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MEMORANDUM FOR: Ronald L. Ballard, Chief
Technical Review Branch
Division of High-Level Waste Management

THRU: David Brooks, Acting Section Leader
Geochemistry Section
Technical Review Branch
Division of High-Level Waste Management

FROM: Paul J. Bembia
John Bradbury
Geochemistry Section
Technical Review Branch
Division of High-Level Waste Management

SUBJECT: TRIP REPORT FOR THE NRC QUALITY ASSURANCE AUDIT OF THE
LOS ALAMOS NATIONAL LABORATORY MINERALOGY/PETROLOGY SUPPORT
OF THE NNWSI PROJECT, LOS ALAMOS NM, JUNE 7 - 12, 1987

The purpose of this trip was to participate in the NRC QA audit of the NNWSI mineralogy/petrology work being performed at Los Alamos National Laboratory. Our task was to perform the technical portion of the audit and provide technical support to the NRC QA staff. There was much discussion, both internally and with the DOE, concerning the role of the technical staff in the audit process. This discussion examined whether the audit was an appropriate forum to assess the technical adequacy of the program, or whether technical meetings and data reviews would better suit this purpose. It was decided that an appropriate role in the audit was to assess the soundness of the Detailed (technical) Procedures (DP's) and make some determination as to the ability of the LANL investigators to perform quality analyses using these procedures. Broader questions, such as whether the collected data will resolve site issues, will be handled in the SCP review and future technical meetings.

We spent most of the week interviewing the principal investigators, other scientists, and technicians. Through these interviews we closed out the technical checklist questions which had been generated during the pre-audit review of the DP's and the mineralogy/petrology Scientific Investigation Plan. We also had extensive discussions with the PI's concerning their analytical methods and investigative philosophy.

During our discussion several questions arose which we felt merited further investigation. First, we were interested in the criteria which are used to disqualify data points or data sets from use in publications, and how this disqualification process is documented. Also, we wanted to know what is being done with "good" data that are not used in publications, and how these data sets are documented and tracked. Third, we were interested in the qualifications of the scientists and technicians to characterize the mineralogy

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and petrology of Yucca Mountain or to perform the Detailed Procedures, and in the documentation of these qualifications.

Concerning the disqualification of data, we found that acceptance criteria, which are used to determine whether or not a data point or data set will be disqualified, do exist for at least some of the major analytical procedures used in the mineralogy/petrology investigations. Where they do exist, the criteria are documented in various laboratory documents. The criteria are not, however, documented in the Detailed (technical) Procedures (as required by the LANL-NNWSI QA Program Plan), and vary somewhat for different investigators using the same analytical technique on the same phases. Since the QAPP requires that acceptance criteria be documented in the Detailed Procedures, LANL should address this inconsistency. The lack of acceptance criteria in the detailed procedures will be reported in the final audit report as a deficiency.

If data are found to be unacceptable, an investigator may erase the data set from the computer disk it is recorded on during the analytical session. The investigator may also discard the paper output. According to one of the principal investigators, there is apparently no requirement to document the reason that a particular data set was disqualified from use. This is a situation that the NRC staff should be cognizant of, and discussions should be held internally within the NRC to determine whether guidance should be given to the DOE concerning the disqualification and tracking of data.

Data which are considered to be "good" data, but are not used in publications are apparently adequately documented and are traceable. The individual PI is required to keep a hard copy of the raw data, and the analyses are also stored on magnetic disk. These records can apparently be traced from the notebook kept with each instrument to the actual data set. It may not always be clear, however, why good data are not published, and discussions should be held internally within the NRC to determine whether guidance should be given to the DOE concerning unpublished data.

The qualifications record for each scientist is apparently not adequate to survive the licensing process. There is insufficient detail in the qualification records to adequately document that personnel are qualified to perform a particular task. Several investigators also mentioned that occasionally procedures are included in their certification documents which they feel should not be there. The lack of an adequate certification procedure and certification documentation was identified by the audit team as a finding. This will have to be responded to in writing by LANL through the DOE after the issuance of the final audit report.

A number of programmatic problems were identified by the other two audit teams. A total of four findings, fourteen deficiencies, and four observations were drafted by the audit team. These problems, which were primarily programmatic, were considered to be sufficiently serious as to question the acceptability of data in the licensing process. DOE and LANL were therefore informed at the closeout meeting that the NRC does not consider their quality assurance program

to be qualified at this time. They were also told that they apparently do not have an adequate appreciation of the licensing process. Their response was that they will anxiously await further NRC guidance as to how to qualify the mineralogy/petrology program.

The technical audit team made two general comments concerning the quality of staff and procedures in the mineralogy/petrology program. The first, which dealt with the qualifications of the LANL scientists, stated

"The LANL technical staff includes experts and specialists with extensive experience in the disciplines of mineralogy and petrology. The NRC technical audit team, after interviews with these scientists is confident in their ability to perform quality work."

The second general statement concerned the detailed technical procedures and stated

"The detailed technical procedures are written in a non-specific form such that they may be applied by qualified technical personnel to various NNWSI investigations. Because of their general nature, the procedures alone will not guarantee quality analyses. However, the NRC technical audit team is confident that this current group of investigators can use the existing detailed procedures to perform quality analyses."

These general comments were presented orally to the DOE-NNWSI personnel at the closeout meeting by Jim Kennedy.

When the general comments concerning the ability of personnel and procedures to produce quality work was made at a pre-closeout meeting, we were cautioned by Don Oakley (the LANL TPO) that we may not be qualified to make such statements. We feel this comment is a result of the DOE's contention that any personnel or laboratory facilities used to assess the work of the DOE and the DOE contractors have qualifications equal to the personnel performing the work. The technical audit team does not agree with this philosophy, and we feel that a scientist with knowledge of the appropriate techniques is capable of evaluating the ability of the personnel using the procedures to produce quality work.

During the audit we were asked to make a judgement concerning the "adequacy" or "validity" of the data being produced by LANL. We strongly resisted making this judgement, as we felt that our approach to the investigation would not allow such a judgement to be made. Without an understanding of the DOE performance assessment requirements for the data, the NRC technical audit team could not address the "adequacy" of the data being collected through the current mineralogy/petrology program. For example, if future performance assessment calculations require precision of mineralogical analyses that exceed the capabilities of the methods currently used in the program, these analytical methods would be considered "inadequate." Furthermore, we did not approach our investigation as a data review, where raw data are checked and tracked through

the data reduction process to a conclusion. We therefore felt that any judgement concerning the validity data would be difficult to defend.

We feel that if the technical staff will be called upon in the future to make judgements concerning the adequacy of a technical program or the validity of data, we must resolve: 1) the definition of "technical adequacy" and "valid data" 2) the differences between the NRC and the DOE concerning the ability of the NRC staff and contractors to assess the validity or adequacy of the technical program and collected data, and 3) the investigative approach that will make such an assessment possible. We feel that these issues must be resolved or the NRC technical staff may have no more than a supporting role in future audits.

Finally, we would like to acknowledge the cooperation of the Los Alamos mineralogy/petrology personnel. They were much more than accommodating, and made us feel welcome as we interrupted their daily schedules. Their assistance and cooperation made our job easier and more pleasant than we had hoped.

We have copies of the draft findings, deficiencies, and observations which were drafted by the audit team. We also have a copy of the technical checklist used as a questioning guideline during the audit. If you have any questions, or would like to see any of this information, please feel free to contact either of us.

ORIGINAL SIGNED BY

Paul J. Bembia

ORIGINAL SIGNED BY

John Bradbury

JUL 07 1987

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