that the Review is closed.

5.3.9 Effectiveness Review of Closed Items

Effectiveness reviews are required for closed CAPS of nonconformances and management concerns. iTrack will send an email to the Effectiveness Reviewer notifying them when the effectiveness review is due. The purpose of the effectiveness review is to determine if the actions taken effectively addressed the Item and root cause; or if further actions are necessary if the initial actions were found to be ineffective in resolving the Item and root cause.

a) RESPONSIBLE: The Effectiveness Reviewer assigned when the CAP is closed will conduct the effectiveness review on the causal analysis and the actions taken to address the Item. This shall be completed within 30 days.

b) ACTION: *FOR ACTION PLANS ONLY:* iTrack will send the Effectiveness Reviewer an email 90 days after the closure of the Item notifying them that an effectiveness review is required. The email will contain a link to the iTrack Effectiveness Review page where information of the effectiveness review will be entered. Evidence of the effectiveness review must be entered into the iTrack Effectiveness Review page.

Corrective actions are effective when the causal chain of events leading up to the problem are broken and remain broken. Degree of validation will be commensurate with complexity, risk, and cycle time associated with affected processes. Some actions may be validated formally by inspections, tests, reviews, surveillances, audits, or other assessments. Other issues may simply be monitored to ensure the ongoing effectiveness of the actions taken.

The effectiveness review will result in one of two outcomes:
- The effectiveness review found the actions taken effectively resolved the initial item and root cause. With this outcome, the Effectiveness Reviewer will update the iTrack Effectiveness Review page accordingly and no further actions are necessary.
- The effectiveness review found the actions taken did <u>not</u> effectively resolve the initial item and root cause, and the item Action Plan will be reopened. With this outcome, the Effectiveness Reviewer will update the iTrack Effectiveness Review page with an explanation why the actions taken were ineffective. iTrack will then automatically reopen the Action Plan and Item, and the Responsible Party will return to <u>section 5.3.6</u> to determine a modified Action Plan. The effectiveness review will re-open when the modified Action Plan is complete and closed in iTrack.

c) <u>COMMUNICATION</u>: 90 days after the Item has been closed in iTrack, the system generates an automatic email that is sent directly to the Effectiveness Reviewer. The email includes a link to the iTrack Effectiveness Review page. iTrack will generate a second automatic email alerting the Responsible Party and direct manager if the Item was reopened. The email includes a link to the reopened Item and details that a modified Action Plan needs to be established.

5.3.10 Escalation Process
a) <u>RESPONSIBLE</u>: iTrack

b) <u>ACTION</u>: Once a month the iTrack system sends emails to Responsible Parties alerting them of what Items they are required to address. An escalation process is added to these notification emails and CC's members of Fermilab's management team after due dates have passed.

c) <u>COMMUNICATION</u>: The list below details who receives on automatic iTrack emails based on how far beyond the due date the Item is.

- 1 MONTH past due: Responsible Party
- 2 MONTHS past due: Responsible Party + CC Direct Manager
- 3 MONTHS past due: Responsible Party + CC Direct Manager + CC Division Head

- 4 MONTHS past due: Responsible Party + CC Direct Manager + CC Division Head + CC Chief + CC Chief Operating Officer + CC Chief Safety Officer + CC Office of Quality Assurance Head

5.3.11 Verification Process

a) <u>RESPONSIBLE</u>: Office of Quality Assurance and Division Safety Officers (DSOs)

b) <u>ACTION</u>: Once per quarter, iTrack generates mandatory verification reviews for Items assigned a Risk Code of 1 (Critical) or 2 (Serious) and randomly selects samples for verification review. Verification reviews ONLY occur for closed NONCONFORMANCES. Risk Code 1 and 2 Nonconformances are verified at 100%, and risk code 3 is verified from the sample set at 10%. The Items are reviewed to determine whether the actions taken to resolve the original issue are *effective* or *ineffective*.

<u>Effective</u> – the corrective actions taken have been deemed sufficient to address the corresponding issue and no occurrences have taken place since original issue.

<u>Ineffective</u> – corrective actions taken are deemed insufficient to address the issues; there has been a recurrence or there is a perceived need for additional improvement.

Office of Quality Assurance Verification Steps
The Office of Quality Assurance verifies Nonconformances from the following Review categories in iTrack.
1. Project Activities
2. External Reviews
3. Internal Laboratory Activities
4. Assessments

- The Office of Quality Assurance will receive a reminder email from iTrack that random Moderate (risk code 3) item samples have been selected for verification, and all Critical (risk code 1) and Serious (risk code 2) items require verification.
- They will verify the samples to ensure all actions taken were effective. These actions can include follow-up with the original Responsible Parties to determine if actions were adequate, and review of evidence provided.
- A determination will be made as to whether the nonconformance was closed adequately.
- The item verification determination is updated in iTrack to show that the actions taken were either effective or ineffective, and justification text for both scenarios shall be included.
- If any Item's actions are found to be ineffective, the Item can be re-opened so that further actions can be taken to resolve the issue.

DSO Verification Steps
DSOs verify Nonconformances from the following review categories in iTrack.
1. ES&H Activities
2. Incidents or Events

- The DSO will receive a reminder email from iTrack that random Moderate (risk code 3) item samples have been selected for verification, and all Critical (risk code 1) and Serious (risk code 2) items require verification.
- They will verify the samples to ensure all actions taken were effective. These actions can include follow-up with the original Responsible Parties to determine if actions were adequate, and review of evidence provided.
- The DSO will determine whether the Nonconformance was closed adequately.
- The Item verification determination is updated in iTrack to show that the actions taken were either effective or ineffective, and justification text for both scenarios shall be included.
  o If any Item's actions are found to be ineffective, the DSO will follow-up with the original Responsible Parties to ensure they are aware of the outcome so that mitigation actions can be taken (only if applicable), and to avoid ineffective implementation results with future items.
  o The Item can also be re-opened so that further actions can be taken to resolve the issue. This may only occur in specific instances where an issue is still unresolved.

5.4   Risk Assessment Codes

As stated in section 5.3.3, a risk code must be determined for each Item entered in the database. (See Technical Appendix A for guidance on how the risk code is calculated.) The Risk Assessment Codes identify five levels of risk (see below). In general, Items should be addressed in order from highest to lowest risk. D/S/P or Management System Owners may wish to establish specific internal guidelines for addressing this matter. However, it is recognized that there may be occasional exceptions to dealing with deficiencies in rank order due to resource limitations and scheduling difficulties. Whenever a Risk Assessment Code of 1 or 2 is calculated, iTrack will send an automatic e-mail message to the Chief Safety Officer, the Laboratory Director, the Chief Operating Officer, and the Deputy Director for Research. Immediate measures shall be taken to reduce the risk associated with such items.

Risk Assessment Code	Risk Level
1	Critical
2	Serious
3	Moderate
4	Minor
5	Negligible

"No risk identified" is the Risk Level assigned in iTrack when the Risk Assessment Code equals 0. This result is calculated from a *Hazard Severity* of "N/A" or *Mishap Probability* of "Does not apply." This Risk Level should only be assigned when no risk has been identified.

5.4.1 Risk assignment changes

Division Safety Officers, Division/Section heads and Project Directors/Managers are free to change risk assignments for items resulting from internal D/S/P assessments. However, changes to the risk assignments for external items require concurrence from the QS Head. For changes to risk assignments for ESH-related items, the QS Head will obtain further concurrence from the CSO and other stakeholders as necessary. Such revisions may be sought because of disagreement with reviewer-assigned values or because of actual changes in the level of risk (e.g., due to progress in addressing the item). Each request to change a risk assignment should include the item number, a justification, and the name of a person most familiar with the risk associated with the item. The changes shall be communicated in writing to the responsible D/S/P head(s).

5.4.2 Qualifications to perform risk assignment

Personnel conducting reviews should be familiar with Technical Appendix A of this Chapter.

5.5 Causal Analysis

5.5.1 Nonconformances and Management Concerns

NCs and MCs require identification of a root cause to assure that the corrective and preventive actions taken will be effective in preventing recurrence. A review using HPI (Human Performance Improvement) principles may also be required depending on the type of Item identified (e.g., ORPS). Refer to QAM 12110 - *Human Performance Improvement*, FESHM 3010 - *Significant and Reportable Occurrences*, and QAM 12050 - *Root Cause Analysis* for more information.

5.5.2 Root Cause Analysis Method

The RCA method used to conduct the Causal Analysis must be recorded in iTrack. It is strongly recommended that supporting documents be uploaded to the same page.

5.5.3 Effectiveness Review of Causal Analysis and RCA Method

The Office of Quality Assurance will review a sample of the causal analysis and root cause methods recorded in iTrack for closed CAPs relating to Nonconformance and Management Concerns.

The database will tally the number of methods identified in iTrack for closed CAPS and apply programmed logic to determine when the system will notify the Office of Quality Assurance that an analysis is available for review.

- A member of the Office of Quality Assurance will review the RCA method and causal analysis identified along with any supporting documents to confirm the method and analysis were effective in getting to the root cause.
- 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 RCA Method.
- If the method and analysis require a follow up, the 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 Root Cause analysis or method is required. Further action may include expanding on the analysis with the selected method or using a different root cause method.
- The member of the Office of Quality Assurance will collaborate with the RP to resolve the issue. After a satisfactory resolution has been determined, the Office of Quality Assurance will record this in iTrack, and the effectiveness review of the RCA Method will be closed.

6.0   References

Quality Assurance Policy
Fermilab Quality Tool Suite User Guide
FESHM Chapter 3010 - *Significant and Reportable Occurrences*
QAM Chapter 12010 - *Fermilab Lessons Learned Program and Procedures*
QAM Chapter 12050 - *Root Cause Analysis*
QAM Chapter 12110 - *Human Performance Improvement*

7.0   Technical Appendix A – Determining the Risk Assessment Code

A risk assessment is required for a Nonconformance or Management Concern. The steps to determine the risk assessment code are below.

1. Estimate the Hazard Severity as Critical, High, Medium, Low, or Minimal using Table 1. Consider the worst potential consequence that is likely to occur as a result of the deficiency.

2. Estimate the Mishap Probability as A, B, C, D, or E using Table 2. This should be based on an assessment of such factors as location, exposure in terms of cycles or hours of operation, and affected population. Other circumstantial factors that should be considered include the following:

- Number of workers exposed.
- Frequency of exposure or duration of employee overexposure to contaminants.
- Employee proximity to the hazardous conditions.
- Use of appropriate personal protective equipment (PPE).
- Medical surveillance program.

- Other pertinent working conditions.

3. Use Table 3 to determine the Risk Assessment Code from the Hazard Severity and Mishap Probability estimated above.

TABLE 1 HAZARD SEVERITY

SEVERITY	PEOPLE	ENVIRONMENT	COMPLIANCE	PROPERTY	PROCESS/PROJECT
CRITICAL	Multiple deaths from injury or illness; multiple cases of injuries involving permanent disability; or chronic irreversible illnesses.	Permanent loss of a public resource (e.g., drinking water, air, stream, or river).	Willful disregard for the rules and regulations.	Loss of multiple facilities or program components (>$5,000,000 total cost*)	Total breakdown identified resulting in loss/shut down of a process or project.
HIGH	One death from injury or illness; one case of injury involving permanent disability; or chronic irreversible illnesses.	Long-term loss of a public resource (e.g., drinking water, air, stream, or river).	Major noncompliance that exposes the Lab to significant potential fines and penalties.	Loss of a facility or critical program component (>$5,000,000 total cost*)	Major breakdown identified resulting in the failure to attain the budget, schedule, key performance indicators or customer expectations.
MEDIUM	Injuries or temporary, reversible illnesses resulting in hospitalization of a variable but limited period of disability.	Seriously impair the functioning of a public resource.	Significant noncompliance that requires reporting to DOE or other authorities.	Major property damage or critical program component ($1,000,000 - $5,000,000 total cost*)	Significant compromise to the attainment of the budget, schedule, key performance indicators or customer expectations which exposes process/project to potential failure if gap cannot be immediately resolved.
LOW	Injuries or temporary, reversible illnesses not resulting in hospitalization but with lost time.	Isolated and minor, but measurable, impact(s) on some component(s) of a public resource.	Programmatic noncompliance with the Lab's Work Smart set.	Minor property damage or critical program component ($50,000 - $1,000,000 total cost*)	Minor breakdown or gap identified which does not result in significant compromise to the attainment of the budget, schedule, key performance indicators or customer expectations; gaps can be resolved.
MINIMAL	Injuries or temporary illnesses requiring only minor supportive treatment and no lost time.	No measurable impact on component(s) of a public resource	Specific instance of a noncompliance with the Lab's Work Smart set.	Standard property damage or critical program component (<$50,000 total cost*)	Minor gaps identified which do not compromise the attainment of the budget, schedule, key performance indicators or customer expectations; gaps can easily be resolved.

TABLE 2 MISHAP PROBABILITY

PROBABILITY	DESCRIPTION
A	Could occur annually
B	Could occur once in two years
C	Occurring not more than once in ten years
D	Occurring not more than once in thirty years
E	Occurring not more than once in one-hundred years

TABLE 3 RISK ASSESSMENT CODE

HAZARD SEVERITY	MISHAP PROBABILITY				
	A	B	C	D	E
Critical	1	1	1	2	3
High	1	1	2	3	4
Medium	1	2	3	3	4
Low	2	3	3	4	5
Minimal	3	4	4	5	5

"No risk identified" is the Risk Level assigned in iTrack when the Risk Assessment Code equals 0. This result is calculate from a *Hazard Severity* of "N/A" or *Mishap Probability* of "Does not apply." This Risk Level should only be assigned when no risk has been identified.

Fermilab Quality Assurance Manual   12030-23

WARNING: This manual is subject to change. The current version is maintained on the Office of Quality Assurance website.   Rev. 2/2022

8.0   Technical Appendix B – Definitions of Activities

Triennial ES&H (Environments, Safety & Health) Assessment - An assessment whose purpose is to determine if the Laboratory is in compliance with a specific DOE Order or contract requirement.

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

Division/Section Head/Project Manager (D/S/P) Self-Assessment - An assessment conducted entirely by D/S/P personnel and reported internally to the D/S/P leadership to measure the degree of compliance with plans, DOE orders, FESHM, FRCM, QAM, other internal requirements, or state/federal agency directives.

D/S/P Management Walkthrough - A less formal assessment conducted by Senior Management.

DOE Reviews - A review planned and managed by the Fermi Site Office (FSO). Review items are formally transmitted to Fermilab along with requests for corrective or preventive actions. Review results should be considered when developing Fermilab's Integrated Assessment Plan.

Formal ES&H investigation - Investigations required by applicable standards and Local, State, and Federal legal requirements, including Computerized Accident Investigation Reporting System and Occurrence Reporting and Processing System investigations, as well as formal internally initiated investigations**.**

Highly Protected Risk Inspections - ES&H inspections of buildings conducted by the Fire Protection personnel and members of the assessed organization.

Incident/Accident - Work related event(s) in which an injury or ill-health (regardless of severity) or fatality occurred or could have occurred.

Notes: *(1) An accident is an incident which has given rise to an injury, ill health or fatality.*
(2) An incident where no injury, ill health, or fatality occurs may also be referred to as a "near miss", "near-hit", "close call", or "dangerous occurrence."
(3) An emergency situation is a particular type of incident.

Inspections/Walk-throughs - 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.

Integrated Assessment Plan – The plan of assessment activities to be conducted across the laboratory during a specified timeframe, typically per fiscal year.

Management System Assessment – An assessment conducted or managed by the Management System Owner to measure compliance to Management System requirements or to identify improvement opportunities.

Management System Evaluation – A review of specific aspects of a Management System. An example of a Management System Evaluation is the Management Systems Maturity Evaluation conducted by MSOs.

Regulatory Agency Inspections - Inspection by agencies external to DOE including State and Federal agencies such as EPA, IEPA, and USDOT.

Third Party Audits/Assessment - Audits and/or assessments performed on the organization by agencies external to Fermilab.

Tripartite Assessment - A major component of the Fermilab self-assessment program. The Tripartite assessment is typically performed on an ES&H topic or area; and is planned and performed jointly by a D/S, the ES&H Section, and FSO, and led by a member of the organization being assessed.

9.0   Technical Appendix C - Guidance for Determining the Item Category

iTrack requires the user to categorize a new item upon its creation. The category of an item is a classification of the issue into a general topic; it is not the root cause of the issue. There are 19 categories listed in iTrack from which to choose. Below are the options along with examples of items for each category.

Category Name	Example of an Item in the Category
Communication	No formal way to discuss work or tests for the upcoming period.
Cost/Budget	A comprehensive review of bottom-up cost estimate should be performed.
Design	Check 2-phase flow design for liquid droplet separation.
Documentation	Develop operational procedure/checklist
ESH Issue	The operator unknowingly overloaded the forklift.
Funding	DOE must provide a funding profile.
Issues Management	Open CAPs have not been addressed.
Other – Use of this category should be limited.	
Planning	Develop a detailed transportation plan.
Policy	There are no guidelines limiting eating/drinking in controlled areas
Process	Review downstream loss-of-vacuum scenarios
Records	No detailed notes of testing during incident.
Requirements/Specifications	Verify requirements for Waveguide Pressurization
Resources	Inadequate equipment.
Risk, Risk Management	Inadequate risk assessment performed prior to activity.
Roles and Responsibilities	Roles for all aspects relating to the Quantum Program and not clearly defined.
Schedule	The project schedule includes activities with high float values. These should be resolved before approval.
Technology	Evaluate script used to validate report data.
Training	Standardize shift personnel training for experiment operations.