



Contractor Guide

For

Performance of Effectiveness Reviews

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Performance of Effectiveness Reviews

Introduction

Effectiveness reviews as described in this document are performed to verify the effectiveness of corrective actions implemented to prevent the recurrence of significant issues, problems or events.

This document provides guidance for conducting and documenting the performance of effectiveness reviews. The document describes the bases for including effectiveness reviews as an integral part of the contractor's corrective action program and provides a methodology (including key process elements) for the successful completion and documentation of the process. It also provides a generic process structure that can be utilized in performing an effectiveness review.

Discussion

There are many business reasons for ensuring that performance improvements are being sustained and that actions taken to correct or prevent problems have been effective. These include on-going protection of the worker, public, and environment; cost effectiveness of operations; cost avoidance resulting from minimizing repeat violations and civil penalties associated with the failure to effectively correct and prevent problems; and, increasing the regulatory margin or customer confidence. While guidance available to contractors for performing effectiveness reviews continues to be developed and issued by the U.S. Department of Energy (DOE) and multiple industry groups, DOE has:

- provided a clear expectation that the contractor will identify the causes of problems and work to prevent recurrence of the problems as part of their corrective action process in the Quality Improvement Criterion cited in 10 CFR 830, *Nuclear Safety Management*
- explicitly identified effectiveness reviews in the requirements section of DOE M 231.1-2, "*Occurrence Reporting and Processing of Operations Information*," stating that contractor/facility managers are to assess the effectiveness of corrective actions to prevent recurrence using a graded approach
- provided guidance for DOE's use through such avenues as the Price Anderson Amendment Act (PAAA) Enforcement Guidance Supplement 01-02, December 17, 2001, for 10 CFR 830, DOE Guide 414.1-1A, *Management Assessment and Independent Assessment Guide*, and, DOE Guide 414.1-5, *Corrective Action Program Guide* , and,

- required the use of effectiveness reviews as part of its corrective action management program and the feedback and improvement function of the Integrated Safety Management System (ISMS) in DOE Order 414.1B, *Quality Assurance*

In general, Effectiveness Reviews are typically performed on only the most significant problems and those associated corrective actions designated to prevent recurrence. A formal root cause analysis is normally performed as part of the corrective action process for these types of problems. Recurrence of problems can result from a number of conditions, including (1) the actions identified from the root causes did not adequately prevent recurrence, (2) the analysis failed to identify all the root causes, or (3) the action is not adequately implemented. The effectiveness review process is intended to evaluate implementation of selected corrective actions specifically designed to correct the underlying causes and to prevent recurrence of the same or similar problems. The intent of the effectiveness review process is not to assess, or verify, the completion of each individual corrective action, but rather to determine whether an identified problem still could result in (1) a failure to satisfy requirements, (2) incomplete implementation of management systems, or (3) unresolved issues remaining. The validation that a corrective action is effectively implemented does not always imply the absolute elimination of a problem, or, that similar negative outcomes will not reoccur. Rather, the probability or frequency of recurrence should be greatly reduced. A corrective action is effective if it has achieved what was intended.

It is important to understand the purpose and meaning of terms used in this paper.

- Effectiveness is measured by a significant change in one or more of these four measures:
 - (1) the probability of the original event recurring
 - (2) the frequency of the problem recurring
 - (3) reduction in the magnitude or severity of the problem
 - (4) elimination of the original problem
- Problems, as used in this paper, describe the aggregate of findings or issues requiring corrective action(s). Problems can be identified from many sources including operational events such as reportable occurrences and Price-Anderson Amendment Act (PAAA) nonconformance's or from review-based assessments (i.e., Independent and Management Assessments).
- Recurrence is another similar negative outcome from the same cause.

A review designed to determine the effectiveness of the corrective actions in resolving or preventing recurrence of a problem should contain certain key elements. Other external organizations such as the Institute of Nuclear Power Operations (INPO), commercial; nuclear power facilities, and publications from codes and standards bodies such as the American Society of Mechanical Engineer's standard for Nuclear Quality Assurance programs (ANSI/ASME NQA-1), have developed guidance for performing effectiveness reviews. Drawing on both available industry and DOE guidance, the effectiveness review process should include the following key elements:

- Identification of higher-level or significant findings for which greater analysis is appropriate. In general, these types of problems are subject to both causal analysis and effectiveness reviews, using a graded approach.
- Reviews being scheduled following the completion of the last corrective action intended to prevent recurrence. In fact, after the last corrective action is completed, sufficient time should be allowed to elapse to ensure that all corrective actions have been able to take effect. Reviews can be conducted anytime after a corrective action is completed and has taken effect. This time could be as soon as one month or as long as a year after implementation, however, six months is typically the recommended period to ensure completed corrective actions to prevent recurrence have been given sufficient time for implementation.
- Identification of the scope of the review
- A clear definition of the acceptance criteria for determining effectiveness. This is essential for providing a defensible result from the review.
- Selection of the method/extent of the review, based on the significance/complexity of problem (e.g., assessments, database review of trending, etc.)
- Performance of the review by assessors/personnel who are independent of implementation of the corrective action. Organizations should select appropriate personnel to conduct the effectiveness review to ensure the validity of the outcome.
- Documentation of the results and reporting of the findings to management

Results of the effectiveness review will provide confidence that the corrective action(s) is effective, or, the review will identify that the original corrective action(s) identified to prevent recurrence either was not adequate or not implemented to the extent necessary for the desired results. When the corrective action(s) to prevent recurrence is considered ineffective, it must be addressed. The reason for the ineffectiveness may be obvious (i.e., actions not implemented or implemented inconsistently), or, it may require a re-

examination or re-accomplishment of the original causal analysis. In either case, additional corrective action(s) must be developed and implemented to prevent recurrence. The ineffective correction of problems can raise other fundamental issues which should be evaluated. That is, “Why was recurrence not prevented through the current corrective action process?” and “What changes are necessary in the corrective action process to prevent recurrence?”

Management also should determine if and when effectiveness reviews of significant corrective actions should be incorporated into the ongoing assessment program to verify continuing compliance with the requirements of corrective action implementation.

Attached is detailed guidance for performing and documenting effectiveness reviews.

Guidance for Performing Effectiveness Reviews

1. Applicability

Effectiveness reviews are conducted on the implementation of corrective actions to significant event-based or review-based problems. An effectiveness review is performed on corrective actions or a set of corrective actions designed to prevent or significantly reduce recurrence of the problem(s) identified by the root cause analysis.

Effectiveness reviews can involve considerable resources and should be undertaken using a graded approach. For example, effectiveness reviews may be appropriate for corrective actions in response to the DOE Occurrence Report and Processing System (ORPS) Significance Category 1 and 2 reports, PAAA Noncompliance Tracking System reports, and significant findings of systemic noncompliance with rules and regulations. At the other end of the graded approach, effectiveness reviews may not be appropriate for corrective actions implemented to remedy low significance problems or for an action such as terminating personnel in response to willful and intentional violations.

2. Responsibility

The manager responsible for the corrective action plan should schedule, track, and ensure performance of effectiveness reviews

3. Scheduling

The responsible manager should ensure that an effectiveness review is scheduled after the corrective action(s) is completed and has had time to take effect. There should be adequate time for opportunities to challenge implementation of the corrective action or for the problem to reoccur. This could be as soon as one month or as long as one year after implementation. It is anticipated that most, but not all, effectiveness reviews can be conducted within approximately six months after implementation of the corrective actions designated to prevent recurrence.

The responsible manager may decide to do a mid-point review of the effectiveness of corrective actions. This approach is useful for large, multi-step actions or lengthy sets of corrective actions. The review may identify whether conditions are improving or worsening and allow for midcourse corrections.

4. Corrective Action Effectiveness Review Planning

The assessor should develop a written plan for accomplishing the effectiveness review, tailoring the extent of the review to (1) the complexity of the problem and (2) the associated corrective action(s) designated to prevent recurrence. This plan should:

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- identify the scope and the extent of the review based on the significance and the complexity of the problem
 - describe the aspects of the problem and the root cause(s) that the particular corrective actions were designed to remedy (e.g., inadequate programs, processes, procedures, training, implementation, etc.)
 - identify and document conditions needed to ensure the performance of a valid review
 - determine the acceptance criteria for the potential outcomes from the effectiveness review. This is essential for providing a defensible result from the review.
 - determine the method or mixture of methods (e.g., assessments, database review of trending; see attachment A) to be used during the review
 - assign assessors/personnel who are both knowledgeable of the work scope and independent of implementation of the corrective action to conduct the effectiveness review
 - document what is required to happen prior to performing an effectiveness review, and review the original problem to determine scenarios that could be construed as a recurring condition and whether an opportunity for recurrence has existed (e.g., if the condition could occur only during performance of particular activities).
 - document, if an opportunity for recurrence has not occurred, whether the opportunity is needed to validate effectiveness of the corrective action and, if re-scheduling of the effectiveness review is necessary, obtain upper management approval

5. Conducting the Effectiveness Review

An effectiveness review may be performed by an individual or a team. The manager may request the performance of a QA surveillance/audit, independent assessment, or management assessment as part of the methodology for the review, or, may conduct a joint assessment with the affected organization(s). Independent of the methodology selected for the review, the following steps for performing the review are recommended.

- A.** Implement the methods identified in Section 4 above, and document the results of the activities
- B.** Using the acceptance criteria, analyze the results to determine if the corrective action(s) to prevent recurrence of the problem was effective. If effective, then proceed to Section 6.
- C.** If the results of the review determine that corrective action(s) has been ineffective, the responsible manager should

- determine and implement appropriate compensatory action(s), if any
- determine if the identified conditions represent an additional problem that requires reporting through ORPS under DOE M 231.1-2, and/or to the DOE Noncompliance Tracking System (NTS) if the problem is determined to be a PAAA noncompliance. If not reportable in one of the DOE systems, the problem should be processed/managed as part of the contractor's corrective action program.
- determine the root cause for the corrective actions failing to solve the original problem and for any inadequacies in the corrective action process (e.g., inadequate implementation, inadequate causal analysis, inadequate corrective actions, etc.)
- develop and implement a new corrective action to correct the original problem or to correct a failure in the corrective action process
- schedule an effectiveness review to be performed on the new corrective action(s)
- document closure of the original effectiveness review in accordance with section 6

6. Documentation and Closure

- Provide a closure summary stating (1) what was done to evaluate the problem and (2) the overall results of the effectiveness review. (See Attachment B for a sample effectiveness review report outline.)
- If applicable, close the effectiveness review action in the appropriate corrective action/tracking system.
- Manage any findings from the effectiveness review in accordance with the contractor's corrective action and assessment processes.
- The responsible manager should concur with and/or approve the effectiveness review report.

7. Sustaining Effectiveness

Although not required, it is recommended that the following be considered as part of the post-effectiveness review actions:

- Incorporating all, or portions, of the specific effectiveness review lines of inquiry (1) in future independent/management assessment programs or (2) as part of the on-going performance analysis activity to evaluate continued effectiveness
- Applying lessons learned from the effectiveness review in future assessments or reviews

Attachment A

Methods for Conducting Effectiveness Reviews

The method selected for conducting effectiveness reviews should be appropriate for the specific corrective actions. The more direct the observation method, the more it is preferred. Methods to apply when conducting an effectiveness review include but are not necessarily limited to the following:

1. Observe the conduct of work or the performance of an evolution.
2. Conduct facility inspections, self-assessments, or activity monitoring.
3. Use performance measures and indicators to track and trend the number and frequency of recurrences, or, use lessons learned to ensure that the actual root cause(s) of the issue has been identified and adequately addressed.
4. Review appropriate databases for similar problems if subsequent assessments were likely to have identified the same or similar problems.
5. Run a test to challenge the system or process.
6. Run a mock item through the process, or complete a performance test.
7. Perform a walkthrough of the work, process, or evolution.
8. Interview managers and workers on their understanding of, and involvement with, the implemented corrective action(s).
9. Review a documented, previously completed equivalent evaluation of the original problem prior to initiating the effectiveness review.

The selected approach for evaluating effectiveness for externally identified issues may depend on external requirements, commitments, and/or management decisions, (e.g., increased rigor required for effectiveness reviews for DOE investigation issues).

Attachment B

Effectiveness Review Report Outline

It is recommended that the report of the completed effectiveness review include the following sections with sufficient discussion to ensure the reader can reach a logical conclusion as to the results of the review.

- A. Executive Summary
- B. Background
- C. Problem/Issue and Summary of Corrective Action(s)
- D. Approach/Plan for Conducting the Review
- E. Review Acceptance Criteria
- F. Review Results
- G. Conclusions
- H. Recommendations