

QA ACCEPTANCE PROGRAMS

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OCT 24 1990

Mr. Dwight Shelor, Acting Associate Director
for Systems Integration and Regulations
Office of Civilian Radioactive Waste Management
U.S. Department of Energy, RW 30
Washington, D.C. 20585

Dear Mr. Shelor:

SUBJECT: ACCEPTANCE OF PARTICIPANT QUALITY ASSURANCE (QA) PROGRAMS FOR THE
HIGH-LEVEL WASTE GEOLOGIC REPOSITORY

This letter responds to the Stein to Browning letter dated September 12, 1990, requesting the U.S. Nuclear Regulatory Commission (NRC) to accept six of the U.S. Department of Energy, Office of Civilian Radioactive Waste Management (DOE/OCRWM) participant quality assurance (QA) programs for the Yucca Mountain Project (YMP). NRC acceptance has been requested for the following DOE/OCRWM participant QA programs accepted by DOE:

- (1) Lawrence Livermore National Laboratory (LLNL)
- (2) Sandia National Laboratories (SNL)
- (3) Fenix and Scisson of Nevada (FSN)
- (4) Holmes and Narver (H&N)
- (5) Reynolds Electrical and Engineering Co. (REECO)
- (6) U.S. Geological Survey (USGS)

One of the concerns (Objection 2) resulting from the NRC review of DOE's Site Characterization Plan for the YMP, pertained to having a QA program which meets the NRC requirements of Subpart G of 10 CFR Part 60 in place prior to the start of the new site characterization activities. Consistent with previous NRC/DOE agreements, the NRC staff recommended that DOE complete its development and acceptance of DOE and the participant QA programs and then obtain NRC acceptance prior to the start of new site characterization activities. NRC also noted that this objection could be lifted incrementally for individual QA programs and program areas as DOE demonstrated and NRC agreed on their acceptability.

DOE submitted QA Program Plans (QAPPs) for the above program participants for NRC staff review and acceptance in early 1989. DOE concluded that these QAPPs were in compliance with the DOE/YMP 88-9 QA Plan, and consequently, in compliance with the NRC requirements of Subpart G of 10 CFR Part 60 and Appendix B of 10 CFR Part 50. The NRC staff performed its own independent review and concluded in six NRC Safety Evaluations (SEs) issued in October 1989, that these QAPPs addressed the applicable criteria of Subpart G of 10 CFR Part 60 and Appendix B of 10 CFR Part 50. The SEs stated that the participant QAPPs could serve as an adequate framework for developing specific policies, plans, and procedures to implement the QA Program for the YMP.

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QA ACCEPTANCE PROGRAMS

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Before the DOE/OCRWM program participant QA programs could be determined to be acceptable for start of new site characterization activities, it was necessary for DOE to verify and NRC to concur that the participant QAPPs were being effectively implemented. After an initial round of audits on participant program implementation, NRC and DOE agreed at the April 27, 1990, QA Meeting on the criteria to demonstrate that the QAPPs were being effectively implemented. The criteria included the following:

- (1) Review and resolve open QA program deficiencies identified by the DOE auditors that could have a quality or technical impact on output products;
- (2) Identify the extent of the program implementation since the last DOE audit, including the areas of activity audited or surveilled and the end products produced;
- (3) Determine whether the program can be effectively implemented;
- (4) Identify what areas of the program are on hold; and
- (5) State the DOE position of whether the program is adequate for further implementation to conduct new site characterization activities.

The NRC staff has reviewed the information in DOE's September 12, 1990, letter and finds that DOE has provided sufficient information to address the five criteria. The enclosures to the letter for each participant QA program indicate that DOE has reviewed the open QA program deficiencies, and, based on follow-up audits and/or surveillances, determined that, with the exception of open QA issues on procurement, software QA, and access to personnel qualifications for some participants, there were no items that could have a technical or quality impact on output products. The DOE review verified that: a) significant deficiencies previously identified by DOE audits and surveillances have been resolved; b) there are no areas of the QA programs presently affected by a stop work order; and c) open QA issues for procurement, software QA, and access to personnel qualifications are in the process of being resolved. DOE has determined that the QA programs for SNL and LLNL are being effectively implemented and are in compliance with the DOE/YMP 88-9 QA Plan and the applicable NRC QA requirements, and they are acceptable to initiate new site characterization activities. The QA programs for FSN, H&N, REECo, and USGS were also found by DOE to be effectively implemented and to be acceptable to initiate new site characterization activities, pending resolution of the open QA issues for procurement, software QA, and personnel qualifications.

Based on the NRC staff observations of DOE audits and surveillances of the participant QA programs and review of the information provided in DOE's September 12, 1990 letter, the NRC staff agrees with the DOE conclusion that the participant QA programs for SNL and LLNL are acceptable for implementation of new site characterization activities for the YMP. NRC acceptance of the participant QA programs for FSN, H&N, REECo, and USGS is conditional upon satisfactory resolution of the exceptions noted in DOE's September 12, 1990, letter. The open QA issues pertaining to procurement procedures, software QA, and personnel qualifications for the FSN, H&N, REECo, and USGS QA programs should be resolved in the near future. DOE should notify the NRC staff of the

resolution of these exceptions, and receive NRC acceptance of the appropriate resolution prior to the start of any new site characterization work that might be adversely affected by these exceptions.

The NRC staff will continue to monitor the participant QA programs by participating on a selective basis as observers in the DOE/OCRWM surveillance and audit process, or by performing its own independent audits to verify the adequacy and effectiveness of implementation of the DOE/OCRWM and participant QA programs.

Should you have any questions concerning our review, please contact Mr. Kenneth Hooks on (301)/FTS-492-0447.

Sincerely,

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John J. Linehan, Director
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste Management
Office of Nuclear Material Safety
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