



Enforcement Guidance Supplement
EGS 00-02
Appendix E- *Operational Procedures
for Enforcement*

Department of Energy
Washington, DC 20585

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MEMORANDUM FOR DOE PAAA COORDINATORS
CONTRACTOR PAAA COORDINATORS

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SUBJECT: Enforcement Guidance Supplement 00-02:
Price-Anderson Amendment Act (PAAA) Program Reviews

Section 1.3 of the *Operational Procedures for Enforcement*, published in June 1998, provides the opportunity for the Office of Enforcement and Investigation (EH-Enforcement) to periodically issue clarifying guidance regarding the processes used in its enforcement activities.

During 1999, EH-Enforcement began an initiative to conduct formal reviews of contractor programs for identifying, reporting, tracking and closing PAAA noncompliances. Four main objectives were associated with this initiative:

1. Encourage the establishment of effective programs for noncompliance identification and reporting across the complex;
2. Enhance the uniformity of PAAA noncompliance identification and reporting among contractors;
3. Provide EH-Enforcement with first-hand information on program effectiveness for those contractors with little previous enforcement interaction (i.e., low-reporters); and
4. Establish a mechanism for the feedback of program implementation lessons-learned into existing EH-Enforcement guidance.

To date, nine initial and one follow-up contractor PAAA Program Reviews have been conducted; EH-Enforcement plans to conduct similar reviews at all major DOE sites over the next few years. To aid in contractor preparation, this guide has been developed to define the purpose, scope, and logistics of such reviews. In addition, the

attachments to this guide provide the review criteria used by EH-Enforcement staff in the conduct of PAAA Program Reviews.

The conduct of an effective PAAA Program includes implementation of both mandatory and non-mandatory program elements. Mandatory elements include those actions and management efforts necessary to implement and ensure compliance with nuclear safety requirements as contained in departmental nuclear safety rules. Non-mandatory PAAA Program elements include those elements directed towards noncompliance identification, screening and reporting. The scope of the EH-Enforcement PAAA Program Review is largely focused on these non-mandatory PAAA Program elements. Although non-mandatory, successful implementation of these elements is in the contractor's best interest, since timely noncompliance identification and reporting is a potential mitigation factor considered by DOE during enforcement actions.

PAAA Program Functions

The contractor's program for noncompliance identification and reporting should accomplish the following basic functions:

1. Identification and Screening - A diverse set of information sources should be screened to identify actual or potential PAAA noncompliances.
2. Evaluation for Reportability - Once identified, potential PAAA noncompliances should be reviewed for reportability to the DOE Noncompliance Tracking System (NTS). This review should include an evaluation of noncompliance trends, to identify potential repetitive or programmatic noncompliances.
3. Cause Determination - Appropriate cause determinations should be developed for identified noncompliances and effective corrective actions should be implemented to prevent recurrence.
4. Noncompliance/Corrective Action Closure - Identified noncompliances and associated corrective actions should be formally tracked to completion, with corresponding validation of closure.

The EH-Enforcement PAAA review process is intended to evaluate contractor performance of the above functions, as well as the adequacy of supporting program elements (e.g., formal procedures, staffing, training, adequacy of assessments). The EH-Enforcement PAAA Program Review occurs in several phases as described below.

Scheduling/Site Selection

PAAA Program Reviews are conducted on a schedule-permitting basis, when EH-Enforcement staff is not otherwise occupied by activities of a more reactive nature (investigations, etc.). As a consequence, planning and scheduling of PAAA Program

Reviews is typically conducted on a near-term, quarterly basis. No formal schedules are distributed; however, individual sites are contacted prior to the review in conjunction with the document request (see below).

Site selection is based on a number of factors, including input from Field Office personnel, site NTS reporting history, EH-Enforcement familiarity with contractor program, proximity to other sites, etc. On occasion, EH-Enforcement may conduct a PAAA Program Review at a site in conjunction with an investigation at that site. Again, EH-Enforcement's intent is to complete baseline reviews at all major DOE sites over the next few years.

Notification/Request for Documentation

DOE and contractor PAAA coordinators will be formally notified (via e:mail) of planned PAAA Program Reviews approximately four weeks in advance of the review. The EH-Enforcement staff member leading the review will coordinate with the DOE PAAA Coordinator prior to issuing the notification. The notification will contain details on participants, scheduling, agenda items, and other logistics.

As part of the notification, EH-Enforcement will request specific documentation from the contractor relating to the implementation of their PAAA Program. Specifics regarding the document submittal will be included in the request; typically the contractor is requested to provide documentation within 10 working days. Attachment A provides a standardized PAAA Program Review document request that may be tailored based on the specifics of the review.

Onsite Review

The PAAA Program Review is generally conducted by two or three EH-Enforcement representatives and is typically two days in duration. Unlike investigations, EH-Enforcement staff routinely conducts formal entrance/exit meetings as part of the PAAA Program Review. Preliminary findings of the review are discussed during the exit meeting. A typical agenda for the review is shown below:

Day 1

- ◆ Initial informal meeting with local DOE to provide overview of review and discuss contractor performance (1 hour)
- ◆ Entrance meeting with contractor, DOE (1/2 hour)
- ◆ Overview presentation by contractor on PAAA Program implementation (1-2 hours)
- ◆ Personnel interviews/document review (through end of day)

Day 2

- ◆ Personnel interviews/document review (typically half day)
- ◆ DOE only pre-exit meeting (1/2 hour)

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- ◆ Contractor/DOE exit meeting (1/2 hour)

Contractor interviewees may include the PAAA Coordinator, QA Manager, Radiological Control Manager, Lessons-Learned Program Manager, personnel performing PAAA screens, individuals responsible for tracking corrective actions, personnel performing QA or radiological control assessments, members of PAAA committees, and individuals with knowledge of specific events resulting in NTS reports.

EH-Enforcement staff utilizes the review criteria identified in Attachment B as guidance for the conduct of the review. The actual scope of the review may be broader or more limited than the scope reflected by the criteria, depending on the specifics of the review. These review criteria are updated periodically to reflect lessons-learned identified during the performance of site reviews.

In addition to evaluating PAAA program implementation, the EH-Enforcement review may include evaluation of a "special topic" area. This topic is chosen to reflect EH-Enforcement emphasis areas or in response to performance deficiencies/enforcement actions occurring across the DOE complex. For example, PAAA Program Reviews conducted over the next several months may include a limited evaluation of Bioassay Program implementation as a follow-up to previous enforcement activities in this area. Attachment C identifies documents to be requested and review criteria for the Bioassay Program special topic review.

Report Generation and Distribution

A draft report describing the scope and results of the review is sent to the local DOE office for review within approximately one month of the onsite review. This draft is for DOE internal review only, and is not shared with the contractor. The final report of the PAAA Program Review and accompanying transmittal letter are typically distributed within 1 - 2 weeks of receipt of local DOE comments. Copies of the final report are mailed directly to the contractor and local DOE; all Program Review Reports are also posted on the EH-Enforcement webpage.

The final report describes both program strengths and weaknesses identified during the review. EH-Enforcement intends that contractors correct identified weaknesses after appropriate consultation and approval by local DOE; however, such action is not mandatory (except as discussed below) and typically no response to the report is required. Contractor program strengths are identified in the report in an effort to promote communication and lessons-learned among the contractor PAAA community. EH-Enforcement recognizes, nevertheless, that some strengths may be program or site specific; it is not intended that all contractor programs unilaterally implement the program strengths described in each site report.

In selected instances, EH-Enforcement staff may identify noncompliances not previously recognized or addressed by the contractor and deserving of enforcement action (typically an Enforcement Letter or Preliminary Notice of Violation (PNOV)). In

such cases, the contractor must comply with the response requirements identified in the action.

This enforcement guidance will be incorporated into the Office of Enforcement and Investigation Operational Procedures for Enforcement and will be made available on the Office of Enforcement and Investigation webpage (<http://tis-nt.eh.doe.gov/enforce/>). If you have any questions regarding this enforcement guidance, please contact me or Tony Weadock of my staff at (301) 903-4283.

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**PAAA PROGRAM REVIEW
STANDARD DOCUMENT REQUEST**

The following documentation is typically requested in advance of an EH-Enforcement PAAA Program Review. This standard list may be modified based on specifics of the review or the site.

- ◆ Contractor organization chart which shows the reporting position of the PAAA Coordinator, the Radiological Control Manager, and the QA Manager. Sections of site procedures identifying roles and responsibilities of these positions should be included.
- ◆ Site implementing policy and procedures addressing the following PAAA topics: noncompliance identification, screening, cause determination, NTS and internal reporting, corrective action tracking, corrective action closeout and validation, and training.
- ◆ Site procedures related to Quality Improvement and the Corrective Action Process, Deficiency Reporting, and Nonconformance/Quality Problem resolution.
- ◆ Summary listing (including title and status) of all site internally tracked PAAA noncompliances over the past 24 months. The listing should be sorted by year, if possible.
- ◆ Copies of logs/spreadsheets used in the initial screening of potential noncompliance issues for the 12-month period prior to request. Documentation should list title of the issue, screening outcome, and status of corrective actions, if possible.
- ◆ Summary listing (including title and status) of all site radiological deficiency/awareness reports for the 12 month period prior to request.
- ◆ Copies of any external assessments of the QA or RP programs conducted for the 12-month period prior to request.
- ◆ Copies of internal RP assessment(s) performed to meet triennial audit requirements (for current 3-year period) of 10 CFR 835.102.
- ◆ Copies of any recent contractor assessments of implementation of the PAAA Program.

In addition to the above, the contractor is encouraged to provide any additional information that would provide a perspective on the implementation of the site PAAA Program (i.e., annual PAAA activity report). If the information requested above is not maintained or sorted by the contractor, it should not be specifically created for this review. The contractor should instead supply the closest equivalent document.

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**PAAA PROGRAM REVIEW
REVIEW CRITERIA**

The following criteria have been developed by EH-Enforcement staff as a guide for the performance of PAAA Program Reviews. The criteria may be used (wholly or in part) during the conduct of the review; additionally, EH-Enforcement staff may evaluate other areas as appropriate. Many of the following criteria may be evaluated prior to the actual onsite evaluation through the review of documentation obtained independently or through the document request.

I. General

- A. Verify through discussion and document review that formally approved policy/procedures are in place to describe the PAAA program. PAAA procedures should describe key program elements (roles and responsibilities, training, screening/reporting, trend evaluation, cause determination, tracking and completion of corrective actions, closure validation) with sufficient detail to provide for effective implementation.
- B. Verify through discussion and review of organizational charts that a contractor PAAA coordinator/manager has been formally designated and has adequate authority and independence to make decisions without undue pressure from the line organization. Determine if adequate numbers of qualified support/matrix staff are available to meet program responsibilities.
- C. Verify through discussion and document review that formal PAAA training has been established and is being implemented on site (may be category/target specific - general PAAA training for managers, specialized training on forms/procedures for screeners, etc.).
- D. Verify through discussion that the scope of the site PAAA program is applicable to activities performed by subcontractors and suppliers, as well as principal site contractors. Ensure through review that policies and procedures should reflect this scope.

II. Identification and Screening of Noncompliances

- A. Verify through review that PAAA identification/screening procedures ensure a diverse set of source documents (assessments, NCRs, ORPS, employee concerns, external assessments, deficiency reports) are forwarded for screening.
- B. Verify through review that PAAA procedures ensure all PAAA noncompliances are captured; noncompliances should not be screened out on the basis of

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inappropriate criteria. (Note: Examples of inappropriate criteria noted to date include ruling out noncompliances on the basis of prompt corrective action, judgement of low significance by evaluator, or since noncompliance did not directly involve the handling of nuclear material.)

- C. Verify through interview that personnel performing initial screens of source documents are qualified (typically require subject matter experts in areas of QA, radiological controls) and have received training on screening process.
- D. Review screening documentation for the past year to verify a broad spectrum of source documents is represented. Determine if input from secondary sources (i.e., subcontractor/supplier-related information) is being included.
- E. Prior to site visit, independently review recent site operating experience via review of ORPS, DNFSB trip reports, etc. Evaluate for potential trends, programmatic issues, etc. Determine through onsite review whether these deficiencies were appropriately dispositioned.
- F. Independently select several contractor source documents (e.g., assessment reports, deficiency reports) identifying deficiencies that represent potential noncompliances. Determine through review of screening documentation whether these source documents were formally screened and appropriately dispositioned.
- G. Verify that items identified as PAAA noncompliances are forwarded for review of NTS-reportability (see next section)
- H. Verify that items identified as PAAA noncompliances are entered onto formal tracking system and identified as PAAA noncompliances on that system.
- I. Review status list of non-reportable PAAA noncompliances identified by contractor over the past year for the following:
 - ◆ A "reasonable" number of noncompliances were identified, based on volume of activities and number of source documents screened.
 - ◆ The noncompliances reflect a mix of 10 CFR 830 and 10 CFR 835 items, and were identified through the assessment program as well as through events
 - ◆ Corrective actions are completed on schedule, with appropriate follow-up if not completed.
- J. Review selected ORPS and deficiency report items that were judged not to be PAAA noncompliances to evaluate contractor judgement process.

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III. Evaluation for Reportability

- A. Verify through review that procedures used to describe/control the process of evaluating identified noncompliances for NTS reportability include the following:
 - 1. Identification/designation of individuals with responsibilities for evaluation for reportability, approval, and NTS report generation.
 - 2. Formal process to be used for reportability determination, with documentation of results. Specific evaluation criteria/thresholds should be included in the procedure.
 - 3. Methodology used for evaluating potential repetitive or programmatic noncompliances.
- B. Verify through interview that individual(s) making final determination on NTS reportability are qualified and have received appropriate training.
- C. Verify reportability threshold criteria and reporting timeframes contained in PAAA procedure(s) are consistent with EH-Enforcement guidance. Also verify that procedures do not provide for the screening-out of reportable noncompliances through use of inappropriate criteria (see II.B above).
- D. Review status list of non-reportable PAAA noncompliances identified by contractor over the past year for the following:
 - 1. Observable trends and/or potential programmatic noncompliances are appropriately recognized and reported by the contractor.
 - 2. For selected noncompliances of apparent significance, review judgement process that was used by the contractor to determine NTS non-reportability.
 - 3. Evaluate the ratio of total number of NTS non-reportable/reportable PAAA noncompliances. *(Note: Although ratios will vary, one would expect the number of non-reportables to be greater than reportables, particularly at sites with a well-functioning assessment program.)*
 - 4. Review documentation for several recent instances where PAAA noncompliances were evaluated as requiring NTS reportability. Determine if the decision process was performed in accordance with procedure, if the conclusion was appropriate, and if NTS reporting was timely (generally within 20 calendar days after determining a noncompliance condition exists).
 - 5. Review the process used by the contractor to evaluate PAAA noncompliances for repetitiveness. Ensure appropriate timeframes are used to make this judgement. *(Note: At one reviewed site, contractor procedures required an*

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annual review for trending/repetitiveness. This timeframe did not provide for effective and timely identification of recurring deficiencies. More commonly, sites review each noncompliance as they occur against previous occurrences - a "rolling window.")

- E. Determine whether program performance indicator data (number of NTS reportable noncompliances, total number of PAAA noncompliances, etc.) is maintained and routinely reported to senior management.

IV. Cause Determination/Corrective Action Closure

- A. Verify through review that contractor procedures include/require the following elements relative to corrective action development, tracking and closure:
 1. Identified PAAA noncompliances and associated corrective actions are formally tracked.
 2. Significant noncompliances are evaluated by formal causal analysis. Corrective actions are developed and implemented in a timely manner.
 3. Validation/verification of completion of corrective actions for significant noncompliances prior to closure.
- B. Review documentation for selected NTS reportable noncompliances to ensure the following:
 1. A formal investigation/causal analysis is performed in a timely manner (generally within 45 days of determining a noncompliance exists).
 2. Developed corrective actions correlate to causes identified through analysis.
 3. For repetitive noncompliances, the causal analysis for the more recent noncompliance takes into account earlier noncompliances, corrective actions, and their efficacy.
 4. NTS report and corrective actions provided input into site Lessons-Learned process, as appropriate.
 5. Actions actually taken to close a corrective action are the same as those committed to in the original action.
 6. Verification process for corrective actions was effectively implemented in accordance with procedures.
- C. Review summary of corrective action closure status for identified PAAA noncompliances and any related databases (deficiency reports, ES&H

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assessments, etc.) to determine if contractor is completing actions within committed milestone dates.

V. Assessments/Quality Improvement

- A. Pre-site visit: Review requested assessments for overall adequacy, clarity of findings, etc.
- B. Verify that identified assessment findings are reviewed for PAAA applicability and NTS reportability. Independently select several significant assessment findings and crosscheck them against PAAA screening/evaluation documentation to verify they were appropriately reviewed.
- C. Review completed 10 CFR 835 internal audits for the following:
 - 1. Coverage of all major 10 CFR 835 areas (subparts) over a three year period.
 - 2. Should be conducted by qualified individual(s) who are organizationally independent from the organizations responsible for developing and implementing the Radiation Protection Program (ref: DOE G 441.1-1, *Management and Administration of Radiation Protection Programs Guide*, 3/17/99).
 - 3. Findings are appropriately PAAA screened, tracked, and closed.
- D. Compare EH-Enforcement PAAA review findings with the results of contractor assessments of this area. Discuss differences with appropriate staff (PAAA coordinator, lead auditor, etc.).

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BIOASSAY PROGRAM REVIEW

An EH-Enforcement limited review of Bioassay Program implementation is being conducted as part of the PAAA Program Review in follow-up to previous enforcement activities (Bioassay Moratorium, July 1999 EH-Enforcement Guidance Supplement 99-02). For sites that performed a self-assessment and formally reported results to the NTS system within the timeframe of the 1998 bioassay moratorium, EH-Enforcement review will typically be limited to review of NTS report corrective action status. For sites not reporting under the moratorium, a broader review of Bioassay Program implementation will be performed. The following standardized document request and performance objective/review criteria were developed to support such a review.

Document Request

- ◆ Index of Bioassay Program procedures.
- ◆ Bioassay Program procedures describing/controlling the following activities: assignment of workers to monitoring regimens, baseline and routine monitoring, special or follow-up monitoring; implementation of work restrictions.
- ◆ Bioassay Program performance indicator data (if maintained) for previous 12-month period identifying the following: number of uptakes, magnitude of uptakes, uptake source (event or routine bioassay), number of delinquent bioassay samples, number of incomplete bioassay dose evaluations.
- ◆ Copies of four job-specific RWP worked in the previous six months featuring special or non-routine bioassay requirements.
- ◆ ALARA reviews and RWP worker sign-in sheets for above four RWPs.
- ◆ Bioassay Program assessments completed during the previous 12 months.

Performance Objectives/Review Criteria

1. Pre-site visit: Review recent site operational experience (via ORPS or other methods) to identify potential Bioassay Program deficiencies for further onsite review.
2. Review recent Bioassay Program assessments for significant issues, etc. Review closure status of identified deficiencies to evaluate timeliness of corrective actions.
3. Based on review of relevant procedures/interview of personnel, verify the following topics are adequately addressed in procedures:

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- ◆ Worker selection/assignment for bioassay program participation.
 - ◆ Bioassay frequency requirements and follow-up actions for missed sampling.
 - ◆ Trigger points (workplace and analysis result) for follow-up investigation.
 - ◆ Sample quality control.
 - ◆ Work restriction for ongoing dose investigation or missed sampling.
 - ◆ Dose investigation/evaluation.
4. Verify through interview that an adequate number of qualified personnel are available to support program implementation.
 5. Review performance indicator data for negative trends, declining performance, etc. Discuss such trends and their corresponding corrective actions with cognizant personnel.
 6. Randomly select worker names from RWP sign-in sheets requested above. Compare worker bioassay sample submission and result records against relevant RWP requirements.

ATTACHMENT D

**CONTRACTOR PAAA COORDINATOR
EXPECTATIONS AND RESPONSIBILITIES**

To be completed at a later date.

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