

September 22, 1999

Dr. Yoon Chang

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Subject: Program Review Letter

PAAA Noncompliance Screening and Reporting, and Application of Quality Assurance (10 CFR Part 830.120) and Radiological Protection (10 CFR Part 835) Rules

Dear Dr. Chang:

The Office of Enforcement and Investigation performed a review on July 21-22, 1999, of your Price-Anderson Amendments Act (PAAA) nuclear safety program. The review included (1) your process for identification and reportability evaluations of potential PAAA violations and (2) the scope of implementation of 10 CFR Part 835 (Occupational Radiation Protection) and 10 CFR Part 830.120 (Quality Assurance) requirements to activities at Argonne National Laboratory-East (ANL-E). 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, interviews with individuals and key managers responsible for implementation of these programs, and information provided subsequent to our visit. Based on our review we have identified several areas where processes or intended application of requirements do not meet DOE expectations. Our review identified significant weakness in your processes to self identify and report potential noncompliances, in your process for trending and causal evaluation of events. These weaknesses are contributing to a failure to (1) recognize programmatic problems, (2) establish corrective actions that are comprehensive, and (3) prevent similar events from occurring. In general, it appears that problems are addressed in a reactive rather than proactive mode.

Our review did note that the recently performed Triennial assessment of the radiological protection program appeared to have been comprehensive and rigorous. It identified a number of areas with compliance issues, and thus identifies the areas needing attention in order to achieve an improved radiological protection program. Many of the findings have been grouped into broader generic categories needing attention. DOE's review concluded that each of these broad issues represents a programmatic noncompliance issue, and as such these should be reported into the NTS.

One significant process weakness is an inadequate causal analysis process after an event. Our review determined that little or no causal analysis is performed to identify the potential for a similar problem to exist at some other location onsite, or a program weakness that could allow the problem to recur in the future. Insufficient effort is focused on identifying and fixing these potential problems.

Also your interpretation of applicability of DOE's nuclear safety requirements to activities at ANL-E is a significant concern. Our review identified areas where noncompliance with a PAAA Rule requirement was clearly established, but the evaluation of PAAA applicability performed by your staff determined that the noncompliance was not PAAA applicable. More details on these issues and DOE's position on how it would consider applicability of nuclear safety requirements in an enforcement review are included in an enclosure to this letter.

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 ANL-E 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 will make the determination of which cases it deems to warrant further DOE evaluation or investigation. Contractors have not been delegated the right to screen such cases to determine for DOE which matters should be reviewed. We address these issues and DOE's position on changes in the process that would enhance your reportability determinations in the enclosure.

One example of an issue not reported was the use of external dosimeters at the Advanced Photon Source Facility since April 1996 that were not accredited by DOE's Laboratory Accreditation Program. As discussed in the enclosure, prior approval is required before use of such devices is permitted.

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 needs to have confidence in your noncompliance review and tracking process, and in particular that the process demonstrates timely identification, reporting, and correction of the noncompliance, in order for DOE to credit the contractor in deciding to refrain from an enforcement action on these self-tracked items. The issues identified with your self-tracking process, also summarized in the enclosure, do not allow DOE to place the desired reliance on this process.

Also, our review of several assessments of procurement practices and interviews with personnel from the Procurement Division and the Alpha-Gamma Hot Cell Facility has

concluded that significant programmatic weakness exists in your procurement process to qualify and select vendors who supply items and services to your nuclear facilities.

Our review also concluded that your procurement process does not meet the requirements of the Quality Assurance Rule and your Quality Assurance Plan and if your process is not adequately corrected, subsequent enforcement actions could be taken. Such program weaknesses and instances of inadequate controls in this area are discussed in the enclosure.

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 specific noncompliances and your application of Parts 835 and 830.120 to activities at ANL-E. In addition, should DOE not find programmatic 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 and that adequate corrective actions are being implemented. Further, we are continuing to review several specific noncompliances and you will be notified by separate correspondence when those reviews are completed.

Should you desire DOE consideration of mitigation in future enforcement deliberations, it is recommended that your PAAA evaluation and reporting process be revised to address the above issues. If you have any questions, contact Howard Wilchins of my staff at (301) 903-0107.

Sincerely,



R. Keith Christopher
Director
Office of Enforcement and Investigation

Enclosure:
Evaluation of the ANL-E PAAA Program

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EVALUATION OF THE ARGONNE NATIONAL LABORATORY-EAST PRICE-ANDERSON AMENDMENTS ACT PROGRAM

I. ANL-E Program for Screening and Reporting PAAA Noncompliances

ANL PAAA Policy

The ANL-E contractor, the University of Chicago, implements the Quality Assurance Rule (10 CFR Part 830.120) and the Occupational Radiological Protection Rule (10 CFR Part 835) through top-level plans approved by DOE, implementing procedures, and management and personnel in line organizations and various support groups.

ANL-E has put in place a top-level document to define ANL-E's policy for nuclear activity rule compliance. This information is stated in Chapter 1-2 of the ANL-E Environment, Safety & Health Manual, dated January 22, 1998. This document provides a concise and reasonable summary of ANL-E's regulatory obligations under Price-Anderson Amendments Act (PAAA), and the DOE Enforcement Process and Policy in 10 CFR Part 820 and its Appendix A. It establishes the position of an ANL-E PAAA Coordinator, and defines the responsibilities of that position. It also establishes specific responsibilities of division and facility line managers and employees for compliance with and implementation of nuclear safety requirements.

Screening and Reporting

Chapter 1-2 of the ANL-E's Environment, Safety & Health Manual also places responsibility for identification of potential violations of nuclear safety requirements with division and facility line managers. They are required to inform the ANL-E PAAA Coordinator of such issues. The chapter also assigns responsibility for (1) assisting line management in the identification of PAAA noncompliances, (2) screening ORPS, assessment results and other sources for potential reportability, and (3) maintaining a tracking system for nuclear safety noncompliances. The ANL-E PAAA Coordinator is also designated as the individual responsible for entering reportable nuclear safety noncompliances into the DOE Noncompliance Tracking System (NTS).

To enhance the process of screening potential PAAA noncompliances, ANL-E identified several improvements in January 1999, which included the following:

- ◆ All ORPS reports involving radiological protection issues or nuclear facilities will include a review for PAAA noncompliance and a statement from the ANL-E PAAA Coordinator.

- ◆ A review group of health physics and quality assurance professionals was established to advise the ANL-E PAAA Coordinator on potential PAAA issues and recommended actions.
- ◆ Line management was instructed to ensure that all potential PAAA issues are forwarded to the ANL-E PAAA Coordinator.
- ◆ The DOE-ARG and the ANL-E PAAA Coordinators will meet monthly.
- ◆ The Nuclear Safety Review Committee will annually review PAAA issues.

It does not appear that these “changes” to the PAAA Program were formalized into any process or program procedures in January 1999. In June 1999, one of these items, the use of a Review Group to advise the Coordinator, was formalized through the issuance of Procedure Q0008.00, “ANL-E PAAA Review Group,” dated June 26, 1999. The Review Group advises the Coordinator on matters of whether the issue is a PAAA noncompliance, and whether it should be reported into the NTS. That procedure also provides that the ANL-E Coordinator should consider the recommendations of the Review Group, deciding the reportability of the issue, development and verification of corrective actions, and the closure process. Decisions on compliance and reportability rest with the ANL-E PAAA Coordinator.

Prior to the formation of the Review Group, the Coordinator maintained a database of PAAA issues that included follow-up dates and actions taken by the Coordinator. Beginning in January 1999, the Review Group began tracking the issues that they reviewed, including conclusions on regulatory noncompliance and recommendations on reportability. Additionally, the ANL-E PAAA Coordinator continued to maintain a separate log of matters reviewed by the Coordinator. Files generated by the Review Committee are supplemented by the Coordinator, so that only one file is maintained on an issue that proceeds through the screening, reporting and closure process.

II. PAAA Program Weaknesses

The EH-Enforcement site visit reviewed the PAAA Program as described in the above control procedures. Additionally, the EH-Enforcement team reviewed a number of specific noncompliance case files for issues that were judged by ANL-E to be below the NTS reporting threshold. Additionally, EH-Enforcement personnel met with the ANL-E PAAA Coordinator and various members of the Review Committee. The EH-Enforcement 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 the NTS.

Failure to recognize certain failures as noncompliances with nuclear safety regulatory requirements could affect the priority and attention given to correcting these problems. More broadly, incorporating resolution of these issues into the ANL-E management scheme will more closely achieve the safety objectives of DOE's nuclear safety policy and requirements.

Regulatory Compliance Determinations

EH-Enforcement found that ANL-E was applying a narrow interpretation as to when an issue represented a noncompliance with nuclear safety requirements under Price-Anderson. From a review of several specific cases, EH-Enforcement identified a number of criteria or methods that were being used to incorrectly conclude that the particular case did not represent a noncompliance with quality assurance or radiological protection requirements. Because these cases were classified incorrectly, ANL-E did not consider whether these needed to be reported into the NTS or tracked as PAAA noncompliances in the internally tracked system. The following summarize the criteria or methods that are not consistent with PAAA or Enforcement Policy criteria:

1. 'Potential for Harm' as Precondition for Noncompliance: ANL-E in several cases had been applying a judgment that the circumstances of the particular case did not represent the potential for harm or significant harm to workers, and, therefore, was not a PAAA noncompliance. A PAAA noncompliance exists when a nuclear safety requirement established by the Rule and your implementing documents or processes is not met. Any judgment on the potential for harm resulting from the noncompliance is part of the determination of significance and does not change the fact that a PAAA noncompliance occurred. If, for example, workers violate several levels of safety controls specified in their work control procedures, but still have one layer of defense remaining, one cannot conclude the procedural violations are not a PAAA violation. An individual noncompliance with a nuclear safety requirement may not constitute an immediate safety problem, but does constitute a weakening of the safety program and is none-the-less a noncompliance. Another example is the reluctance of health physicists to conduct monitoring in areas adjacent to those where contamination is identified. One case, which was identified during the site visit, was the failure to survey cabinets in uncontrolled areas following the identification of some uncontrolled material in such a cabinet.
2. Assumed Safe vs. Questioning Attitude or Conservative Approach: Several examples were noted in which the workers failed to plan and take precautions for a potential unsafe condition by assuming that conditions were safe prior to undertaking the activity. Thus, when unexpected conditions occurred, they were not adequately prepared. The appropriate nuclear safety philosophy should be a questioning attitude and conservative approach that confirms the conditions are safe and that no unanticipated conditions exist before proceeding. An example

identified during the site visit was a case in which workers were going to test a sealed source to confirm its integrity. The workers approached the job assuming the source was not leaking, and did not take appropriate planning and work control precautions. This action led to contamination of one of the workers.

3. Legacy Material Noncompliance With 10 CFR Part 835: Several instances of finding radiological material in areas that are not posted was concluded to be legacy material and, therefore, not a noncompliance with Part 835. The material was not in a controlled area, posted, etc., as required by Part 835. Such conditions are not in compliance with Part 835 requirements, should be considered noncompliances, and should be screened, reported, tracked, and corrected accordingly. Legacy material is not exempt from the PAAA program and should be treated like all other material.
4. Prompt Correction of Deficiencies: Several past cases were identified where ANL-E justified that the issue was not a PAAA noncompliance because it was corrected quickly. Such a criterion is not a condition of PAAA nuclear safety requirement compliance. If the condition is not in compliance with a nuclear safety requirement, then it is a PAAA noncompliance, no matter the duration. Such issues should be identified, screened, reported, tracked, and corrected as such. DOE has the exclusive statutory responsibility to consider mitigation or apply discretion and refrain from an enforcement action due to, among other things, the responsiveness of the contractor in correcting the noncompliance condition.

During the site visit, it was indicated by ANL-E that they had previously recognized that this approach was not permitted by the Enforcement Policy (10 CFR 820, Appendix A) or other regulatory requirements, and they changed their practice of using this justification.

5. Assessment Observations: DOE's review of several ANL-E self-assessments found instances in which noncompliances were identified by ANL-E assessment personnel, but were labeled as "Observations." Since these were classified as Observations, they received a lower level of importance by the line organization and were not treated with the rigor reserved for findings. Thus, problems that were identified were not addressed in a manner that would assure their prompt correction. Further, they were not considered as PAAA noncompliances. It appears that greater care should be applied to the "Observation" designation or that all findings and observations from self-assessments should be reviewed for potential PAAA noncompliance.

Reporting Threshold for NTS

EH-Enforcement found that ANL-E was applying an unrealistically high threshold before reporting an issue into the NTS. The particular items identified by EH-Enforcement in its review included the following:

1. Applying a Safety Significance Judgment in Addition to the Reporting Thresholds in DOE's Guidelines: In the examples reviewed, ANL-E was commonly making a judgment on safety significance and labeling the issue as "minor" even if the issue could be considered programmatic or repetitive, or otherwise met the reporting threshold of DOE's reporting guidelines. The EH-Enforcement review team explained that DOE was not expecting contractors to decide which issues were sufficiently safety significant, even if above the reporting threshold, such that the issues should be reported to and reviewed by DOE. DOE intended to exercise its own judgment on safety significance if the issue was NTS reportable.
2. Roll-up Issues vs. Programmatic: EH-Enforcement noted several cases in which ANL-E identified generic noncompliance issues and labeled them as "roll-ups," but did not conclude that these were programmatic and, thus, reportable issues. ANL-E compiled related problems or findings into a "roll-up" of the issue, in order for management to consider the issue more systematically and to develop broader corrective actions. When issues rise to this level, DOE considers these to be programmatic (i.e., roll-up as used by ANL-E equates to programmatic). As explained in DOE's reporting guidance,¹ programmatic applies to instances of occurrences of multiple noncompliances that are related but not identical, indicating a common breakdown in a program or program area.
3. Review for Repetitive Problems or Trends: The PAAA screening process does not appear to routinely review each issue in the light of prior history with similar problems. Such a review is important both from a quality assurance standpoint as well as for NTS reporting considerations. Proper consideration of prior noncompliances, trends, repetitive problems, and common causes is important in order to ensure that appropriately comprehensive corrective actions are developed and implemented as required by Quality Improvement provisions of the QA Rule. Additionally, for such cases, reporting into the NTS is appropriate as identified in DOE's guidance on reporting of repetitive and programmatic issues.¹

Triennial Assessment Report

ANL-E's Triennial Radiological Protection Assessment Report dated February 8, 1999, identified a number of problem areas. While the evaluation was considered to be a comprehensive assessment of compliance with Part 835 requirements, the subsequent failure to report the findings into the NTS is inappropriate. At the time of the EH-Enforcement site visit, DOE advised ANL-E that these appeared to be NTS reportable, and that it would be acceptable to submit these in a single roll-up report.

¹ DOE's Operational Procedure "Identifying, Reporting and Tracking Nuclear Safety Noncompliances under Price-Anderson Amendments Act of 1988," dated June 1998.

Rule Implementation Issues

In the course of performing this review, EH-Enforcement identified two areas in which the implementation approach by ANL-E is not consistent with DOE's expectations. DOE will refrain from taking enforcement action at this time. Pending review of corrective actions, failure to correct these approaches could lead to a more serious condition which might merit an enforcement action in the future, however. These two areas are (1) the use of unaccredited personnel dosimeters at the APS facility, and (2) inadequate procurement controls being applied to items and services for nuclear facilities.

Use of Unaccredited Dosimeters

One example of an issue not reported was the use, since April 1996, of external dosimeters at the Advanced Photon Source (APS) Facility. These dosimeters were not accredited by DOE's Laboratory Accreditation Program (DOELAP). An application for technical equivalency for the new dosimeters was submitted by the University of Chicago to DOELAP prior to the APS's debut. However, authorization to use the new external dosimeters had not been provided to ANL-E in time for that event. It is true that DOELAP personnel did not provide a timely decision regarding the technical equivalency request. ANL-E was nonetheless obligated to pursue the issue of technical equivalency beyond simply submitting an application and should have refrained from using the new dosimeters until the matter was resolved. In fact, the University of Chicago allowed the new dosimeters' prolonged use at the APS without obtaining the required DOE approval. This action was in direct contrast to 10 CFR Part 835, that specifically requires that only DOELAP accredited dosimeters be employed. ANL-E should be clear that prior approval is required before using such devices.

Procurement Weaknesses

EH-Enforcement reviewed several assessments conducted at ANL-E that identified a breakdown in implementation of the procurement requirements of the QA Rule. Our review of these assessments and the procurement process at ANL-E related to the purchase of nuclear facility items and services concluded that significant programmatic weakness exists in the identification of appropriate quality levels in procurement documents and in the establishment of a process to ensure vendors are adequately qualified to provide the item or service. Our conclusions are based upon the following:

- ◆ Final Report of Supplier Evaluation of ECT-Central Shops, April 7, 1998, concluded: "There appears to be no system in place to evaluate suppliers of materials or outsourced work at CS, nor to monitor product being received from outside suppliers to ensure it conforms to requirements. In addition, there does not appear to be a root cause analysis process used when unsatisfactory product is received from an outside vendor."

- ◆ QA Assessment of Alpha-Gamma Hot Cell Facility, March 31, 1998, identified the following finding: “Although AGHCF had specified a Quality Level B or C for inclusion on purchase requisitions (PR-52321, 52337, 52444, 52461, and 52463) the purchase requisitions were not submitted for review by the ETQAR as required in the AGHCF QA Program Plan (IPS-210-00-00). In addition, the associated purchase orders failed to identify any quality level by the Procurement Division.”

The Alpha-Gamma Hot Cell Facility QA Plan establishes quality levels (Levels B and C) for procurements that affect safety-significant Systems, Structures, and Components (SSCs) or are otherwise safety-related and require higher levels of quality control. In addition this QA Plan establishes the following: “The database of acceptable and selected vendors, which is maintained by PRO, shall be used by PRO to identify suitable vendors for level B procurements. PRO shall assure that the selected vendor can meet the criteria for the item being procured.” During our interviews with the ANL-E Procurement Department (PRO), EH-Enforcement was informed that PRO maintains no list of qualified vendors and does not perform any audits of vendor quality programs. Personnel in PRO stated the facility personnel are responsible to identify the vendor. Personnel at the Alpha-Gamma Hot Cell Facility provided EH-Enforcement with their procedure for establishing Quality Levels for procurement, AGHCF Operations Manual, 8.0 Administrative Controls, but stated they perform no assessments of vendors and per their QAP expect the qualification of vendors to be performed by PRO. The EH-Enforcement investigation found no evidence that a process to qualify vendors or ensure they continue to provide acceptable items or services for the appropriate quality assurance levels is used at ANL-E for procurements involving nuclear facilities.

Conclusion

The above summarizes EH-Enforcement's review of the PAAA Program at ANL-E, and the specific weaknesses observed by the EH-Enforcement review team from its visit of July 21-22, 1999. Although these weaknesses are not being cited by DOE as violations at this time, they are issues that should be addressed by ANL-E management. DOE will monitor actions to correct these programmatic weaknesses before a decision is made whether to close these matters without further action. Such actions to address these weaknesses should be appropriately coordinated with responsible DOE Area and Program Office management.