



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

ATTACHMENT J

JAN 28 1987

Mr. James Knight, Director
Siting, Licensing and Quality Assurance Division
Office of Civilian Radioactive Waste Management
U.S. Department of Energy RW-20
Washington, DC 20545

Dear Mr. Knight:

The purpose of this letter is to provide the NRC staff's comments on the DOE Office of Geologic Repositories' "Quality Assurance Plan for High-Level Radioactive Waste Repositories," OGR-B-3, Revision 1, dated July 1986. This Plan was provided to us in your July 17, 1986 letter to the NRC. The staff provided comments on an earlier version of the plan in a letter to William Furcell of DOE dated October 11, 1985. The plan was subsequently revised by DOE and issued in its present form. Attachment 1 contains our comments on this revision of the plan.

The OGR plan furnished with the July 17, 1986 letter consisted on two major sections--the plan itself and an appendix containing Supplements giving guidance on selected topics, such as the Q-List, to Headquarters, the project offices and DOE contractors. For this review, the staff has provided comments on the plan and all of the supplements except number 4, "Quality Assurance Records." Comments for this supplement are still being developed and will be provided in the near future.

In August 1986, DOE issued the above QA Plan in DOE/RW-0095. In addition to containing the sections described above, this revision of the plan contained an Appendix A of detailed procedures (Quality Implementing Procedures or QIP's) for internal OGR use along with the supplements described above in a new Appendix B. These implementing procedures and similar ones for the project offices and DOE contractors will be reviewed during NRC audits. Those which are novel or unique such as peer review or qualification of existing data will be reviewed prior to the audits and comments formally provided to the DOE for resolution.

It is our understanding that the August 1986 version of the plan is nearly identical to the July 1986 version reviewed by the staff and that the few differences are minor. We request that you formally indicate the differences so that the August 1986 revision can become the standard for our discussions with your staff.

Our current review resulted in the enclosed request for additional information. We suggest a working meeting between our staff and OGR personnel so that we can develop a firm understanding of the functioning QA relationships and QA

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responsibilities of OGR and discuss how our earlier comments on the plan were resolved by DOE. Of particular interest to us is the independence of the QA function within OGR and the basis for why DOE believes this is an adequate arrangement. We would also discuss in such a meeting the other comments provided in the attached enclosure.

Your letter of July 17, 1986 not only provided the OGR QA Plan, but also furnished the following for NRC staff review:

- °Basalt Waste Isolation Division (BWID) QA Plan
- °Salt Repository Project Office (SRPO) QA Plan
- °Basalt Quality Assurance Requirements Document (BQARD))
- °Waste Management Project Office Requirements Documents (NVO-196-17)

The staff has provided formal comments on NVO-196-17 in letters dated August 25 and November 21, 1986. The staff expects to complete its review and provide formal comments on the remaining documents listed above within the next month or so.

As we noted in our letter to you on the NNWSI QA Plan dated November 21, 1986, it is critical that the limits of the review of QA program plans be recognized. The extent that the program is actually used throughout the high-level radioactive waste program as a management tool as proposed to being put in place merely to satisfy an NRC requirement cannot be measured through a QA program plan review. In the several cases where serious construction quality problems occurred at nuclear power plants, QA program plans had been reviewed and found acceptable by the NRC as meeting the requirements of Appendix B of 10CFR Part 50. However, these programs were not properly implemented. The QA program plan review provides only a portion of what is necessary to develop confidence that work will be done adequately--that is, to assure that adequate information on the quality of work implementation is being developed for management and being met in a demonstrable fashion. A most important indicator of the successful implementation of these plans will be the detailed, results-oriented technical reviews that will be performed by the NRC staff as work progresses.

Questions on the enclosed comments or arrangements for a meeting between our staffs should be referred to James Kennedy of my staff on 427-4786.

Sincerely,



John J. Linehan, Acting Chief
Repository Projects Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Staff's Comments on the DOE OGR
"Quality Assurance Plan for High-Level
Radioactive Waste Repositories"

cc: C. Newton, DOE HQ
D. Vieth, NNWSI
L. Olson, BWIP
J. Neff, SRPO

Attachment 1

Request for Additional Information
OGR QA Plan for High-Level Radioactive Waste Repositories

A. General

1. The OGR QA Plan was written prior to NRC's June 1986 draft generic technical positions (GTPs):
 - a. Qualification of existing data (Federal Register Vol. 51, No. 128, pg. 24455, July 3, 1986).
 - b. Peer review (Same reference as item a).
 - c. Items and activities subject to 10 CFR 60 QA requirements (Federal Register Vol. 51, No 147, pg. 27477, July 31, 1986 and No. 153, pg. 28643, August 8, 1986).

The plan (including its supplements) should be revised as necessary to reflect these GTPs. Differences between the revised plan and the GTPs should be noted and justified.

2. Include a list of abbreviations used in the plan.

B. OGR/B-3, Revision 1, July 1986: QA Plan

1. The September 1984 version of the OGR QA Plan stated that the Associate Director, OGR, has ultimate responsibility for establishing and implementing an effective QA program for the OGR subprogram and for verifying that field project offices have established and are implementing effective QA programs. The July 1986 version does not clearly assign these responsibilities. Indicate (by position title) who now has these responsibilities. (1.1)*
2. Section 4.3.2.f of the OGR QA Plan addresses participation of OGR QA in project office audits of "major contractors." Clarify any differences between "major contractors" used in 4.3.2.f and "contractors" as defined in section 1.4.1 of the plan. Specify the frequency of OGR audits. (1.4)
3. Section 3.3 of the OGR QA Plan indicates that the manager of each operations office has line management responsibility and accountability for overall project implementation. Clarify the reporting relationship of the manager of the operation offices and the OGR. (1.7)

*The number in parentheses after an RAI refers to the specific guidance in the NRC Review Plan.

4. Clarify whether the OGR QA Manager is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality and is sufficiently independent from cost and schedule. (1.10a)
5. Section 3.2 of the OGR QA plan indicates that each OGR Division and Branch will be responsible for quality achievement and assurance of quality within their areas of responsibility. Clarify that the assurance of quality (or verification of conformance to established requirements) is accomplished by individuals or groups who do not have direct responsibility for performing the work being verified.
6. The last item in Section 3.4 of the OGR QA plan indicates that OGR QA can stop, or cause to be stopped, unsatisfactory work, through established channels. The QA organization need not have authority to stop work if the individual to whom the person responsible for managing the QA program reports has this authority. Describe how stop-work requests are initiated and completed. (1.12)
7. Describe provisions for the resolution of disputes involving quality arising from a difference of opinion between OGR QA personnel and other OGR personnel. (1.13)
8. Section 5 of Supplement 8 addresses rationale for assigning Quality Levels. Clarify whether these rationale include system analyses and definition of numerical performance objectives and standards. Justify why not if not. Identify items and activities covered by the QA program. The staff information needs defined in the "Q-list" GTP (See A.1.C. for complete title) should be used as guidance. If items and activities important to safety or waste isolation as defined in 10 CFR 60.2 will be identified in the project offices QA plans, so state. (2.1)

C. Supplement 1, Revision 0, June 10, 1986: Personnel

1. Section 1.0 of this supplement indicates the supplement applies to personnel performing or verifying activities that affect quality. Sections 2.0, 5.1, 5.2, 5.4, 5.5, and 5.6 address personnel who perform activities affecting quality, omitting personnel who verify activities affecting quality. Conversely, the examples given in Section 3.0 are all verifiers. Clarify that the entire supplement applies to both doers and verifiers.
2. Section 1.0 of this supplement should be revised to be consistent with the other supplements to the OGR QA Plan.

D. Supplement 2, Revision 0, June 10, 1986: QA Overviews

1. Section 4.1 of Supplement 2 states that overview encompasses effectiveness assessments, technical reviews, readiness reviews, audits, and surveillances. Section 5 of the supplement should be expanded to address each of these component parts of overviews.

2. Section 5.2 of this supplement should require that overview procedures include the criteria for determining the acceptability of the QA program documentation. Timeliness of document review should also be addressed.
3. Section 5.3 of Supplement 2 requires surveillance. The qualification requirements of surveillance personnel should be specified.
4. Section 5.4 of Supplement 2 addresses external audits as part of the overview process. Clarify that both technical and QA programmatic audits are performed to:
 - a. Provide a comprehensive independent verification and evaluation of procedures and activities affecting quality.
 - b. Verify and evaluate suppliers' QA programs, procedures, and activities.

Audit teams should be led by an appropriately qualified and certified lead auditor from the QA organization.

E. Supplement 3, Revision 0, June 10, 1986: Q-List

1. Prior Supplement 3's addressed the control of measuring and test equipment. Identify where within the OGR QA Plan these controls are now specified.
2. Section 5.0 of this supplement requires a procedure for determining what is placed on each project's Q-List. Clarify that each project's Q-List will be reviewed by HQ-OGR and submitted to the NRC.
3. The first paragraph of the summary of Attachment A of this supplement refers to items and activities "important to safety and waste isolation." Change the "and" to "and/or" or justify not doing so. This same paragraph quotes from a preliminary draft NRC document. The quotation and paragraph should reflect the draft GTP and should be revised per Comment A.1, above, item c. For example, this section indicates that only Q-List items and activities will be subject to NRC licensing review and oversight. In addition to the Q-Listed items and activities important to safety and/or waste isolation, other items and activities will be associated with demonstrating that DOE meets all of the 10 CFR Part 60 licensing requirements. For example, 10 CFR Part 20 requirements, which are referenced in 10 CFR Part 60, will need to be addressed in the license application. Although these additional items and activities are not covered by the 10 CFR 60 Subpart G QA requirements (which apply only to items and activities important to safety and/or important to waste isolation), assurance measures are needed to provide confidence that the requirements have been met. Certain assurance measures, such as use of written procedures, documentation of completed work, and monitoring of radiation levels, are currently prescribed in the regulations and, although not explicitly stated as quality assurance requirements, provide a basis for demonstrating

compliance with the licensing requirements. Therefore, these assurance measures are also subject to NRC licensing review and oversight. Modify this section to clarify this point or justify not doing so.

4. The supplement on the Q-list states that DOE will utilize an annual probability value of 1×10^{-5} as a limit for accident scenarios for identification of the Q-list. As noted in the staff's letter to J. Knight, DOE, dated March 7, 1986, it is the staff's position that credible initiating events and accidents should not be bounded by a specific probability value at this stage of the repository program until DOE and NRC have agreed on the rationale for such a limit.

F. Supplement 5, Revision 0, June 10, 1986: Experiments and Research

1. Clarify the last sentence in Section 3.0 of this supplement which states: "Data... shall be conducted... ." Also, from the same sentence, identify the "other applicable requirements identified in the OGR QA Plan," and/or clarify what these words mean.
2. The signature of the experimenter and the signature of a competent technical reviewer do not appear to be adequate for Quality Level 1 or 2 data. Clarify.

G. Supplement 6, Revision 0, June 10, 1986: Problem Reporting

1. Prior Supplement 6's addressed the control of computer software. Identify where within the OGR QA Plan these controls are now specified.
2. The title of this supplement, "Quality Problem Reporting;" Sections 2.0 and 5.3; and the QAA format shown in Attachment A of the supplement are all limited to quality problems and quality problem reporting. Sections 3.0, 4.2, 5.1, 5.2, and 6.1 indicate that quality improvement is also included in Supplement 6. Clarify the supplement to eliminate this inconsistency.
3. This supplement needs to be edited to take care of questions like the following:
 - a. Are the requirements of the supplement to be used in conjunction with the requirements specified (or embodied) or referenced in the governing QA plans and procedures?
 - b. Should "information" in the first sentence be "improvements?"
 - c. Should the text always refer to "significant quality problems" and "substantial quality program improvement?" (Underlines added)
 - d. Should "consequently" in 5.1 be "subsequently" or, rather, should it be deleted?

- e. Section 5.2 refers to the "applicable immediate supervisor" and Section 5.3 refers to the "immediate supervisor." Do these supervisors have any responsibilities that should be listed in Section 5.0?
- f. When there is no need to expedite, does the telephone requirement of Section 5.2 still apply?
- g. On the QAA form, does the "RECIPIENT ACTION" require feedback?
- h. Are no signatures required on the form?

H. Supplement 7, Revision 0, June 10, 1986: Peer Review

- 1. This supplement, being issued prior to issue of the GTP on peer review, should be revised to reflect the GTP. (See Comment A.1 above, item b.) For example, the definition of peer review in Section 4.1 of Supplement 7 references the NRC QA Review Plan, Appendix A, Section 3.8. It would be preferable to reference NRC's draft GTP on peer review. As noted in the definition of peer review in the draft GTP, the definitions in Section 4 of this supplement should point out that peer reviews confirm (validate) the adequacy of work whereas technical reviews verify conformance to predetermined requirements. The emphasis (underlining) on data that "go beyond the existing state of the art" should be removed as the definition is revised to reflect the draft GTP. Section IV.1 of the draft GTP addresses the applicability of peer reviews.
- 2. The records required by Section 5.4 of the supplement should include objective evidence of the independence of the reviewers. Section IV.3.b of the draft GTP discusses reviewer independence.

I. Supplement 8, Revision 0, June 10, 1986: Graded QA

- 1. Section 5.1.1 of Supplement 8 indicates that, once a quality level is selected, further grading shall be accomplished by technical and quality system personnel working as teams. Clarify who (by position title) is responsible for selecting quality levels. As noted, Section 5.1.1 refers to "quality system" personnel. Clarify that these are "quality assurance system" personnel as they are referred to in Section 5.1.2.
- 2. The list of OGR QA Plan Supplements on page 2 of Attachment A needs to be updated to reflect the latest supplement titles.

J. Supplement 9, Revision 0, June 10, 1986: Data Reliability

- 1. This supplement, being issued prior to the GTPs on peer review and qualification of existing data, should be revised to reflect these GTPs. (See Comment A.1 above, items a and b.)

2. Section 3.0 of Supplement 9 addresses the scope of the supplement. Its scope should be extended to data collected prior to NRC acceptance of the QA program description under which the data were collected and NRC verification of acceptable implementation of the program.
3. Section 5.2.1 of the supplement should include the qualifications of the original investigator as part of the documentation made available to the reviewers.
4. The list of documentation in Section 5.2.1 of this supplement should include the list in Section 5.3.1.
5. The written reports required by Section 5.2.2 and 5.3.2 of the supplement should include the qualifications of the reviewers and objective evidence of their independence.
6. Although most definitions of QA indicate that QC is a subset of QA, Section 5.2.2(d) would be more clear if it requires a description of the "quality control/quality assurance methods" rather than a description of just the "QA methods." Instead of a description of such methods that "may have been used," 5.2.2(d) should require a description of such methods that "were used." Objective evidence of the use of such quality control/quality assurance methods should be available.
7. A better description should be provided of the qualification requirements of the reviewers in Section 5.4 of the supplement. The supplement should indicate any allowable and/or any prohibited reporting relationships of these individuals. Further guidance in the area of peer qualification and independence is given in Section 3 of the GTP on peer review. (See Comment A.1 above, item b.)

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The limited oversight role of the NRC for defense wastes described in this supplement is a concern expressed previously by the staff (see the December 11, 1986 minutes from meeting with DOE on the Defense Waste Processing Facility, DWPF). Further DOE/NRC discussions are necessary to develop an acceptable approach for NRC oversight.

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Place SAIC LAS VEGAS, N.V.

Date 1-29-87

ATTENDANCE LIST

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JERRY REESE	CHIEF, QA	DOE / SRPO	FTS 976-5916
SANDRA K. CROWE	YAKIMA INDIAN NATION	— TROPENISH, WIA	509-815-5131 EX 394
DON PROUST	Performance assessment Mgr	State of Washington	206-459-6711
SUSAN ZIMMERMAN	Geologist	State of Texas	512-463-2100
Abdul J. Alkezweeny	Nez Percé and Umatilla Tribes On-site Representative	CERT	(509) 943-5301
John Wolf Data coord.	Confederated Tribes of the Umatilla Indian Reservation	Pendleton, OR	503-525-1111
Floyd K. Ryznaruk	Tech Coordinator	NEZ PERCE TRIBE	(208) 843-2253
Larry Collins	Confederated Tribes of the Umatilla Indian Reservation	Pendleton, OR	503-525-1111
J.P. KNIGHT	Dir. Site Lic of SA Div	DOE/HQ	202-525-1111
CARL NEWTON	QA Manager	DOE / HQ	FTS 986-5059 Comm 202-586-50
TOM COLANOREA	EEO/UNWMB QA CONSULTANT	UNWMB	(619) 487-7510
Bud Kehew	QA MANAGER	DOE/RTD	FTS 972-2315
John Prestholt	On-site Rep. KRIEGL	NRC	173 698 6111

Place _____

Date _____

ATTENDANCE LIST

NAME (Please Print)	Position Title	Organization Represented	Telephone (For Contact)
Jim Kennedy	Section Leader	NR e	301-427-4786 (FTS)
Doug Smith	Branch Mgr., QA	SAIC	575-1721
JOHN B. SILVERWOOD	CONSULTANT	BWIP (MAC)	509-376-5234
Roger T. Johnson	Quality Assurance, Mgr.	RHO BWIP	509-376-8658
E.P. SAGET	Quality Systems Director	DOE BWIP	509-376-7250
J. J. Lehman	CNWI & Mgr.	SRPC / BWIP	FTS 476 7250
HAL STEINBERG	QA MANAGER. OSTIS-HQ	DOE-OSTIS-HQ	FTS 896-5612 (202) 586-5612
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