



Department of Energy
Washington, DC 20585

November 18, 2005

Dr. Leonard K. Peters
Laboratory Director
Battelle Pacific Northwest National Laboratory
P.O. Box 999
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Subject: Price-Anderson Amendment Act Program Review

Dear Dr. Peters:

From September 27-28, 2005, the Office of PAAA Enforcement (OE) conducted an onsite review of the Battelle Pacific Northwest National Laboratory (PNNL) PAAA Program. Our review included an evaluation of processes to screen noncompliances for applicability under the PAAA, reporting and tracking in the Noncompliance Tracking System (NTS) and internal tracking systems, and correcting deficiencies in a timely manner. OE also conducted a limited review of PNNL's management and independent assessment programs.

Overall, we found your program to be effective, with necessary program elements in place. Our review identified several program strengths, including the following:

- The PNNL PAAA Program Manager implements an active and multi-phased self assessment process, which includes "benchmarking" the PNNL program against other sites.
- The PNNL PAAA Program is well-integrated with the site's various quality problem resolution systems.
- PNNL is routinely conservative in making determinations of PAAA applicability for identified deficiencies.
- The PAAA Program Manager's direct accessibility to the Laboratory Director has been formally established and the Program Manager routinely meets with laboratory senior management.
- PNNL has established an integrated web-based action tracking and corrective action system that can be accessed by anyone onsite.
- The Single Point of Contact call-in number acts to encourage the identification of any adverse event or condition, and consequently promotes workforce responsibility for safety and continuous improvement.

- For noncompliances determined to be NTS reportable based on occurrence reporting (event) thresholds, PNNL has developed a streamlined reporting process that does not require a decision from the PAAA Working Group.
- The Operations Management Forum provides an effective mechanism for laboratory management to monitor data on operations and safety performance. An example was noted in which the forum pursued further improvement in the absence of any negative performance trends.
- The PAAA Program Manager has developed and led a PAAA “scenario” training course for personnel making PAAA applicability or reportability decisions.

Our review did identify several weaknesses, including the following:

- Several examples were noted of apparent repetitive PAAA noncompliances that were not reported to NTS nor forwarded to the PAAA Working Group for consideration of NTS reporting.
- A significant percentage of PNNL NTS reports involved issues identified through external (primarily DOE Facility Representative) sources.
- Several deficiencies were noted related to PNNL PAAA Program documents and procedures, including a nonconservative annual trending requirement, the failure to procedurally describe the PNNL “scenario” training course, and deficiencies with PNNL screening forms.

A significant area of concern was the current performance level and direction associated with meeting the Independent Assessment requirements of 10 CFR 830. OE found that staffing levels associated with the Independent Oversight group were limited and that the majority of assessments completed by the office were reactive in nature, of narrow scope (event or cause analysis review), and conducted in response to a request by line management. Consequently, there was no evidence that independent assessments were being scheduled based on a more strategic, risk-based prioritization of vulnerabilities potentially affecting the laboratory. Significant management attention should be directed towards this area.

On a positive note, PNNL is taking broad steps to substantially improve the corrective action management and assessment program areas. However, these measures are not sufficiently mature to demonstrate that they are effective. Accordingly it is difficult to make any conclusions on the long-term strengths of these areas at this time. Management attention to these areas will be critical to ensure that they become effective processes supporting better compliance with nuclear safety requirements and continuous improvement in nuclear safety.

Failure to correct the weaknesses noted above may result in a potential reduction or loss of mitigation as described in the DOE Enforcement Policy (10 CFR 820 App. A) for any future PNNL enforcement action. In addition, should these weaknesses persist, OE would be less likely to exercise enforcement discretion for nuclear safety noncompliance issues that are of lesser significance. Details of the OE review are provided in the enclosure. No reply to this letter is required. If you have any questions regarding this review, please contact me at (301) 903-0100 or have your staff contact Tony Weadock at (301) 903-4283.

Sincerely,



Stephen M. Sohinki

Director

Office of Price-Anderson Enforcement

Enclosure

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ENCLOSURE

BATTELLE PACIFIC NORTHWEST NATIONAL LABORATORY PRICE-ANDERSON AMENDMENTS ACT PROGRAM REVIEW

I. Introduction

From September 27-28, 2005, the Office of Price-Anderson Enforcement (OE) performed an onsite review of the Battelle Pacific Northwest National Laboratory (PNNL) Price-Anderson Amendments Act (PAAA) Program. This was the second PAAA Program Review conducted at PNNL; the first review was conducted by OE in September 2000. The current review included an evaluation of contractor processes for identification and screening of potential noncompliances, reporting and tracking noncompliances in the Noncompliance Tracking System (NTS) and internal tracking systems, and the formal tracking and resolution of quality issues. OE also conducted a limited review of PNNL's management and independent assessment programs.

Overall, the PNNL PAAA Program was viewed as effective, with necessary program elements in place and several notable program strengths. The OE review did identify several areas for improvement, which should be addressed to ensure appropriate mitigation consideration during possible future enforcement actions as well as continued OE exercise of discretion for noncompliances of lesser significance. The results of the review are summarized below.

II. General Implementation

Since the prior OE review in 2000, PNNL has transitioned from a centralized to a decentralized PAAA Program. PAAA screening is performed by representatives from the various PNNL divisions. Issues deemed to be potentially reportable are referred to the PAAA Working Group for determination of reportability.

The PNNL PAAA Program Manager provides overall direction and administration of the PNNL PAAA Program and acts as chair of the PAAA Working Group. The PAAA Program Manager is organizationally located within the Office of Audit & Oversight, which reports to the Laboratory Director.

Implementation of the PNNL PAAA Program is described in the following two documents with sitewide applicability:

- *Price-Anderson Amendments Act Compliance Assurance Program*, dated April 2001 (program description)
- *Basic Approach for PAAA Screening of Assessment Data*, dated April 2005 (subject area).

A number of additional PNNL procedures have been developed to describe organization-specific PAAA functions. Various other site procedures (i.e., those dealing with Radiological Problem Reports (RPR), trending Quality Problem Reports (QPR), Assessment Management and Corrective Action Management) also contain PAAA requirements or functions.

PNNL has established an Operations Management Forum which meets regularly to review site performance issues and trending information. The PAAA Program Manager routinely reports on PAAA and/or NTS issues at that meeting.

The following program strengths were noted:

- The PAAA Program Manager's direct accessibility to the Laboratory Director has been formally documented and the Program Manager meets routinely with laboratory senior management.
- The PNNL PAAA Program is well-integrated into the site's various quality problem resolution systems. Implementation of those systems (i.e., RPRs, QPRs, assessments, corrective action tracking) results in automatic entry to the PAAA screening function.
- In addition to providing basic PAAA training for project management and personnel performing screening functions, PNNL has recently begun providing a supplemental PAAA training course which involves the review and group discussion of various PAAA scenarios. Although noted as a strength, this scenario training has not been formalized by procedure (see below).
- The PAAA Program Manager implements an active and multi-phased self-assessment process which compares favorably to other reviewed sites. During 2004, PNNL hosted a team of PAAA Coordinators from other DOE sites who performed an assessment of the PNNL PAAA Program. Over the past two years, the PNNL PAAA Program Manager also conducted eighteen targeted assessments to evaluate various specific aspects of program implementation. Assessed areas included PAAA screening results and PAAA training status. The PAAA Program Manager also routinely "benchmarks" her program against other DOE sites by review and formal comparison against newly issued OE PAAA Program Review reports. Improvement

items identified through the above means have been added to a formal PAAA Improvement Plan.

The following weaknesses were noted:

- The PAAA Program Manager has not reviewed the PAAA screening procedures developed by the various PNNL organizations performing screening as part of her self-assessment process.
- The PAAA “scenario” training discussed above has not been included in the PAAA procedures.
- The document *Price Anderson Amendments Act Compliance Assurance Program* has not been updated to reflect issuance of the revised event-related NTS threshold criteria in EGS 03-02.
- The document *Basic Approach for PAAA Screening of Assessment Data* requires trending be performed to identify programmatic and repetitive issues “at least annually”. OE views this frequency as non-conservative; it also does not compare favorably with the more frequent trending reviews performed by other sites. OE noted however, that more frequent trending reviews of operational events, RPRs, and QPRs are being performed at PNNL and are just not being reflected in the procedure.
- The *PAAA Screening Questions* form contained in the “*Basic Approach*” document does not contain a screening question related to event-based NTS reporting thresholds. Also, the form indicates that “additional supporting information” related to determining repetitive, willful, or programmatic noncompliances is available in Attachment B. However, no such information is provided in Attachment B.
- The PNNL procedure *Evaluation and Trending of Potential Noncompliances with the QA Rule/QA Order* includes a checklist for evaluating potential noncompliances. OE found Part I of the checklist to be too restrictive in evaluating the impact of the identified problem to nuclear safety. The screening question focused solely on radioactive releases; other mechanisms which could result in radiological harm (i.e., direct exposure) are also potentially available.
- PNNL procedures/subject areas related to Employee Concerns and Occurrence Reporting did not clearly require a review of the identified concern/event for PAAA applicability. OE interviews determined that such items were in fact being reviewed for PAAA applicability, and therefore the procedures should be modified to reflect actual practice.

III. Identification and Screening

OE evaluated PNNL processes for screening of potential PAAA noncompliances by interview of personnel and review of selected screening documentation. PAAA

screening is performed by designated individuals within the various PNNL line and support organizations. Identified PAAA issues are entered onto a centralized action tracking system (the Assessment Tracking System, or ATS) by those individuals.

OE noted through review of ATS items that PNNL is being routinely conservative in making determinations of PAAA applicability for identified deficiencies. OE also noted that a diverse set of information sources (including events, assessments, employee concerns, etc.,) was being screened for PAAA noncompliances. OE found that managers and personnel across the Lab appeared to have gained a substantive understanding of the nuclear safety rules, their implications, and the functions and processes used by the PAAA Program Office. These were noted as program strengths.

One area for improvement was noted. Users entering an item into the ATS system are prompted to make a determination of PAAA applicability for the item. Clicking the “PAAA Applicability” explanation link provides a definition which relates to noncompliances with the Standards Based Management System, and does not explain or define “PAAA Applicability”. This link should be revised.

IV. Evaluation of NTS Reportability

PAAA issues identified as being potentially reportable are forwarded to the PAAA Working Group for evaluation. The PAAA Working Group meets monthly and includes senior representatives from the various laboratory line and support organizations performing PAAA screening activities. Review of PAAA Working Group meeting minutes indicated that, in addition to reviewing identified deficiencies for PAAA applicability or reportability, the group routinely discusses overall PAAA performance and trending and PAAA lessons-learned information (results of enforcement actions and program reviews at other sites). OE also noted that the Working Group meetings are routinely attended by DOE.

The following program strengths were identified:

- PNNL’s NTS reporting has remained at consistent levels over the past several years. A significant percentage (40 – 50 percent) of NTS reports are self-identified through means of assessment or “roll-up” of lower significance events.
- The PNNL reportability determination process includes a streamlined process for those issues determined to be reportable based on occurrence reporting (event) thresholds. For such issues, a Working Group determination of reportability is not required. Instead, a draft NTS report is generated and sent to the Working Group for review and comment.
- The PAAA Working Group appears to be an effective mechanism for communicating PAAA lessons-learned information back to the various PNNL line and support organizations.

- Categorization of a PAAA noncompliance as NTS reportable subsequently requires completion of a formal causal analysis, completion of an extent of condition determination, and scheduling of a corrective action effectiveness assessment.

The following weaknesses were identified:

- OE identified (through review of the ATS and RPR systems) several issues that appeared to have repetitive aspects warranting consideration for NTS reporting. However these issues, which included multiple personnel contaminations during the use of a single glovebox (RPR 05-009) and the apparent “historical” practice of leaving unmarked radioactive and hazardous material in a specific facility area (ATS 6986) were not forwarded to the Working Group for consideration of reportability.
- OE also noted that a significant percentage of recent PNNL NTS reports (30 – 40 percent in recent years) involved issues identified through external sources. Further inquiry indicated that these issues were largely identified through the efforts of the DOE facility representatives. Although this percentage reflects positively on the efforts of the facility representatives, it indicates the need for PNNL improvement in the area of quality problem identification.

V. Corrective Action Management

A. Quality Problem Resolution/Corrective Actions

A DOE Office of Independent Oversight & Performance Assurance (OA) assessment during November-December 2003 identified programmatic deficiencies in the PNNL management assessment and corrective action management processes. As a result of this OA finding, PNNL submitted an NTS report (NTS-RL--PNNL-PNNLBOPER-2004-0001) that outlined broad actions being taken by PNNL to improve the corrective action management and self-assessment processes. Steps being taken in the corrective action management area included the development of a site-wide corrective action management program, with tools to monitor for trends, emerging issues, and repetitive problems.

During the current review, OE evaluated PNNL progress to-date. A number of strengths were identified:

- PNNL has expanded their ATS to serve as the single, web-based corrective action process for the site. The ATS can be accessed by anyone onsite and replaces the multiple local tracking mechanisms previously used. The ATS database includes assessments that are planned and conducted, conditions that are identified in those assessments, corrective actions for each of the conditions, and other significant issues or problems that have been identified outside of assessments, such as events, RPRs and QPRs. The revised ATS also incorporates a significance category level for items to facilitate prioritization, rigor and management of issue resolution.

- PNNL has established a central call-in number (the Single Point of Contact System) to be used by site employees to report any issue or adverse condition, no matter how small. Usage data reflects an increase in such calls, which PNNL is interpreting as a growing willingness on the part of its employees to report deficiencies. OE views the establishment of such a system, with its low threshold for capturing issues, as a positive step towards increasing workforce ownership of safety and reflective of an attitude of continuous improvement.
- In February 2004, PNNL formed an Operations Management Forum consisting of senior laboratory operations and safety managers. The Forum meets regularly to monitor feedback on operations and safety performance, and to develop recommendations to the Deputy Laboratory Director on potential improvements.
- PNNL actively monitors and trends operational data for a number of parameters, with an emphasis on identifying adverse trends. OE noted that the trending performed on RPRs is particularly comprehensive.

While representing a positive step towards problem identification, OE commented on the opportunity to further improve performance by looking beyond the “adverse trend” endpoint during trending analysis. For example, PNNL could use such analysis to focus attention on dominant contributors to risk. One such example of looking beyond adverse trends was noted during the review, based on review of meeting minutes for the Operations Management Forum. OE determined that on one occasion the forum pursued further improvement opportunities related to contamination control when there was no adverse trend in contamination events identified.

OE noted that although the web-based ATS appears to be a comprehensive corrective action process, it has not been in place for a sufficient period to demonstrate that it is working effectively to resolve problems and preclude recurrence, or to identify substantive programmatic or emerging issues. OE noted, for example, that although issues/deficiencies are placed into ATS, ATS is not currently serving as the sole system for analyzing trends.

B. Causal Analysis

PNNL has established significance categories for items placed in ATS, with higher categories receiving a greater level of causal evaluation. Causal analyses are required for all conditions that are classified as high or medium impact. By definition NTS reports are classified as medium impact, and thus a causal analysis is required to be performed for all NTS reports. In reviewing sample NTS files, OE confirmed that these NTS issues received a causal analysis. PNNL has also developed guidance in the selection of the complexity level of causal analysis that is appropriate for the condition under evaluation. The graded approach to application of causal analysis techniques and the comprehensive guidance provided for the classification and conduct of causal analysis is a strength of the program.

C. NTS Report Closeout

For each NTS report, the PNNL PAAA Program Manager builds a file that includes the NTS, critique, working group agenda and minutes, causal analysis, and documents to demonstrate completion of each corrective action. The PAAA Program Manager reviews the documentation provided as the basis for closure, and judges the adequacy of this basis before proceeding to a meeting with DOE. At the DOE meeting, the NTS owner, typically a line manager, presents the basis for closure to DOE. Additionally, the line has the responsibility to conduct an effectiveness review to confirm the adequacy of the corrective actions. OE found the comprehensive nature of the PNNL process to close out an NTS report to represent a program strength.

VI. **Assessment Program**

As part of this Program Review, OE evaluated implementation of the PNNL management and independent assessment programs, since OE believes that an effective assessment program is the most proactive method to identify and address nuclear safety problems before they result in serious nuclear safety incidents. It should be noted that OE's review in this area was limited in scope, and does not constitute a comprehensive evaluation of the PNNL assessment program.

A. Management Assessment

As noted above, DOE's OA assessment of November and December 2003 identified substantial deficiencies in PNNL's corrective action management and self-assessment programs. PNNL's corrective actions included the development and implementation of a more comprehensive and consistent program of line and management system self-assessments (i.e., management assessments). During the current review, OE evaluated progress to-date and additional actions planned to improve these areas.

OE found that PNNL is implementing a multi-level program of formal self-assessments that include cognizant space manager assessments of workplace conditions, subject matter expert topical compliance verifications, assessments of work activities, and assessments performed by managers. A database tool has recently been developed (the Integrated Operations System, or IOPS) which facilitates the development of assessment checklists for assessment of workplace conditions. Assessment results are entered directly into the ATS, which provides for subsequent search and trending capabilities. OE review of completed self-assessments indicated that over the past year, a significant number of assessments had been performed and that higher significance issues were being identified as a result of the assessments.

During the review PNNL acknowledged the process was in the early stages of implementation, and discussed a number of areas on which they are focusing attention to further improve the performance of these self-assessments. OE noted during its review of assessment status documentation that performance in completing assessments varied across divisions, and that not all divisions appeared to have a complete understanding of the new process. Consequently, although the planned self-assessment approach appears to represent a significant improvement over past activities currently the process does not have a history of performance and will require continuing senior management attention for successful implementation.

B. Independent Assessment

PNNL's Independent Assessment program is conducted by its Office of Internal Audit & Independent Oversight (IO). OE reviewed the performance of this group by discussion with cognizant personnel and review of various program documentation, including a listing of independent assessment activities completed over the prior year. The following weaknesses were identified during this review:

- Staffing resources directed towards implementation of the independent assessment program appear limited. Within IO, only 2-1/2 individuals (one individual also supports the PAAA Program Office) support the implementation of the independent assessment program. The office is currently in the process of procuring outside resources to augment the existing PNNL staff. However, this had not been finalized at the time of the OE review.
- Review of the listing of completed assessments identified that the majority were of narrow scope (event or causal analysis review), reactive in nature, and were conducted by specific request of operational line management. Few if any were based on a strategic judgment by IO to focus on areas of risk, such as areas of past performance problems, new processes or activities, or areas of significant potential consequence.

OE noted that IO appears to be functioning more as a service organization to operations than as a functioning independent oversight body. Based on the relatively limited scope and reactive nature of the completed assessments, OE concluded that it is questionable whether the independent assessment requirements of 10 CFR 830 are being met.

PNNL management indicated that, in addition to the planned staffing support discussed above, PNNL would be scheduling assessments for the next year based on a risk-based prioritization and scheduling process. OE noted, however, that neither of these planned improvements was captured in a formal corrective action or improvement plan. OE concluded that substantial management attention should be directed to this area to ensure that 10 CFR 830.120 independent assessment requirements are effectively met.

VII. Conclusion

The above summarizes OE's review of the PNNL PAAA program conducted from September 27-28, 2005. In general, the program has improved since the prior review by OE in late 2000. Weaknesses identified during this review should be addressed to facilitate OE's exercise of discretion for noncompliance conditions that are less significant, for mitigation consideration in any future enforcement action, and to ensure that nuclear safety problems receive appropriate recognition and corrective action. Any actions taken to address these items should be appropriately coordinated with the local DOE office.