Department of Energy
Washington, DC 20585

JAN - 8 1987 JAN 13 P12:55

Mr. Terry Husseman, Director
Office of Nuclear Waste Management
Department of Ecology
State of Washington
Olympia, WA 98504-8711

Dear Mr. Husseman:

Thank you for your review of our Quality Assurance Plan and for the comments in your letter of November 20, 1986. We appreciate your careful review and your interest in our program. We are currently evaluating your comments to see what changes we can make to our QA program to strengthen and improve it.

At the Quality Assurance Coordinating Group Meeting, which is being held on January 29, 1987 in Las Vegas, we plan to address verbally the major comments you and the other States have made. We will also be happy to answer any questions you or your representatives may have and to discuss our response. A written response for each of the comments in your letter of November 20, 1986 will also be provided to you.

We have enclosed, for your information, a copy of the comments we received from the State of Texas and those from the State of Nevada. We have not yet received comments from the Nuclear Regulatory Commission (NRC), but will supply you with a copy when we receive them. The NRC comments are expected shortly.

Thanks again for your review and comments. I look forward to seeing you in Nevada.

Sincerely,

S. H. Kale

Stephen H. Kale
Associate Director for
Geologic Repositories

Enclosures:

WM Record File
102.7

WM Project 11
Docket No.
PDR
LPDR

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Governor

STATE OF NEVADA

ROBERT R. LOUX
Executive Director

AGENCY FOR NUCLEAR PROJECTS
NUCLEAR WASTE PROJECT OFFICE
Capitol Complex
Carson City, Nevada 89710
(702) 885-3744

December 4, 1986

Mr. Carl Newton
Quality Assurance Manager
Office of Geologic Repositories
Office of Civilian Radioactive Waste Management
U.W. Department of Energy
Washington, DC 20585

Dear Mr. Newton:

Attached to this letter are the comments of this Office on the Office of Geologic Repositories document "Quality Assurance Plan for High-Level Radioactive Waste Repositories", dated August, 1986. Revision One. Comments on the document were requested by your letter of November 6, 1986. I request the Department give these comments serious consideration during the next revision of the document.

If you require any clarification, do not hesitate to contact myself or Carl Johnson of my staff.

Sincerely,

Robert R. Loux
Executive Director

RRL/CAJ/sjc

Attachment

COMMENTS OF THE
STATE OF NEVADA
ON
OFFICE OF GEOLOGIC REPOSITORIES
QUALITY ASSURANCE PLAN
FOR HIGH-LEVEL RADIOACTIVE
WASTE REPOSITORIES

AUGUST 1986 (REVISION ONE)

1. Section 1, Page 2. Text states that additional definitions are contained in NQA-1-1983. NQA-1-1983 has been replaced with NQA-1-1986. Text should be revised to incorporate the latest definitions and requirements.

2. Section 3, Page 8. Figure 3.1 indicates that the OCRWM Quality Assurance Manager is not in a direct-line management role to the Director of OCRWM. It appears the QA Manager is responsible to the Director of Policy and Outreach and who may in fact evaluate the QA Manager's job performance. This organization does not appear to provide adequate access to top management, or provide the required independence. Nevada has commented on this organizational structure previously.

3. Section 3, Page 9. Figure 3.2 appears to be unchanged from previous documents commented on by this Office. The organizational structure does not provide the OGR QA Manager adequate access to top management. This structure provides little confidence that QA problems will be adequately considered.

4. Section 3, Page 12. Section 3.2.6.2 (a) (ii) should be revised to state: "Coordinating the QA programs of the project offices and providing interface with federal regulatory agencies and affected States and Tribes."

5. Section 3, Page 13. Section 3.2.6.2 (f) should be revised to indicate that the quarterly and annual QA status reports will be documents available to the public.

6. Section 3, Page 15. Section 3.5.2 should be revised to recognize the lawful requirements of DOE to interact with affected States and Tribes also. This interaction should include State/Tribal participation in audits, either by DOE-HQ or the project offices.

7. Section 4, Page 17. Section 4.2 states that the project offices will develop QA programs. Who at DOE-HQ will be responsible for ensuring consistency between the project offices.

8. Section 4, Page 21. Section 4.5 discusses the dissemination of Quality Assurance information. Affected States and Tribes and the NRC should be included in the list of those entities receiving information.

9. Section 5, Page 24. Section 5.3.2 describes the QA documents which the project offices must submit to DOE-HQ. Affected States and Tribes and the NRC should also be included for receipt of documents from the project offices.

10. QIP 2.0, Page 2. Section 7.0 indicates that records of DOE-HQ review of projects' QA plans and procedures are nonpermanent records and will be retained for five years minimum. This retention period is inadequate, given the long-term frame of the project. What is the NRC position on retention period for non-technical QA records?

    This comment on the five-year retention period is also applicable to other QIPs which identify record retention for five years.

11. QIP 16.0. The Corrective Action Report does not identify the corrective action plan and schedule required by Section 6.5 and the analysis and approval for that plan and schedule. How are comments on the plan and schedule resolved and by whom?

12. QIP 18.3. This procedure requires that a technical specialist also be a trained auditor. If in the context of an audit, a technical specialist is only utilized to provide technical expertise to the audit team, then auditor training is not necessary. This requirement should be deleted.

13. Supplement 3, Page 6. Section 3.3 Retrieval of Emplaced Waste is a generalized discussion. It borders on being a flippant response to a serious subject. Retrieval will probably occur because the repository is not performing as anticipated and the waste must be removed before further environmental degradation occurs. Items, equipment, and activities necessary for retrieval may be quite different from emplacement, and thus should be on a separate Q-list.

14. Supplement 7, Page 2. This Office has commented in the past that peer reviewers must be independent of both the technical work under review and the organization performing the work. That comment is still applicable to Section 5.0.

15. Supplement 8, Page 2. Section 5.0 requires each project to review and assign Quality Levels to items and activities. Who at DOE-HQ will be responsible for evaluating the consistency of assignments among the projects? What criteria will be used in that evaluation?

16. Supplement 8, Page 2. Section 5.3.2.2. states that Quality Level 2 applies to items and activities that have potential impact on public and occupational radiological health and safety under 10 CFR 20. It is our understanding that any items or activities related to radiological health and safety should be Quality Level 1. Items or activities with a potential impact on occupational health and safety, such as OSHA and MSHA regulations, could be considered Quality Level 2.

    Also, define those field and laboratory investigations considered under Quality Level 2. In our view, most field and laboratory investigations provide data for licensing the repository, thus the investigations should be considered Quality Level 1.

17. Supplement 9, Page 2. Section 5.2 states that acceptability of non-journal data or data interpretations shall be based on independent reviews. In our view these independent reviews can only be accomplished by appropriately qualified technical reviewers not associated with DOe or its contractors.

(Newton
Schmitt
Joe
Knight
f.u. 12.5.2

MARK WHITE
GOVERNOR

OFFICE OF THE GOVERNOR
STATE CAPITOL
AUSTIN, TEXAS 78711-2428

November 21, 1986

Mr. Carl Newton, RW-24
OGR QA Manager
U.S. Department of Energy
Washington, D.C. 20585

Dear Carl:

Attached are the State of Texas comments on the OGR QA Plan and its supplements. Thank you for the opportunity to review and comment on this document. Please give these comments serious consideration in any revision of the QA Plan.

Sincerely,

Susan W Zimmerman

Susan W. Zimmerman, Geologist
Nuclear Waste Programs Office

SWZ:dp
attachments

(970)

State of Texas Comments on OGR QA Plan for
High-Level Waste Repositories

Comment 1

On page viii, the Revision/Change Board refers to CCBD/BCP numbers B-119 and B-126. How do these documents relate to OGR/B-3 and DOE/RW-0095?

Page 2, Section 1.4: This section states that NQA-1-1983 definitions apply. It is our understanding that NQA-1-1986 will be invoked in the new QA specifications. How will this new version of NQA-1-1986 affect the OGR QA plan?

Comment 2

Figure 3.1: The organizational position of the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Manager is not in direct line to the Director of OCRWM. The fact that the QA Manager answers to the Director of Policy and Outreach (who answers to the Director of OCRWM) does not provide adequate access to top management.

Figure 3.2: The same inadequate organizational structure exists in the Office of Geologic Repositories (OGR) matrix. The OGR QA Manager answers to the Chief of Licensing and QA Branch, who reports to the Director of Siting, Licensing, and Quality Assurance, who reports to the Associate Director of OGR. This structure does not provide adequate access to top management.

What is the relationship between the OGR QA Manager and the OCRWM QA Manager, i.e., who is in charge of what?

Comment 3

Page 7: OGR Associate Director responsibilities should include ensuring adequate staffing of QA personnel in all areas of the OCRWM QA program.

Comment 4

On page 12, Section 3.2.6.2(a)(ii) should read "Coordinating the QA programs of the project offices and providing interface with federal regulatory agencies and appropriate agencies of affected States and Tribes.

Comment 5

Page 13, Section 3.3: The Project Manager does not have the degree of independence necessary to be responsible for the QA program and at the same time be responsible for the implementation and execution of the project. The PM may have the responsibility for establishing the program, however, its implementation must be carried out with a proper level of independence.

Comment 6

Section 3.5.2 should be expanded to include notice to and participation by affected States and Tribes.

Comment 7

Page 17, Section 4.2: The development of different QA programs by the various divisions and projects could result in substantial inconsistencies in QA application. This could affect the implementation or decisions in the future when similar activities are being carried out by different organizations with OCRWM.

Page 21, Section 4.4: This section needs more elaboration, detail. How will management perform these assessments? Will additional guidance be issued for the objectives and implementation of the assessments?

Comment 8

Page 21, Section 4.3.2: Who is responsible for verifying the QA programs for the various subcontractors?

Page 21, Section 4.5: The affected States and Indian tribes should be included in the list of those receiving information, along with POs, contractors, and OCRWM.

Page 24, Section 5.3.2(b): The affected states and Indian tribes should be included in recipients of this information.

Comment 9

QIP 2.0, Section 6.2.2: This section states that "The procedures may be: Approved, Approved with comment, or Disapproved". Section 6.1.2 states the status of the QA Plan will be approved, approved with comment, or disapproved. Why is the wording different?

Section 7 states that records of Headquarters reviews of Projects' plans and procedures are nonpermanent. This means they must be retained for only five years. These records may provide valuable insight for future revisions to plans and procedures and should be kept for a longer period of time.

The Quality Assurance manual Evaluation Checklist does not require the reviewers to be identified.

Comment 10

QIP 2.1, Section 7.1: Records of training activities are considered to be nonpermanent (minimum five year retention). This retention period is inadequate, considering the time scale of the project.

All handouts and copies of visual aids used in training sessions should be included in the records.

Comment 11

QIP 5.0, Section 4.1.1: This section has a typographical error. The word "of" has been omitted.

Records of reviews of QIPs and Activity Plans and subsequent resolution of comments are considered nonpermanent. The five-year minimum retention period is not adequate, considering the project timetable.

Comment 12

QIP 16.0: The record retention time of five years (minimum) is inadequate.

The Corrective Action Report form does not require a schedule for the completion of the corrective action. The procedure in Section 6.5 does require a schedule.

Comment 13

QIP 17.0: This procedure requires the review of nonpermanent records prior to the removal from the system. This addresses some of the previous comments that a five-year retention period is inadequate. The review process is defined as one that confirms whether or not the continued retention record is required. This could lead to the destruction of some documents that are not required at the five-year period but could possibly be needed at some later time in the project.

Comment 14

QIP 18.0: Records of audits are required to be maintained for a minimum of five years. This is an inadequate time span. Same comment for QIP 18.1 and 18.2.

Comment 15

QIP 18.3: This procedure states that the Technical Specialist must be a trained auditor. A provision should be made to allow technical personnel not qualified as auditors to assist and observe the audit team. The term "technical observer" would probably satisfy this need.

Is the term Audit Team Leader synonymous with the term Lead Auditor for this QA program?

Does the Lead Auditor examination, as administered by DOE, fulfill the requirements of Section 6.1.5 for auditor qualification?

Comment 16

Supplement 2, Section 5.4: The first sentence lacks a verb.

Comment 17

Supplement 3, page 1: The first sentence of the first quote in the middle of the page reads "...important to safety not waste isolation". This should probably read "important to safety nor waste isolation. This entire document should maintain consistent statement referencing the definition in 10 CFR 60 and other NRC regulations.

Page 5: A truly conservative approach at the SCP design stage would be to include all site characterization activities on the Q-list.

Page 6: Retrieval of the waste cannot be considered to be just the reversal of the emplacement procedure. If the waste needs to be retrieved then that could imply that the repository is not functioning properly and there is the possibility of contamination. In this case, which is a very viable scenario, the items and activities needed for retrieval would be far different than the ones needed for the emplacement. Therefore, items and activities necessary for retrieval should be on the Q-list separately from the items and activities for waste emplacement.

Comment 18

Supplement 4: The list of records for lifetime storage should be expanded to include the records commented on previously regarding the five year retention limit.

Section 5.5 and 5.6: Since no licensed repository has ever been designed or constructed, it is improper to refer to "typical" records. In addition, the presented lists should not be considered limiting, and a statement to that effect should be included. The recognition of nonpermanent records "and still available" points up earlier comments about records retention time.

Comment 19

Supplement 5: Research is often a combined effort by several people. This supplement implies that only one project notebook would be generated. This would not be the case where several groups develop input into a single report. The Activity Plans developed and approved for each activity will satisfy many of the requirements of this supplement, and perhaps the Activity Plans should be referenced in the document.

Comment 20

Supplement 6: Section 4.1: The term "adverse impact" needs clarification and "a quality problem that possesses generic traits ..." needs better definition.

Section 4.2: Define the "various participants".

Section 5.2: Does the Project QA Manager of each office have sufficient knowledge of the overall program to be able to determine quality problems generic to all offices? The OGR QA Manager should be responsible for issuing generic QAs.

Define "fast relaying". Is there a specific length of time that correlates to this term?

Section 6.1: How will deteriorating quality conditions be identified by the project personnel?

In condition (d), define the term "remarkable experience/innovations".

Section 6.2.2(a): If "other means of communication" are used for the "fast relaying" of QAAs, then there should be a requirement that formal written transmittal of the QAA should follow the initial communication within some definite time span, such as 3 days.

Section 6.2.2(d): Who assigns the unique tracking/identification number to the QAA and, if it is done at the Project Office level, how will the different Project Offices keep track of the numbers used by the different offices?

Comment 21

Supplement 7, page 2, Section 5.2: Peer review panels should require the inclusion of at least one person independent of DOE and its contractors.

Comment 22

Supplement 8, page 1, Section 3: Define how the term "economic considerations" is used in this section.

Supplement 8: Assignment of Quality Levels by the different projects could lead to inconsistencies between projects and affect the decision process.

Attachment B indicates that all records that support licensing activities are Quality Level 1. Records such as qualification of personnel, audit findings, and corrective actions might be part of the licensing activities. Therefore, taking the conservative approach, these documents should have a considerable retention period, if not lifetime.

Page 5, Section 5.3.1.2: The statement that "Activities covered under Quality Level 1 include: ... site characterization." implies that all aspects of site characterization are covered under this level. Is this true?

Page 6, Section 5.3.2.2: Definition is needed for which field and laboratory investigations are covered under Quality Level 2. If these investigations have to do with site characterization, shouldn't Quality Level 1 apply?

Why are items and activities with potential impact on public and occupational health and safety only Qulity Level 2?

Comment 23

Supplement 9, page 2, Section 5.2: Independent review panels should require at least one reviewer not associated with DOE or it contractors.

Section 7 states that records of Headquarters reviews of Projects' plans and procedures are nonpermanent. This means they must be retained for only five years. These records may provide valuable insight for future revisions to plans and procedures and should be kept for a longer period of time.

The Quality Assurance manual Evaluation Checklist does not require the reviewers to be identified.

Comment 24

Supplement 11, Section 1.0: For waste that is to be accepted in the repository, the waste must have been processed under a QA program that complies with 10 CFR 60, Subpart G, not the OGR QA Plan.

Section 5.1.1: The QA Program must comply with 10 CFR 60, Subpart G, not to 10 CFR 60.2 which does not even adderss any requirements.

Section 5.2(a): If the DOE HQ-OGR does not intend to review the technical procedures for processing the waste, will audits of the program include audits of the technical procedures and, if the procedures are determined to preclude the waste from being accepted by the repository, how will this be resolved?

Comment 24

Section 5.4: The NRC must be able to determine that the waste form from the defense facilities will be acceptable by and compatible with the repository. This can only be achieved by active NRC QA oversight of the defense waste facilities, not by depending on the DOE to overview themselves. This section states that the DOE HQ-OGR will advise the NRC about the adequacy and implementation of the QA programs at the defense waste facilities, but it does not mention how often this will be done. Will there be only one report to cover the entire length of the program? This is unacceptable.

If this report is issued, affected States and Tribes should be allowed review and comment on the report.

Comment 25

Supplement 12: This supplement does not belong in the QA Plan. It is more of a policy statement.

Section 3.0: Does the one observer allowed mean one observer from each interested affected State and Tribe, or one observer to be picked by DOE if more than one affected State and Tribe are interested in observing the audit?

Section 4.0: Define "certified auditor". To our knowledge, there is no defined requirements for certification of auditors, only the requirements for certification of Lead Auditors. Have there been changes in the QA training of

auditors as required by NQA-1 or is this just a requirement of DOE for State and Tribe observers? If auditors are now required to be certified, does DOE plan to require their own auditors to be re-trained in accordance with these unknown requirements?

Does the DOE Lead Auditor training course qualify as training, qualification and certification of an auditor?

Section 5.1: Since this section requires 21 day written notice for observer participation in a DOE audit, we would like the requirement that 30 days written notice of scheduling of audits be given the affected States and Tribes.

This section also states that the observer be trained, qualified, and certified in accordance with QIP 18.3. We would like the statement changed to state "in accordance with ... QIP 18.3 or its equivalent .

Section 5.2: The documents sent to the audit observer should also include a list of the audit team members.

Section 6.2.2: How will possibly conflicting comments of the audit observer be resolved and who will be responsible for the resolution?

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