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MEMORANDUM FOR:

Robert E. Browning, Director
Division of Waste Management
Office of Nuclear Material Safety and Safeguards

FROM:

Brian K. Grimes, Director
Division of Quality Assurance, Vendor,
and Technical Training Center Programs
Office of Inspection and Enforcement

SUBJECT:

REVIEW OF BASALT QA REQUIREMENTS DOCUMENT (BQARD)

In response to a request from the Repository Projects Branch, the QA Branch reviewed the "Basalt Quality Assurance Requirements Document," (BQARD) Revision 0, dated January, 1986 against the "Criteria for QA Program (High Level Waste Repository Program)," (Appendix A of Enclosure 1 to the Browning to Bennett letter of June 29, 1984). This review resulted in the enclosed request for additional information (RAI).

We suggest the enclosed RAI be forwarded to DOE for response. We also suggest a working meeting between Basalt Waste Isolation (BWI) Division personnel and NRC so that we can develop a firm understanding of the functioning QA relationships and QA responsibilities for the BWI Project. We have found such meetings to be most beneficial when they are held after draft responses to RAIs have been prepared. We have several editorial comments which can also be discussed at the suggested working meeting.

The second page of the introduction to BQARD states: "The NQA-1 supplements (or parts thereof) are explicitly utilized wherever they provide additional clear and relevant guidance and do not contradict Appendix B/Review Plan." This appears to conflict with the QA management requirements expressed by OCRWM in its October 1985 document, "Quality Assurance Management Policies and Requirements." Section 5.2 of that document states: "... ANSI/ASME NQA-1 is the basic QA requirements standard for the (Civilian Radioactive Waste Management) Program...." Although the NRC has not endorsed NQA-1 for use on the Program, BWI Division should be asked to explain, as a point of information, why the NQA-1 supplements are not utilized in their entirety in BQARD.

Sheet 6 under Criterion 7 states that the guidance given in NRC Review Plan Section 7.5 is on hold by DOE-RL until receipt of NRC clarification. Section 7.5 reads as follows: "In developing quality assurance requirements for data

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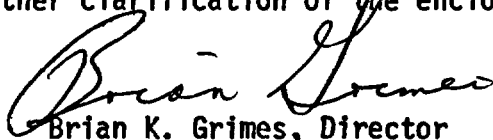
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Robert E. Browning

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collection test equipment and other equipment, consideration should be given to whether proper performance of a test can be determined during or after testing (i.e., whether failure or malfunction of test equipment can be detected). When no specific QA controls are found to be necessary, special quality/performance verification requirements shall be established and described in procedures governing the use of the equipment." We are unaware of any request for clarification of this, but this item should be on the agenda for the meeting proposed above.

Your staff or DOE representatives should contact J. Spraul before the suggested meeting if further clarification of the enclosed RAI is desired.



Brian K. Grimes, Director
Division of Quality Assurance, Vendor,
and Technical Training Center Programs
Office of Inspection and Enforcement

Enclosure: As stated

REQUEST FOR ADDITIONAL INFORMATION
BASALT QUALITY ASSURANCE REQUIREMENTS DOCUMENT (BQARD)
REVISION 0, January 1986

1. A statement used throughout BQARD is: "Therefore, the intent of this requirement will be met if implemented as stated." As a requirements document, BQARD should address meeting a requirement rather than meeting "the intent" of a requirement. Also, requirements document should use "shall" instead of "will" or "may". Further, the term "if implemented" should be clarified as was done on Sheet 3 under Criterion 3. Therefore the quoted statement should read: "Therefore, this requirement shall be implemented as stated," or words to that effect.
2. Sheet 10 under Criterion 2 addresses requirements for personnel performing quality-related activities. For these personnel (the "doers"), reference is made to NRC's Review Plan items 2.8a, c, and d. Item 2.8e, "Qualified personnel are certified in accordance with applicable codes and standards," should also be referenced as some of these personnel (welders, for example) require certification. The second sentence under item 1 should read: "Therefore, this requirement shall be met by implementing the requirements of 2.8a, c, d, and e as stated."
3. The note on Sheet 12 under Criterion 2 indicates that test inspectors (i.e., inspectors of testing activities) can be "... assigned to the testing organization and designated by the testing supervisor to be an in-process Inspector...." Clarify that "in-process Inspectors" do not have direct responsibility for performing the work being verified. The quality control function may be part of the line organization provided that the QA organization performs periodic surveillance to confirm sufficient independence from the individuals who performed the activity.
4. The note on Sheet 7 under Criterion 3 limits the use of the word "validating" to the context of computer codes. The definition of validation from NUREG-0856 should be expanded to: "Assurance that a model is a correct representation of the process or system for which it is intended." Note that the definition of verification in ANSI N45.2.11 expands the definition in NUREG-0856 in a similar fashion.
5. The first paragraph on Sheet 1 under Criterion 4 states that site characterization participants have the option of controlling procurement activities per the requirements of either Criterion 4 or Criterion 7. While there may be some duplication in these criteria, there are also differing requirements, and the requirements of both criteria should be met.
6. The last paragraph on Sheet 2 under Criterion 4 states that construction participants have the option of using either the Site Characterization Criterion 4 or NQA-1 Basic Requirement 4 and Supplement 4S-1. Here again there are differing requirements, all of which should be met. The

proviso at the end of this paragraph does not appear to address this. A comparable comment applies to Criteria 5 through 18.

7. Supplements 4S-1 and 7S-1 of NQA-1 do not address the involvement of the QA organization in the various activities. The NRC Review Plan Sections 4.2 and 7.2 do. BQARD should require that these sections of the review plan be met. (See Sheet 3 under Criterion 4 and Sheet 3 under Criterion 7.)
8. The second paragraph on Sheet 1 under Criterion 9 implies that tests conducted per Criterion 11 do not require qualified procedures, qualified equipment, qualified personnel, and monitoring of process variables. This implication should be eliminated.
9. The first sentence under BWIP Project Implementation on Sheet 2 under Criterion 9 indicates that the NRC has "reworded" Criterion 9. The NRC has not reworded Criterion 9, and this sentence should be deleted or revised. A similar problem exists on Sheet 10 under Criterion 10, Sheets 7 and 9 under Criterion 11, Sheet 2 under Criterion 12, Sheet 2 of Criterion 14, Sheet 4 of Criterion 16, and on Sheets 5 and 6 under Criterion 18.
10. The discussion of inspection on Sheets 1 and 2 under Criterion 10 needs clarification. The first sentence indicates inspection is an "independent verification," but the third paragraph indicates that in-process inspections may be performed by the supervisor of the activity. We agree that the doer's supervisor is directly responsible for the work, and we believe that supervisors can and should make (or have made) in-process checks (i.e., nonindependent verification) and final checks before having work inspected. We do not agree that a doer's supervisor has the independence required to perform inspections, and the discussion should be revised to reflect this. Note that some work may require inspection during processing, some may require checking, and some may require neither.

The first sentence on Sheet 2 under Criterion 10 states: "Final (General) Inspection provides independent confirmation of the adequacy of the supervisor's conclusion," indicating a personal inspector vs. line supervisor relationship which is not desirable. The inspector's responsibility is neither to confirm nor deny "the adequacy of the supervisor's conclusion," and the sentence should be deleted or revised. Finally, clarify the significance of the parenthetical words in the third and fourth paragraphs under Criterion 10.

11. Sheet 6 under Criterion 10 indicates that Section 8 of 10S-1 of NQA-1 will be implemented to ensure that inspection results are documented and evaluated and that their acceptability is determined by a responsible individual. Beyond documentation, Section 8 does not appear to address this guidance. Clarify.
12. Explain the last sentence on Sheet 10 under Criterion 10 which states: "For the BWIP project, refer to the PMP/SEMP for identification of the BWIP designated inspectors."

13. Item C on Sheet 4 under Criterion 11 addresses the fact that QA should, as a minimum, audit the test program. Item C should specify that this will be done.
14. Under Criterion 11, BQARD should address whether testing will test the item under conditions which will be present during normal and anticipated off-normal operation when practicable.
15. The last paragraph on Sheet 8 under Criterion 11 states, "The requirement for test records will be met by implementing the requirements of the NRC Review Plan Section 17.3, in lieu of the requirements of NQA-1-1983, Supplement 11S-1, paragraph 5." Test records should meet both Section 17.3 of the NRC Review Plan and paragraph 5 of supplement 11S-1 of NQA-1, and the paragraph should be so clarified.
16. Under criterion 18, clarify that both technical and QA programmatic audits are performed and that audit team membership includes personnel (not necessarily from the QA organization) having technical expertise in the areas being audited.