

QAM 12030: iTRACK PROCEDURES AND RISK ASSIGNMENT

Revision History

Author	Description of Change	Revision Date
Jemila Adetunji Kathy Zappia T.J. Sarlina	<ul style="list-style-type: none">• The procedure was updated to reflect upgrades to iTrack. This include a new Effectiveness Review process that is completed by responsible parties, and the incorporation of an Escalation Process.• The procedure was also updated to reflect the change in how ES&H Walkthroughs/Inspections, like HPR inspections, are captured in iTrack.• Removed iTrack Item Type “Finding” in order to streamline the process within iTrack.	September 2017
Jemila Adetunji Kathy Zappia	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

1.0	INTRODUCTION	3
2.0	DEFINITIONS	3
3.0	RESPONSIBILITIES	4
3.1	Fermilab Quality Assurance Manager	4
3.2	Chiefs, Division/Section (D/S) Heads and Project Managers	4
3.3	Division Safety Officers (DSO)	4
3.4	iTrack Assigned Responsible Parties	4
3.5	Quality Assurance Representatives (QARs)	4
4.0	PROGRAM DESCRIPTION	5
4.1	Item Definitions	5
5.0	PROCEDURES	6
5.1	iTrack Uses	6
5.1.1.	Reviews and Items tracked in iTrack	6
5.1.2.	Reviews and Items NOT tracked in iTrack	6
5.2	iTrack Users	6
5.2.1.	iTrack Administrator	7
5.2.2.	iTrack Data Entry User	7
5.2.3.	iTrack Responsible Party/General User	7
5.3	iTrack Procedures	7
5.3.1.	Review complete, enter details into iTrack	8
5.3.2.	Entering new Items	8
5.3.3.	Delegating Responsibility	9
5.3.4.	Determining Root Cause – If required based on Item Type	9
5.3.5.	Determining Action Plan or Response	10
5.3.6.	Complete and Close Action Plan or Response	10
5.3.7.	Closing a Review	10
5.3.8.	Effectiveness Review of Closed Items	11
5.3.9.	Escalation Process	11
5.3.10.	Verification Process	12
5.4	Risk Assessment Codes	13
5.4.1.	Risk assignment changes	13
5.4.2.	Qualifications to perform risk assignment	14
5.5	Causal Analysis	14
6.0	REFERENCES	14
7.0	TECHNICAL APPENDIX A – DETERMINING THE RISK ASSESSMENT CODE	15
8.0	TECHNICAL APPENDIX B - DEFINITIONS OF ACTIVITIES	17

1.0 INTRODUCTION

iTrack is a database used to document and facilitate the resolution of items of any nature arising from formalized activities where reports are typically generated.

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, the procedures for using iTrack, the procedures to determine effectiveness of implemented corrective actions using iTrack, and the procedures for assigning risk values to items entered into iTrack. This chapter follows Fermilab's Quality Assurance Policy.

2.0 DEFINITIONS

Assessment - A review, evaluation, surveillance, or audit where a systematic approach is used to evaluate processes, systems or services to determine compliance to specified requirements and effectiveness; with the goal of identifying areas of non-compliance and best practice. An assessment may or may not result in corrective actions where appropriate resolution is required.

Corrective Action - The action taken to eliminate the cause of a detected non-conformance or other undesirable situation.

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

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 - Defined as non-conformances, opportunities for improvement, recommendations, best practices, and management concerns that are the outputs to reviews that are tracked in iTrack.

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.

Notable or Observation - Worthy of note: significant, interesting, or unusual enough to deserve attention or to be recorded.

Preventive Action - The action taken to eliminate the cause of a potential non-conformance or other undesirable potential situation.

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

Risk 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 Fermilab Quality Assurance Manager

- Manage the iTrack database and providing training for its use.
- Ensure the results of assessments conducted by external organizations are entered.
- Perform 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.
- Review periodic trending and analyses to determine if associated programs need to be redirected, to verify that root causes are being adequately addressed, and lessons generated.
- Ensure that the effectiveness of implemented corrective and preventive actions is reviewed and documented within iTrack.
- Verify that all Items with a Risk Code of 1 or 2 have their corrective or preventive actions verified within 90 days of reported closure.
- Ensure 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.

3.2 Chiefs, Division/Section (D/S) Heads and Project Managers

- Ensure results of internal assessments, inspections, project-specific reviews, and Tripartites, including all nonconformities, observations, opportunities for improvement, recommendations, and best practices (open and closed), are entered into iTrack.
- Implement corrective or preventive actions for issues and closing them out in iTrack.
- Periodically review the contents of iTrack to check on the appropriateness and status of follow-up actions, and to identify trends.
- Verify that corrective or preventive actions were implemented as reported.

3.3 Division Safety Officers (DSO)

- Ensure execution of the Verification Process detailed in section 5.3.10.

3.4 iTrack Assigned Responsible Parties

- Ensure assigned items in iTrack are addressed appropriately, including providing detailed information of actions taken or decisions made, and provide evidence where applicable.
- Ensure effectiveness reviews are completed for all required items in a timely manner.

3.5 Quality Assurance Representatives (QARs)

- Assist their Division/Section/Project (D/S/P) by monitoring open items in iTrack, assisting with resolution if necessary, and escalate overdue items.
- Actively review iTrack metrics and identify necessary actions to resolve negative trends in D/S/P.

4.0 PROGRAM DESCRIPTION

iTrack is a database that is used at Fermilab to support process performance monitoring and follow-up of associated items regardless of discipline. In particular, iTrack plays a key role in monitoring the status of Fermilab's self-assessment program and other issues. Metrics have been developed and implemented to assist in the monitoring of Fermilab's self-assessment program. These metrics are available through [FermiDash](#), and are provided to Fermilab's Management team and Quality Assurance Representatives through a variety of regularly scheduled meetings.

For consistency, iTrack calls activities that generate items "reviews". "Item" refers to non-conformances, management concerns, recommendations, opportunities for improvement, and best practices that are the output of these reviews. Definitions and requirements are listed below.

4.1 Item Definitions

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.

Requirements in iTrack:

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

Management Concern - An issue that management has identified as a concern requiring actions to be taken to ensure risk associated with that issue is mitigated.

Requirements in iTrack:

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

Recommendation - A suggestion or proposal from the Reviewer as to the best course of action to be taken on an identified topic.

Requirements in iTrack:

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

Opportunity for Improvement - Suggestions identified 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

Best Practice - Method or technique that has consistently shown results superior to those achieved with other means, and that may be used as a benchmark.

Requirements:

- Best Practices entered into iTrack do not require a root cause to be identified

- Best Practices do not require any Corrective/Preventive Actions or Responses
- They are entered into iTrack to be shared for information only

5.0 PROCEDURES

5.1 iTrack 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 reviews 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 Self-Assessments (Quality, D/S/P, Tripartite, etc.)
- Fermilab Internal Reviews (Director's Reviews, FRA / CAS Reviews, 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 (also to be entered into the established Lessons Learned DB per [QAM 12010 – Contractor Assurance/Lessons Learned Program & Procedures.](#))

5.1.2. Reviews and Items NOT tracked in iTrack

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 can include:

- Fire Department inspections (extinguishers, fire hoses, etc.)
- Non-critical or routine items found during Formal ES&H Inspections and Walkthroughs, such as 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.

5.2 iTrack Users

iTrack has 3 levels of users, defined below. Each level has unique privileges within the system.

5.2.1. iTrack Administrator

An iTrack Administrator has unique privileges in iTrack to ensure 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 and items for any D/S/P
- Maintains nomenclature in Oracle
- Maintains Oracle iTrack data specific to
 - Action Plan / Response Types
 - External Agencies
 - Item Types
 - Hazard Severities & Mishap Probability – Risk Code Map
 - Project List
 - Review Categories
 - Unsafe Codes
- Maintains iTrack email distribution for
 - High Risk Code notification
 - Corrective Action Verification

5.2.2. iTrack Data Entry User

An iTrack Data Entry User has data entry privileges in iTrack specific to their assigned organization. Some Data Entry Users may be assigned to multiple organizations (Divisions, Sections, or Projects). A Data Entry User is authorized to:

- View all open reviews performed on their Division, Section or Project
- Enter new reviews
- Enter new items
- Edit reviews
- Edit items
- Close items
- Run reports
- Query the database
- Extract data to Excel

5.2.3. iTrack 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 – update and close items assigned to them only

5.3 iTrack Procedures

Please refer to the [iTrack Data Entry User Guide](#) found on the [ESH&Q iTrack Homepage](#) for detailed instructions on how to enter reviews and items into iTrack, and for detailed descriptions of the data entry fields and for information on which fields are required and optional for data entry into the system.

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

There are 6 main Review Categories in iTrack:

- External Reviews
- Incidents or Events
- ES&H Activities
- Internal Laboratory Activities
- Project Activities
- Self-Assessments

The following iTrack steps define 3 key pieces of information for each individual step:

- Responsible: This is the person responsible for executing the step.
- Action: Detailed actions to be taken by the responsible person executing the step.
- Communication: Explanation of the automatic communication iTrack sends when that step is completed, including whom the recipients are.

5.3.1. Review complete, enter details into iTrack

- a) RESPONSIBLE: Person or Organization that performed or sponsored the Review – the designated Data Entry User.
- b) ACTION: A Review occurs and the information needed to enter the Review into iTrack is gathered. Information entered into iTrack about the Review includes:
 - Review title and description
 - Dates the review occurred
 - Who was involved in the review (participants)
 - Link to final report if applicable and available
- c) COMMUNICATION: None

5.3.2. Entering new Items

- a) RESPONSIBLE: Person or Organization that performed or sponsored the Review – the designated Data Entry User.
- 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
 - What type of item was found (see section 4.0 for definitions of each Item type)
 - Non-Conformance
 - Management Concern
 - Opportunity for Improvement
 - Recommendation
 - Best Practice
 - Where and when the item was found

- Risk associated with that item if applicable (see section 4.0 for a list of items this applies to, and the Technical Appendix for how to perform a Risk Analysis)
 - What management system the item is associated with
 - Responsible Party assigned to the item
 - 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 from iTrack 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.

5.3.3. Delegating Responsibility

- a) **RESPONSIBLE:** Responsible Party assigned to the Item
- b) **ACTION:** The Responsible Party has 3 options to assign the action (delegate responsibility)
- Solely to one other person,
 - To multiple people, or
 - Keep responsibility with themselves and not delegate responsibility.

The Responsible Party must know:

- 5-digit Fermilab IDs of the people they are delegating to or sharing responsibility with
 - Due dates will default to due date initially assigned to the item
- 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 5.3.2.

5.3.4. Determining Root Cause – If required based on Item Type

- a) **RESPONSIBLE:** Responsible Parties (and identified team to assist with the task if applicable – external to iTrack)
- b) **ACTION:** Non-Conformances and Management Concerns require a Causal Analysis to be completed 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
 - Provide a detailed description of the method chosen to determine the root cause

Note: A Cause needs to be identified before the Item is allowed to be closed.

- c) **COMMUNICATION:** None

5.3.5. Determining 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 identified determines what Action Plan or Response is appropriate to resolve their portion of the item.
 - A Non-Conformance or Management Concern requires **CORRECTIVE** or **PREVENTIVE ACTION PLANS** be determined and entered into iTrack.
 - Opportunities for Improvement and Recommendations require only a **RESPONSE** be determined and entered into iTrack.
- c) COMMUNICATION: Responsible Party and direct manager
 - The Responsible Party and their direct manager are automatically notified by iTrack via email that a new Action Plan or Response has been added in iTrack.

5.3.6. 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.
 - *FOR ACTION PLANS ONLY*: To be able to close the Action Plan appropriately evidence of what actions occurred needs to be entered into iTrack Evidence can include brief descriptions of the actions taken, and hyperlinks to completed documents of evidence.
 - *FOR 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 justification as to why the OFI or Recommendation will not be acted upon at this time.
- c) COMMUNICATION: Responsible Party and direct manager
 - Once the **ACTIONS** 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 ACTIONS/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.

5.3.7. Closing a Review

- a) RESPONSIBLE: iTrack System
- b) ACTION: The 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.

5.3.8. Effectiveness Review of Closed Items

- a) **RESPONSIBLE:** All Responsible Parties assigned to an Item
- b) **ACTION:** *For Action Plans Only:* Responsible Parties will conduct an effectiveness review on the actions taken to address the item. iTrack will send the Responsible Party a notification email 90 days after the closure of the item that requires review. The email will contain a link to the iTrack Effectiveness Review webpage where information of the effectiveness review will be entered. 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. Evidence of the effectiveness review must be entered into the iTrack Effectiveness Review page.

The effectiveness review will result only one of two outcomes:

- The effectiveness review found the actions taken effectively resolved the initial item and root cause. With this outcome, the Responsible Party will update the iTrack Effectiveness Review webpage accordingly and no further actions are necessary.
 - The effectiveness review found the actions taken did not effectively resolve the initial item and root cause, and the item Action Plan must be reopened. With this outcome, the Responsible party will update the iTrack Effectiveness Review webpage accordingly including an explanation why the actions taken were ineffective. iTrack will then automatically reopen the Action Plan, and the responsible party will go back to step 5.3.5 to determine a new Action Plan.
- c) **COMMUNICATION:** 90 days after the item has been closed in iTrack, the system generates an automatic email that is sent directly to the Responsible Party. The email includes a link to the iTrack Effectiveness Review webpage. iTrack will generate an 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 new Action Plan needs to be established.

5.3.9. Escalation Process

- a) **RESPONSIBLE:** iTrack
- b) **ACTION:** Once a month the iTrack system generates 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) **COMMUNICATION:** The list below details who is copied on automatic iTrack emails based on how much time has passed beyond the due date:

- 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 Division Chief + CC Chief Operating Officer + CC Chief Safety Officer

5.3.10. Verification Process

- a) **RESPONSIBLE:** ESH&Q QA Group and Division Safety Officers (DSO's)
- b) **ACTION:** Once per quarter, iTrack generates mandatory verification reviews for items assigned a Risk Code of 1 (Critical) or 2 (High) and randomly selects samples for verification review. Verification reviews **ONLY** occur for closed **NON-CONFORMANCES**. Risk Code 1 and 2 Non-Conformances are verified at 100%, and risk code 3 is verified from the sample set at 10%. The items are reviewed to determine whether or not the actions taken to resolve the original issue are *effective* or *ineffective*.

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

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

ESH&Q Quality Assurance Group Verification Steps:

ESHQ QA verifies non-conformances from the following review categories in iTrack:

1. Project Activities
 2. External Reviews
 3. Internal Laboratory Activities
 4. Self-Assessments
- ESH&Q QA 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 Non-Conformance 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:

DSO's verify non-conformances 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.
- A determination will be made as to whether the Non-Conformance 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 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.
 - 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

In step 5.3.2 a risk code must be chosen to enter the item into the database (see the Technical Appendix A for guidance on how to choose a risk code). The Risk Assessment Codes identify five levels of risk (see below). In general, items should be addressed in order of highest to lowest risk. D/S/P 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 entered, iTrack sends an automatic e-mail message to the Chief Safety officer, the Director, the Chief Operating Officer, and the Chief Research Officer. Immediate measures shall be taken to reduce the risk associated with such items.

Risk assessment code	Adjective rating
1	Critical
2	Serious
3	Moderate
4	Minor
5	Negligible

5.4.1. Risk assignment changes

Division Safety Officers, division/section heads and project managers are free to change risk assignments for items resulting from internal division/section/ project assessments. However, changes to the risk assignments for external items require concurrence from the Assistant Director of ESH&Q. 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 division/section head(s).

5.4.2. Qualifications to perform risk assignment

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

5.5 Causal Analysis

NON-CONFORMANCES and MANAGEMENT CONCERNS entered into iTrack require a cause to be identified to assure that the corrective and preventive actions taken will be effective in preventing recurrence. A HPI (Human Performance Improvement) investigation may also be required depending on the type of item identified (ORPS for example). Refer to [FESHM 3010](#) – Significant and Reportable Occurrences for more information and [QAM 12050](#) – Root Cause Analysis.

6.0 References

Quality Assurance Policy: <http://directorate-docdb.fnal.gov/cgi-bin/RetrieveFile?docid=63iTrack>
Data Entry User's Guide: <https://esh-docdb.fnal.gov:440/cgi-bin/RetrieveFile?docid=2598>

iTrack General User Guide: <https://esh-docdb.fnal.gov:440/cgi-bin/ShowDocument?docid=3009>

FESHM 3010 – Significant and Reportable Occurrences: <http://esh-docdb.fnal.gov/cgi-bin/ShowDocument?docid=526>

QAM 12010 – Contractor Assurance/Lessons Learned Program and Procedures: <http://esh-docdb.fnal.gov/cgi-bin/ShowDocument?docid=2496>

QAM 12050 – Root Cause Analysis: <http://esh-docdb.fnal.gov/cgi-bin/ShowDocument?docid=2687>

7.0 Technical Appendix A – Determining the Risk Assessment Code

iTrack PROCEDURES DETERMINING THE RISK ASSESSMENT CODE FOR A NON-CONFORMANCE OR MANAGEMENT CONCERN

1. Estimate the Hazard Severity as Critical, High, Medium, Low, or Minimal using Table 1 below. 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 below. 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 measureable 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 TABLE	
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					
	PROBABILITY				
SEVERITY	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

8.0 Technical Appendix B - Definitions of Activities

Triennial ES&H (Environment, Safety & Health) Assessments - 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) Internal 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, or other state or federal agency directives.

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

DOE Reviews - A review planned and conducted 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 and D/S/P self-assessment plans.

Environment, Safety, Health and Quality Section Assessments - Assessments conducted on an as-needed basis by the ESH&Q Section that are scheduled outside of the Tripartite process. Such supplemental assessments may be motivated by an incident, a perceived program weakness, a verification of effectiveness, or a new requirement. These also include QA Assessments.

Formal ES&H investigation - Investigations required by Fermilab's Work Smart set of standards, 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 Engineer 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.

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 Fermilab's ESH&Q's self-assessment program. The Tripartite assessment is performed and planned jointly by a D/S, the ESH&Q Section, and FSO and led by a member of the organization being assessed.