



Environmental Management
Office of Standards and Quality Assurance

Quality Procedure

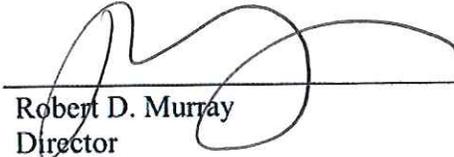
Subject Area: *Causal Analysis and Trending*

QP-3.2, Revision 0

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1. PURPOSE

This Quality Procedure describes the process for reviewing and analyzing the cause(s) of issues and findings identified from Office of Quality Assurance oversight activities and reporting trends as a result of this review.

2. SCOPE

This procedure encompasses the review of causal factors in response to issues and findings identified in oversight activities performed by the Office of Standards and Quality Assurance. A trend report resulting from this review is issued to identify positive indicators that provide evidence of sustained effective site performance and to identify processes needing improvement that would require site attention.

3. APPLICABILITY

This procedure applies to the Office of Standards and Quality Assurance personnel who participate in evaluating corrective actions and associated causal factors to issues and findings identified in oversight activities. This procedure also applies to actions required of Office personnel to implement trending through oversight activities and is intended to be responsive to applicable requirements within DOE mandating objective measurement of performance.

4. REQUIREMENTS & REFERENCES

The most current version of the following requirements and references are applicable to this procedure.

Requirements

- 4.1 DOE Order O 414.1D, *Quality Assurance* (including Administrative Change 1)
- 4.2 ASME NQA-1-2008/2009a, *Quality Assurance Requirements for Nuclear Facility Applications*
- 4.3 EM-QA-001, *EM Quality Assurance Program*

References

- 4.4 SSQ-3.1, *Corrective Action*
- 4.5 EM Corrective Action Hub Guide

5. DEFINITIONS

- 5.1. Adverse Trend – A trend of deficiencies (issues) with the potential to result in a finding (condition adverse to quality) if not corrected.
- 5.2. Apparent Cause – The most probable cause(s) that: explains why the event happened; can reasonably be identified; local or facility management has the control to fix; and for which effective recommendations for corrective action(s) to remedy the problem can be generated if necessary.

- 5.3. Cause Analysis –An organized process, using an established analytical methodology, through which a condition is analyzed and the most likely causes for that condition are identified, validated, and reported.
- 5.4. Causal Factor –An event or condition that either caused the occurrence under investigation or contributed to the unwanted result. If it were not for this event or condition, the unwanted result would not have occurred or would have been less severe.
- 5.5. Extent of Condition –The transportability of the identified condition. Once an event or cause and effect are identified, it is determined where else this type of condition could exist.
- 5.6. Root Cause –The most basic cause(s) that explains why the event happened, that can reasonably be identified, that senior management has the control to fix, and for which effective recommendations for corrective action(s) to remedy the problem, prevent specific recurrence of the problem and preclude occurrence of similar problems can be generated if necessary. This is typically one level further in analysis beyond the Apparent Cause(s).
- 5.7. Trend – A trend is identified where numbers of deficiencies reported in specific categories are evaluated and determined to be sufficient in number to indicate an adverse trend.

6. RESPONSIBILITIES

- 6.1. Deputy Assistant Secretary (DAS) for Safety, Security and Quality Programs
 - 6.1.1 Directs the Office of Standards and Quality Assurance to implement this procedure in accordance with the Oversight Policy.
- 6.2. Director, Office of Standards and Quality Assurance
 - 6.2.1. Responsible for implementation and management of the Office trend evaluation process.
 - 6.2.2. Responsible for the preparation, revision, and approval of this procedure.
 - 6.2.3. Designates a Trend Coordinator to conduct causal analysis and trending.
- 6.3. Office of Standards and Quality Assurance Trend Coordinator
 - 6.3.1 Conduct a review of corrective actions and associated causes submitted by evaluated organizations in response to a finding or an issue identified in Office of Standards and Quality Assurance audits and assessments.
 - 6.3.2 Gather and analyze data obtained during the review of causal factors and determine if trending is necessary. Report the results of the analysis and trending efforts, at a minimum, to the Office Director for issuance.
- 6.4. Office of Standards and Quality Assurance Personnel
 - 6.4.1 Ensure that documented issues and findings (primarily from oversight activities) and completed corrective actions (submitted by evaluated organizations) are submitted in the Issues Management System for trending purposes.

- 6.4.2 Review the supporting information for corrective action (causal factors, apparent cause, root cause if applicable, extent of condition, etc.) submitted by the evaluated organization is adequate and complete.

6.5 Responsible Organization

- 6.5.1 Investigate and respond to the Office of Standards and Quality Assurance for potential adverse trends identified and reported to the organization.

7. GENERAL INFORMATION

The objectives of the Office causal analysis and trending process are to ensure: that the issues or findings identified during oversight activities are submitted into the Issues Management System; that corrective actions addressing the finding and/or issue are deemed adequate and complete and adequate with support information/data (causal factors, apparent cause, extent of condition, etc.); that support information/data to the corrective action are gathered, analyzed, and trended to determine if a significant recurring problem, event, or condition exists or if evidence of sustained effective performance is present. Trends are evaluated to determine the effectiveness of a system, procedure, or program; to determine the relative extent and severity of a specific problem, event, or condition; and to determine if it is applicable to other EM Site activities. Results of the trending process are reported to the Office Director.

8. CAUSAL ANALYSIS AND TRENDING PROCESS

8.1. Conducting Analysis of Findings and Associated Corrective Actions

- 8.1.1 Each Office personnel responsible for issues or findings (including significant findings) identified during an assessment or audit ensures that documented issues or findings are submitted in the Issues Management System.

Note: EM currently uses the EM Corrective Action Hub as its Issue Management System and is accessible at <http://correctiveactionhub.em.doe.gov/CAP/default.asp>.

- 8.1.2 Each Office personnel responsible for issues or findings identified during an assessment or audit ensures that the evaluated organization submit corrective actions to address issues or findings in the Issues Management System.

- 8.1.3 Each Office personnel responsible for issues or findings identified during an assessment or audit evaluates that corrective actions are adequate. Each Office personnel completes the action (EM Response to Corrective Action) in the Issues Management System.

Note: Corrective actions are provided by the evaluated organization to address the causal factor and apparent cause, address the specific problem, fix similar problems (extent of condition as needed or for significant conditions adverse to quality), and correct the process that creates the problem.

Note: For significant findings, a formal root cause analysis provided by the evaluated organization is required and included in the Issues Management System.

- 8.1.4 The Trend Coordinator accesses the Issues Management System and obtains a list of issues or findings (including significant findings) and associated corrective actions identified during the calendar year.

- 8.1.5 The Trend Coordinator performs an analysis of the status of issues or findings (including significant findings) that were initiated, that are still open or that were closed during the calendar year. This analysis and report are accessed in the Reports section of Issues Management System (EM Corrective Action Hub).
- 8.2. Reporting Results of Trending
- 8.2.1 Annually, the Trend Coordinator prepares a Trending Report by accessing the Reports section of the Issues Management System, specifically "Audit Trends and Analysis".
- Note: The report in the Issues Management System identifies trends in the number of findings by activity noting, as a minimum, cited requirements from issues or findings, open and closed findings, and the frequency of findings per EM site. It also includes a comparison to previous reporting periods.
- 8.2.2 The Trend Coordinator submits a report to the Office Director for issuance to the EM Sites, either electronically or in hard copy, as soon as completed. The report identifies any potential adverse trends relative to specific Site organizations. Similarly, trending and reporting of positive indicators are completed to provide evidence of sustained effective site performance.
- 8.2.3 The Office Director notifies the responsible Site organization, facility, or project if an adverse trend is identified within their program. The adverse trend is added and tracked to closure in the Issues Management System per SSQ-3.1Q, *Corrective Action*.
- 8.3. Trend Report Response and Closure
- 8.3.1 The responsible Site organizations, facility, or project that receive notification of an adverse trend within their program conducts an investigation to appropriately determine the impact of the identified adverse trend and provide a response to the Office of Standards and Quality Assurance detailing the action taken to correct the trend in the Issues Management System.
- 8.3.2 The assigned Office of Standards and Quality Assurance personnel evaluates the response(s) by the responsible Site organization(s) for acceptability, return rejected corrective action responses to the responsible organization(s), and evaluate revised responses for acceptability per SSQ-3.1Q, *Corrective Action*.
- 8.3.3 The assigned Office personnel provides a status of corrective action response to the Office Director and the Trend Coordinator.
- 8.3.4 The assigned Office personnel tracks completion of responsible organization's corrective actions, determine when actions taken by responsible organizations satisfactorily correct the adverse trend, and inform the Office Director, responsible organizations, and the designated Causal Analysis and Trending Lead when the corrective actions are complete.

9. RECORDS

Records listed below are collected per QP-4.3, *Records Management*, as individual records or included in a records package, as specified. Final disposition of QA records resulting from audits is based on the EM Records Disposition process.

Lifetime QA Record: None

Nonpermanent Records: Trending Report and associated memoranda/emails

10. FORMS

There are no forms generated from this procedure.

11. ATTACHMENT

There are no attachments generated from this procedure.

RECORD OF REVISION

DOCUMENT: QP-3.2 Revision 0; Subject Area: *Causal Analysis and Trending*

Revision Number	Description of Changes	Revision on Pages	Effective Date
0	Original	All	8/31/2015