QAM 12040: CORRECTIVE AND PREVENTIVE ACTIONS

Revision History

Author	Description of Change	Revision Date
Kathy Zappia / Jemila Adetunji	Review of procedure to align with the minor updates made within the other QAM Chapters	August 2014
Rafael Coll	Initial release of QAM Chapter 12040 moves the former OQBP Procedure 1004.1001 to the QA Manual and cancels the OQBP Procedure upon publication.	November 2013

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1.0 INTRODUCTION

This procedure is intended to provide terminology and basic structure for investigations of any nature where corrective and preventive actions are required with the purpose of implementing a corrective and preventive action (CAPA) program for continuous improvement that meets DOE O 414.1 Quality Assurance.

This procedure is to be followed when corrective and preventive actions are necessary to correct quality and safety program non-conformances or opportunities for improvement. The procedure applies to all Fermilab employees, subcontractors, and users performing formal corrective or preventive actions in the quality and safety programs.

2.0 DEFINITIONS

Assessment - A review, evaluation, surveillance, or audit where a systematic approach is used to evaluate processes, systems or services to determine compliance to specified requirements and effectiveness; with the goal of identifying best practices and/or areas of non-compliance. An assessment usually results in corrective actions where appropriate resolution is required

CAPA - Corrective and Preventive Actions

Corrective Action - Action to eliminate the cause of a detected non-conformance or other undesirable situation. There can be more than one cause for non-conformance. Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

Independent Assessment – Assessments conducted on an aspect of Fermilab operations by the ESH&Q Section Quality Assurance Group or an outside organization.

Non-conformance - Non-fulfillment of a requirement. A non-conformance can be a deviation from work standards, practices, procedures, legal requirements or applicable code of federal regulations.

Preventive Action - Action to eliminate the cause of a potential non-conformance or other undesirable potential situation. There can be more than one cause for a potential non-conformance. Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

Procedure - Specified way to carry out an activity or process.

Record - Document stating results achieved or providing evidence of activities performed.

Remedial Action - An action taken to alleviate the symptoms of existing non-conformance or any other undesirable situation. Also known as correction or compensatory action, remedial action is used to minimize the effects before the root cause and best solution may be identified. It is a reactive, short term action to stop immediate effects of the problem.

Risk - Combination of the likelihood of an occurrence of a hazardous event or exposure(s) and the severity of injury or ill health that can be caused by the event or exposure(s).

Root Cause - An identified reason for the presence of a defect or problem or the source of origin of an event. The most basic reason, which if eliminated, would prevent recurrence.

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

3.0 RESPONSIBLILITIES

3.1 Chief Safety Officer

- Manage, improve and administer the Fermilab CAPA Program.
- Request, review, and track CAPA's for non-conformances, best practices or opportunities for improvement relevant to the issues tracked by the Fermilab Assurance Council, identified during assessments or audits sponsored or conducted by ESH&Q, or resulting from third party audits or activities.
- Advise the Director and Chief Operating Officer if a non-conformance is reportable to the DOE Occurrence Reporting and Processing System or other reporting systems.
- Analyze individual and collective non-conformances or opportunities for improvement to detect trends or potential systemic weaknesses.

3.2 Division/Section Heads and Project Managers

- Comply with and support this procedure for their areas of responsibility.
- Ensure timely response, submittal, and implementation of CAPA's that are appropriate to the level of risk associated with a non-conformance or opportunity for improvement.
- Provide the necessary resources to develop and implement CAPA's.
- Analyze individual and collective non-conformances or opportunities for improvement to detect trends or potential systemic weaknesses

3.3 All Employees, Contractors, and Users

- Identify and report non-conformances and opportunities for improvement to line management.
- Participate in corrective and preventive actions as requested by line management.
- Complete corrective and preventive actions commensurate with the level of assigned risk.

4.0 PROGRAM DESCRIPTION

4.1 Corrective & Preventive Action Procedure

This procedure is intended to provide terminology and basic structure for investigations of any nature where corrective and preventive actions are required. Figure 1 is an illustration of the generalized process for feedback and continuous improvement utilized in the Fermilab corrective and preventive action program.

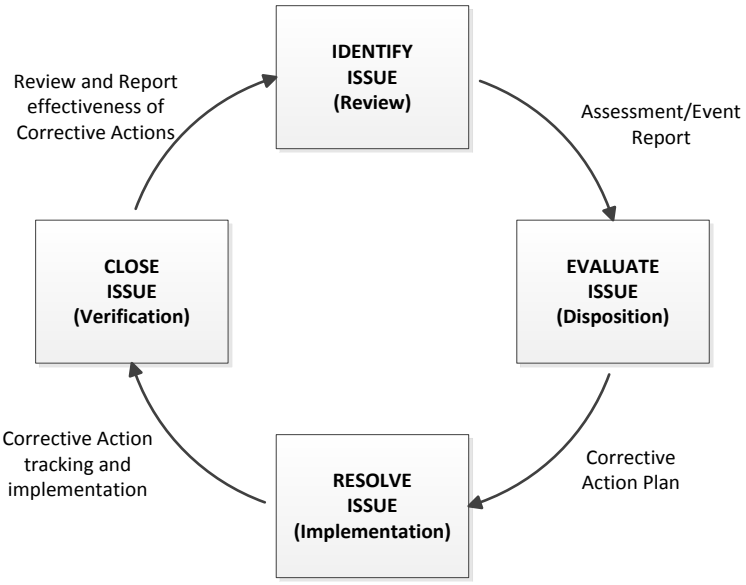

Figure 1. Feedback and Improvement

The sequence begins with the identification and reporting of a non-conformance or opportunity for improvement.

All employees, contractors, subcontractors, and Fermilab users are encouraged to report any non-conformances or opportunities for improvement to their immediate supervisor. Other sources of non-conformances may be identified during routine item inspections and tests, reviews, assessments or audits. Persons leading such reviews, assessments or audits may request CAPA's from affected line management in order to close open findings. In some cases the ESH&Q Section (ESH&Q) may request CAPA's from line management on behalf of persons who lead a Fermilab review, assessment or audit. ESH&Q may also request CAPA's as a result of an assessment conducted by or sponsored by ESH&Q. The issues management database, (iTrack) is an excellent tool to track actions until completion. See QAM 12030 for detailed information regarding the use of iTrack.

Responsible line management will respond to the CAPA request. The response may contain a planned date for a completed corrective action plan, or it may contain a completed CAPA depending on the complexity of the non-conformance or opportunity for improvement. If the CAPA is not submitted with the response, the responsible manager submits the CAPA to the requestor at a later date as indicated in the response.

Each CAPA will contain detailed information regarding division/section/project responsible, who is designated to manage resolution, the facts supporting the identification of root cause, lessons learned (where applicable), and timelines for resolution commensurate with the complexity, and actual or potential significance/risk.

A graded approach is used to perform root cause analysis. This approach matches the risk level and severity of the non-conformance with the level of resources and depth of examination used to perform

the root cause analysis. See QAM 12050 the Fermilab Root Cause Analysis Procedure for guidance on conducting a root cause analysis.

During a root cause analysis, the responsible person may question not only if existing controls need to be updated but also whether or not the activity has the correct controls under current operating conditions. Under these circumstances, QAM 12070, "Fermilab Graded Approach Procedure," may be applied where the responsible person determines that corrective or preventive actions require a more formal approach to risk evaluation and control selection.

The CAPA should also contain a description of actions that will be undertaken to prevent the occurrence of similar events in similar situations when such opportunities are identified. If corrective actions will require significant time to complete and implement, the CAPA must include interim corrective and/or remedial measures that will be implemented pending completion of the corrective action to reduce the possibility of the event or condition recurrence. Where corrective actions require training or re-training, records of such training are maintained. The identified CAPA should be entered into iTrack with the corresponding item.

The requestor of the CAPA reviews the response for:

- Completeness and correct identification of the cause,
- Likelihood of resolving the identified root cause of the issue,
- Likelihood of preventing recurrence in the area where identified,
- Identification of lessons learned if applicable,
- Likelihood of preventing the occurrence of similar issues in the same area or other areas or processes within the laboratory.

Upon acceptance of the CAPA, the responsible person implements the necessary actions. The responsible person notifies the requestor upon completion of the necessary actions. The requestor ensures completion is verified before closing the corrective action request in iTrack.

After a corrective action request is closed in iTrack, it may be subject to validation by the requestor, responsible person, or the ESH&Q Quality Assurance Group to determine the effectiveness of actions taken. Corrective actions are effective when the causal chain of events leading up to the problem or opportunity 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.

4.2 Management Review of Corrective & Preventive Action Data

Line management will analyze individual and collective problems or opportunities for improvement to detect trends or systemic weaknesses, and to identify additional opportunities for improvement.

5.0 RECORDS

Corrective & Preventive Action Plans in iTrack
Records of Reviews, Assessments, Audits, Inspections, and Tests