

SUBJECT:	IMS Corrective & Preventive Action Procedure	NUMBER:	10.001.000
RESPONSIBILITY:	Quality Assurance Manager	REVISION:	001
APPROVED BY:	Director, Office of Quality and Best Practices	EFFECTIVE:	

1.0 Purpose

The purpose of this procedure is to describe the Fermilab process to implement a robust corrective and preventive action program for continuous improvement in compliance with DOE O 414.1C Contractor Requirements Document Section 3c Management/Criterion 3 – Quality Improvement. This procedure also describes the Fermilab system for issues management in compliance with DOE O 226.1 Contractor Requirements Document Appendix A Section 5 Issues Management.

2.0 Applicability

This procedure applies to Fermilab Research Alliance, LLC (including all legal entities under its exclusive control) and all its employees, contractors, subcontractors, and Fermilab users.

This procedure describes the application of corrective and preventive actions to lab wide management issues which need to be raised to the Fermilab Assurance Council (AC), and tracked by the Office of Quality and Best Practices (OQBP).

3.0 Authority

The Director, Office of Quality and Best Practices (OQBP) authorizes this document by signature.

4.0 Procedure

Figure 1 illustrates an overview of the generalized process for feedback and continuous improvement utilized in the Fermilab corrective and preventive action program.

When each step is satisfied start and due dates for the next step are updated in the system. The OQBP provides periodic reports to the office of the Directorate, the AC, responsible managers and others as necessary, to ensure the appropriate level of resources is applied to bring open issues to successful and timely closure.

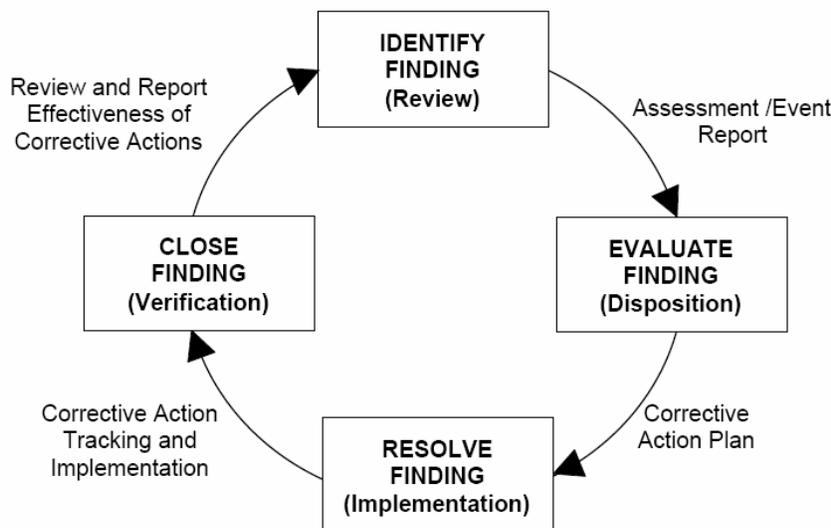


Figure 1. Feedback and Improvement

SUBJECT:	IMS Corrective & Preventive Action Procedure	NUMBER:	10.001.000
RESPONSIBILITY:	Quality Assurance Manager	REVISION:	001
APPROVED BY:	Director, Office of Quality and Best Practices	EFFECTIVE:	

4.1 The sequence begins with the identification and reporting of a problem finding (or issue).

All employees, contractors, subcontractors, and Fermilab users are encouraged to report any issues to their immediate supervisor. Issues should be resolved at the lowest possible level of the organization except where mandatory or regulatory escalation is required. For issues of immediate concern and high priority, interim corrective actions, including work stoppage if necessary, shall be taken without waiting for a formal report to be issued.

Issues escalated to Directorate through the OQBP and / or the Fermilab Assurance Council are subject to an initial review to determine if the issue is relevant to the Fermilab IMS or if the issue should be managed through other Fermilab channels*. Where deemed necessary, or appropriate, the AC and / or OQBP, may raise the issues to the Director of Fermilab and / or DOE. Where required by applicable DOE requirements, the OQBP will raise the issues to DOE and the Director of Fermilab.

The OQBP enters relevant management issues into the Fermilab Issues Management System (IMS), assigns a priority level (using a graded approach based on significance and risk), and sets the start and due dates for a response in the system. The IMS system automatically assigns a unique "item" number to each issue entered. Any issues originating from the same report are grouped as a unique "project" in the IMS. The OQBP assigns each issue to the responsible division or section head for resolution and provides a Corrective Action Plan (CAP) form to be completed. The CAP form will contain pertinent issue identification, division/section assignment, and an initial risk level grade, and comments if necessary.

* Individual environmental, safety and health issues are managed by Fermilab's ES&H section and by safety representatives throughout Fermilab using a computer system called ESHTRK.

4.2 In the next step the responsible manager evaluates the finding and provides a response to the OQBP.

Depending on the complexity of the issue, the response may contain a planned date for a completed corrective action plan (CAP), or it may contain a completed CAP. If the CAP is not submitted with the response, the responsible manager submits the CAP at a later date as indicated in the response.

Each CAP must contain detailed information regarding department/Division/Section responsible, who is designated to manage resolution, facts supporting the identification of root cause, required root cause depth**, lessons learned, and timelines for resolution commensurate with the complexity, and actual or potential significance/impact (graded approach).

The CAP 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. If corrective actions will require significant time to complete and implement, the CAP must include interim corrective and/or 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 shall be recorded in the TRAIN computer system.

**See the appendix for determination of root cause depth.

SUBJECT:	IMS Corrective & Preventive Action Procedure	NUMBER:	10.001.000
RESPONSIBILITY:	Quality Assurance Manager	REVISION:	001
APPROVED BY:	Director, Office of Quality and Best Practices	EFFECTIVE:	

4.3 The QQBP reviews the response and CAP for completeness and likelihood of resolving the identified root cause of the issue, proposed root cause depth, likelihood of preventing recurrence, identification of lessons learned, and if applicable, likelihood of preventing the occurrence of similar issues in the same area or other areas of the laboratory.

4.4 Upon acceptance of the CAP, the responsible manager implements the corrective actions and notifies the QQBP of completion. QQBP may request interim status reports prior to completion.

4.5 The QQBP verifies completion before closing the issue. Each issue is tracked step by step in the IMS from open, response, accept response, submit CAP, implement CAP, verify completion, to the closed status.

4.6 After an issue is closed, it may be subject to validation by the QQBP and / or responsible person, to determine the effectiveness of corrective actions taken. Corrective actions are effective when the causal chain of events leading up to the issue are broken and remain broken.

A graded approach will be used to decide the degree of validation required. Some issues may be validated by audits or assessments and / or included in the quality audit schedule by QQBP. Some issues may simply be monitored to ensure the ongoing effectiveness of the corrective actions. If it is determined that the corrective actions were not effective, the issue may be subject to reopening under the original unique issue tracking number (by demotion from the closed step to a prior step in the sequence).

4.7 The QQBP will analyze individual and collective issues in the IMS to detect trends or potential systemic weaknesses, to identify additional opportunities for preventive actions throughout the laboratory, and to optimize the allocation of resources for quality improvement within the laboratory. This includes those issues which are identified as commendable or best practices.

5.0 Responsibilities

5.1 The Fermilab Director

- Holds senior leaders accountable for implementation of, and compliance with, this procedure
- Provides financial support to senior leaders for pertinent activities
- Reviews periodic status reports from the QQBP.

5.2 Division and Section Heads

- Comply with and champion this procedure for their areas of responsibility
- Ensure timely response, submittal and implementation of CAPs.
- Provide the necessary resources as appropriate to the findings/issues using the Fermilab graded approach

5.3 The Office of Quality and Best Practices

- Manages, improves and administers the Corrective and Preventive Action and Issues Management programs
- Manages, the Fermilab Issues Management System
- Determines reportability

SUBJECT:	IMS Corrective & Preventive Action Procedure	NUMBER:	10.001.000
RESPONSIBILITY:	Quality Assurance Manager	REVISION:	001
APPROVED BY:	Director, Office of Quality and Best Practices	EFFECTIVE:	

- Provides periodic status reports to the Fermilab Assurance Council, the Laboratory Director, responsible managers, and others as appropriate
- Provides support to responsible management in resolving open issues

5.4 Fermilab Assurance Council

- Ensures that the organization maintains effective processes for communicating issues up the management chain to senior management, using a graded approach that considers hazards and risks
- Provides guidance regarding priority of laboratory improvement efforts
- Ensures that there are processes for resolving disputes, and for documenting and communicating dissenting opinions
- Advises the laboratory Director of the status of relevant activities

5.5 MIS

- Hosts, maintains and enhances the Fermilab Issues Management System

6.0 References

- 6.1 DOE O 226.1 Implementation of Department of Energy Oversight Policy - Contractor Requirements Document, Appendix A Contractor Assurance Systems, Section 5. Issues Management
- 6.2 DOE O 414.1C Quality Assurance – Contractor Requirements Document, Attachment 2 Management/Criterion 3 – Quality Improvement
- 6.3 DOE G 414.1-5 Corrective Action Program Guide
- 6.4 10.001.000 Form 1 Corrective Action Plan Form
- 6.5 10.002.000 Graded Approach Procedure
- 6.6 10.002.000 Form 1, Table 1a Consequence Code

7.0 Definitions

7.1 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. (DOE O 414.1C)

7.2 Graded Approach: The process of ensuring that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with: the relative importance to safety, safeguards, and security; the magnitude of any hazard involved; the life-cycle stage of a facility or item; the programmatic mission of a facility; the particular characteristics of a facility or item; the relative importance to radiological and non-radiological hazards; and any other relevant factors. (10CFR830)

7.3 Issue: a problem finding (or commendable practice / best practice) which is typically the result of; an audit, an assessment, a review, observation, or a specific event. An issue may also include other items which need to be tracked by the OQBP such as contractual or corporate commitments which require deliverables.

SUBJECT:	IMS Corrective & Preventive Action Procedure	NUMBER:	10.001.000
RESPONSIBILITY:	Quality Assurance Manager	REVISION:	001
APPROVED BY:	Director, Office of Quality and Best Practices	EFFECTIVE:	

7.4 Root Cause: The fundamental cause of an issue or event which when eliminated should prevent recurrence of the issue or event.

SUBJECT:	IMS Corrective & Preventive Action Procedure	NUMBER:	10.001.000
RESPONSIBILITY:	Quality Assurance Manager	REVISION:	001
APPROVED BY:	Director, Office of Quality and Best Practices	EFFECTIVE:	

Appendix

Determination of Required Root Cause Depth

Table 1 MUST PROVIDE FORMAL ROOT CAUSE ANALYSIS AND REPORT

The Fermilab Director issues a mandate to complete
The event(s) / issue(s) violate a barrier to safety
The event(s) / issue(s) cross a consequence threshold of ≥ 3 (moderate).
The event(s) / issue(s) was a near miss that could have resulted in a consequence of ≥ 4 (high)
The event(s) / issue(s) occurrence rate is significantly higher than assumed in an original risk assessment

The responsible person must conduct a formal root cause analysis and provide a written root cause report when any of the conditions in Table 1 above are met.

Table 2 MAY PROVIDE FORMAL ROOT CAUSE ANALYSIS AND REPORT

The event(s) / issue(s) consequence is ≤ 2 (low) and the frequency is unacceptable
The event(s) / issue(s) was a near miss that could have resulted in a consequence of ≤ 3 (moderate)

The responsible person may conduct a formal root cause analysis and provide a written root cause report when any of the conditions in Table 2 above are met.

Table 3 MUST PROVIDE AT LEAST AN INFORMAL ROOT CAUSE ANALYSIS

The event(s) / issue(s) consequence is ≤ 2 (low)

The responsible person must conduct at least an informal root cause analysis when the condition in Table 3 above is met.

SUBJECT:	IMS Corrective & Preventive Action Procedure	NUMBER:	10.001.000
RESPONSIBILITY:	Quality Assurance Manager	REVISION:	001
APPROVED BY:	Director, Office of Quality and Best Practices	EFFECTIVE:	

Table of Revisions

Author	Description	Revision	Date
Jed Heyes	Draft	000	06/25/07