

NOTICE OF DEVIATION

Based on the results of an NRC inspection conducted on July 24-28, 1978, it appeared that certain of your activities were not conducted in full accord with your commitments as indicated below.

The Black & Vetach (B&V) QA program is documented in the Quality Assurance Program - Nuclear (QAP-N) manual which by statement in Section 1 "is intended to comply with regulatory requirements, including those of 10 CFR 50, Appendix B"

- A. The QAP-N manual commits to ANSI N45.2.11 in paragraph 2.1 and Table 2-1.11. Paragraph 10 of ANSI N45.2.11 states in part:

"Design documentation and records which provide evidence that the design and review process was performed in accordance with the requirements of this standard shall be collected, stored and maintained in accordance with the requirements of ANSI N45.2.9.

"The documentation shall include not only the final design documents such as drawings and specifications, and revisions thereto but also records of the important steps . . . which support the final design."

Contrary to the above commitments, neither the Project Design Manual (PDM) for Black Fox Station (Volumes I and II), the QAP-N manual, nor revisions to these manuals are being collected, stored, or maintained by the system developed by B&V as being in compliance with the requirements of ANSI N45.2.9.

Appendix A to ANSI N45.2.9 lists the type of documentation and records that are considered subject to the requirements of N45.2.9. Included in this list are "Design Procedures and Manuals." The PDM is a design document containing criteria and requirements and the QAP-N manual contains design procedures.

- B. The QAP-N manual commits to ANSI standards N45.2.12 and N45.2.13 in paragraph 1.2.2 and Table 2-1. Paragraph 12 of N45.2.13 states that audits of suppliers shall be conducted in accordance with N45.2.12 to assure that items or services being procured are in accordance with the applicable QA program and procurement document requirements. Further, paragraph 3.5 of N45.2.12 states in part, "Applicable elements of the quality assurance program shall be audited at least annually or at least once within the life of the activity, which ever is shorter."

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Contrary to the above commitments:

1. Procured services for geotechnical studies, both onsite and in the vendor's laboratory, were audited only once in each location (site and laboratory) in early 1974, even though these studies began in early 1974 and continued well into 1976.
 2. It does not appear that B&V has audited all applicable elements of their QA program, for example neither document control (particularly procedure and manual control) nor QA records per se have been audited except when segments of these activities were incidental to the performance of an audit with a totally different scope.
- C. The QAP-N manual commits to ANSI N45.2.12 in paragraph 1.2.2. Section 4 of ANSI N45.2.12 states in part, "... a post-audit conference shall be held with management of the audited organization . . . an audit report shall be written and signed by the audit team leader The audit report shall be issued within thirty days after the audit."

Contrary to the above commitments:

1. Post-audit conferences relative to B&V internal audits are not held with the audited organizations, consistently, for example of five (5) audit reports reviewed only one provided evidence that a post-audit conference was held.
2. The results of two (2) B&V internal audits reviewed were not documented in the form of an audit report.
3. Two (2) of five (5) B&V internal audit reports reviewed were not signed by the audit team leader.
4. Two (2) of five (5) B&V internal audit reports reviewed were issued more than thirty (30) days after the audit (one 52 days the other 46 days after the audit), further standard procedure SP 18.2 of the B&V Quality Assurance Program - Nuclear manual states in part, "The audit report shall be issued . . . within 30 working days." which also appears contrary to N45.2.12 requirements.