Department of Energy
Washington, DC 20585

July 24, 2001

Dr. William J. Madia
[ ]
Oak Ridge National Laboratory
P.O. Box 2008
Oak Ridge, TN 37831-6255

Subject: Oak Ridge National Laboratory Price-Anderson Amendments Act Program Review

Dear Dr. Madia:

During the period June 26-28, 2001, the Department of Energy (DOE) Office of Price-Anderson Enforcement (OE) conducted a review of the Oak Ridge National Laboratory (ORNL) 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 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 through formal procedures, (2) the PAAA Program is appropriately staffed with knowledgeable and experienced personnel dedicated to task, (3) comprehensive training of personnel involved in the various aspects of the Program is provided, (4) a multidiscipline and independent review board for determining NTS reportability is utilized by ORNL, (5) corrective actions for NTS reportable noncompliances are evaluated for effectiveness before closure, (6) NTS corrective action completion target dates are rarely exceeded, and (7) the Program seems to be supported by ORNL senior management. This last observation is evidenced by the Program's being managed by a Level 1 manager with direct report to you.

Our review also identified areas for Program improvement. Of particular concern is the checklist used by ORNL line organization personnel in screening potential PAAA noncompliances. The strict adherence to the checklist by excluding potential noncompliances which may involve support services or activities would significantly limit the scope of the quality assurance (QA) rule and is contrary to guidance provided by my office. The continued use of this checklist in its present form undermines the credibility

of your PAAA related self-identification and reporting processes. Other areas of concern include timeliness of evaluating NTS reportability of some potential

noncompliances, and lack of maturity associated with the trending of non-NTS noncompliances for repetitive or programmatic deficiencies.

As I stated earlier, your PAAA Program staff is knowledgeable and experienced. However, their effectiveness appears limited by the information they receive from the ORNL line organizations. We clearly agree that line organization involvement is critical to the success of your PAAA Program, but at the current level of maturity of your Price-Anderson Program Officer (PPO) concept and the apparent inconsistencies in screening potential noncompliances is hindering the effectiveness of your PAAA Program. We are encouraged that your PAAA Program staff is conducting independent assessments of the ORNL line organization PAAA screening and reporting process. This, combined with continued training, should aid in bringing your PAAA Program to a greater state of maturity.

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

In addition, OE is currently involved in the development of an Enforcement Guidance Supplement (EGS) to outline our enforcement position relative to implementation of the Independent and Management Assessment requirements of 10 CFR 830.122. Towards that end, our onsite visit also included a review of the implementation of your Independent and Management Assessment Programs. Information obtained during our review will prove valuable in our development of the EGS; a summary of our review in this area is enclosed.

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

R. Keith Christopher
Director
Office of Price-Anderson Enforcement

Enclosures: PAAA Program Review Report
Independent and Management Assessment Summary

cc: S. Cary, EH-1
M. Zacchero, EH-1
R. Day, OE
T. Weadock, OE
D. Stadler, EH-2
F. Russo, EH-3
R. Jones, EH-5
J. Decker, SC-1
R. Schwartz, SC-83
L. Dever, ORO
M. McBride, ORO
B. Hawks, ORO
D. Rosine, DOE-ORNL PAAA Coordinator
M. Walls, ORNL PAAA Coordinator
Docket Clerk, OE

OAK RIDGE NATIONAL LABORATORY
PRICE-ANDERSON AMENDMENTS ACT PROGRAM REVIEW

1. Introduction

During June 26-28, 2001, the Department of Energy (DOE) Office of Price-Anderson Enforcement (OE) Team conducted an onsite review of the UT-Battelle, LLC Price-Anderson Amendments Act (PAAA) Program at Oak Ridge National Laboratory (ORNL). The Laboratory encompasses 11 nuclear facilities and over 800 radiological areas/activities. UT-Battelle LLC took over from Lockheed Martin Energy Research on April 1, 2000, and has undertaken several efforts aimed at improving their PAAA Program. 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 internally 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 ORNL personnel and reviewed documentation pertinent to the review.

2. General Program Implementation

ORNL has established a PAAA Program infrastructure that is formalized, in large part, by a procedure titled *ORNL P-AAA Compliance Monitoring and Noncompliance Reporting.* 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 ORNL PAAA Program to be well established and implemented by formal procedure. However, requirements and guidance with regard to trending and criteria for internally reportable noncompliances is lacking. Specifically, ORNL described a comprehensive structure for trending NTS and non-NTS noncompliances where line organizations, functional cross cutting organizations (i.e., radiation services and quality) and the PAAA organization all had responsibility for trending and identifying repetitive or programmatic noncompliances. Implementation of this structured approach to trending is at a very immature phase in development with much reliance on an expert based approach (mentally reviewing past data for trends) rather than a

formalized approach to develop and trend useful performance metrics. Of concern is the apparent lack of progress in trending made by ORNL since this issue was originally identified in the February 2000 *Independent Assessment of Price-Anderson Amendments Act Program Implementation at Oak Ridge National Laboratory*. ORNL has recently initiated an effort titled *Lab Level Roll-Up of Low-Level Deficiencies* to address this concern. In addition, ORNL distinguishes between noncompliances, which require trending, and those, which are internally reportable. However, this distinction is not proceduralized and no criteria have been established to aid in this determination.

Three full time personnel, who are experienced, knowledgeable and dedicated to task, staff the ORNL PAAA Program. ORNL senior management commitment to the Program is demonstrated by the fact that the Program has been assigned to a Level 1 manager with direct report to the Laboratory Director. At the current level of activity, the staffing dedicated to the ORNL PAAA Program is adequate. However, it is apparent that when full implementation and compliance with the ORNL Price-Anderson Program Officer (PPO) concept is realized, the current staff will be quickly overwhelmed with the task of evaluating the influx of potential noncompliances from the PPOs. In addition, ORNL line management's expectation with regard to PPO resources may not be in line with that needed to meet the ORNL PAAA Program expectations. This issue will need to be addressed by senior ORNL management.

PAAA related training provided by ORNL PAAA Program staff is determined to be both complete and comprehensive and is noted as a significant strength. PPOs are provided a three-day introductory training session covering all major aspects of the PAAA Program and exercises in case studies utilizing historical noncompliances and enforcement actions from across the DOE complex. In addition, monthly PPO working group meetings are sponsored by the ORNL PAAA Program staff to facilitate lessons learned and to communicate emerging PAAA related issues. ORNL PAAA Review Board staff is also provided training specific to the evaluation of potential noncompliances forwarded from the PPOs. PAAA Awareness training is offered to line management on an as requested basis. Worthy of special mention is the ORNL PAAA Program staff training provided to support organizations such as Procurement and Human Resources. This training covers all general PAAA topics with a special emphasis on those aspects of the ORNL PAAA Program, which impact their activities. Currently the ORNL General Employee Training does not address PAAA as such. Consequently, line organization workers may be unaware of the relationship between nuclear safety requirements, as promulgated through ORNL policies and procedures, and the ORNL PAAA Program.

The Team reviewed appropriate documentation to assure that the breadth of the ORNL PAAA Program extends to both subcontractors and vendors. Through discussions with ORNL personnel and review of pertinent documentation, the Team concluded that the ORNL Program captures subcontractor and vendor work subject to PAAA nuclear safety rules.

3. Identification and Screening of Potential Noncompliances

ORNL has made progress over the past year to improve the processes by which they identify and screen potential noncompliances. ORNL makes use of a comprehensive set of source documents from which potential PAAA noncompliances are identified. At ORNL, line management is responsible and held accountable for the identification of potential PAAA noncompliances. This approach relies heavily on PPOs from ORNL nuclear and radiological divisions as well as key support divisions to assure that (1) a comprehensive set of documentation feeds into the PPOs for consideration, (2) these documents are appropriately reviewed, (3) potential noncompliances are identified and reported, (4) root cause and corrective actions are identified, and (5) identified issues are tracked and trended to determine repetitive or programmatic deficiencies. Although procedures are in place and training has been provided to assure that PPOs uniformly perform their intended function, actual performance varies considerably between line organizations and falls somewhat short of expectations. This observation was supported by a review of several PPO spreadsheets to examine the extent by which Radiological Event Reports (RERs) are being screened and reported as potential PAAA noncompliances. Numerous examples were noted that line PPO's failed to review and/or report RER related potential noncompliances to the ORNL PAAA Program staff. Additionally, the level of detail and documentation observed for screening by the PPO varied significantly between the PPOs.

A commonly used tool by the PPOs to screen and identify potential PAAA noncompliances is the ORNL *Price Anderson Amendments Act Potential Noncompliance Evaluation Guide.* The checklist, integral to this guide, directs the PPO through a series of questions. OE's review of the checklist identified that, if strictly adhered to, ORNL PPOs could inappropriately screen out all potential noncompliances unless they involved nuclear [ ] material or impacted the facility authorization basis. This narrowing of the scope of the QA rule is contrary to the intent of the rule and guidance provided by OE (see EGS 00-03). It is acknowledged that this limitation incorporated into the checklist is contrary to that found in ORNL procedures and that communicated through training. There is evidence that some potential noncompliances related to support services or activities are being captured at ORNL. However, there remains a concern that many such noncompliances may not be completely and consistently addressed across ORNL line organizations.

4. Evaluation of NTS Reportability

At ORNL potential PAAA noncompliances are identified by the line organization's PPOs and forwarded to the ORNL PAAA Program staff for reportability evaluation. The ORNL PAAA Program staff performs an initial screen and those issues determined to be reportable are forwarded to the ORNL PAAA Program Review Board. Those issues determined to be non-reportable are tracked and trended. The Review Board then uses the ORNL *Price Anderson Amendments Act Potential Noncompliance Evaluation Guide* checklist and/or guidance provided by OE to

determine if the potential noncompliance is NTS reportable. Those determined not to be NTS reportable are considered internally reportable. The Review Board is staffed by a multidiscipline group of professionals who are trained and knowledgeable in their assigned duties and are empowered to act on behalf of the Laboratory Director. The Review Board meets frequently (typically every two weeks) and is flexible in its meeting schedule as increased activity may demand. The ORNL PAAA Program staff is also proactive in identifying and evaluating potential noncompliances through their review of Occurrence Reporting and Processing System (ORPS) reports and other sources of information.

A review of the ORNL *Price Anderson Amendments Act Potential Noncompliance Evaluation Guide* checklist used by the Review Board to aid in determining NTS reportability identified that the checklist is not complete in capturing the criteria listed in Table 3-2 of the OE operational procedures *Identifying, Reporting, and Tracking Nuclear Safety Noncompliances under Price-Anderson Amendments Act of 1988.* Specifically, ORPS Unusual Occurrences related to fires/explosions, loss of control of radioactive material, equipment degradation, and safety system actuations are not addressed by the checklist. A review of NTS or internally reportable PAAA noncompliances over the past year suggests that some of these types of occurrences are being captured. However, there remains a concern that some of these occurrences are not being captured.

A review of the *ORNL P-AAA Compliance Monitoring and Noncompliance Reporting* procedure does not provide for any criteria by which the ORNL PAAA Program Coordinator determines which potential noncompliances are forwarded to the Review Board for their consideration. Discussion with the PAAA Coordinator revealed that this decision is based on his expertise and experience and no specific criteria exist. This lack of criteria could adversely impact the ORNL PAAA Program in that reporting consistency would be compromised should the current coordinator leave the Program or is absent for an extended period of time.

A review of the 129 potential PAAA noncompliances submitted by the PPOs over the past year and recorded in the Price-Anderson Issues Management System (PIMS) database indicated that approximately 40% of these noncompliances were open and required additional information for reportability determination. Some of these noncompliances have been open pending additional information for over a year. A sampling of these open noncompliances revealed that, in some cases, the information had been obtained and the noncompliance had been processed. However, the database had not been updated. In other instances, the information had not been obtained and the timeliness of reportability determination is being significantly affected.

5. Cause Determination

The Team reviewed the ORNL PAAA Program implementation documents for requirements pertaining to causal analysis for both NTS and internally reportable noncompliances. It was found that root cause analysis is required for all reportable PAAA noncompliances. New training has been established for the conduct of formal critiques for the more significant events at ORNL that should aid in the ORNL causal analysis effort.

6. Corrective Action Identification and Closure

ORNL has formalized procedures for identification and tracking of corrective actions to include those determined to be NTS or internally reportable PAAA noncompliances. Corrective actions are entered and tracked using the Laboratory Issues Database System (LIDS). Corrective action validation and verification is performed by the line organization(s) responsible for implementation of the corrective action(s). NTS reportable noncompliances are not closed until jointly agreed to DOE/ORNL closure criteria have been met and an evaluation of the effectiveness of the implemented corrective actions has been determined. Discussion with DOE and ORNL in conjunction with a sampling of NTS reports reveals that ORNL has been extremely diligent in meeting target completion dates for identified corrective actions.

The Team observed through the course of its review, that corrective actions identified by a given line organization only address those corrective actions associated with its organization. This approach hinders ORNL's ability to identify corrective actions that may be needed to address those causal factors that have sitewide implications.

7. Issues Management Systems

The LIDS serves as the Laboratory's central repository for issues management. Corrective actions associated with both NTS and internally reportable PAAA noncompliances are tracked in the LIDS. The ORNL PAAA Program staff recently developed a much needed database (PIMS) to capture all potential PAAA noncompliances reported by the ORNL line organization PPOs.

Due to limitations of the LIDS, many line organizations have developed their own unique issues management systems. Most often these systems are designed without consideration to compatibility with other systems outside their organization. This fragmented approach has led to a great deal of difficulty in tracking an issue that may be common to several line organizations. An effort is currently underway at ORNL that will address this issue.

The PIMS is an issues management system used by the ORNL PAAA Program staff to track potential PAAA noncompliances submitted from the line organizations. Although, an important recent developmental effort, the database is lacking in

several areas. Specifically, the database is not kept current as new information is obtained and some inaccuracies in data entry were noted. A review of the "Detail Reports" provided by the database indicates that, in many cases, the ORNL PAAA program staff communicated extensively with the line organizations to resolve reportability issues.

OE reviewed the various issues management systems used by the ORNL line organization to track line specific potential PAAA noncompliances. This review revealed significant diversity in the format and content of the spreadsheets. Some line organizations had a very comprehensive and complete system while others were very lacking in the information provided which often led to difficulty in tracking an issue from their system to the PIMS.

8. Bioassay Program

As a follow-up to the 1998 "bioassay moratorium," OE staff reviewed selected elements of the implementation of the ORNL Internal Dosimetry Program. This included review of selected procedures, discussion with cognizant personnel, and evaluation of selected documents associated with program implementation (surveys, RERs, bioassay results).

Strength was noted in the internal dosimetry program regarding a program developed to attempt to ensure ORNL employee compliance with bioassay monitoring requirements. This program has two notable features. The first includes automated notification of the Internal Dosimetrist when an individual logs onto a Radiological Work Permit (RWP) which has bioassay requirements. The program automatically checks the individual's bioassay profile and if the RWP requires monitoring for radionuclides for which the individual is not already required to be monitored for, it adds those radionuclides to the individual's required bioassay profile. The second strength in this program is the automatic notification of individual's of their scheduled bioassay. The program generates a list of individuals whose bioassay is due and automatically informs them of the requirements and schedules them for an appointment. If the individual is a no-show for their appointment, that person is rescheduled automatically for another appointment and a no-show letter is sent to the supervisor. If the individual again does not show up for an appointment, that person is again rescheduled and a no-show letter is sent to the next level of management. If the individual fails to obtain that bioassay, that person is again rescheduled and a no-show letter is sent to the next level of management. This system appears to be very effective in ensuring bioassay program participation.

A concern was also noted associated with the implementation of procedural requirements for special bioassay monitoring. The Internal Dosimetry Program Technical Basis Document and ORNL-RP-520, "ORNL Bioassay Program" require special bioassay monitoring, "Following any incident or occurrence in which an unexpected intake/uptake of radioactive materials is suspected…" ORNL-RP-520

further states, "… the DSS Internal Dosimetrist, in consultation with RSS personnel, shall determine on a case-by-case basis when special monitoring is required. RSS personnel shall initiate bioassay monitoring under the following conditions if the Internal Dosimetrist (or designee) is absent or otherwise unavailable for consultation: …" The procedure then cites several examples of personnel contamination that would trigger the special bioassay monitoring requirements. A review of RERs was conducted and four personnel contamination events were picked, which met the special bioassay monitoring thresholds, to verify that special bioassay monitoring was conducted in accordance with the procedural requirements. Of the four individuals reviewed, one individual received a special bioassay 17 days after the event, one individual received a special bioassay one-month after the event, and the other two did not receive special bioassay monitoring. The procedure allows special bioassay not to be conducted after consultation with the Internal Dosimetrist. However, there does not appear to be any documentation to verify that the Internal Dosimetrist was consulted regarding the two individuals who did not receive special bioassays. Further, the Internal Dosimetrist did not remember being consulted about the events. It appears that there may be an issue with procedural compliance in ensuring that the special bioassay monitoring requirements of the procedure are adequately implemented.

9. Conclusion

The OE Team review of the ORNL PAAA Program found the Program to be established by procedure and staffed with experienced and dedicated personnel. OE views the independent assessment of the ORNL PAAA Program in February 2000 and the ORNL line organization PAAA independent assessments being performed by the ORNL PAAA Program staff as a strong asset to continuous improvement of the Program. However, OE has concern with (1) the checklist used by the PPOs to screen potential noncompliances that if strictly applied could limit the scope of the QA rule, (2) inconsistency in identifying and reporting potential PAAA noncompliances by the PPOs, and (3) the lack of progress made by ORNL in the area of trending nonreportable issues that may collectively indicate a programmatic or repetitive noncompliance.

Overall the OE Team considers the Laboratory's PAAA Program to be mature in some areas and failing to meet OE expectations in other areas. The areas in which improvements are needed seem to be understood by ORNL and, in some cases, corrective action is currently underway. OE encourages ORNL to continue its efforts to bring their PAAA Program to a greater state of maturity.

OFFICE OF PRICE-ANDERSON ENFORCEMENT
INDEPENDENT AND MANAGEMENT ASSESSMENT REVIEW
OAK RIDGE NATIONAL LABORATORY

I. INTRODUCTION

During the period June 26-28, the DOE Office of Price-Anderson Enforcement (OE) reviewed elements of the UT-Battelle Oak Ridge National Laboratory (ORNL) Independent and Management Assessment (IMA) Program. This pilot review was performed to collect information for an Enforcement Guidance Supplement (EGS) that is currently being developed by OE. Once completed, the EGS will outline the OE enforcement position relative to the IMA requirements of 10 CFR 830.122 and will serve as a guide for future OE formal reviews of contractor IMA programs.

Despite the pilot nature of the review, OE did identify areas of positive performance that are described below. The OE review also identified several deficient areas that, subsequent to the formal promulgation of the EGS, may reflect potential noncompliance with 10 CFR 830.122 requirements. These are also summarized below.

II. OVERVIEW

Independent Assessment activities are conducted largely through the activities of the ORNL Quality Services Division (QSD) and the Office of Independent Oversight (IO). The QSD provides matrix quality assurance (QA) staff support to the various laboratory line organizations, and performs various assessments (vendor inspections, etc.) in support of line programs. The IO organization reports directly to the Laboratory Director, and performs evaluations of the effectiveness of line program operational processes.

Laboratory Management Assessment (termed self-assessment) activities are conducted by the various line organizations in accordance with ORNL procedure ORNL-QA-P03, Rev. 2, *ORNL Self-Assessment Program* and various division-specific operating procedures. Divisions identify annual assessment plans to self-evaluate performance in areas reflective of company, division and/or facility specific goals.

III. RESULTS

A. The OE review identified various observations (both positive and negative) that are considered highly relevant to the development of the EGS criteria. These observations are summarized below.

The following program strengths and/or positive initiatives were noted during the subject review:

1. Although the responsibility for Independent Assessment activities is shared by both QSD and IO, the assessment activities of the QSD were noted to be largely driven in response to customer (line management) request. Consequently, the IO organization fulfills a needed function in providing a more independent focus/role.

2. Recent reviews by the IO organization have included an emphasis on line management PAAA program implementation and processes. The IO organization is also initiating a series of reviews with emphasis on line management Corrective Action Programs.

3. The QSD assessment process was described in approved procedures and included requirements for auditor qualification/certification and standard terminology for issues.

4. The Operational Awareness Program (OAP) was generally noted as a positive initiative. Implementation has resulted in significant benefits (i.e., generation of lessons-learned) and has provided opportunity for DOE and contractor partnering.

B. The following areas of deficient implementation were also noted during the current review. Subsequent to issuance of the EGS and more formal OE reviews of this area, several of the following deficiencies would be considered potential noncompliances of 10 CFR 830.122 requirements.

1. Formal documentation describing the ORNL assessment programs is not fully in place. The ORNL QA Plan did not describe ORNL's current assessment strategy. Various implementing procedures were in draft form.

2. Several of the ORNL systems functioning to identify quality problems (IO assessments, OAP reports, Radiological Event Reports) left it to the discretion of the issue recipient/owner to evaluate the issue, determine whether it required formal tracking, and disposition the issue. No drivers were in place to ensure a response to or tracking of the issue independent of the owner. Discussion with various contractor participants to the process indicated inconsistencies in the consequent level of issue response across Divisions. ORNL has recognized deficiencies with the issue management system and is evaluating an improved process.

3. Reviewed ORNL assessment reports used a variety of undefined terms to designate a quality problem or issue (i.e., deficiency, potential vulnerability, etc.). Consequently, it was not obvious which issues were of greater or lesser significance, which represented problems deserving response, etc.

4. Implementation of the Radiological Support Services (RSS) self-assessment program was providing effective follow-up to previously identified issues. The focus of the assessments was noted to be limited to performance by the RSS organization, however, rather than line management implementation of the Radiation Safety program. Trending of identified issues was also focused on specific details of the issue, rather than more generalized concerns (i.e., a general trend of radiological procedural noncompliance was not recognized as such since each individual radiological procedure was only violated once or twice).

5. Review of a recent QSD waste certification audit and associated documentation identified that several identified corrective actions were overdue, with no specific follow-up. Discussion with QSD staff indicated that audit team leads were not routinely requesting a response to transmitted audits nor concurring in developed corrective actions as required by their internal QSD audit procedure.

The above items are provided for appropriate consideration by UT-Battelle. No response to OE is required for this pilot review report.