FESHM 12040: CORRECTIVE AND PREVENTIVE ACTIONS

Revision History

Author	Description of Change	Revision Date
Rafael Coll	Initial release of FESHM Chapter 12040. This chapter moves the former OQBP Procedure 1004.1001 (same topic) to the FESHM 12000 series and cancels the OQBP Procedure upon publication.	November 2013

TABLE OF CONTENTS

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 nonconformities 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, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.

CAPA- Corrective and Preventive Actions

Corrective Action - Action to eliminate the cause of a detected nonconformity 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.

Nonconformity - Non-fulfillment of a requirement.

Note: A nonconformity can be any deviation from work standards, practices, procedures, legal requirements, or applicable code of federal regulations.

Preventive Action - Action to eliminate the cause of a potential nonconformity 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.

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 nonconformities 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. The most basic reason, which if eliminated, would prevent recurrence. The source or origin of an event. Root cause is also known as the system cause.

Third Party Audits - Any audit not classified as internal or from the US DOE.

3.0 RESPONSIBLILITIES

3.1 ESH&Q Section Head

- Manages, improves and administers the Fermilab Corrective and Preventive Action Program.
- Requests, reviews and tracks CAPAs for nonconformities or opportunities for improvement relevant to the issues tracked by the Fermilab Assurance Council or resulting from third party audits or activities.
- Requests, reviews and tracks CAPAs for nonconformities or opportunities for improvement identified during assessments or audits sponsored or conducted by ESH&Q.
- Advises the Chief Operating Officer if a nonconformity appears to be reportable to the DOE Occurrence Reporting and Processing System (ORPS) or other reporting systems.
- May analyze individual and collective nonconformities or opportunities for improvement to detect trends or potential systemic weaknesses.

3.2 Division/Section/Center Heads and Project Managers

- Comply with and support this procedure for their areas of responsibility.
- Ensure timely response, submittal, and implementation of Corrective & Preventive Action Plans (CAPAs) that are appropriate to the level of risk associated with a nonconformity or opportunity for improvement.
- Provide the necessary resources to develop and implement CAPAs.
- Analyze individual and collective nonconformities or opportunities for improvement to detect trends or potential systemic weaknesses

3.3 All Employees, Contractors, and Users

- Identify and report nonconformities 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 risk as assigned.

4.0 PROGRAM DESCRIPTION

4.1 Corrective & Preventive Action Procedure

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.

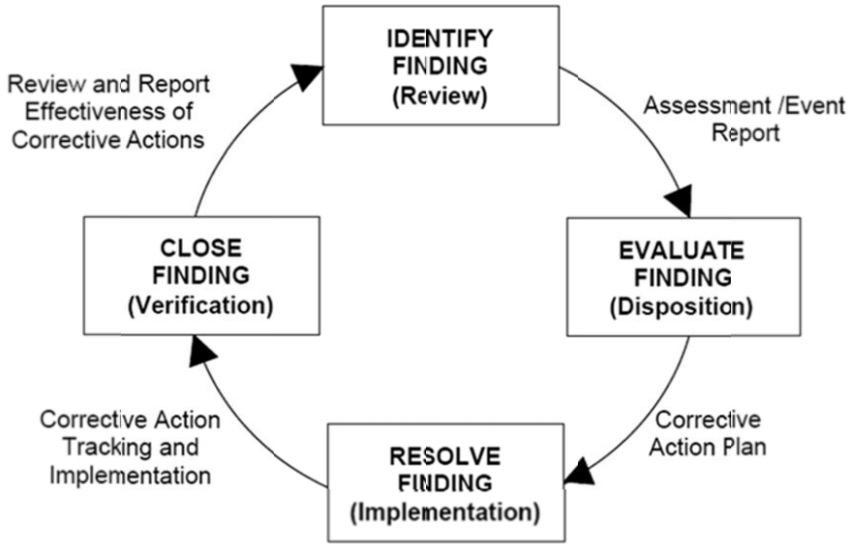

Figure 1. Feedback and Improvement

The sequence begins with the identification and reporting of a nonconformity or opportunity for improvement.

- All employees, contractors, subcontractors, and Fermilab users are encouraged to report any nonconformities or opportunities for improvement to their immediate supervisor. Other sources of nonconformities may be identified during routine item inspections and tests, reviews, assessments or audits. Persons leading such reviews, assessments or audits may request CAPAs from affected line management in order to close open findings. In some cases the ESH&Q Section (ESH&Q-S) may request CAPAs from line management on behalf of persons who lead a Fermilab review, assessment or audit. ESH&Q-S may also request CAPAs as a result of an assessment conducted by or sponsored by ESH&Q-S. The issues tracking database, (iTrack) is an excellent tool to track actions until completion. See FESHM 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 nonconformity 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 department/division/section/center/ project manager responsible, who is designated to manage resolution, facts supporting the identification of root cause, lessons learned (where relevant), 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 nonconformity with the level of resources and depth of examination used to perform the root cause analysis. See FESHM 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 FESHM 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 opportunities for preventive actions that will be undertaken to prevent the occurrence of this or similar events in the same and / or different areas 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 (compensatory) 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 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 of 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.

- After a corrective action request is closed, it may be subject to validation by the requestor or responsible person 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 corrective/ preventive 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 potential systemic weaknesses, and to identify additional opportunities for preventive actions.

5.0 RECORDS

Corrective & Preventive Action Plans
Reports of Reviews, Assessments, Audits, Inspections, Tests, etc.

6.0 REVIEW CYCLE

This chapter will be reviewed at 5 year intervals.