

## **Best Practice #255**

**Facility:** Regulatory and Reporting Technical Subgroup

**Best Practice Title:** Best Practice for Effectiveness Review

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**Brief Description of Best Practice:** The best practice is to share lessons learned from the EFCOG Safety Working Group community that may help DOE Contractors through the logistics of preparing for and conducting an effectiveness review as part of their issues management process.

**Why the best practice was used:** Enforcement Coordinators within the Contractor Community have different levels of experience in preparing for and conducting an effectiveness review.

**What are the benefits of the best practice:** The best practice provides a guide for effectiveness reviews.

**What problems/issues were associated with the best practice:** Enforcement Coordinators within the Contractor Community have different levels of experience and varying degrees of complexity applied for effectiveness reviews.

**How the success of the Best Practice was measured:** This guidance document was vetted through the EFCOG Community and the DOE Office of Enforcement. Much of the information provided in this document was discussed during EFCOG Working Group meetings.

**Description of process experience using the Best Practice:** The guidance provided in the document reflects best business practices used through the DOE complex.

**EFCOG Report**

# **Best Practice for Effectiveness Review**

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**May 2022**

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## ACRONYMS

CAP	corrective action plan
ER	effectiveness review
LOI	line of inquiry
NTS	Noncompliance Tracking System

## 1. INTRODUCTION

This paper provides guidance for conducting and documenting effectiveness reviews (ERs). The guidance provided does not contain requirements, and it is intended to provide recommendations and tools for incorporation into a contractor's own site requirements and procedures.

A common condition identified in Integrated Safety Management System Core Function 5 (Feedback and Continuous Improvement) is a less-than-adequate follow-up to corrective action implementation that determines the effectiveness of actions to resolve and preclude recurrence of identified problems. As a means to better understand whether actions taken achieve the intended result and preclusion of recurrence, an ER can be performed.

ERs can be performed for any condition, event, or issue, and many contractors regularly perform ERs for corrective actions associated with events or conditions reported to the Office of Enforcement (i.e., Noncompliance Tracking System [NTS] actions) or those reported into the Occurrence Reporting and Processing System or the Safeguards and Security Information Management System. A manager can also request an ER for any condition, event, or issues, regardless of its significance. An ER may not be appropriate for events involving personnel disciplinary action or limited-scope action plans (i.e., one-time parts replacement); instead, they could be documented with concurrence from the appropriate level of management to provide justification supporting the decision to not document a review.

## 2. PURPOSE OF AN EFFECTIVENESS REVIEW

The ER process is a performance-based assessment focused on ensuring the effective implementation and sustainment of corrective actions that should include the observation of work. ERs are employed to validate whether a corrective action:

- Adequately addresses associated causes
- May preclude recurrence (or the likelihood of recurrence) of an issue
- Sustainability.

The effectiveness of corrective actions is not judged solely on the lack of recurrence, but also on whether a corrective action addresses the identified issue. The review focuses on determining whether the sum of the corrective actions implemented for a specific issue effectively resolved the problem.

## 3. PROCESS

### 3.1 Timing of an Effectiveness Review

The date of an ER should be chosen based on the periodicity of the factors that could propagate the original problem. For example, if a corrective action is implemented to ensure a monthly activity occurs, the activity may be monitored by the process owner for the first few months with an effectiveness review performed and documented the following quarter.

If factors propagating the event are uncertain or random, performance of an ER is recommended at 6 to 12 months following completion of the final corrective action or at the completion of the work evolution under review. Sufficient time is needed to allow for the corrective actions to be challenged. Ideally, this would merit having a longer or shorter time period from corrective action closure, depending on the issue.

Interim ERs should be considered to evaluate the timely implementation of corrective actions. Interim ERs can be a useful tool where corrective actions are delayed, perhaps well-reasoned or not, and the rationale to extend due dates is equally important as the action itself. This allows the process owner to course-correct implementation issues partway through the execution of a corrective action plan (CAP) rather than identify that the plan was ineffective after all actions are complete. For situations where no actions are being implemented or desired outcomes are not being realized, management may elect to revise actions to address the cause more effectively. Contractors may want to perform interim ERs for programmatic or repetitive conditions and for adverse trends when (a) sitewide extent of conditions are performed, (b) significant safety or security events are identified, or (c) meeting a consent order or settlement agreement action.

### 3.2 Developing Effectiveness Review Plans

The manager sponsoring the ER is usually responsible for developing the written plan. The plan should include:

- Scope and objectives of the review
- How the review will be conducted
- Who will conduct the review (e.g., the process owner, someone outside the organization, the Manager, the desired degree of independence)
- ER schedule (start and stop dates)
- Reporting format
- Description of the issues and causal factors, to include root or apparent causes that the corrective actions are to resolve

**NOTE:** *Not all corrective actions must be validated for effectiveness. However, if the actions are not validated, then justification should be provided to demonstrate why the corrective action were not validated.*

- A list of the completed corrective actions to review, and how discrepancies, including ineffective actions, will be handled and tracked via the contractor's procedures and processes
- A discussion of ER activities (e.g., personnel to be interviewed, activities to monitor, funding for the review team, and the time allotted for the review, types [specified below])
- Lines of inquiry (LOIs)/acceptance or success criteria for determining effectiveness of the corrective actions reviewed

**NOTE:** *Some contractors establish and document a minimum set of criteria to assist in the performance of an ER during the cause-evaluation process. If this is the case, ensure that criteria are included in the ER plan.*

- The objectives outlined in the “Conducting the Effectiveness Review” section listed in Section 4 unless addressed by the LOIs.

The types of review activities to be used by the ER team may include:

- Documentation review
- Performance-indicator reviews
- Work observation and facility tours
- Performance testing
- Interviews.

### **3.3 Effectiveness Review Participants**

Trained and qualified personnel who possess the technical skills and operational knowledge of the area they will be reviewing participate in reviews. The review participants can be federal or contractor personnel. Depending on the nature and significance of the issues being evaluated, a person independent from the issues and corrective actions might be a better choice. This may include individuals external to the organization.

The sponsoring manager may decide to select an individual to manage the planning, conduct, administration, logistics, and reporting of the review. This may include:

- Coordinating and recording all review activities and results
- Managing and coordinating ER participants
- Monitoring and delegating ER participant activities
- Preparing the final ER report.

If management of the ER activities transfers from one person to another midway through a review, the plan and information obtained during the ER are transferred to maintain consistency.

### **3.4 Conducting Effectiveness Reviews**

The ER lead ensures the following objectives are met while conducting reviews.

#### **3.4.1 Documentation Review**

Determine whether the corrective actions have been completed as intended per the CAP. The following questions should be answered:

- Determine whether the closure documentation (objective evidence) provided is consistent with the documentation stated in the CAP. Reference any associated attachments and documentation that are being used to determine action has been completed as assigned.

- Determine whether, collectively, the corrective actions were effective in resolving the problem or precluding recurrence. Consider the following:
  - Are the actions still in effect? If not, is there an adverse impact of them not being in effect?
  - Have the actions created any new or potentially undesirable outcomes?
  - How are the actions being sustained?

### 3.4.2 Performance-Indicator Reviews

Determine whether the organization is using metrics to evaluate process performance. Consider the following:

- Was there an indication of significant improvement in the performance of the process coincident with the implementation of the corrective actions?
- Has additional monitoring of the process performance determined whether the corrective actions were sustainable?
- Input data collected is it done by people or automated systems? Is the data collection, thresholds, or impacts subjective or subject to changes?
- Is the emphasis on high volume leading to a higher threshold for action or does the metric need only one input to a high visibility outcome? Consider the types of small to large corrective actions to adjust to small or large metric inputs that can significantly change the outcome.

**NOTE:** *The primary goal during work observation is to obtain the most complete picture possible of the performance, which should then be put into perspective relative to the overall program, system, or process.*

### 3.4.3 Work Observation/Facility Tours

Determine through observation of actual work activities whether they are being performed in accordance with work-control instructions and requirements. Consider the following:

- The frequency of the work activity being performed and how is it sustainable.
- Work-control instructions and requirements are new or changed since the last time the work active was performed.
  - Correct revision is being used
  - Relevant documents were modified
  - Record-keeping requirements were modified
  - Changes have been followed consistently



- Workers' familiarity with the work-control instructions and the purpose of any changes that may have occurred
- Check if output measures identified to monitor are within specification and verify that the process is achieving the desired results
- Review identified hazards to the workers and how they are being mitigated from a hierarchy of control perspective
- Check if skill of the craft is being used to perform the work activity and how was their knowledge and proficiency determined
- Pre-job brief requirements, performance, and personnel engagement
- Check work environment for good housekeeping practices.

#### **3.4.4 Performance Testing**

Performance testing is used to observe the response of personnel or equipment by creating a specific situation and noting the resulting performance. This technique is especially helpful when activities of interest would not normally occur during an assessment visit. It is also useful when the timeliness and appropriateness of the response are critical (i.e., emergency responses). Consider the following:

- Obtain approval from the management of the organization for the proposed performance test
- Determine who will develop the test scenario and administer the performance test
- Determine whether the performance test showed a level of proficiency
- Note whether additional training is needed
- Determine whether the implemented improvements can be validated
- Analyze the performance compared to requirements and expectations
- Note areas of improvement.

#### **3.4.5 Interviews**

Interviews provide the means of verifying the results of observation and document reviews, inspections, and performance testing. Interviews:

- Allow the responsible person to explain and clarify the results of the review
- Mitigate (and often eliminate) misunderstandings about program implementation
- Provide a forum where apparent conflicts or recent changes can be discussed
- Can describe organizational and program expectations.

**NOTE 1:** *The effectiveness of corrective actions is not judged solely on the lack of recurrence, but on the absence of conditions that caused the original occurrence.*

**NOTE 2:** *Recurrence of previously reported issues prior to the completion of an ER does not necessarily mean the corrective actions are not effective. Similar issues may result from causes different from those previously identified.*

### **3.5 Possible Reasons for Determination of Ineffectiveness**

Any of the following can be the reason for a determination of ineffectiveness:

- Corrective actions developed to address the causal factors were inadequate or insufficient
- The problem recurred
- The corrective actions were not implemented in a timely manner
- The corrective actions were not implemented for a period that would allow the issue to occur (i.e., did not have enough run time)
- The corrective actions were not adequately completed
- The corrective actions were not sustainable or sustained
- The corrective actions created a new or different problem (unintended consequences)
- The organization did not understand the issues
- The organization did not assign ownership of the corrective action
- Causal factors were incorrectly identified.

### **3.6 Possible Reasons for Determination of Effectiveness**

The following are possible reasons for determination of effectiveness:

- Identification of an opportunity for recurrence of the issue, that did not result in recurrence
- Self-critical investigation of the event and credible CAP
- Conducting thorough assessments
- Improving safety and security performance monitoring
- No recurrence of similar issues
- Near misses versus observant or ‘good catches’ driven by staff behaviors and not written corrective actions.

### 3.7 Outbrief to Management

Consult internal processes or the ER plan to determine whether ERs require a formal outbrief to management. Ensure data collected, observations made, and concerns identified during the ER are validated with the reviewed organization to ensure factual accuracy. This should be done prior to the results being presented to management.

### 3.8 Effectiveness Review Report

The results and recommendations of the ER should be formally documented, and the sponsoring manager should concur with both. The use of a formal report is the preferred method for documenting the ER; however, other means, such as the use of forms or electronic systems to document the review, are also acceptable.

The report should address the following:

- ER activities and results. This may include the status of corrective actions (completed or not completed).
- ER team conclusions regarding the corrective actions implemented and the ability of the corrective actions to effectively resolve issues and preclude recurrence (and consideration of those actions were required by the CAP and Quality Assurance Program to prevent recurrence).
- Identification and explanation of any specific corrective action found not to be effective.
- Recommendations from the ER Team, if applicable.

Specific corrective actions selected for review or the overall review maybe given a rating as defined below:

- **Effective.** Corrective actions are implemented as intended, have addressed the causes of the issues, have reasonably assured a precluding of recurrence of the issues identified, and demonstrate sustainability.
- **Partially Effective.** Corrective actions are implemented as intended and have partially addressed the causes of identified issues, but do not preclude recurrence or demonstrate sustainability.
- **Ineffective.** May indicate any of the following inadequacies. Corrective actions:
  - Were not implemented as intended
  - Do not address the causes of the issues
  - Do not demonstrate sustainability.

If the determination of partially effective or ineffective corrective action was due to run time between the completion of the corrective action and the ER being inadequate to determine effective implementation and sustainability, another review should be scheduled several months out to reevaluate the effectiveness of the implementation.

If the corrective actions have been determined to be ineffective at resolving or precluding recurrence of the issues, the reasons for those conclusions and any recommendations should be documented.

### **3.9 Following up the Corrective Action Effectiveness Review**

Upon concurrence of the ER, recommendations outlined in the report should be implemented as directed by management. Recommendations involving new or revised corrective actions are reflected in accordance with the contractor's issues management process. Additional corrective actions may be needed to address inadequate corrective actions.

The results of a contractor's ER for an NTS-reported noncompliance may require supplemental NTS reporting. If the review concludes that corrective actions have been ineffective in resolving the noncompliance, then the contractor either updates the existing NTS report (if it remains open) or submits a new version. Updated information includes the results of the ER and newly developed corrective actions.

## **4. REFERENCES**

- DOE Guide 414.1-1C. (2014) "Management and Independent Assessments Guide." Section 4.7.4. "Independent Assessment Techniques." March 27, 2014. pp. 24.
- DOE Order 226.1B. (2007) "Implementation of Department of Energy Oversight Policy." Appendix A, "Contractor Action Processes and Assessments." July 31, 2007.
- DOE. (2021) "Safety and Security Enforcement Coordinator Handbook." Appendix A, "Contractor Action Processes and Assessments." Department of Energy Office of Enterprise Assessments. August 27, 2021.