Department of Energy

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MEMORANDUM FOR: DOE AND CONTRACTOR PRICE-ANDERSON AMENDMENTS ACT COORDINATORS

FROM: STEPHEN M. SOHINKI
DIRECTOR
OFFICE OF PRICE-ANDERSON ENFORCEMENT

SUBJECT: Enforcement Guidance Supplement 05-01: Contractor Investigation, Causal Analysis, and Corrective Actions

Section 1.3 of the *Operational Procedures for Enforcement*, published in June 1998, provides the opportunity for the Office of Price-Anderson Enforcement (OE) to periodically issue clarifying guidance regarding the processes used in its enforcement activities. Such guidance is typically issued in the form of an Enforcement Guidance Supplement (EGS).

As part of the investigation of potential nuclear safety noncompliances, OE routinely reviews the contractor's investigation of the noncompliance, the associated causal analysis, and the corrective actions developed by the contractor to resolve the noncompliance and prevent recurrence. A high percentage of enforcement actions undertaken by OE feature recurrent events or deficiencies, indicating weaknesses associated with contractor processes to develop and implement effective corrective actions. In response, OE has developed this EGS to disseminate information regarding observed deficiencies as a potential lessons-learned for the DOE contractor community. Attachment A provides enforcement case examples highlighting performance deficiencies specific to this subject area.

I. Relevant Requirements

With respect to the subject areas of this guide, 10 CFR 830.122 (c) Criterion 3 – *Management/Quality Improvement*, establishes relevant DOE requirements for the investigation of identified nuclear safety deficiencies, the determination of underlying causes, and the development and implementation of effective corrective actions to both correct the deficiency and work to prevent recurrence.

OE review activities during the course of a noncompliance investigation extend to the evaluation of both the scope and methodology of the contractor's investigation and associated causal analysis of the noncompliance, and the corrective actions developed to resolve the noncompliance and prevent recurrence. Based on such reviews, OE has noted a wide variation in the scope and rigor of contractor investigations into nuclear

safety noncompliances. In response, OE developed this EGS to discuss some of the commonly noted weaknesses associated with contractor's investigation/causal analysis processes. The following information also outlines the approach and expectations used by OE in its evaluation of contractor investigations and corrective actions.

It should be noted this EGS is not intended to establish new requirements nor serve as a comprehensive guide on the methodology or approach for the performance of causal analysis or corrective action management. A variety of such information has already been developed by the Department[1].

II. Discussion

OE's general expectation is that a contractor conducting an investigation/causal analysis will ensure that personnel conducting the investigation are adequately trained and qualified, that the investigation includes appropriate scope and depth, and that corrective actions are timely and clearly relate to identified causes. This expectation applies both to contractor investigations of events and to investigations of nuclear safety issues identified as a result of more proactive means (e.g., assessments).

Consistent with 10 CFR 830.7, OE recognizes that the level and effort of the contractor investigation and corrective actions should be commensurate with the significance and complexity of the problem, i.e., a graded-approach should be applied. As an example, identification of apparent causes may be an appropriate endpoint when investigating less significant problems, while the conduct of a root cause analysis would be appropriate for more significant or complex issues. As one acceptable point of reference, OE has noted that many contractors use the criterion of Noncompliance Tracking System (NTS) reportability as one of several thresholds for determining whether a root cause analysis (rather than the less rigorous apparent cause analysis) will be performed.

III. Scope of Investigation

Once a deficiency or quality problem has been identified, it must be fully evaluated and characterized so that it may be effectively corrected. As part of its review of a contractor's investigation of a nuclear safety quality problem, OE determines whether the investigation included the following elements:

- Extent of condition review
- Precursor or historical review (including effectiveness of prior corrective actions)
- Evaluation of assessment performance.

[1] see DOE G 414.1-2A, *Quality Assurance Management System Guide for use with 10 CFR 830.120 and DOE O 414.1*; DOE-NE-STD-1004-92, *Root Cause Analysis Guidance Document;* DOE 231.1-2, *Occurrence Reporting Causal Analysis Guide*; DOE G 225.1A-1, *Implementation Guide for use with DOE O 275.1 Accident Investigation*.

A. Extent of Condition Review

Once a significant quality problem has been identified, a review should be performed to determine the full extent and generic implications of the problem. This includes determining whether the same problem/condition exists elsewhere (i.e., transportability of condition); and whether the same root or underlying causes of the problem/condition may be affecting performance in other applications (transportability of cause). Such a review may be termed an extent of condition (EOC) review. Areas to be covered as part of an effective EOC review will vary with the specifics of the identified problem, but generally include the following:

- looking for the same problem in applications, locations or facilities other than where originally found;
- looking for other manifestations of the identified root or underlying causes of the problem;
- looking for similar or related problems, or problems that can be anticipated based on the identified problem;
- reviewing prior applications of the deficient process or procedure to see if earlier deficiencies had gone unnoticed.

The approach used in conducting an EOC review may also vary based on the details and significance of the identified problem (i.e., a graded approach). Typically a series of focused field observations or assessments in conjunction with document reviews are performed; it is unlikely that a simple review of site trending data or quality problem tracking systems will provide the specificity needed to adequately assess the scope of the problem.

The most frequently observed performance deficiency in this area is the simple failure to do an EOC review for deficiencies with a clear potential generic applicability. OE has also noted instances in which contractors have conducted event database searches for similar prior events or for general negative performance trends, and have termed these reviews “extent of condition” reviews. Although OE understands such database reviews have value (see following precursor review section), they do not constitute an effective EOC review. Inappropriate use of this terminology may provide senior management a false confidence that an identified problem is limited in scope.

B. Precursor/Historical Review

A contractor's investigation and analysis of an identified quality problem should also include a precursor or historical review to determine if the same or similar problem has occurred previously. In making this determination, it is appropriate to look at both the problem condition and underlying causes to determine if the problem is recurrent.

If a quality problem is determined to be recurrent, the contractor's analysis should include an evaluation to determine why prior corrective actions were not effective in preventing the recurrence of the problem. The results of that evaluation should be factored into the development of corrective actions for the current event or problem. Unlike an EOC review, a precursor or historical review is retrospective in nature and can usually be effectively conducted using site database information on events, assessment results, etc.

C. Evaluation of Assessment Performance

Over the past two years, OE has increasingly focused on the implementation and effectiveness of a contractor's assessment programs in improving nuclear safety performance. OE has concluded that the self-identification of nuclear safety deficiencies through implementation of an effective internal assessment program (rather than by reacting to events) represents a cost-effective method of improving nuclear safety performance, and that contractors should strive towards implementing an assessment-driven (vice event-driven) nuclear safety program.

Consistent with the above, during the conduct of an event investigation OE typically questions whether the subject nuclear safety noncompliance should have reasonably been identified through implementation of the contractor's assessment program. Based on the initial answers, follow-up questions can lead to the identification of deficiencies in assessment scheduling, quality, or corrective action development and implementation. OE recommends that, where appropriate, contractors perform a similar evaluation as part of their investigation of an event or other nuclear safety problem.

IV. Causal Analysis

The conduct of an effective causal analysis is an essential step in developing appropriate corrective actions for an identified nuclear safety quality problem. Numerous causal analysis techniques and methodologies are currently being utilized by the DOE contractor community. OE has no preference assuming each is used in an appropriate fashion by trained and qualified personnel.

A. Depth of Analysis

The depth of the contractor's causal analysis should reflect the significance and complexity of the nuclear safety quality problem or event under analysis. Some problems may be easily understood, while others may require considerable in-depth analysis.

Based on review of a large number of contractor causal analyses, OE considers the most frequent deficiency in this area to be the tendency for analyses to truncate before getting to underlying issues, i.e., they don't go "deep" enough. In particular, OE has found that contractors frequently conclude the analysis at some failure condition (i.e., failure to follow procedures, inadequate training, inadequate

administrative controls) and then identify this condition as the root or underlying cause. Although convenient for binning and trending purposes, these failure conditions often do not represent satisfactory endpoints. A more detailed causal analysis should go further and ask why the procedure was not followed, why the training was inadequate, or why there was an inadequate administrative control.

B. Cultural/Organizational Factors

The endpoint of "worker failure to follow procedures" has been frequently cited as an underlying cause in contractor causal analyses, and corrective actions have consequently been focused on retraining or disciplining the worker or revising the procedure or process. Although such actions may be appropriate in some cases, contractors should also evaluate organizational and management issues for any contribution to the failure. A variety of cultural or organizational factors may underlie worker procedural compliance issues, and can include the following:

- Perceived differences in management's actions versus their words;
- Local supervisory influences contrary to management's stated expectations;
- Emphasis on production or schedule;
- Inconsistent standards applied across the institution;
- Long-standing organizational practices conflicting with procedures and becoming the default process;
- Examples set by fellow workers;
- Desire for a successful experiment or evolution.

A comprehensive investigation of a nuclear safety problem should attempt to identify all the particular influences that are causing the problem, including the management or supervisory influences that affect workers' behaviors. OE recognizes these underlying factors are potentially difficult to identify or "get to" in an investigation, and may require a senior level effort, special expertise, or a number of one-on-one interviews.

C. Breadth of Analysis

An additional concern noted by OE is that some causal analyses simply do not identify all significant issues associated with an event. For example, OE is typically just as interested in the reasons why a long-standing nuclear safety noncompliance persisted without identification as to the specific causes of the original noncompliance. Questions such as these are generally not asked as part of the causal analysis, which tends to focus on the specific failure condition.

V. Corrective Actions

OE evaluates contractor Corrective Action Plans (CAP) as part of the routine review of submitted NTS reports, during the conduct of Price-Anderson Amendments Act (PAAA) Program Reviews and as part of an investigation into a nuclear safety problem. As part of its review, OE uses the general criteria outlined below to evaluate corrective actions. OE also relies on the judgement of cognizant DOE/National Nuclear Security Agency (NNSA) representatives when evaluating the adequacy of contractor corrective actions.

- Clear linkage to causal analysis – OE's review includes identifying whether the contractor has developed corrective actions for all root and significant contributing/underlying causes identified through the causal analysis process.

- Appropriateness of corrective actions – OE's review includes verifying that stated corrective actions make sense and appear appropriate for the problem being addressed (i.e., behavioral or culture issues are not being addressed by a procedure revision) and that deliverables are clearly stated and achievable.

- Timeliness of corrective actions – OE's review includes verifying that schedules for corrective action completion reflect an appropriate priority and do not extend out past a reasonable timeframe. OE expects that any delays in corrective action completion will be justifiable and limited in number and extent.

- Verification of effectiveness – OE's review includes determining whether the contractor has included an effectiveness verification (described below) as a planned corrective action for significant or complex nuclear safety problems.

Several contractors have implemented the practice of conducting an "effectiveness verification" as a corrective action for a significant nuclear safety issue. This verification, typically performed several months after completion of the other corrective actions, is intended to assess workplace performance in the subject area and to determine whether the corrective actions have been effective. Effectiveness verifications can also be performed as an element of the independent assessment process.

OE views the practice of conducting verification assessments as a positive one, which should reduce the incidence of recurrent events. For nuclear safety noncompliances reported to the NTS, it is the contractor's option whether the planned verification assessment is formally listed as one of the NTS report's corrective actions (which may involve keeping the NTS report open for a longer period of time) or whether it is tracked separately. It should be noted that the implementation of a verification assessment approach does not alter OE's expectation of a verification of completion of the proposed corrective actions by the contractor and local DOE personnel before closing an NTS report.

This enforcement guidance will be made available on the Office of Price-Anderson Enforcement webpage (http://www.eh.doe.gov/enforce/). Additional OE observations related to this subject area are contained in site PAAA Program Review Reports which are also accessible from the OE webpage. If you have any questions regarding this enforcement guidance, please contact me at (301) 903-0100 or Tony Weadock of my staff at (301) 903-4283.

ATTACHMENT A

EGS 2005-01
Investigation/Causal Analysis Lessons-Learned

The following case studies drawn from prior enforcement actions were chosen to illustrate frequently observed performance deficiencies associated with the areas of event investigation, cause analysis, and/or corrective actions.

Case Studies

1. A prior enforcement action at a DOE site was associated with that site's unauthorized staging and storage of transuranic (TRU) waste from 1996 to 2001. A temporary, butler-type building was used for staging and storage of the waste; however, no safety analysis for the temporary building had been generated and consequently, no analysis of the storage conditions had taken place. The butler building was located adjacent to a permanent Category 2 nuclear facility. Through a series of poor communications and assumptions, it was assumed the storage of the TRU waste was analyzed and covered in the larger facility's documented safety analysis. Upon discovery, the waste was relocated to the Category 2 facility until additional controls (establishing a limit for Material at Risk and combustible loading limits) could be developed.

   The site performed an investigation of the incident and identified as a root cause the historical failure to appropriately implement the site's Unreviewed Safety Question (USQ) procedure when first considering staging TRU waste in the butler building. No corrective actions were identified as a result of the contractor's investigation; the USQ procedure had since been revised and site management believed it was being effectively implemented.

   OE's review of the site's investigation/causal analysis identified two basic concerns. No EOC review had been performed to identify if there were other situations/conditions similar to the above-described situation. Additionally, the site's investigation failed to ask why the above-described condition could exist for such an extended period without identification through normal management processes or through assessment. After prompting by OE, the site undertook additional investigation into the above concerns and subsequently identified additional corrective actions.

2. A 2003 event at a DOE facility involved the higher than anticipated exposure of several employees during glovebox work activities. A number of performance deficiencies were associated with the event, including an inadequate pre-job briefing, failure to follow Radiation Work Permit (RWP) requirements, and failure to adequately respond to radiological alarms.

During the subsequent OE investigation, facility management briefed OE staff on the "extent of condition" review that had been performed. To conduct the review, a team of site personnel had reviewed a broad set of site indicator data (including occurrence and assessment reports) to look for general issues or trends. Although two adverse trends were noted, no issues rising to the level of "programmatic" were identified as a result of the review.

Although OE found the above desktop analysis approach to be a useful technique for identifying quality problems, OE disagreed with the use of the term "extent of condition review " to describe the above approach. The contractor's review was essentially a re-review of existing site performance information. It consequently relied heavily on the judgement and conclusions of the personnel originally generating the data. The review was essentially independent of the unanticipated exposure event; it contained no "active" review of the specific performance deficiencies or causes associated with the current event to see if they were isolated problems, or symptomatic of a larger systemic problem.

As part of the investigation, OE did find that the site was also initiating a series of facility reviews as a corrective action to the subject event. These facility reviews would assess each facility's performance against evaluation criteria developed from the causal analysis of the unanticipated exposure event. OE indicated that the planned series of facility reviews better met the objective of assessing the extent of condition of the event-related performance deficiencies than the desktop analysis described above.

3. During an older enforcement action, OE reviewed a contractor's investigation into multiple material movement deficiencies at a specific facilty (Facility XYZ). The contractor's investigation identified that the need to use and adhere to the controlling material movement procedure had not been adequately communicated to Facility XYZ process operations personnel. A contributing factor was that the material movement procedure had been inappropriately categorized as a general information/use procedure. Procedures categorized at this level were not required to be present at the worksite and the user was only responsible for compliance with the general intent (vice verbatim compliance) of the procedure.

   Upon identification of this contributing factor, the contractor appropriately reviewed the categorization of other significant procedures to ensure that they were adequately categorized. This extent of condition review was limited, however, to facility XYZ procedures, and resulted in the re-categorization of seven procedures. Subsequent to questioning by OE, the contractor expanded this review to evaluate categorization at other site facilities. Ultimately, 115 of 387 site operational procedures were found to be inappropriately categorized for their respective activities.

4. A 2003 event that was subsequently investigated by OE involved decontamination and decommissioning (D&D) activities within a nuclear facility. To support the D&D of a large size-reduction enclosure contained within the facility, facility workers had routed the two air-mover discharges of the size reduction enclosure into one of the facility's remaining Zone 2 ventilation plenums. An engineering analysis had been performed prior to the routing. Subsequent operation of one of the enclosure air-movers resulted in a flow reversal and the discharge of airborne radioactivity from the Zone 2 vent ducting into the facility. As a result, several personnel were identified as either externally contaminated or as having received intakes of radioactive material.

   The contractor's investigation identified the direct and root cause of the event as equipment failure – due to material degradation of a damper position mechanism, a damper in the facility main ventilation ducting appeared to be open to operators when it was in fact closed. OE found the contractor's investigation to be superficial; although the damper position played a factor, it represented only one example of a larger concern. OE found that the engineering evaluation performed to support the ventilation modifications was inadequate, because key assumptions used in the analysis (such as maximum airflow, face velocities, etc.), were never verified or tested prior to operation of the air-movers. The contractor subsequently re-performed their causal analysis and identified additional deficiencies in their engineering evaluation and conduct of operations that expanded the original set of corrective actions.

5. During 2004, OE conducted an investigation into performance deficiencies associated with a DOE contractor's oversight of a supplier fabricating modular radwaste containments. The contractor's investigation report cited deficiencies in training and qualifications, project planning, design change control, lessons-learned, management oversight, and procedural compliance. The contractor investigation identified the root cause of the event as a failure of project management to adequately plan, execute and oversee fabrication of the modular containments.

   OE took exception to the contractor's determination of the root cause. OE viewed the above statement as being an accurate overall summary of the problem condition, but not a true underlying or root cause. OE found, however, that this point of contention was largely semantic; the contractor's investigation had identified several contributing causes (including an overemphasis on project schedule) which appeared to collectively bound the root cause and were addressed by appropriate corrective actions.

6. As part of a 2003 investigation, OE reviewed an event in which a workgroup accessed the roof of a radiography facility while radiography operations were taking place. Roof access during such operations is unauthorized due to the potential for radiation fields on the roof. The contractor's investigation into the event identified deficiencies associated with rooftop posting, compliance with the work Activity Hazard Analysis, communication of hazards among and between the facility and

work groups, and the work control process. OE's review of the event and discussion with personnel, however, identified an additional significant concern that had not been identified as part of the contractor's investigation.

The division operating the facility maintained a procedure specifically identifying controls to be implemented for posting and controlling access for facility radiological areas during radiography operations. OE's investigation identified that facility operating personnel did not view this procedure as applicable to rooftop access situations such as those associated with the subject event, even though the procedure specifically identifies controls for accessing facility rooftops. Consequently, the controls identified in the procedure were not complied with during the subject event, and had not been implemented for any of the regular maintenance visits to the facility rooftop over the past year. This long-standing procedural noncompliance situation, and its potential implications, were neither identified nor reviewed as part of the contractor's investigation.