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William J. Purcell, Associate Director
Office of Geologic Repositories
Department of Energy
1000 Independence Avenue, S.W.
Washington, DC 20585

Dear Mr. Purcell:

The purpose of this letter is to provide the NRC staff's comments on the DOE Office of Geologic Repositories (OGR) Quality Assurance Plan for Siting and Site Characterization of High Level Radioactive Waste Repositories dated September, 1984.

The plan completed by OGR is the primary quality assurance planning document for quality assurance activities conducted by OGR for siting and site characterization of high-level radioactive waste repositories. For each of the three sites selected for site characterization, the Field Project Office must also prepare planning documents that describe the quality assurance activities and assigned responsibilities for each respective site. The NRC staff will review and comment on each of the Field Project Office planning documents when OGR provides the NRC with copies approved by OGR as meeting the requirements outlined in 10 CFR 60. In addition the NRC staff will review and comment on the quality assurance plans prepared by principal contractors after DOE approval of the plans.

The NRC staff's review of quality assurance planning documents is only a part of the overall NRC review to assure that DOE quality assurance programs in place at the start of any work which will potentially support the construction authorization application meet the requirements of 10 CFR 60. The NRC staff is also developing technical positions on specific issues, attending DOE audits as observers, and meeting with the DOE staff to discuss and resolve issues pertinent to the overall quality assurance program. The NRC's objective is to have no unresolved comments concerning the QA programs when site characterization work begins.

General Conclusions

The plan is written to be applicable to OGR only, not to OCRWM or to the Field Project Offices although it does contain directives to the Field Project Offices. The Field Project Offices are to develop their own QA plans which will be submitted to OGR for approval.

QA plans for items and activities important to safety or waste isolation which are not the direct responsibility of OGR are not addressed in the plan. For

example, the waste form, which could impact the performance of the repository systems, can be prepared within the DOE defense program and the West Valley Demonstration Project, not OGR. The QA plans for items and activities such as these and the interfaces between these various programs should either be described or referenced in the OGR QA Plan.

In Appendix A of the quality assurance plan, OGR depicts in a table the applicability of each of the 18 criteria of 10 CFR 50, Appendix B (referenced in 10 CFR 60, Subpart G) to OGR, and to the Field Project Offices. OGR is shown as being responsible for:

Criterion	I.	Organization
	II.	Quality Assurance Program
	III.	Design Control (and Peer Review)
	V.	Instructions, Procedures and Drawings
	VI.	Document Control
	XVI.	Corrective Action
	XVII.	Quality Assurance Records
	XVIII.	Audits

The remaining criteria are shown as not applicable to OGR activities. This may be acceptable. If any activities related to the deleted criteria are to be performed by the OGR, however, the criteria should be addressed in the plan. For example, if OGR procures consulting or other services which are important to safety or to design and characterization of barriers important to waste isolation and to activities related thereto, as defined in 10 CFR 60 Subpart G, the OGR QA Plan must address Criterion IV "Procurement Document Control" and Criterion VII "Control of Purchased ... Services."

Under the QA Plan's Section V "Quality Assurance Program Requirements," program requirements are presented in two parts. Part A describes the OGR internal activities and Part B describes the OGR overview of Field Project Office QA activities. The staff was unable to evaluate the adequacy of the OGR internal activities from the information presented in the plan. The plan states: "Activities affecting quality will be performed by the responsible OGR personnel in accordance with written Quality Implementing Procedures (QIPs)," which have not been provided to the staff.

The OGR QA plan must describe the internal activities in sufficient detail that the staff can determine how the applicable requirements of 10 CFR 60 are satisfied. Internal activities related to Criteria II, Quality Assurance Program; III, Design Control (& Peer Review); V, Instructions, Procedures & Drawings; VI, Document Control; XVI, Corrective Action; XVII, Quality Assurance Records; and XVIII, Audits must be described.

OFC	:WMRP:kb	:WMRP	:WMRP	:IE	:IE	:DWM	:DWM
NAME	:DHedges*	:JKennedy*	:HJMiller*	:WAltman*	:TAnkrum*	:MJBell*	:REBrowning*
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The plan states that the Director, Office of Civilian Radioactive Waste Management (OCRWM), has ultimate responsibility for establishing and maintaining an effective OCRWM program-wide quality assurance program. The Associate Director, OGR, has been delegated "...ultimate responsibility for establishing and implementing an effective Quality Assurance Program for the OGR subprogram at its four Headquarters Divisions, for providing QA policy guidance and direction to the field project offices, and for verification that field project offices have established and are implementing effective Quality Assurance Programs." The Associate Director, OGR delegated the quality assurance responsibilities to the Director, Engineering and Licensing Division. The Director further assigned the quality assurance responsibilities to the Licensing and QA team Leader who has on his staff a full-time dedicated position to assist in discharging the QA responsibilities. The staff believes that the DOE has relegated the quality assurance organization to a position too far down in the organization and the result will not be a strong management-oriented quality assurance program which is paramount for the success of this project. It is for that reason that the NRC staff included in its QA Review Plan the following criterion for acceptability of the organization elements responsible for QA program:

> DOE and its prime contractor [should] identify a management position within each respective organization that retains overall authority and responsibility for the QA program. This position, occupied by an individual with appropriate management and QA knowledge and experience has the following characteristics:
>
> a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.
>
> b. Has effective communication channels with other senior management positions.
>
> c. Has responsibility for approval of QA Manual(s), changes thereto, and interpretations thereof.
>
> d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters.

Enclosure 1 lists additional information needed by the staff to evaluate the OGR quality assurance program. The staff may have additional comments on the revised plan and new material submitted for review. I am certain you will

OFC	:WMRP:kb	:WMRP	:WMRP	:IE	:IE	:DWM	:DWM
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agree that it is important for the success of the site characterization program that a well-planned QA program be in place before work starts; therefore completion of this plan and resolution of the identified issues must be expedited. The NRC staff is available to meet with and assist you in meeting this objective. If you have questions or desire to arrange a meeting, please call me on 427-4177 or Dale Hedges of my staff on 427-4491.

Sincerely,

"ORIGINAL SIGNED BY"

Hubert J. Miller, Chief
Repository Projects Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Request for Additional Information

cc: M. Langston, DOE
C. Head, DOE
C. Newton, DOE
R. Stein, DOE

Record Note:

The primary basis for this letter was a memorandum from B. Grimes of IE to R. Browning dated August 28, 1985. Two points raised by IE have not been included in the letter: DOE's use of a matrix organization with project offices reporting both the field offices and OCRWM, and DOE's use of the term "siting" in the title of the plan, as opposed to "site characterization." For the first point, DWM staff will request additional information from IE on the applicability of reactor matrix organizations and their attendant problems to the repository program before formally presenting this comment to DOE. For the second point, the Commission is now involved in determining the NRC's role in "siting" decisions in connection with the interpretation of when a "preliminary determination" should be made. This comment is therefore being withheld until the Commission has given the staff additional guidance.

Theis letter was coordinated with Chip Cameron of ELD.
*See previous concurrence page.

OFC	:WMRP:kb	:WMRP	:WMRP	:IE	:IE	:DWM	:DWM
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Request for Additional Information
OGR QA Plan dated September 1984

1. Part IV.B3 of the plan (page 10, last ball) states that the Licensing QA Team Leader (L&QATL) is responsible for auditing HQ-OGR and field project offices. Specify the frequency of these audits. (1.4)*

2. Describe the management, QA, and technical experience and knowledge requirements for the person(s) assigned to the quality assurance function. (1.10).

3. Describe the scope of the OGR QA program. If items and activities important to safety or waste isolation as defined in 10 CFR 60.2 will be identified in the field project offices QA plans, so state. (2.1)

4. Clarify that OGR will not develop, control, or use computer programs that are important to safety or waste isolation as defined in 10 CFR 60.2 or provide a commitment that such activities will be conducted in accordance with NUREG-0856 and the QA program. (2.2)

5. Part IV.B3 of the plan (page 10, first ball) indicates the L&QATL coordinates the development of OGR procedures which implement the plan. Clarify that the L&QATL reviews and documents concurrence with these procedures relative to QA requirements. (2.4, 5.1, 6.2, and 16.1)

6. Describe how management (above or outside the L&QAT) regularly assesses the scope, status, adequacy, and compliance of the OGR QA program to subpart G of 10 CFR 60. (2.7)

7. It appears that design control has been delegated to the field project offices. However, part V.B.6d of the plan (pages 14-15) calls for HQ technical reviews of design. Appendix A of the plan (pages 19 and 20) commits OGR to design control per the basic and supplemental requirements of NQA-1, and Appendix B of the plan (page 21) indicates OGR has three Quality Implementing Procedures in the area of design control. Clarify OGR responsibilities for design control and describe how OGR will meet these responsibilities. Address each of the applicable design control criteria in Appendix A of the NRC's QA Review Plan. (3)

*The numbers in parentheses after each RAI refer to the criterion in the QA Review Plan.

8. Describe the OGR program for controlling internal documents as well as documents being transmitted to and from field offices and other project participants to assure controlled transmittal, receipt, internal distribution, filing, and recall. Address each of the applicable document control criteria in Appendix A of the QA Review Plan. (6)

9. Part IV.B.3 (page 10, last ball) of the plan indicates that the L&QATL is responsible for performing QA audits of HQ-OGR, but Part VI.A (page 16) does not show these audits as a source of identification of QA-related problems and issues. Clarify. (18.6)

10. Part VI.B.4 of the plan (page 16) indicates that procedures provide for dispositioning quality and QA-related problems and issues. Describe measures which assure that procedures identify personnel (by position title) authorized to make such dispositions and that the dispositions include signature approval by these authorized personnel. Clarify that the L&QATL documents concurrence that QA requirements are satisfied. (15.1, 15.3, and 16.2)

11. Describe the OGR records management system. Address each of the applicable QA records criteria in Appendix A of the QA Review Plan. (17)

12. Part IV.B.3 of the plan (page 10, last ball) indicates that the L&QATL is responsible for performing QA audits of HQ-OGR and field project offices and for participating in field project offices QA audits of their contractors. In this regard, address audit criteria 18.2, 18.3, 18.4, 18.5, and 18.7 in Appendix A of the QA Review Plan. (noted)

13. Clarify the meaning of GRD on page 8 of the plan, QACG on page 16, and RD&D on page 6.

14. The ANSI/ASME NQA-1a-1983 addenda to ANSI/ASME NQA-1-1983 edition were issued December 31, 1983. Provide the OGR position with respect to following the ANSI/ASME NQA-1a-1983 addenda.

15. A number of the 18 QA criteria of 10 CFR 50, Appendix B, are shown in Appendix A of the OGR QA plan as being not applicable because activities are not performed by OGR. This is acceptable. However, if any such activities are performed by OGR, the criteria should be addressed. For example, if OGR procures consulting or other services which are important to safety or waste isolation as defined in 10 CFR 60.2, the OGR QA plan should address both Criteria IV, "Procurement Document Control," and VII, "Control of Purchased...Services."

"Inspection" and "Test Control" are two of the criteria shown as being not applicable to OGR. As noted above, this is acceptable. However, this leaves OGR audits as the principal means for OGR to independently verify conformance to established requirements. Since audits are "after the fact" checks, discuss the degree to which contemporaneous technical surveillance of activities selected on the basis of their importance to safety or waste isolation will be used to identify quality and QA-related problems on a timely basis. Also discuss the degree to which the QA audits will be based on technical evaluation of work products as opposed to programmatic checks.

16. The plan makes no reference to the "NRC QA Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories." Identify and justify differences between the guidance in the NRC QA Review Plan and the DOE positions in the revised Headquarters QA Plan. In cases where NQA-1 provides more detailed guidance than the QA Review Plan but does not contradict the Plan, no justification need be provided.

17. In the meeting minutes from the SRPO QA meeting in December, 1984, the NRC staff had the following comment:

    A geologic repository is a disposal system that consists of both engineered (i.e., waste form and packaging) and natural barriers. The DOE license application must ensure that data of adequate quality are obtained for the waste form and packages as well as for the site and underground facility. An issue for follow-up with DOE-HQ is how DOE plans to assure that an appropriate level of quality is applied to the total geologic repository system (i.e., inclusion of West Valley and DWPF wastes, and data from WIPP which may be utilized in licensing a commercial repository).

    Discuss the relationship between OCRWM and these other programs which may support OCRWM/OGR in licensing. Where necessary, revise the OGR QA Plan to incorporate these programs.