

May 21, 1999

Dr. C. Paul Robinson  
[ ]  
Sandia Corporation  
Sandia National Laboratories  
P.O. Box 5800  
Albuquerque, NM 87185-0127

Subject: Program Review Letter  
PAAA Noncompliances Screening and Reporting, and  
Application of Quality Assurance Rule 10 CFR Part 830.120

Dear Dr. Robinson:

The Office of Enforcement and Investigation performed a review between March 9-11, 1999, of your Price-Anderson Amendments Act (PAAA) nuclear safety program. The review included (1) your process for reportability evaluations of potential PAAA violations and (2) the scope of implementation of Part 835 Radiological Protection and Part 830.120 Quality Assurance requirements to activities at Sandia National Laboratories (SNL). The purpose of this review was to ensure consistency with DOE's regulatory expectations in these areas. Our review was based on material you provided prior to and during our onsite evaluation and interviews with individuals and key managers responsible for implementation of these programs. Based on our review we have identified several issues where processes or intended application of requirements should be enhanced to meet DOE expectations.

A positive observation from our review was the Radiation Protection Safety Committee activities that provide oversight of the radiation protection program and operations. Our review of their activities and interviews with members provided confidence that this function provides substantial benefit in reducing or preventing significant radiological occurrences.

DOE identified a concern related to determining those cases or noncompliances that should be reported to DOE via the Noncompliance Tracking System (NTS). Our review identified that the process being used by Sandia was not consistent with DOE's PAAA noncompliance reporting expectations. The intent of DOE's NTS reporting thresholds is for contractors to report those cases that are above the reporting threshold, so that DOE is well informed of conditions and trends related to potential violations of PAAA nuclear safety requirements. DOE intends to make the determination of which cases it deems warrant further DOE evaluation or investigation, and not have contractors screen such cases to determine for DOE which cases it should review. We address these issues and DOE's position on changes in the process that would enhance your reportability determinations in an enclosure to this letter.

Additionally, we identified a number of concerns with respect to your self-tracking of noncompliances that are below the DOE NTS reporting threshold. These concerns included ineffective trending of noncompliances and inadequate identification of PAAA noncompliances. DOE, in crediting (i.e., deciding not to take enforcement action) your self-tracking process for those noncompliances that are below the NTS threshold, expects that such a process demonstrates identification, reporting, and correction of the noncompliance. The issues identified with your self-tracking process, also summarized in the attached, do not allow DOE to place the desired reliance on this process.

Another significant concern is your interpretation of applicability of DOE Quality Assurance requirements in 10 CFR Part 830.120 to activities at SNL. In the attachment, we also discuss these issues and DOE's position on how it would consider applicability of quality assurance requirements in an enforcement review.

No reply to this letter is required; however, DOE will continue to monitor performance in these areas and may decide in the future to again review your internally-tracked noncompliances that you determined to be non-NTS reportable and your application of Parts 835 and 830.120 to activities at SNL. In addition, should DOE not see improvement in these areas, selected PAAA assessments may be scheduled in the future to provide confidence that reportable noncompliances are being identified and reported to DOE.

Should you desire DOE consideration of mitigation in deliberations of enforcement action, it is recommended that your PAAA evaluation and reporting process be revised to address the above issues. If you have any questions, contact Susan Adamovitz of my staff at (301) 903-0125.

Sincerely,

R. Keith Christopher  
Director  
Office of Enforcement and Investigation

Enclosure:

cc: D. Michaels, EH-1  
R. Kiy, EH-1  
M. Zacchero, EH-1  
S. Adamovitz, EH-10  
G. Podonsky, EH-2  
O. Pearson, EH-3  
J. Fitzgerald, EH-5  
V. Reis, DP-1  
D. Minnema, DP-45  
J. Owendoff, EM-1

L. Vaughan, EM-10  
R. Glass, DOE-AL  
B. Eichorst, DOE-AL  
M. Zamorski, DOE-KAO  
R. Simonton, DOE-KAO  
B. Wellberry, SNL  
R. Azzaro, DNFSB  
J. Lieberman, NRC  
Docket Clerk, EH-10

## ENCLOSURE

### EVALUATION OF THE SANDIA NATIONAL LABORATORIES PRICE-ANDERSON AMENDMENTS ACT PROGRAM

#### **Sandia National Laboratories (SNL) Process for Price-Anderson Amendments Act (PAAA) Issue Screening and Reporting**

##### SNL PAAA Policy

The SNL contractor, Lockheed-Martin Sandia, implements the Quality Assurance Rule (10 CFR Part 830.120) and the Occupational Radiological Protection Rule (Part 835) through top level plans approved by DOE, implementing procedures, and management and personnel in line organizations and various support groups. SNL has put in place a top-level document to define SNL's corporate program for responding to the nuclear safety requirements contained in regulations promulgated as a result of the PAAA, PG470195, Issue A, March 31, 1997, Nuclear Safety Requirements Program. This document provides a concise and reasonable summary of SNL's regulatory obligations under PAAA, and the DOE Enforcement Process and Policy in 10 CFR Part 820 and its Appendix A.

##### Screening and Reporting

Additionally, SNL has established a PAAA screening and review process through an internal procedure, Section 18G of the SNL ES&H Manual, Reporting Nuclear Safety Rule Noncompliances, (MN471001, Issue B, January 18, 1998). This document established the process to be used for screening potential noncompliances. Responsibility to identify PAAA noncompliances is placed on workers and facility, department and program managers, and to forward these to the SNL PAAA Program Manager. The PAAA Program Manager would then draft the Noncompliance Tracking System (NTS) report, and present this to the PAAA Review Board. The PAAA Review Board is made up of the PAAA Program Manager, SNL legal counsel, the Radiological Protection Program Manager, the Chairperson of the Radiological Protection Safety Committee, and a subject matter expert. The Review Board then makes a final determination as to whether a noncompliance is NTS reportable. SNL is in the process of revising this procedure, to be superseded by a document titled the Price-Anderson Amendments Act Noncompliance Review Process, which incorporates changes to address DOE's guidance contained in DOE Operating Procedure Identifying, Reporting, and Tracking Nuclear Safety Noncompliances under Price-Anderson Amendments Act of 1988, issued June 1998.

## Radiological Process Improvement Report (RPIR) Process

Noncompliances below the Noncompliance Tracking System (NTS) reporting threshold are tracked in SNL's local tracking system. The process used is governed by Procedure RPO-02-202, Issue No. 4, Radiological Process Improvement Report. The process applies to any radiological deficiency, issue, event, or noncompliance, with each one designated as an RPIR with a unique identifier number. The process uses information provided in occurrence reports, assessments, or verbal information and follow-up. The process then assigns responsibility to address the problem area, but the RPIR does not include documentation for the determination of causes of the problem, appropriate corrective actions, and tracking of corrective actions. It also does not provide designation of being a PAAA noncompliance, even if below the NTS reporting threshold. This process is intended for radiological deficiencies and does not cover Quality Assurance issues.

Each RPIR is subjected to the screening process described above and is governed by Section 18G of the ES&H Manual. The RPIR is screened by the PAAA Program Manager, and, if determined to be potentially NTS reportable, is forwarded to the PAAA Review Board. The PAAA Review Board makes the determination on whether the RPIR is NTS reportable. RPIR's also include non-PAAA deficiencies. Since March of 1998, no NTS reports have been filed by SNL, until two recent NTS reports following the Office of Enforcement and Investigation's (EH-10) site visit of March 9 -11, 1999.

## Tracking Quality Deficiencies

As noted previously, the responsibility to identify potential PAAA noncompliances rests with the line organization, through responsibility placed on workers, supervisors and managers. If they identify any such issues, they then are required to forward them to the PAAA Program Manager. As of the time of the EH-10 site visit, no quality issues had been forwarded to the PAAA Program Manager by the line organization.

The EH-10 review team requested information on the various processes that are used in the SNL nuclear facilities to identify, track, and manage resolution of quality deficiencies, including those that may represent noncompliances with Part 830.120 requirements. The processes identified were multiple and each was developed for a specific purpose. In some cases the process was related to the type of deficiency and in other cases the process was due to the source of how the deficiency was identified. The processes included the following:

- a. Management Surveillance Findings process governed by AOP 95-46.
- b. The Nonconformance Corrective Action Report governed by AOP 94-18.
- c. Performing Root Cause Analysis and Developing Corrective Actions per procedure SNL-GN470036.
- d. Action Item Tracking System, for Technical Area V.
- e. Equipment Status Log and Narrative Log for other deficiencies in Tech Area V.
- f. Deficiency Tracking Program at Manzano Nuclear Waste Storage Facilities for Inspection Deficiencies.

#### g. Manzano Self-Assessment Data Base.

These processes provide mechanisms to identify or designate deficiencies, assign responsibility, determine causes where appropriate, identify required actions, and track to closure. They do not specifically designate items as potentially PAAA related. They also do not appear to have specific steps to determine whether the issue is potentially PAAA reportable.

As noted previously, the requirements of Section 18G of the SNL ES&H Manual place responsibility on workers, supervisors, and managers to identify potential PAAA noncompliances and forward these to the PAAA Program Manager. Despite this requirement, none of the numerous equipment and process quality issues that have been identified and managed through the above management processes have been forwarded to the PAAA Program Manager. Thus, it is not surprising that no quality deficiencies have been screened by the PAAA Program Manager for potential reportability or forwarded to the PAAA Review Board for approval to submit an NTS report.

#### **PAAA Program Weaknesses**

The EH-10 site visit reviewed the PAAA Program as described in a number of process control procedures. Additionally, the EH-10 team reviewed how a number of specific RPIR cases that were judged by SNL to be below the NTS reporting threshold were handled, and met with the various individuals and Committees responsible for PAAA implementation, screening and reporting. The review team also evaluated the various deficiency identification and resolution processes that were being implemented at SNL's nuclear facilities to meet the requirements of 10 CFR Part 830.120, *Quality Improvement*. The EH-10 review identified a number of process weaknesses that were contributing to both the failure to identify various problems as PAAA noncompliances, and the failure to properly consider identified PAAA noncompliances for reporting into NTS.

Although these weaknesses may not fully meet DOE's expectations for screening and reporting, such process weaknesses do not in themselves represent noncompliances. They do, however, represent weaknesses such that DOE would not be able to allow mitigation consideration for noncompliance reporting in its deliberation of possible enforcement action for the potential violations that may be involved. More broadly, incorporating resolution of these issues into the SNL management scheme will more closely achieve the safety objectives of DOE's nuclear safety policy and requirements.

#### Quality Assurance Rule Exclusions

The EH-10 review team reviewed a number of recent self-assessments by the contractor related to the nuclear facilities in Technical Area V (TA-V). The assessment reports, and, in particular, the response to the assessment reports by the TA-V management, raise a number of concerns with the practices being applied in implementing the Quality Assurance Rule at SNL. The principal issue is that the

responses imply that a very narrow interpretation of the applicability of Part 830.120 is being applied at SNL, or at least in TA-V. As an example, the March 16, 1998, response to the annual self-assessment, number AS-137, indicates that a number of the issues raised in the assessment are considered by TA-V management to be outside the scope of 830.120 applicability. EH-10 generally disagrees with the conclusions of this response with respect to the applicability of Part 830.120. It appears that SNL is (1) partitioning work, procedures, processes, and (potentially) equipment that may be associated with a nuclear facility, and (2) claiming that some portion of these are not subject to Part 830.120. Part 830 does not provide any such sub-category in a nuclear facility.

If an activity or facility reaches the classification of a nuclear facility (reactor or non-reactor nuclear facility) under Part 830, then 830.120 applies to that facility. The Rule applies to the “items, services and processes” for that facility in a “graded approach.” Any exclusion of portions of the facility (equipment, procedures, activities, etc.) would have to first be specifically approved by DOE through an exemption processed in accordance with Part 820. The following are examples of issues contained in the March 1998 response:

- a. The numerous issues identified in the assessment report are identified as “Observations” even though many of them represent noncompliances with 830.120, as discussed in the following items. Classification as Observations results in a lesser degree of management attention and formality of correction.
- b. Various management control processes including “Control and Verification of Analyses and Calculations” and “Assembly Procedures” were concluded by TA-V management to be “outside 10CFR830.120 ‘space’.” These are work control or design control processes that would be governed by 830.120. Noncompliances with these should be identified as PAAA issues, addressed and corrected in accordance with 830.120 Quality Improvement requirements, and evaluated and screened for reportability considerations.

The issue raised in the assessment is whether these should be included in the 830.120 implementation matrix. It should be recognized that not all items, processes and services that are subject to 830.120 can be reasonably listed in the implementation matrix. Such a matrix serves a useful purpose to ensure that QA requirements are implemented and governed by appropriate top-level management control procedures. Such top-level procedures may be listed in the matrix. Omission of the numerous other lower level procedures, or procedures or activities subject to these management controls, does not limit the applicability of 830.120 or the ability of DOE to take enforcement action for violations of those other items, processes or services not listed in the implementation matrix.

- c. Numerous noncompliances with mandatory corporate ES&H training, continuing training, and new-hire training were identified. To the extent that these deficiencies pertain to workers involved in one of the nuclear facilities in TA-V, DOE considers that such training is governed by 830.120. Failure to accomplish the required

training is a noncompliance with 830.120, and should be treated as such.

Statements that the only training TA-V management takes credit for in meeting the 830.120 requirement is the Nuclear Facility Operator training are not valid. Such a narrow application of 830.120 training requirements for the nuclear facilities at TA-V would have to be approved through an exemption, and no such exemption has been approved.

- d. The self-assessment raises a question related to the requirements in a particular quality plan for a Plant Protection System (PPS) modification for the Annular Core Research Reactor (ACRR). The document includes a statement that identifies only a portion of the procedure as being applicable to 830.120, and that compliance with other steps of the procedure were not necessary for 830.120. DOE takes issue with such an approach. This is a document that is intended to control a work activity at the ACRR, namely a modification of the PPS. As such, the entire document is subject to being followed as required by 830.120, not just for some of the steps or sections identified as required to be met in the document.
- e. Similarly, the lack of a formal management assessment process for TA-V is another example of an apparent 830.120 noncompliance, that at the time should have been (1) identified as a finding, (2) addressed through the Quality Improvement process, and (3) reviewed for reportability considerations.

#### Reporting Threshold for NTS

EH-10 found that SNL was applying a fairly high threshold before reporting an issue into the NTS. The particular items identified by EH-10 in its review were the following:

- a. Applying a significance judgement in addition to the reporting thresholds in DOE's guidelines. In the examples reviewed, SNL was commonly making a judgement on safety significance and labeling the issue as "minor" even if the issue could be considered programmatic or repetitive, or, otherwise, if the issue met the reporting threshold of DOE's reporting guidelines. The EH-10 review team explained that DOE was not expecting contractors to decide which issues were sufficiently safety significant, and that the issues should be reported to DOE. DOE intended to exercise its own judgement on safety significance if the issues were NTS reportable.
- b. Use of global statistics to identify a programmatic issue. The triennial Radiological Protection Assessment Report dated January 29, 1999, used some statistical arguments to establish that although a number of noncompliances had been identified, these occurred in only a small percentage of questions asked to ascertain compliance with Part 835. While this is a valid approach to determine if there are widespread or gross breakdowns in the program, it should not be relied upon as the determinant of whether problems are programmatic. If management review determines that the frequency of occurrence is sufficiently high that some attention should be given to the area to improve performance, then it should be considered to be a programmatic problem. If processes or procedures need to be changed, even due to the findings from a single occurrence, then it represents a

determination that the problem is programmatic in nature, as opposed to a single occurrence by an individual.

- c. Several RPIR problem areas with multiple occurrences appeared to be indicative of potential programmatic problems, and thus should have been reported into the NTS. None of these were reported into the NTS, but are being investigated separately by EH-10 from this PAAA Program evaluation discussion. If DOE considers that these problem areas are candidates for enforcement consideration, they will be addressed separately in an Investigation Summary Report.
- d. The Triennial Audit Report also has several problem areas that appear to represent programmatic issues. At the time of the EH-10 site visit, DOE advised SNL that these appeared to be NTS reportable and that it would be acceptable to submit these in a single roll-up report. SNL submitted an NTS report on March 24, 1999.

#### Quality Assurance PAAA Noncompliance Identification

The above discussion indicates the multiple processes being used to identify and manage resolution of deficiencies associated with the nuclear facilities. These processes collectively are intended to meet, among other things, the requirements of 10 CFR Part 830.120 with respect to Quality Improvement. The above discussion also noted that no potential PAAA QA noncompliances were being forwarded to the PAAA Program Manager for review and screening. The following issues were identified with respect to this portion of the PAAA Program:

- a. Workers, supervisors and managers are placing too high a threshold on the consideration of potential PAAA QA noncompliance. With no issues being passed from these individuals to the PAAA Program Manager, it is clear that this stage is not working correctly. Most sites tend to identify dozens or even hundreds of such issues, with some typically screened out as not being a PAAA noncompliance, and most found to be below the NTS reporting threshold and tracked internally.
- b. Placing responsibility for PAAA expertise on line workers, supervisors and managers to identify PAAA QA noncompliances may not be reasonable. It is a substantial responsibility for such individuals to understand all the various procedural and policy requirements for performing their specific duties. To also be asked to be regulatory experts in the nuances of the various nuclear safety rules may be expecting too much. More effective PAAA Programs in the DOE complex tend to place a low threshold on the set of issues to be screened by appropriate experts for PAAA applicability.
- c. Review or critique of line organization determinations of PAAA applicability is not provided by the PAAA Program Manager, as the program is currently implemented. As the organization's individual with principal responsibility for proper PAAA Program implementation, not having the PAAA Program Manager provide some oversight of line organization PAAA determinations would appear to be a hole in the process. Alternatively, in order to address some the issues above, such oversight

of the line organization PAAA determinations would not be necessary if the PAAA Program Manager were to perform applicability screening.

### Role of PAAA Review Committee

The role of this Committee, as presently structured, is to review for NTS reportability those issues that the PAAA Program Manager has determined are potentially reportable. No location in the organization appears to provide the overall ownership to the PAAA Program. This Committee, given the program structure being employed by SNL, would appear to be the best location to have overall ownership and responsibility for the PAAA Program. As such its functions could be expanded to include the following:

- a. Review or oversight of PAAA screening functions by the line organization and by the PAAA Program Manager.
- b. Judgements on adequacy of the PAAA Program, apparent weaknesses (e.g., lack of QA issues), and actions to improve the program.
- c. Routine review of industry experience and determination of program changes, dissemination of lessons learned, or management briefings that are appropriate. Input may come from enforcement actions, enforcement letters, program examples obtained from other contractors, and EFCOG conferences and sessions.
- d. Better representation on the Committee of QA functional areas and Conduct of Operations as well as consideration of performance in such areas.

### Tracking of Corrective Actions for PAAA Issues

DOE has indicated in the Enforcement Policy (10 CFR Part 820, Appendix A) that it may exercise discretion and mitigate enforcement action where a contractor has self-identified in a timely manner and reported to DOE the potential violation, and has taken comprehensive corrective actions. DOE's Operational Procedure, Identifying, Reporting and Tracking Nuclear Safety Noncompliances under Price-Anderson Amendments Act of 1988 (Section 3.0) indicates that for non-NTS reportable noncompliances, DOE will credit as reporting to DOE a contractor's reporting of such noncompliances into its self-tracking system. Section 3.0 of that Operational Procedure indicates that such internally tracked noncompliances should be annotated to indicate those noncompliances that are PAAA noncompliances, should be retrievable as PAAA noncompliances for review by DOE, and should be readily accessible by DOE Coordinators and EH-10 representatives when onsite. For DOE to credit contractor self-tracking as achieving the mitigation criteria of identification, reporting and timely corrective action, the self-tracking process needs to demonstrate that these steps have been achieved.

The SNL self-tracking process is embedded in the RPIR process for radiological noncompliances. That process has certain weaknesses in terms of achieving the

above described objectives for the self-tracking process. Additionally, no similar process appears to exist for PAAA QA noncompliances. In summary, the weaknesses are as follows:

- a. No process of self-tracking of PAAA QA noncompliances was identified at SNL.
- b. The self-tracking process for radiological protection noncompliances (RPIR process) does not document the corrective actions to be taken to correct the noncompliance, the responsible party for each action, and the schedule for completion of the corrective actions.

### Review for Programmatic or Repetitive Problems

The present process being applied by the PAAA Program Manager to identify potential programmatic or repetitive issues is to perform a quarterly review of data over the past quarter. Such a process has several weaknesses, including the following:

- a. Review of only the data over the most recent quarter may exclude critical and relevant data of similar problems or cases. Depending on the significance of the problem, it may be appropriate to look back over a greater period of time than what might be appropriate for a more routine review.
- b. Using a quarterly review frequency may not provide timely identification of repetitive or programmatic problems. Such consideration should be part of each review since that noncompliance is being reviewed for potential reportability considerations as well as internal considerations of safety significance and need for immediate action.

### **Radiological Protection Safety Committee**

SNL has structured a Radiological Protection Steering Group composed of senior SNL line managers to oversee the uniform implementation of the Radiological Protection Program at SNL. Additionally, SNL formed the Sandia Radiation Protection Safety Committee (RPSC) which is comprised of the following: line managers responsible for radiological activities, SNL's Deputy Radiological Protection Program Manager, and the PAAA Program Manager. This committee is chartered as an advisory committee that provides corporate level oversight of the radiation protection program and operations, including Part 835 compliance; Radiation Protection Program Manual implementation. Resolution of selected technical or site-wide problems; review of performance metrics; review of results of periodic program audits; and dissemination of lessons learned.

The EH-10 review team met with members of the RPSC, reviewed recent issues or topics addressed by the Committee, discussed functions and roles of the various subcommittees, and reviewed areas of focus for the coming year. The EH-10 review team concluded that this committee and the Steering Group are functioning effectively in providing a corporate leadership and direction to the radiation protection safety area. Their efforts are comprehensive; they are acting in a proactive manner to address issues; and the focus is appropriately weighted to resolution of the more safety

significant issues. In contrast, it is not evident that a similar level of leadership and direction is occurring for the QA area.

### **Conclusion**

The above summarizes EH-10's review of the PAAA Program at SNL, and the specific weaknesses observed by the EH-10 review team from its visit of March 9-11, 1999. Although these weaknesses do not, in themselves, represent PAAA noncompliances or violations, they are issues that should be considered by SNL management if they expect to receive mitigation consideration in any future enforcement deliberation. As such they represent what may be viewed as variances from the safety management philosophy that is embodied in the Enforcement Policy (Part 820, Appendix A), and that DOE is attempting to encourage through application of its enforcement program.

Actions on the part of the contractor are voluntary in order to address the above issues. This evaluation should not be viewed as a direction to accomplish the suggested improvements. Such need to be appropriately coordinated with responsible DOE Area and Program Office management. No reply to the Office of Enforcement & Investigation for the above issues is necessary.