



Department of Energy
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MEMORANDUM FOR: DOE PAAA COORDINATORS
CONTRACTOR PAAA COORDINATORS

FROM: R. KEITH CHRISTOPHER *R. Keith Christopher*
DIRECTOR
OFFICE OF PRICE-ANDERSON ENFORCEMENT

SUBJECT: Enforcement Guidance Supplement 01-02:
Management and Independent Assessment

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.

OE typically issues such guidance in the form of Enforcement Guidance Supplements (EGSs), which provide information or recommendations only and impose no requirements or actions on DOE contractors.

DOE enforcement activities to date have indicated the need for improvement in contractor compliance with the Management and Independent Assessment (M&IA) requirements of 10 CFR 830.122. This EGS signals an increased emphasis by OE in this area, and describes the general approach that will be used by OE in evaluating compliance of nuclear-safety related M&IA Programs.

Background

10 CFR 830.121(a) requires that contractors conducting activities that affect, or may affect, the nuclear safety of DOE nuclear facilities must conduct work in accordance with the Quality Assurance (QA) criteria in 830.122. 10 CFR 830.122(i) identifies criteria specific to the conduct of Management Assessments. 10 CFR 830.122 (j) identifies criteria relative to the conduct of Independent Assessments. Both assessment functions are required but, where appropriate, must be implemented in a graded-approach fashion consistent with 10 CFR 830.7.

Supplemental DOE guidance specific to assessments has been provided in DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide*. DOE G

414.1-1A provides significant detail and guidance on assessment program purpose, objectives, and implementation that goes well beyond the scope of this EGS.

When conducted effectively, contractor assessment activities serve as a significant performance feedback loop, allowing for the proactive identification and correction of nuclear safety deficiencies that might otherwise result in significant events. DOE enforcement activities over the past several years, however, have indicated the need for improvement in the conduct of contractor assessment programs. The following general concerns have been identified:

- A lack of assessment activity in significant nuclear-safety related areas,
- Ineffective assessments, as evidenced by the absence of assessment findings in areas where programmatic problems have been disclosed through other means (i.e., operational history, events),
- Weaknesses in the effective correction and closure of assessment issues, with resulting recurrent and long-standing deficiencies.

During investigations of potential Price-Anderson Amendment Act (PAAA) noncompliances, OE typically reviews contractor assessment performance and results as they specifically relate to the subject area of the investigation. In light of the above concerns, however, OE will be increasing its emphasis on evaluating the implementation of contractor assessment programs as described in the Implementation section below.

M&IA Program Review Criteria

During the first half of CY 2001, OE staff conducted pilot reviews of contractor M&IA programs as subsets of three ongoing PAAA Program Reviews. These pilot reviews were used as an opportunity to generally overview contractor assessment performance and to develop and refine draft M&IA review criteria. During this period, OE refrained from the enforcement of assessment noncompliances identified during the course of the pilot reviews.

The draft review criteria were subsequently distributed for limited review by members of the DOE and contractor PAAA and QA communities, and revised as appropriate to reflect those comments. The resulting M&IA review criteria are provided in Attachment A. OE intends to use the review criteria as an internal guide during evaluations of contractor assessment program implementation, to promote consistency of OE review activities. The M&IA review criteria largely reflect relevant 10 CFR 830.122 requirements, logical extensions of those requirements, or the evaluation of contractor performance against their applicable procedures. The criteria do not reflect supplemental DOE or external guidance relative to M&IA Programs, and OE will not be using such supplemental or external guidance to evaluate contractor programs except as it is incorporated into contractor Quality Assurance Program (QAP) documentation.

This evaluation approach merely reflects OE's regulatory perspective, however, and should not be viewed as encouragement to contractors to downscope their programs.

Implementation

Concurrent with the issuance of this EGS, OE will increase the level of emphasis it directs towards the evaluation of contractor assessment program compliance through the following means:

- Broadening the scope of routine noncompliance investigations to include increased evaluation and follow-up of contractor assessment program deficiencies,
- Continued monitoring of contractor reporting information with increased attention to assessment or corrective action related items,
- As necessary, the conduct of contractor M&IA Program compliance reviews (in response to negative performance indicators or DOE request).

Consistent with the 10 CFR 830 scope and OE's jurisdictional authority, OE review activities will be directed towards evaluating compliance of contractor M&IA Program activities with Part 830.122 M&IA nuclear safety requirements for those facilities and activities subject to the requirements. Enforcement of identified noncompliances will be pursued as appropriate, consistent with the specifics of the noncompliance and in full consideration of any mitigating factors.

The review criteria contained in Attachment A will be used as an aid to promote consistency and are not intended to represent new or supplemental requirements. Evaluations of contractor compliance performed by OE will be made directly against applicable 10 CFR 830 criteria, the contractor's documented QAP, and associated policies and procedures.

Enforcement Guidance Supplements will be incorporated in later revisions of the DOE Enforcement Handbook and will be made available on the Office of PAAA Enforcement web page (<http://tis-nt.eh.doe.gov/enforce/>). If you have any questions regarding this guidance, do not hesitate to contact me or Tony Weadock of my staff at 301-903-0100.

MANAGEMENT AND INDEPENDENT ASSESSMENT (M&IA) REVIEW CRITERIA

The following criteria have been developed to support OE evaluations of contractor implementation of the M&IA requirements of 10 CFR 830.122. These review criteria are intended to improve the consistency of OE reviews and do not represent new or additional requirements in the M&IA area. Sections I-III contain general programmatic criteria which may be utilized during any review; Section IV contains more focused criteria and is intended for use (along with applicable general criteria from Sections I-III) during an OE investigation of a specific event or noncompliance.

The contractor's documented Quality Assurance Program (QAP) describes how the contractor will satisfy the 10 CFR 830.122 quality assurance criteria consistent with the graded approach provisions of 10 CFR 830.7. The following review criteria should consequently be reviewed and adjusted as necessary to reflect the specific commitments and provisions described in the subject contractor QAP.

I. Programs and Procedures

- A. Verify that the contractor's Quality Assurance Program (QAP) document(s) describes how the contractor is meeting the Management and Independent Assessment (M&IA) criteria of 10 CFR 830.122. Review to determine that the QAP description reflects current conditions, referenced procedures are correct, etc.

- B. Verify that the contractor's Management Assessment (MA) and Independent Assessment (IA) processes are adequately described in approved procedures or instructions. Determine if the procedures adequately address the following:
 - 1. organizational responsibilities;
 - 2. assessment prioritization, planning and methodology;
 - 3. training/qualification requirements;
 - 4. reporting and records.

- C. Also verify that the contractor's quality problem resolution/corrective action process is described in formal procedures. Determine if the procedures adequately address the following:

1. organizational responsibilities;
 2. problem/deficiency significance evaluation;
 3. responsibilities and criteria for conducting causal determinations;
 4. corrective action development and approval;
 5. documentation of disposition and resolution;
 6. corrective action closeout;
 7. verification of effectiveness.
- D. Verify that the group responsible for performing IAs is reasonably and obviously independent from and has no direct responsibility for the work being assessed. Also verify that the IA group has been assigned appropriate authority to perform their assessment function.
- E. Verify that a process has been established to ensure that IA assessors are appropriately trained and qualified and knowledgeable in the areas to be assessed.
- F. Verify that the MA program/procedures require the direct participation of management-level individuals in the conduct of MAs (unless defined differently in contractor procedures, “management-level” or “management” includes second-level supervision and higher). In evaluating level of management involvement, note that specific support activities (i.e., data collection) may be delegated to staff. It is anticipated, however, that managers will be directly involved in the process and that the resulting MAs will represent the evaluation and conclusions of management.

II. Implementation – Management Assessments (MA)

- A. Select at least two MA assessment units (i.e., facilities, operational divisions, etc.) and review the current MA schedule and completion status. Verify that procedural expectations for scope and scheduling are being met and that management processes are being assessed. For assessments that were not completed, evaluate reasons/factors for not completing.
- B. Select examples of completed MAs for detailed review. Review should include the assessment report, supporting documentation as necessary, any associated corrective action plan, and selected corrective action closure documentation. Determine the following:
1. Verify that the assessment was planned, conducted and reported in accordance with procedural requirements.
 2. Verify through review and interview that management was involved in the completion of the assessment (involvement may include participation in the data collection or evaluation of results).

3. Verify that personnel performing the assessment were trained in the assessment process and knowledgeable of the program, system or process being assessed.
 4. Verify that quality problems identified during the assessment were evaluated and that significant problems were entered into a formal corrective action system consistent with site procedures.
 5. Review causal analyses and corrective actions associated with significant assessment findings. Verify that causal analyses evaluate extent of conditions and that corrective actions address causes and appear appropriate to prevent recurrence.
 6. Verify that corrective actions are assigned to specific “owners,” have associated milestone dates, and are being completed/closed in a timely fashion.
 7. Review closure documentation for selected corrective actions to verify that completed actions are consistent with planned actions. Determine if adequate evidence exists to support closure.
- C. Review additional sources of performance information (i.e., prior or subsequent MAs, external assessments, and occurrence reports) for one of the assessment units discussed in item II.B above. Determine if subject MA results are consistent with other indicators of performance and if findings identified during the subject MA represent long-standing or recurring problems.
- D. Review MA program documentation to determine whether the contractor has included methods in addition to assessments (i.e., event review, performance indicators, etc.) in their overall MA strategy. In such instances, evaluate and determine the following for one of the assessment units discussed in II.B above through personnel interview and review of selected documentation:
1. that MA methods are being conducted consistent with applicable procedures,
 2. that identified quality problems are being appropriately tracked, controlled and resolved consistent with procedures.
- E. Based on interview with management representatives and review of MA results (from II.B above), evaluate the effectiveness of the MA process in identifying and correcting problems that hinder the organization from achieving its objectives.

III. Implementation – Independent Assessments (IA)

- A. Review the current IA schedule. Verify that procedural expectations for scope and scheduling are being met. The IA schedule should demonstrate that

assessments are being performed to measure item and service quality; to measure the adequacy of work performance; and to promote improvement.

Although OE emphasis in this area should focus on evaluating performance against the contractor's procedural requirements, the OE reviewer should consider the following during review of the IA schedule:

1. The scheduling process should consider factors such as risk, time since last assessment, operational activities during the assessment period, feedback from trending, events, or other assessments, etc.
 2. The schedule should reflect that significant facilities, operations, and functional areas are being assessed on a periodic basis.
 3. The IA schedule (or individual assessment scope) should reflect the observation/evaluation of work activities and practices.
- B. Review completion status of the IA schedule. For scheduled assessments that were not completed, evaluate the reasons/factors for not completing.
- C. Select several completed IAs for detailed review (assessments selected by the OE reviewer should reflect a mix of facilities and topic areas). Review should include the assessment report, backup assessment documentation as necessary, selected associated corrective action plans, and selected corrective action closure documentation. Determine/perform the following:
1. Verify that the assessments were planned, conducted, and reported in accordance with procedural requirements.
 2. Verify that assessors participating in the assessments were qualified in accordance with procedures and knowledgeable in the areas being assessed.
 3. Verify that assessment findings (i.e., quality problems, issues) were evaluated and significant findings were entered into a formal corrective action system consistent with site procedures.
 4. Review causal analyses and corrective actions associated with significant assessment findings. Verify that causal analyses evaluate extent of conditions and that corrective actions address causes and appear appropriate to prevent recurrence.
 5. Verify that corrective actions are assigned to specific "owners", have associated milestone dates, and are being completed/closed in a timely fashion.

6. Review closure documentation for selected corrective actions to verify that completed actions are consistent with planned actions. Determine if adequate evidence exists to support closure.
- D. Review additional sources of performance information (i.e., prior or subsequent IAs, external assessments, occurrence reports) for one of the assessed facilities or topic areas discussed in item III.C above. Determine if subject IA results are consistent with other indicators of performance and if findings identified during the subject IA represent long-standing or recurring problems.
- E. Based on interview with IA and line management representatives and review of IA results (from III.C above), evaluate the effectiveness of the IA process in identifying quality problems and promoting improvement.

IV. Review as Part of OE Specific Investigation

- A. As part of the investigation document request (or at onset of site investigation), request any recent (i.e., within approximately 24 months) prior assessments that evaluated performance within the subject area of the investigation. Determine/perform the following:
 1. Review and evaluate general adequacy of the assessments using applicable review criteria II. B or III.C.
 2. If prior assessments identified quality problems similar to those evident during the current investigation, determine the following through review and interview:
 - whether effective causal analyses were performed for the prior quality problems consistent with procedural requirements,
 - whether identified corrective actions for the prior quality problems were reflective of causes identified during the causal analysis and were effectively completed.

If no prior assessments of the subject area of the investigation were performed, determine whether the contractor has been meeting procedural requirements for scope and scheduling using applicable review criteria II.A and III.A.