Dr. Lura J. Powell



Pacific Northwest National Laboratory P.O. Box 999, K1-46 Richland, WA 99352

Subject: Pacific Northwest National Laboratory Enforcement Program Review

Dear Dr. Powell:

During the period October 24-25, 2000, the Department of Energy (DOE) Office of Price-Anderson Enforcement (EH-Enforcement) conducted a review of the Pacific Northwest National Laboratory (PNNL) Price-Anderson Amendments Act (PAAA) Program. This review included an evaluation of the site processes to screen noncompliances for applicability under the PAAA, for reporting and tracking in the Noncompliance Tracking System (NTS) and internal reporting and tracking systems, and for correcting deficiencies in a timely manner.

Our review generally found your PAAA Program to be established with varying degrees of maturity noted among the individual Program functions. Specifically we observed that (1) your PAAA Program is implemented by formal procedure, (2) the PAAA Program is appropriately staffed with knowledgeable and experienced personnel, (3) records of the screening and decision making process for potential PAAA noncompliances are maintained and auditable, (4) PNNL utilizes a multidisciplined and independent working group for evaluating NTS reportability, (5) proper guidelines are used by the working group for determining NTS reportability, (6) the PAAA Program Office monitors the status of corrective actions for issues tracked in the NTS and in the site's local Assessment Tracking System, and (7) senior PNNL management seems supportive of the PAAA Program.

Our review also identified areas for program improvement. The specifics of our observations are documented in the enclosure. DOE's most significant concern is that PNNL is not effectively identifying and analyzing potential repetitive, programmatic or common cause problems. Another concern relates to the review of self-assessments performed by PNNL line management for identification and reporting of potential PAAA noncompliances. These observations are consistent with previous self-evaluations of the PNNL PAAA Program which EH-Enforcement found to be both complete and comprehensive.

Failure to improve the areas identified in the enclosure could result in a reduction or loss of mitigation as describe in the DOE Enforcement Policy (10 CFR 820 Appendix A) for any future enforcement action.

No reply to this letter is required. Should you have any questions concerning our review please contact Richard Day of my staff at (301) 903-8371.

Sincerely,

R. Keith Christopher

Director

Office of Price-Anderson Enforcement

R. Keith Christopher

Enclosure: Enforcement Program Review

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Docket Clerk, EH-10

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

I. Introduction

During October 24-25, 2000, the Department of Energy (DOE) Office of Price-Anderson Enforcement (EH-Enforcement) Team conducted an onsite review of the Price-Anderson Amendments Act (PAAA) Program at Pacific Northwest National Laboratory (PNNL). The Team evaluated the Laboratory's basic PAAA functions related to (1) identification and screening of potential PAAA noncompliances, (2) evaluation of noncompliance reportability into the Noncompliance Tracking System (NTS), (3) cause determination for both NTS reportable and locally reportable noncompliances, and (4) noncompliance corrective action identification and closure. In addition, the team evaluated aspects of the Laboratory's implementation of the PAAA Program through procedures, training, staffing, and breadth of application, as well as the Laboratory's Bioassay Program.

In evaluating site processes, the team held discussions with cognizant PNNL personnel and reviewed documentation pertinent to the review.

II. General PAAA Program Implementation

PNNL established a PAAA Program infrastructure that is formalized, in large part, by a procedure titled *Price-Anderson Amendment Act Compliance Assurance Program.* This procedure identifies the general responsibilities of organizational entities to identify, categorize, report, correct and trend noncompliances with DOE's nuclear safety rules. The team found that, for the most part, the PNNL PAAA Program to be well established and implemented by formal procedure. However, requirements and guidance with regard to trending and identification of both NTS and locally reportable noncompliances for potential repetitive or programmatic issues is insufficient. In addition, there are no clear requirements with regard to causal analysis of both NTS and locally reportable noncompliances.

Two full-time personnel, who are experienced and knowledgeable, staff the PNNL PAAA

Program. There are plans to add a third individual to assist in the Program. The level of qualified personnel assigned to the Program reflects favorably of Laboratory's senior management commitment to PAAA compliance.

PAAA related training has been provided to PNNL staff. Dedicated PAAA Program staff provided the training titled *PAAA:* Protecting the Health and Safety of Employees, the Public and the Environment. The Team evaluated the presentation materials and found them to be complete and accurate. A training class titled Price-Anderson Amendments Act Overview is suggested for PNNL line managers. Based on discussions during the course of this review it does not appear that all PNNL line managers fully understand their roles and responsibilities with regard to PAAA requirements. Thus, it is recommended that this training become mandatory for those involved in nuclear activities. In addition, it is recommended that periodic PAAA refresher training be conducted to assure that PNNL personnel remain cognizant of nuclear safety rule compliance and are kept up to date with any changes to PAAA Program requirements or guidance.

The Team reviewed appropriate documentation to assure that the breadth of the PNNL PAAA Program extends to both subcontractors and vendors. It was concluded through discussions with PNNL personnel and review of pertinent documentation that subcontractor and vendor work that is subject to PAAA nuclear safety rules are captured.

III. Identification and Screening of Potential Noncompliances

PNNL identifies potential noncompliances with nuclear safety rules through the execution of the Integrated Assessment Management System. This system relies on aggressive line management self-assessments, peer review, independent oversight, and internal audit to identify areas of noncompliance. Line organizations are required through the Integrated Assessment Management System to include specific activities in the annual plan to assess their compliance with nuclear safety rules. PNNL procedure Price-Anderson Amendments Act Compliance Assurance Program identifies 20 such activities from which to identify potential noncompliances. Although procedures and programs are in place and comprehensive to capture potential noncompliances, in practice the PNNL PAAA Program falls somewhat short. During PNNL's initial presentation a graphic was displayed which depicted the Laboratory's PAAA potential issue capture threshold. This graphic indicated that higher level activity such as occurrence reports and self-disclosing events are being captured for potential PAAA noncompliance. However, as you go into lower levels of the organization potential noncompliance associated with activities such as self-assessment or management walk through are not totally being captured. The result is that there exists a potential for many PAAA noncompliances not being identified.

As described above, PNNL line management plays a vital role in the identification of potential noncompliances. PNNL PAAA Program staff are actively pursuing efforts to better educate those line managers who are not fully addressing their activities for potential PAAA noncompliance. This effort is expected to take two-three years to bring potential PAAA noncompliance identification to full maturity. Given the importance of PAAA identification and screening it is recommended that PNNL senior management apply resources to complete this effort in a more timely manner.

PNNL Independent Oversight recently issued reports entitled *Annual Price-Anderson Amendments Act Compliance Assurance Program Review* and *Fiscal Year 2000 Annual Report of Independent and External Oversight Assessment*. These reports likewise identified the issue of line management insufficiency in identifying potential PAAA noncompliances from self-assessment activities. These reports are considered complete and comprehensive and address several other PAAA related issues that will be addressed in this report.

Radiation Problem Report issues are being captured and reviewed for potential PAAA noncompliances. The radiation protection organization approach to noncompliance

identification is captured in procedure and independently verified through a peer review process. Repetitive/programmatic trends were analyzed and documented with regard to personnel/facility radiological contamination and unauthorized entries into radiologically control areas. However, this same level of rigor does not seem to be present for Quality Problem Reports where formal procedures and independent review seem to be lacking. On June 16, 1999, an independent audit entitled *Quality Problem Report (QPR) and Deficiency Report (DR) Trending Information Report* was issued indicating that 46% of all QPRs and DRs were related to procurement issues. On January 17, 2000, two similar reports were issued covering the third and fourth quarters of calendar year 1999. In these reports, approximately 60% of all deficiencies were procurement issues and awarding contracts without the required preaward survey was observed as a major negative trend. The team reviewed the PAAA Log for Fiscal Year 2000. This review revealed that many of the QPRs in the log noted the award of contract without the required preaward survey, indicating that PNNL has not addressed this issue and may be in violation of 830.120 (c)(1)(iii). The PNNL PAAA staff indicated that this issue has not been reviewed for potential repetitive/programmatic noncompliance.

The EH-Enforcement team reviewed the process by which PNNL screens potential noncompliances and finds that no inappropriate criteria are used. The Quality Assurance Noncompliance Evaluation Checklists are comprehensive in that all 10 CFR 830.120 criterion are addressed.

The Electronic Prep and Risk (EPR) is a tool used by PNNL management for identifying project work that is PAAA applicable. If used properly, the tool is effective in identifying nuclear safety implications of work performed at PNNL. However, a review of several assessments by the PNNL Independent Oversight Group suggests that the questions used by EPR may not be sufficient and/or line management response to questions may be less than adequate.

IV. Evaluation of NTS Reportability

If a potential PAAA noncompliance has been determined to warrant further consideration as a potential noncompliance, it is then referred to the PAAA Working Group for formal deliberation and determination. The Working Group, convenes at least once a month to discuss potential noncompliances. Each noncompliance is accompanied by a decision package and typically a line representative with familiarity with the issue. The Working Group is an independent and multidisciplinary group consisting of members representing Facility and Operations, Legal, PAAA Coordinator, Quality Assurance, Radiological Control, and Research. The EH-Enforcement Team found this approach to determining NTS reportability to be highly effective.

A review of NTS reports submitted by PNNL reveals the reports to be well written, easily understood and comprehensive in its description of the noncompliance. The quality of PNNL submitted NTS reports compare favorably with other sites in the DOE complex.

The criteria used by the Working Group to determine NTS reportability is consistent with guidance provided in Table 3-1 and 3-2 of *Operational Procedures: Identifying, Reporting, and Tracking Nuclear Safety Noncompliances under Price-Anderson Amendments Act of 1988.*

The PNNL procedure *Price-Anderson Amendments Act Compliance Assurance Program* requires that all noncompliances be reviewed to determine whether there are programmatic, systemic, or recurrent issues that should be presented to the Working Group for their consideration. PNNL does not provide any further guidance on how this should be accomplished. The EH-Enforcement Team reviewed several PNNL Independent Oversight Reports that suggest that self-assessment results are generally not being evaluated to identify programmatic or recurrent issues. The observation was supported through EH-Enforcement Team discussion with PNNL personnel. The previously discussed repetitive procurement problems may be an example of such a problem.

V. Cause Determination

The EH-Enforcement Team reviewed PNNL PAAA Program implementation documents for requirements pertaining to the identification of root, direct, and contributing causes for both NTS and locally reportable noncompliances. Our efforts revealed that PNNL does not have formal procedures or requirements for causal analysis of identified noncompliances. Discussion with PNNL personnel revealed that root, direct, and contributing causes are identified for NTS reportable noncompliances. However, causal analysis for locally reportable noncompliances do not have the same level of rigor and often focus only on direct causes. This lack of formality is having in adverse effect on the Laboratory's ability to trend data for repetitive or programmatic noncompliances.

VI. Corrective Action Identification and Closure

PNNL has formalized procedures for identification and tracking of corrective actions to include those identified in both NTS and locally reportable noncompliances. Corrective actions are entered and tracked using the Assessment Tracking System (ATS). All NTS related corrective actions are verified and validated prior to closure. Locally reportable corrective actions are only sampled for verification and validation prior to closure.

The ATS is a significant improvement over the previously used tracking system. Of note is the use of "push" technology whereby corrective action owners are notified when a corrective action target completion date is approaching and when the target date has arrived. In addition, the ATS has a required field (check box) for PAAA applicability for all corrective actions.

The PNNL PAAA Program staff has nearly completed an effort to combine all PAAA related data from multiple sources (e.g. PAAA log, Quality Assurance Database) into the ATS. Significant efficiency gains will be realized through this effort to include the enhancement of the Laboratory's ability to trend and analyze data for repetitive or programmatic issues.

A review of documentation provided by PNNL has revealed that some of the corrective actions identified in QPRs are not being entered into the ATS. This issue, combined with the previously mentioned problem with self-assessments, raises concern with the EH-Enforcement Team regarding the completeness of the corrective actions entered into ATS.

VII. Bioassay Program

Since PNNL did not submit an NTS report during DOE's 1998-1999 Bioassay Moratorium, the Laboratory's Internal Dosimetry Evaluation Program (IDEP) was assessed according to recommendations provided in Attachment C of EH-Enforcement's Enforcement Guidance Supplement EGS 00-02 *Price-Anderson Amendment Act (PAAA) Program Reviews*.

PNNL was found to have adequate procedures in place for specifying when a radiation worker is to be placed on routine bioassay or is to receive special bioassay attention. These procedures further specify who is to conduct these determinations. Several computerized data bases provide timely information on an individual's current dose and warnings to management staff should a bioassay sample due date be missed.

The number of personnel working for the Laboratory's IDEP is relatively small, however, bioassay sample processing for the entire Hanford site is conducted by a subcontractor whose contract is managed primarily by IDEP staff. Both PNNL and the subcontractor conduct quarterly quality control checks; the subcontractor can be financially penalized if various performance parameters are not met.

PNNL has approximately 1,000 workers participating in the bioassay program annually. Radioactive material uptakes, though, tend to occur for about one percent of this population and [specified isotope] is the primary isotope contributing to these uptakes which result in

committed doses of less than 100 millirem. Occasionally, the Laboratory will experience an uptake that results in a dose estimate exceeding 100 millirem. Due to this dose trend, internal dose performance indicators were not reviewed.

VIII. Conclusion

The EH-Enforcement review of the PNNL PAAA Program found the program to be established by procedure and staffed with experienced personnel. The independent assessments performed by the Independent Oversight group provides a comprehensive and critical review of the Program and are viewed by EH-Enforcement as a strong asset to continuous improvement of the Program. With the exception of causal analysis, procedures are in place, which provide ample coverage of all aspects of the Laboratory's PAAA function. However, the implementation of these procedures falls somewhat short of expectation. This is of particular concern in the area of potential PAAA noncompliance identification through line management self-assessments and in the trending and analysis of potential programmatic or repetitive noncompliances.

Overall the EH-Enforcement Team considers the Laboratory's PAAA Program to be fundamentally sound and meeting most of EH-Enforcement expectations. There are varying degrees of maturity among the various PNNL PAAA Program functions, but the issues hindering this maturation process seem to be well understood and are currently being addressed. EH-Enforcement encourages PNNL to continue is efforts to bring the Program to a greater state of maturity.



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