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NUCLEAR REGULATORY COMMISSION
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MEMORANDUM FOR: Hubert J. Miller, Acting Chief
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Division of Quality Assurance, Vendor,
and Technical Training Center Programs
Office of Inspection and Enforcement

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SUBJECT: REPORT OF OBSERVATIONS MADE DURING A DOE-SPONSORED
AUDIT OF BATTELLE PACIFIC NORTHWEST LABORATORIES

From September 21-25, 1986, I observed an audit conducted by the Department of Energy/Salt Repository Project Office (DOE/SRPO) on the activities of Battelle Pacific Northwest Labs. Battelle's activities related to performance assessment and waste package modeling were the focus of this audit.

In accordance with the NRC agreement with DOE/HQ and DOE/SRPO, NMSS chose to observe this audit and asked specifically for IE participation.

This three-day audit was conducted by two DOE/SRPO employees, one DOE/HQ employee, four Office of Nuclear Waste Isolation (ONWI) employees and two Battelle Project Management Division (BPMD/ONWI) employees.

Two objectives for this observation were identified by NMSS in their audit observation protocol. The first objective was to observe and comment on the effectiveness of the audit team. The second objective was to evaluate the adequacy and implementation effectiveness of the Battelle QA program.

As to the first objective, the audit team performed an effective audit of Battelle's QA program.

As to the second objective, the documented Battelle QA program appears to comply with its contractual and regulatory requirements. However, the audit provided information on implementation weaknesses within Battelle that will require corrective action.

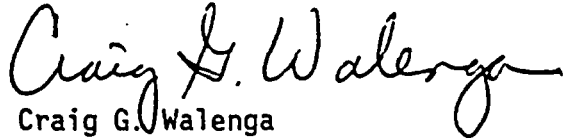
Several weaknesses in the conduct of the audit were noted which reduced the overall audit's effectiveness. This audit was an excellent attempt by DOE/SRPO

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to implement a performance-oriented assessment of a contractor. Appendix A provides observations and associated conclusions concerning the effectiveness of the audit.



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Concurred by:

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Enclosure: Appendix A

APPENDIX A

1. Purpose

The basic purpose of the observation was to assess the effectiveness of DOE/SRPO's audits of Battelle's QA program and its implementation.

2. Criteria

In general, the criteria that were used to assess the audit's effectiveness were synthesized from the NRC recommendations in item 5 of the Minutes of the DOE/NRC Meeting on Quality Assurance, issued December 31, 1985, by the Quality Assurance Manager for the Office of Geologic Repositories. A broad listing of criteria used to assess the audit's effectiveness can be summarized as follows:

- a. Selection of specific areas for the audit's focus, from which most audit activities would evolve.
- b. Effective, detailed audit preparation prior to field deployment of the audit team.
- c. Involvement of appropriate DOE/SRPO technical or QA audit team personnel during the entire audit process. Especially, effective use of technical members.
- d. Conduct of team meetings to discuss findings and observations.
- e. Establishment of self-critiques and other feedback mechanisms for improvement.

3. Areas Observed

This report is based on the observations of the pre-audit team meeting, the pre-audit conference, the audit team daily meetings, the post-audit conference, and the various team reviews of Battelle's computer software activities associated with various performance assessments and waste package modeling activities. By agreement with the audit team, any concerns were promptly identified to the audit team leader and discussed either immediately or at the daily team meetings.

4. Observations

a. Audit Area Selections

Based on the review of the audit checklists and the current status of Battelle's activities, the areas chosen for review were appropriate.

b. Comprehensive Pre-Audit Preparation

There were weak areas in preparation for the audit, which decreased the audit's effectiveness; although, overall, the preparation phase for this audit showed a significant improvement from the previous DOE/SRPO audit conducted at Fluor.

The audit teams spent a significant portion of their time trying to determine what records were available for review or what personnel were available for interview. While some time may need to be spent in these activities during the audit, a determination of what records are available for review, what persons are required to be available for interview, and the dates that the material and individuals must be made available should be established prior to the need for them. Examples of areas where the audit's effectiveness would have been enhanced through better preparation are as follows:

- (1) During the initial performance assessment review, discussions revealed that Battelle was not responsible for specific work activities as DOE/SRPO believed. Early determination of available records would have identified the misconceptions.
- (2) The review of Battelle's QA organization may have been more effective had the audit team leader requested that specific audits, schedules, and appropriate audit team members' qualification records be collected prior to the arrival of the team.
- (3) The Waste Package Modeling assessment started slowly, as the team had to be informed of what records were available for review. Some of the weaknesses identified by the audit team may have been obvious in the preparation phase if specific documents had been requested in advance.
- (4) Tight Battelle security regulations made it extremely difficult to interview several Battelle personnel not located in the area used for the review. Those complications could have been avoided by better planning.

c. Effective Team Preparation and Utilization in the Audit Process

- (1) Coordination between the QA specialists and technical observers was weak. This is especially significant because the very basis for the conduct of this type of audit is the use of technical expertise to determine the effectiveness of the quality program's implementation. One example was the failure of a QA specialist to use his technical observer to assess the training and qualifications of Battelle's employees who were responsible for specific end-products. While the QA specialist could determine if Battelle's employees were trained and had sufficient experience to work in the areas assigned, the technical observer, who was reviewing the end-product, was the one member of the entire audit team who was best qualified to judge each employee's performance to determine whether (a) the persons who performed specific work activities had adequate training and experience to be assigned the task; (b) the training conducted was effective, based on the quality of the product including the quality of the documentation; and (c) the individuals performed their assigned tasks at the required technical levels.

(2) The qualifications and experience of the various audit team members were considered to be excellent.

d. Conduct of Team Meetings

No major concerns were identified about the conduct of team meetings. However, better coordinated review efforts are needed to obtain greater synergistic interaction during the team meetings.

e. Self-Critiques

An excellent audit critique was conducted by the audit team leader as part of his audit function. By observing specific audit team activities, the audit team leader was able to identify weaknesses in the audit process and in individual team member techniques. Additionally, a DOE/HQ representative, who was also an audit team member, was tasked to provide a separate, written critique upon completion of the audit.

Audit critiques, as exemplified in this audit, should continue to be conducted on DOE QA audits until the various DOE project offices determine that their audit staffs understand and are implementing the techniques required for effective assessment of program implementation.

5. Summary

The conduct of the Battelle audit was a significant improvement in the DOE/SRPO efforts to audit for the effective implementation of a QA program. It is apparent that DOE/SRPO has used the results of its previously conducted Fluor audit to significantly upgrade its QA audit process. While some audit implementation weaknesses were identified, the audit reflected more effective preparation, a sharper focus on specific objectives, an improved checklist, a better selection of technical observers to support the objectives, and a good self-critique activity.