Department of Energy

Washington, DC 20585

June 18, 2004

Dr. Michael R. Anastasio
Director
Lawrence Livermore National Laboratory
P.O. Box 808, L-001
Livermore, CA 94550

Subject: Price-Anderson Amendment Act Program Review

Dear Dr. Anastasio:

From March 9-11, 2004, the Office of Price-Anderson Enforcement (OE), in coordination with the Livermore Site Office (LSO), conducted a review of the Lawrence Livermore National Laboratory's (LLNL/Laboratory) PAAA Program. The general purpose of a Price-Anderson Amendments Act (PAAA) Program Review is to evaluate the site contractor's own regulatory processes that are intended to facilitate both improvement in nuclear safety performance and establish a basis on which DOE can exercise enforcement discretion on future matters.

Our review included an evaluation of the Laboratory's processes to (1) identify PAAA nuclear safety rule noncompliances, (2) report and track noncompliance both locally and in the DOE Noncompliance Tracking System (NTS), and (3) analyze and correct noncompliances so as to prevent recurrence and possibly more significant events. Enclosed is a report summarizing the results of this review. The review was intended as a follow-up to a similar review conducted in March of 2000.

In general, LLNL has developed a program that addresses but does not implement effectively all of the elements of a PAAA program. Although the attached report identifies some positive program strengths, OE was concerned by the significant program weaknesses summarized below. Our office also noted that some of the weaknesses listed were similar to those identified in the March 2000 review, the most significant being the problems associated with the identification, reporting, and correction of repetitive and programmatic PAAA noncompliances.

<u>Program areas needing improvement include:</u>

- LLNL has not provided adequate training and supplemental guidance or structure at the Associate Director's (AD) level to ensure consistent program implementation

- The LLNL PAAA Office has not provided sufficient oversight and coordination of overall day-to-day program implementation at the AD level.

- Not all sources of site information are adequately screened for identification of PAAA noncompliances (for example - criticality infractions, facility level deficiency reports, and some assessment reports).

- Potential programmatic and repetitive issues are not consistently identified and reviewed for NTS reporting.

- Only minimal requirements exist for the LLNL causal analysis process; only events with significant consequences typically receive formal causal analysis

- Corrective action tracking is not rigorous and occurs in several different databases or in different versions of DefTrack (i.e., local and institutional levels). Corrective actions at one facility appear to be taking more than a year on average to complete.

- There is no independent verification of NTS corrective actions. The AD "certifies" closure to the PAAA Office. No effectiveness reviews are performed unless they coincide with a scheduled Assurance Review Office audit.

Of specific concern is that LLNL has elected to implement essentially a decentralized program without establishing an adequate level of structure, coordination, and oversight for such an approach. For example, much of the initial identification and screening responsibility for PAAA nuclear safety noncompliances resides at the AD level via AD representatives; however, little training, program coordination, and monitoring activities have occurred at this performance level. OE also identified examples of issues known at the AD level that were not effectively communicated to the LLNL Price-Anderson Project Office (PPO) for required evaluation and trending. There is some evidence that a test of safety significance is applied at the AD level concerning what will formally be screened as a noncompliance and formally communicated to the PPO for evaluation and trending purposes. OE could not determine if this was intentional or not, but nonetheless, it has resulted in a self-regulatory process that lacks sufficient transparency for DOE to rely on. The application of a significance test is inconsistent with DOE expectations that contractors need to identify, correct, and trend lower level noncompliances for the purpose of facilitating enforcement discretion as well as to ensure potential precursors to more significant issues are adequately addressed.

We also recognize that LLNL is in the process of implementing an improved issues management system. As part of this initiative, LLNL should strongly consider (1) integrating the PAAA program elements of noncompliance screening and identification, trending for repetitive and programmatic issues, and more visible corrective action tracking into the new system/process, and (2) adapt the new LLNL system/process to capture even the lowest level deficiencies, without regard to source, so it can provide the most complete and efficient source of information for performance monitoring. It has been OE's experience that sites with single source issues management systems are clearly in a better position to identify and correct programmatic or repetitive issues before they result in significant events in all performance areas even beyond PAAA nuclear safety. My office is willing to share

additional information on issues management systems within DOE that may be of benefit to the Laboratory in developing the site's new approach, should you so desire.

In addition, LLNL should be aware that formal causal analysis is a mandatory requirement in the quality assurance rule. It appears that some significant site deficiencies, including some identified in PAAA NTS reports, are not receiving the required analysis so as to prevent recurrence. A specific example involves the multiple NTS reports submitted on the longstanding Unreviewed Safety Question (USQ) implementation deficiencies.

The deficiencies and issues described above are of a nature that will require senior management involvement to address. No reply to this letter is required; however, our office intends to conduct a follow-up review in six to eight months to re-evaluate the Laboratory's program. Failure to correct the improvement items noted above may result in a potential reduction or loss of mitigation as described in the DOE Enforcement Policy, 10 CFR 820 Appendix A, for any future LLNL enforcement actions. In addition, failure to effectively implement the quality improvement requirements of the rule could result in future enforcement action. If you have any questions, please contact me at 301-903-0100 or have your staff contact Peter Rodrik at (301) 903-5092.

Sincerely,

Stephen M. Sohinki
Director
Office of Price-Anderson Enforcement

Enclosure: Price-Anderson Amendments Act Program Review

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Lawrence Livermore National Laboratory
Price-Anderson Amendments Act
Program Review

I. Introduction

The Department of Energy's (DOE) Office of Price-Anderson Enforcement (OE), in coordination with the DOE Livermore Site Office (LSO), has conducted a review of the Lawrence Livermore National Laboratory's (LLNL/Laboratory) Price-Anderson Amendments Act (PAAA) Program. The general purpose of a PAAA Program Review is to evaluate a DOE contractor's own regulatory processes to facilitate both improvements in site nuclear safety performance and to establish the basis for DOE to exercise enforcement discretion on future specific matters.

This review was conducted in accordance with DOE Enforcement Guidance Supplement (EGS) 00-02, *Price-Anderson Amendment Act Program Reviews*. Specific areas evaluated included (1) methods for identification and screening of PAAA noncompliances, (2) site determinations of noncompliance reportability into the DOE Noncompliance Tracking System (NTS), (3) causal analysis and corrective action processes, and (4) independent and management assessment processes. Review activities included onsite discussions with LLNL and LSO representatives from March 9-11, 2003, as well as a review of applicable procedures and documents.

This PAAA Program review was also in part a follow-up from an initial OE review conducted in March of 2000. Deficiencies identified in the March 2000 review and their associated corrective actions were re-evaluated during this review. Results of the review are summarized in the following report sections.

II. General PAAA Program Implementation

The LLNL PAAA program and associated quality improvement and management assessment processes are formally established by and described in the following documents:

- ES&H Manual Part 4.4 – *Identification, Reporting, and Tracking of Noncompliances with Nuclear Safety Requirements*, Revision 1, May 23, 2003

- S&H Manual Part 4.2 – *Environment Safety and Health Deficiency Tracking*, May 30, 2001

- ES&H Manual Part 4.1 – *Directorate Environment Safety and Health Self-Assessment Program*, Revision 1, March 13, 2001

- ES&H Manual Part 4.5 – *Incidents Notification, Analysis, and Reporting*, Revision 1, October 16, 2003

ES&H Manual Part 4.4, *Identification, Reporting, and Tracking of Noncompliances with Nuclear Safety Requirements*, establishes the Laboratory's process and requirements for implementing its overall PAAA Program. This procedure describes an essentially decentralized but formal PAAA Program.

The LLNL Facility and Program Associate Directors (AD) who are responsible for a particular work area or work activity have the direct responsibility to (1) identify (screen) and determine the reportability of noncompliances, (2) review incidents to determine if a repetitive or programmatic noncompliance exists, (3) report all potential noncompliances to the LLNL PAAA Project Office, and (4) develop and track corrective actions. The AD's have delegated these functions to one or more individuals within their organization; this responsibility is typically a shared or part-time function for these individuals. An OE review of the overall LLNL PAAA program procedures and processes resulted in the following specific observations.

The Laboratory has established a PAAA Project Office (PPO) which is led by the LLNL PAAA Coordinator and also contains two senior professional staff members and an administrative person. The LLNL PAAA Coordinator/PPO reports directly to the Laboratory Deputy Director for Operations.

The PPO is required to provide institutional support for the program by (1) developing PAAA related policy, processes, procedures, and training; (2) serving as the Laboratory Point-of Contact (POC) for PAAA matters; (3) evaluating AD reported noncompliances for trends; (4) assisting the AD and their organizations in the implementation of their PAAA related responsibilities, and (5) preparing NTS reports and tracking closure of NTS corrective actions.

The only LLNL specific written guidance for the AD staff on what constitutes a PAAA noncompliance is contained in ES&H Manual Part 4.4. Although the procedure provides a broad summary of potential noncompliances, including the areas of programmatic, repetitive, radiological, and quality assurance, it does not provide enough site-specific detail in any particular area to be the only source of guidance or information for those conducting screening activities. The AD staff does not use a formal screening form or check-sheet to ensure the process as implemented is consistent and comprehensive from one AD organization to another.

In the past, the LLNL PPO has developed and conducted formal training for AD managers and staff. The three AD representatives interviewed as part of this review who currently conduct PAAA noncompliance screening activities indicated they had not received any formal training in the past two or three years. One of the representatives indicated he had never received any formal training in preparation of his PAAA screening and reporting responsibilities. The LLNL PAAA procedures do not require or identify any PAAA training for personnel who are assigned such responsibilities. The PAAA Coordinator stated that additional PAAA training was being planned.

The identification and reporting of LLNL PAAA noncompliances appears to be inconsistently implemented and negatively impacted by the lack of recent training (initial and refresher), limited procedural guidance, and lack of a documented AD level screening process as discussed in more detail in the following report sections.

The PPO has not developed formal processes to coordinate and ensure the effective implementation of program elements conducted at the AD level. For example, during the past several years, the Laboratory has not conducted either a formal self or independent assessment of its PAAA program. In addition, the PPO does not have a method to routinely coordinate all of the PAAA screening functions, such as monthly meetings, with applicable AD staff and/or mandatory distribution of internal and external assessments and audits. Since a significant part of the program is implemented at the AD line level, a periodic assessment and more formal coordination of its implementation by the LLNL PAAA Project Office could ensure more consistent Laboratory-wide implementation by those with more senior and functional PAAA expertise.

Strengths:

- LLNL has developed a formal PAAA program as documented in site procedures.

- The PAAA Coordinator is well qualified and supported by a knowledgeable staff.

Weaknesses:

- LLNL has not provided adequate training and supplemental guidance/structure at the AD level to ensure consistent program implementation.

- The PPO has not provided sufficient oversight and coordination of program implementation.

III. Identification and Screening of PAAA Noncompliances

As summarized in the previous section, the LLNL ADs have the primary responsibility for identifying and reporting to the PAAA Project Office potential noncompliances. The PAAA Project Office evaluates each referred issue with the AD representatives to determine if it is an actual PAAA noncompliance and whether or not it meets NTS reportable thresholds. The PAAA Project Office staff uses an evaluation form called a Noncompliance Evaluation Form (NCE) which guides them in these determinations and identification of any related noncompliances as part of their rolling trending process.

A review of LLNL internal and external assessments as well as other site documents revealed that the Laboratory adequately screens daily events using both the site Daily Operations Report (DOR) and Occurrence Reporting Processing Screen (ORPS) reports. It appears however, that not all relevant sources of potential PAAA issues are being actively or consistently screened and, in some cases, the actual screening activity does not adequately identify PAAA noncompliances. The PAAA coordinator stated that the primary screening sources at LLNL are ORPS reports and assessments. Specific observations and examples are discussed below.

During a review of LLNL's Assurance Review Office Triennial Criticality Safety Program Assessment, February 4, 2004, OE determined that criticality safety infractions that occurred were not adequately screened by the AD staff and reported to the PPO for logging, evaluation, and trending. From mid-2002 (May) to early-2003 (February), there had been five criticality safety infractions, which represented a significant increase over prior time periods of the same length. Some of these infractions involved exceeding administrative controls for mass limits. OE is concerned that due to inadequate screening, the PPO was not made aware of a PAAA noncompliance as well as a potential programmatic or repetitive issue.

The site does not currently have a centralized site-wide issues management system that is used consistently by all of the ADs. This has complicated PAAA screening activities since there are multiple sources and tracking systems for issues and deficiencies among the different ADs. It appears that some of these multiple databases are not consistently screened. For, example, OE did not find any evidence that lower level facility deficiency reports such as nonconformance reports (NCR) or radiological deficiency reports are being screened and reported to the PPO for evaluation and trending.

It also appears that some LLNL assessments are not adequately screened. OE noted that only a limited number (four) of assessments, were listed on the LLNL PPO screening log for 2003. The PPO is not on direct distribution of all LLNL assessments. The PPO relies on the AD representatives to refer specific

assessments (prescreen) to their office that the representatives believe contain potential noncompliances. During onsite discussions, it appears that a threshold test involving the level of safety significance is applied to determine whether or not an assessment is referred to the PPO. This limits the PPO's ability to conduct their required evaluations for potential programmatic or repetitive issues before they manifest themselves by way of more significant events.

In addition, an analysis of LLNL's 2003 PAAA screening log (see below), which documents the Laboratory incidents or items that were screened for the year, seems to support the conclusion that LLNL PAAA screening activities have not been comprehensive.

- A total of 62 items were screened for the year as listed on the 2003 log – by OE experience, a very low number for the size and scope of work at the site.

- About 80 percent (51 out of 62) were considered event related versus performance assessment driven since they were identified from an ORPS report or from the site DOR – by OE experience a negatively high percentage.

- About 50 percent (33 out of 62) appeared to be officially designated as PAAA noncompliances with only 21 items receiving an evaluation using an NCE form – by OE experience a very low number.

- Only four LLNL assessments were screened as listed on the log – by OE experience a relatively low number.

- No external assessments (DOE or DNFSB) were listed as being screened – by OE experience a highly unusual result.

<u>Strengths:</u>

- LLNL consistently reviews operational information such as ORPS reports for potential PAAA noncompliances.

<u>Weaknesses:</u>

- Not all sources of site information are adequately screened for identification of PAAA noncompliances (criticality infractions, facility level deficiency reports, and assessment reports). Similar screening issues were also identified in the March 2000 review.

- Lack of adequate training and limited guidance or structure at the AD level has negatively impacted screening activities.

IV. Evaluation for Reportability and Trending

LLNL Reporting Processes

OE reviewed the Laboratory's processes for evaluating PAAA noncompliances for reporting into the NTS and interviewed selected LLNL personnel who are knowledgeable of and participate in the process. As previously discussed, the LLNL AD representatives are required by procedure to identify NTS reportable noncompliances.

ES&H Manual Part 4.4 does not establish any time requirements for conducting the PAAA reviews and reporting into the NTS. OE's review of LLNL NTS reporting time frames identified that deficiencies that were screened and reported into the NTS were reported in a reasonable amount of time. LLNL should consider addressing expected time frames in their PAAA procedures to ensure reporting timeliness continues to remain consistent with management expectations.

The AD staff interviewed did not appear to be very knowledgeable of the OE EGS criteria for NTS reporting, or even of the EGS itself. OE's interviews with the PAAA PPO staff and selected personnel from the AD organizations identified that in actual practice the organizations do not perform the review for NTS reporting; rather they notify the PAAA Project Office of potential reportable issues and the evaluation is performed there. The review for NTS reporting is formally documented on a PAAA Noncompliance Evaluation form. The personnel in the PPO and the PAAA Coordinator were knowledgeable of the NTS reporting thresholds and the OE EGS. However, OE was still concerned that the AD staff lacked sufficient understanding of NTS reporting thresholds so as to make appropriate referral decisions to the PPO. OE also noted that LLNL still needs to update its PAAA procedures to incorporate the new OE EGS reporting thresholds that were developed to address the recent revisions to ORPS criteria.

OE determined that most of the issues reported into NTS (approximately 74 percent) in 2003 were from operational events reported into ORPS. OE found some evidence that programmatic and repetitive areas were not being identified and screened for NTS reporting (discussed below under trending processes). These observations were also considered a weakness in the 2000 report. In addition, OE's review found the overall number of LLNL NTS reports for the past two years (2002 and 2003) was roughly half of the number reported in 2000 and 2001.

Although in theory the above reporting trends could be a result of fewer potential issues, the issues discussed in the previous section concerning LLNL screening activities as well as non-conservative judgment calls on what constitutes a programmatic or repetitive issue are more likely causes for the reduction in

reporting. Specifically, the limited reviews in the past year of assessment reports, which are a more common source of non-event PAAA noncompliances, appears to have contributed to the negative reporting trend. The March 2000 review also identified problems with the adequate screening of assessment reports for the identification and reporting of repetitive and programmatic issues.

LLNL Trending Process

The PPO is responsible per ES&H Manual 4.4 to routinely review PAAA noncompliances for repetitive, programmatic, and systemic problems. As previously discussed, this is accomplished by way of a rolling trend analysis in which each screened noncompliance is reviewed using the NCE form. In addition, LLNL has developed some institutional performance monitoring and trending processes. Although designed for a much broader purpose than PAAA issues trending, they can be used in the identification of programmatic and repetitive issues.

During this review OE identified some examples (listed below) where repetitive or programmatic deficiencies appear to have existed without adequate NTS screening and possible reporting. In some cases it appears that the weaknesses discussed with the LLNL PAAA screening processes have negatively impacted this trending process; the trending review is based on an incomplete set of existing PAAA issues. In other cases, it appears that the AD organizations have not adequately integrated PAAA trending into other LLNL institutional performance monitoring processes at the AD level.

- ES&H Manual Part 4.1, *Feedback and Improvement*, requires each directorate to perform a yearly review of ES&H deficiencies. OE's review of one of these reports, the Defense and Nuclear Technologies Directorate 2002 ES&H Annual Report, identified a statement that PAAA issues were trended in a separate section of this report; however, no such section was included, and no PAAA trend data could be identified or located.

- From mid 2002 (May) to early 2003 (February), there had been five criticality infractions, which represented a significant increase over prior periods of the same length of time. Some of these infractions involved exceeding mass limits.

- Six events involving a facility condition that was outside of the authorization basis (AB) involving chemical inventory limits occurred in 2002 and 2003. A causal analysis was performed as part of a response to the Defense Nuclear Facility Safety Board, but no evidence was found that these issues were collectively screened for PAAA NTS reporting.

- A DOE Headquarter Independent Oversight ES&H Evaluation conducted in July 2002 identified significant weaknesses with the Laboratory's issues management processes including root cause analysis and corrective action tracking.

The OE PAAA program review, conducted in 2000, identified several areas of weakness related to the review of PAAA noncompliances for NTS reporting. Most of the areas of weakness were addressed and corrected. OE's current review, however, found one continuing weakness concerning the large percentage of NTS reports that have resulted from events and not from management or independent assessments. This problem is an indicator that the PAAA program is still reactive instead of proactive in finding and correcting programmatic or repetitive PAAA noncompliances and needs significant improvement in this area.

Strengths:

- A formal process (NCE Form) exists for reviewing and reporting into NTS.
- NTS reporting of ORPS-related deficiencies is generally consistent with OE EGS criteria.
- The PPO staff and PAAA Coordinator are knowledgeable of PAAA screening and reporting criteria.
- NTS reporting is generally performed in timely manner.

Weaknesses:

- No formal requirements or expectations exist for time periods for AD screening and providing noncompliance issues to the PPO.
- PAAA Procedures do not reflect the actual review process for NTS reporting and do not contain requirements for training of responsible personnel.
- Potential programmatic and repetitive issues are not consistently identified and reviewed for NTS reporting.

V. Cause Determination/Corrective Action Closure

The corrective action process was reviewed to determine if the causes of PAAA noncompliances are identified and if adequate corrective actions are implemented. In addition OE's review included the timeliness of completing corrective actions and the processes used to verify they were completed and effective.

A formal causal analysis process is not described in or required by LLNL procedures for more significant site deficiencies (including PAAA noncompliances). Causal analysis is required only for events with some level of immediate consequence that require an Incident Analysis Committee. For ORPS reports, LLNL applies a very limited causal analysis process where by direct derivation, a manager or reviewer assigns ORPS cause codes to the particular event or condition.

OE's review of NTS reports submitted in 2002 and 2003 found that a causal analysis was not identified as part of the corrective action process. Since a majority of these NTS reports were based upon events also reported into ORPS, causes were documented in the ORPS report but only as part of the limited ORPS analysis described above. Deficiencies in non-ORPS related NTS reports, however, did not receive any documented causal analysis. Unless adequate causal analyses are conducted, there can be no confidence that appropriate corrective actions will be identified or taken. In reviewing the LLNL NTS reports, it appears that corrective actions could benefit from a formal causal analysis process. A specific example involved the multiple NTS reports and ongoing issues with implementation of the LLNL USQ process. LLNL should develop a more formal causal analysis process, based on a graded approach that (1) applies a level of review based on significance factors, (2) addresses the need for extent of condition reviews, (3) defines acceptable analysis methods, (4) provides for necessary training, and (5) better describes overall management expectations.

ES&H Manual Part 4.2, *Environmental, Safety, and Health Deficiency Tracking System*, identifies the requirements for the LLNL corrective action process. This procedure establishes a Deficiency Tracking System (DefTrack) to capture and track deficiencies. The system consists of a local DefTrack system that is applied at the directorate level to record the status and track deficiencies, and a roll-up version of DefTrack that is used at the institutional level.

Part 4.2 establishes requirements and guidance for the types of deficiencies that directorates are required to enter into DefTrack. In practice, the directorates implement the requirements and guidance differently. OE's review identified that DefTrack is not implemented in a manner that captures all deficiencies across the site. For example, building 332 (B332) uses an additional database, Management Action Database System, to track some deficiencies not in DefTrack.

Corrective actions are placed into DefTrack by each directorate. For items in DefTrack, corrective actions are assigned completion dates and tracked. The responsible manager, however, can revise the due dates for corrective actions for internal deficiencies and no authorization or tracking of these changes are performed. Corrective action completion schedules are not rigorously managed.

The corrective action owner identifies the corrective action priority and schedule, and can revise the schedule without other approvals. The changes to corrective action schedules are not typically tracked; exceptions are NTS reports (PPO must agree) and external LLNL commitments on corrective actions. NTS report corrective actions were generally completed in a timely manner.

Each directorate provides a yearly assessment of corrective actions which indicates late corrective actions. OE's review of corrective actions completion records for one facility, B332 Plutonium Facility, identified that most corrective actions were taking more than a year to be completed and sometimes several years with no apparent basis for the extended time period.

The PPO is notified by the responsible organization when NTS level PAAA corrective actions are completed so they can update NTS. No verification of completed corrective actions is performed outside of the responsible organizations. The exception is when a scheduled audit by the ARO conducts a review in the same area. In addition, effectiveness reviews are not performed of corrective actions for internally generated PAAA deficiencies. The lack of a verification process for completed corrective actions was a weakness identified in the 2000 OE PAAA program review.

LLNL has recognized for some time that DefTrack has not been an effective issues management system. This issue was a concern discussed in the DOE Independent Oversight ES&H Evaluation report of July 2002. The Laboratory is consequently in the process of migrating to a newly designed issues management system/process that is currently scheduled for implementation later this year. OE reviewed some aspects of the new process. It appears that some of the issues discussed above concerning the management and tracking of corrective actions will be addressed by the new system/process. It was not clear, however, whether or not the Laboratory will use the system as a central site-wide issues management system that (1) can resolve through integration some of the PAAA screening and trending issues discussed in the previous report sections, and (2) address some of the concerns with LLNL causal analysis processes discussed above.

<u>Weakness:</u>

- Only minimal requirements exist for causal analysis process; only events with significant consequences typically receive formal causal analysis

- Corrective action tracking is not rigorous and occurs in several different databases or in different versions of DefTrack (i.e. local and institutional levels). Corrective actions at one facility appear to be taking more than a year on average to complete.

- There is no independent verification of the effectiveness and the completion of NTS corrective actions. The AD "certifies" closure to PAAA Office. No effectiveness reviews are performed unless they coincide with a scheduled ARO audit

VI. Management and Independent Assessments

The LLNL Management and Independent Assessment programs were reviewed as part of this PAAA program review. These programs are required by the QA Rule and are not a voluntary part of the PAAA program. OE's review evaluated the formality and completeness of the program and procedures. No review of implementation was performed to determine the effectiveness of these programs. This review was performed using the guidance established in Enforcement Guidance Supplement 01-02, *Management and Independent Assessments*.

The ARO is primarily responsible for performance of independent assessments. ARO has established the following formal procedures to govern independent assessments.

- Assurance Review Office Activity Level Quality Assurance Plan

- QIP 18.0 – ARO Assessments

- QIP 2.1 – Requirements for Qualification of Persons Performing Quality Assessments.

Procedure QIP 18.0 identifies the requirements and responsibilities for the performance of the independent assessment program. Roles and responsibilities are established, and the assessment process is described. The assessment process includes preparation for the assessment, selection of assessment personnel, conduct of the assessment, and development of the assessment report. Completed assessments are formally transmitted to the responsible organization to determine corrective actions. The corrective actions are required to be entered into the DefTrack corrective action management system.

OE's discussions with the ARO personnel identified that corrective actions related to findings in ARO assessments are evaluated for effectiveness in follow-up assessments. The lead assessors are certified, and the assessment team personnel are trained and qualified for the assessments scope. Independent assessments are formally scheduled for a year in advance and are planned and conducted following formal requirements.

Management assessments are primarily performed within each directorate. LLNL procedure Document 41.1, *LLNL Quality Assurance Program*, establishes the requirement for management within each directorate to periodically assess

their QA system. Each directorate has also established a QA plan and implementing procedures specific to the directorate activities. OE sampled the process of one directorate, the W-Program Technologies Engineering Division (DTED). The DTED Quality Assurance Procedure, UCRL-AR-153452, requires Program Managers to assess their management processes and to perform complete assessments of all of their areas at least once every three years. DTED also has a Quality Implementing Guide, DTED-QIG-001 *Quality Assessments,* which provides guidance on the conduct of quality assessments.

OE's review concluded that Management and Independent Assessment programs are formally established and generally meet the criteria in the OE EGS. The ARO program for independent assessments met all of the EGS criteria. Management assessments are required and formally scheduled. In the case of DTED, guidance is provided on the conduct of assessment. The management assessment programs are not as well defined in the areas such as training the assessors and the formal identification and resolution of deficiencies.

VII. Conclusions

LLNL has developed a PAAA Program that addresses but does not consistently implement effectively all of the PAAA program goals of noncompliance identification, screening, reporting, trending, and corrective action. A few strengths were observed as discussed in the previous report sections.

OE however, is concerned with the significant number of weaknesses that were identified in this review. Some of the current weaknesses were similar to those identified in the March 2000 review; the most significant one being those involving problems with the identification, screening and reporting of repetitive or programmatic PAAA noncompliances. Overall, OE found the Laboratory's processes not satisfactory towards actively demonstrating the self-regulating goals of a PAAA program.

No formal response to this review is required. However, the contractor should evaluate and address, as necessary, the observed weaknesses because these weaknesses have the potential to lead to additional noncompliances and/or limit enforcement discretion or mitigation for prompt identification and corrective action in future enforcement actions.