DOE F 1325.8
(12-84)

United States Government | Department of Energy

memorandum

HQO.871015.0201

DATE: OCT 14 1987

REPLY TO ATTN OF: RW-24

SUBJECT: HQ-OGR Review of SRPO Responses to NRC Comments on SRPO QA Plan, Revision 0

TO: J. O. Neff, SRPO

Reference: Letter J. Neff to S. Kale dated September 3, 1987

We have reviewed the proposed SRPO responses to the NRC comments on the SRPO QA Plan, Revision 0. The results of this review are attached (Attachment A).

While we concur with the majority of the responses, there are some resolutions offered that we feel do no sufficiently address the applicable NRC comments. We suggest that the SRPO re-evaluate these and modify the responses to more fully address the NRC concerns. It is also requested that the SRPO response be revised and resubmitted in the form of explanation and proposed QA Plan rewording, since the attached matrix type of response does not provide the NRC with sufficient information to evaluate resolution of their comments.

Attachment B provides the SRPO matrix response to the NRC comments. Attachment C provides the original NRC comments.

We would appreciate it if the SRPO action on this matter could be expeditiously performed, since the DOE has made a commitment to the NRC to have the formal response to their comments submitted by 10/30/87.

Should you have any questions, please contact me at FTS 586-5059 or Karl Sommer at FTS 586-1639.

James P. Knight, Director
Siting, Licensing & QA Division

Attachments

Attachment A

HQ-OGR Review of SRPO Responses to NRC Comments
on SRPO QA Plan, Rev. 0 (Refer to Attachments B and C)

Comment

1. Concur.

2. Concur.

3. Concur.

4. Concur.

5. Concur.

6. Do not concur. - Attachment A to Section 1 of SRPO QA Plan, Rev. 1 does not show offsite elements, i.e., contractors. We suggest revising Attachment A of Section 1 or developing a new chart to depict all onsite and "offsite" participants as per NRC Review Plan criterion 1.7.

7. Concur.

8. Concur.

9. Concur.

10. Concur.

11. Concur.

12. Do not concur. - SRPO resolution references QAAP 5.1. This does not address the NRC comment that existing and proposed QAAPs and technical procedures be identified, etc. We suggest that the plan be revised to document QA and technical procedures related to the criteria of 10 CFR 50 Appendix B. This will satisfy the NRC Review Plan criterion 2.6.

13. Do not concur. - The SRPO response indicates that the resolution to this comment can be found in Section 3.3.2 of the QA Plan, Revision 1. This Section, however, does not provide specific resolution to the elements of this comment. The SRPO should revise the response to specifically address the NRC comment.

14. Concur.

15. Concur. - We note that the NRC's request for clarification of Section 3.3.2.4.a is no longer applicable; Rev. 1 of the Plan deleted this section.

16. Do not concur. - SRPO resolution references Section 3.4.5. However, no change was made from Rev. 0 to Rev. 1 to address the NRC comment. SRPO should respond as to why they feel no incorporation of the comment is necessary. We suggest the following:

"No change required - As used here, design verification includes design checking. 10 CFR 50 Appendix B, Criterion III requires that design verification "or" checking (synonymous) be performed. This verification/checking is performed by means of design reviews, use of alternate calculations, performance of qualification tests, and peer reviews; as described in the Plan and implementing QAAPs, as applicable. Also, the independence of the verifier is covered in Section 3.4.5.3."

17. Concur.

18. Concur.

19. Concur.

20. Do not concur. - SRPO resolution references, sections 3.0, 6.2 and 7.0 of SRPO QA Plan, Rev. 1. This response is not adequate. The SRPO should state, as requested by the NRC, where in these Sections it is specifically clarified that the responsible QA organization reviews and concurs with these documents.

21. Concur.

22. Concur.

23. Concur.

24. Do not concur. - A more appropriate response would be: "Sections 8.2, 9.2 and 10.2 state that the requirements of these sections have been delegated to Prime Contractors for performance and sections 8.3.2.1, 9.3.2.1 and 10.3.2.1, respectively, state that the Quality Assurance Manager is responsible for the performance of audits and surveillances, to verify proper implementation of these sections."

26. Concur.

27. Do not concur. - SRPO response references Section 10.3.2.1. This does not address the NRC comment. This section only states the requirement that the QA Manager is responsible for performing audits and surveillances, to verify the implementation of this section. However, in this comment the NRC is asking what QA's involvement is in "determining" the expertise required... We suggest that the response be revised to address the NRC comment.

28. Concur.

29. Concur.

30. Concur.

31. Concur.

32. Do not concur. - SRPO response references Section 16.3.2. This does not entirely address the NRC comment, i.e., it does not clarify the meaning of and the relationship between the terms, as requested by the NRC.

33. Concur.

34. Concur.

35. Concur.

36. Concur.

37. Do not concur. - It is a requirement of OGR QA Plan OGR/B-3 that, when appropriate, the audit team include a representative who is trained and/or qualified in the technology being audited. SRPO should include this provision for the technical specialist that is referenced in Section 18.4.7 of the SRPO QA Plan, Rev. 1.

38. Concur.

NRC COMMENT	WHERE COMMENT RESOLUTION CAN BE FOUND AND COMMENTS
1.	Subject of comment is not currently addressed in OGR/B-3. SRPO will address when addressed by B-3.
2.	Delagated authority is noted in Attachment B (section 1) and further explanation of "who" is found in Chapter 8.6 of the SCP.
3	Section 1 clarifies this.
4.	Section 1.3.1
5.	Section 1.3.5.1 d, also QAAP 18.2, rev. 0, section 5.1.1.
6.	Attachment A in section 1.
7.	Sections 2.3.3 and 2.3.4, also QAAP 2.5, rev. 0.
8.	Section 15.3.2.1 d; section 16.3.2.1 c and Qaap 15.2, rev. 0.
9.	See section 2.2 which also references OGR/B-3.
10.	Section 2.4.1.
11.	Section 1.3.5.1 g, also QAAP 5.1, rev. 0, section 4.2.4.
12.	See QAAP 5.1 (Responsibility Matrix).
13.	See section 3.3.2 (The RD is baselined).
14.	See sections 3.3.1, 3.3.2, 3.3.3 and 3.3.4.
15.	See section 3.3.3.1.
16.	See section 3.4.5.
17.	See sections 3.4.9 and 3.4.10.
18.	See section 4.3.2. Section 7 refers to Primes (all inclusive)
19.	See sections 5.3.1 and 5.3.2.
20.	See sections 3.0, 6.2 and 7.0.

NRC COMMENT	WHERE COMMENT RESOLUTION CAN BE FOUND AND COMMENTS
21.	Section 7.3.1.1 e clarifies delivered item (s) and responsibility. Section 7.3.3 explains QA Manager.
22.	See sections 7.4.4, 7.4.5 and 7.4.6.
23.	See sections 9.2, 9.3.2 and 9.4.
24.	Rev. 1 of the QA Plan shows that SRPO still approves and overviews (audit surveillance etc.).
25.	See section 10.3.
26.	See section 10.3, 10.3.2 and 10.4.5.
27.	See section 10.3.2.1.
28.	See section 11 in its entirety, activity delegated to Primes.
29.	See section 15.1 and 15.3.2.1 a, 1st bullet, also 15.3.2.1 c.
30.	See sections 16.4.1.2 and 16.4.1.5.
31.	See sections 16.4.2, 16.4.3 and 16.3.4.
32.	See sections 16.3.2 gives responsible position title.
33.	See sections 17.1, 17.2, 17.3.1 and 17.4.2.
34.	See sections 17.3.2.1, 17.3.3.1 and 17.3.5.
35.	Post closure is beyond the scope of SCP activities.
36.	See section 18.4.1 d.
37.	See section 18.4.7 - our issued "Standard Review Plan" does not contain 18.9.
38.	See section 18.4.9 (wording changed). The NRC viewed this as a requirement and it was not intended as such.

NRC REQUEST FOR ADDITIONAL INFORMATION
SALT REPOSITORY PROJECT OFFICE QUALITY ASSURANCE PLAN
REVISION 0, December 4, 1985

1. The SRPO Quality Assurance Plan was written prior to the following NRC June 1986 draft generic technical positions (GTPs):

   a. Peer review.

   b. Qualification of existing data.

   c. Items and activities subject to QA requirements.

   An evaluation should be made against the draft guidance of these GTPs, and differences between the plan and the draft GTPs should be addressed.

2. Section 1.3 of the plan indicates that SRPO delegates some authority for the QA program to Prime Contractors. Identify the SRPO Prime Contractors and describe the major delegation of work involved in establishing and implementing the QA program. (1.2)*

3. Clarify whether the Prime Contractors and other participants under direct contract to DOE for Salt Repository Project work report to DOE-HQ, DOE-CH, or DOE-SRPO. (1.3)

4. Section 1.3.1 of the plan states: "The Project Manager, SRPO executes his QA responsibilities by approving this QA Plan and the implementing Quality Assurance Administrative Procedures (QAAPs) which set forth the requirements of the SRPO QA Program." Revise this sentence to clarify that the Project Manager, SRPO also performs other activities to execute his QA responsibilities, as discussed in the remainder of the section.

5. Section 1.3.3 of the plan indicates the SRPO verifies effective implementation of the QA program. Clarify that this includes at least an annual audit of the Prime Contractors. (1.4)

6. Show the location (e.g., onsite or offsite) of the organizational elements shown on Attachments A and B to Section 1.0 of the plan. This should also be required of other SRP organizations. (1.7)

7. Describe how the extent of SRPO QA controls is determined. (1.8)

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* The number in parenthesis after an RAI refers to the specific guidance in the NRC review plan.

8. Sections 1.3.3. and 1.4.1.2 of the plan address stop work. Describe how stop work requests are initiated and completed, and clarify the retention time of records of stop work requests. (1.12)

9. Identify items and activities covered by the QA program. Clarify whether importance to safety and importance to waste isolation are defined as numerical performance objectives and standards. Justify why not if not. (2.1)

10. Section 2.4.1 of the plan addresses computer software control. Provide a commitment in the plan that SRPO computer activities will meet the commitments of Section 2.4.1 and the guidance of NUREG-0856. (2.2)

11. Section 1.3.3.1 of the plan indicates the Chief, Quality Assurance, is responsible for the development, maintenance, issue, and control of Quality Assurance Administrative Procedure (QAAPs). Clarify that these responsibilities include the review and documented concurrence with all SRPO quality-related procedures relative to QA requirements. (2.4)

12. Identify existing and proposed SRPO QAAPs and detailed technical procedures reflecting that each criterion of 10CFR50, Appendix B, appropriate to specific items and activities will be met. (2.6)

13. Describe measures by SRPO which ensure that applicable regulatory requirements and design bases are reflected in design, procurement, and procedural documents. Also, describe measures which ensure that performance goals are specified for repository subsystems and components to support the establishment of data gathering and analysis needs. Discuss the timeliness of specifying these requirements. At the latest, planned performance allocation should be addressed in the SCP consistent with agreements reached in NRC/DOE meetings of April 17, 1981 and September 26 and 27, 1985 on this matter. (3.2)

14. Describe organizational responsibilities for preparing, reviewing, approving, verifying, and validating design and design information documents. (3.3)

15. Describe measures which ensure that design drawings, specifications, criteria, and analyses are reviewed by a QA organization to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and QA requirements. Also clarify what is meant by "design reports" in Section 3.3.2.4.a of the plan. (3.6)

16. Section 3.4.5 of the plan addresses design verification. Describe measures which ensure that design checking, which includes such things as confirmation of the numerical accuracy and computations and the accuracy of data input to computer codes, will be performed. (Confirmation that the correct computer code has been used is part of design verification.) Design verification should be performed by persons other than those performing design checking. Clarify whether personnel performing design verification can be associated with the responsible design organization. (3.7)

17. Section 3.4.9 of the plan addresses design changes. Clarify whether a configuration control system is in place such that design changes, including field changes, are analyzed to ensure they are required, are subject to the same design controls as the original design, are communicated to all affected groups and individuals, and are considered for changes to procedures and training. (3.10)

18. Section 4.3.2.1 of the plan requires that integrated contractor task agreements include the "applicable requirements of this Section," while Section 4.3.2.1 requires that procurement documents and interagency agreements are in accordance with the " applicable requirements of Section 4.4." Similarly, Section 4.3.2.1 indicates the Chief, Budget and Project Control, is responsible for preparation and implementation of QAAPs, while the Chief, Contracts and Administration, shall ensure that QAPPs are developed and implemented. Clarify the significance of these differences in handling the different types of procurement documents. Also clarify why Section 7.3.1.2 of the plan requires incorporation of applicable requirements of Section 7.4 in procurement QAAPs while Section 7.3.1.3 does not have a comparable requirement for integrated contractor task agreement QAAPs.

19. Section 5.3 of the plan indicates that SRPO retains overall responsibility for assuring that the doers implement the instructions, procedures, and drawings which prescribe activities that affect quality. Identify who (by position title) within SRPO has this responsibility and describe how this responsibility is met. (5.1)

20. Section 6.4.1.a of the plan gives examples of the types of documents controlled in accordance with the document control system. Clarify that the responsible QA organization reviews and concurs with these documents with respect to quality-related aspects. (6.2)

21. Section 7.3.1.e of the plan indicates that SRPO Chiefs are responsible for accepting delivered items. Clarify the responsibilities of the SRPO Chiefs (including the Chief, Quality Assurance) for receipt inspections. (7.2)

22. Describe measures which ensure that suppliers' certificates of conformance are periodically evaluated by audits, inspections, or tests to assure they are valid and the results documented. (7.4)

23. Section 9.2 of the plan includes a number of processes. Differentiate items in the list between processes that will be classified as special processes and those that will not. If necessary, expand the list to provide such examples. (9.1)

24. Sections 10.3, 9.3, and 8.3 of the plan state that SRPO retains the overall responsibility for ensuring that "documents... are controlled... . " Clarify each of these sections to show that SRPO has more than document control responsibilities in the areas of inspection, process control, and item identification and control.

25. Section 10.3.1.2 of the plan indicates involvement of SRPO QA in the QA planning function. Clarify whether SRPO requires similar QA involvement in the inspection planning activities required by Section 10.4.1 of the plan. (10.1)

26. Section 10.4 of the plan addresses inspection requirements. Clarify that Section 10.4 is met by SRPO in its inspection activities. Section 10.4.5 of the plan addresses inspector qualification and permits inspections by personnel outside QA organizations. The inspection 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. Clarify section 10.4.5.c accordingly. (10.2)

27. Section 10.4.5 also refers to personnel with "special" expertise. Describe QA's involvement in determining the expertise required commensurate with the technical complexity of the inspection function and the acceptability of the qualifications of the inspector. (10.3)

28. Describe measures which ensure that, when practicable, tests of structures, systems, and components shall be at conditions which simulate both normal and anticipated off-normal operations. (11.5)

29. Section 15.1 of the plan refers to activities and items which do not conform to the SRPO QA Program requirements. Clarify that the purpose of Section 15.0 is to also address activities and items which do not conform to SRPO technical requirements. Also clarify the first sentence of Section 15.3.2.1.b of the plan which indicates that "use-as-is" and "repair" dispositions will correct the nonconforming condition.

30. Describe measures which ensure that the significance of each nonconformance is assessed to determine whether corrective action is required to prevent recurrence. Identify the organization responsible for this assesment, and identify the management level of DOE responsible to review and assess significant results of nonconformance trend information. (15.4)

31. Clarify that the SRPO responsibilities regarding corrective action (Section 16.3 of the plan) include the verification of activities to preclude recurrence and the establishment of root causes. Identify (by position title) who is assigned these responsibilities for CARs issued to or received by SRPO. Also clarify in section 16.4.1.1 of the plan that significant quality problems are documented. (16.4)

32. Section 16.0 of the plan uses the following terms:

a) Significant condition adverse to quality (defined in Section 111)
b) Condition adverse to quality
c) Significant quality problem
d) Trends adverse to quality
e) Significantly adverse trend

Clarify the meaning of and the relationship between these terms. Identify (by position title) who is responsible to determine when something adverse or a problem is significant and thus requires formal, documented, Corrective Action Reports.

33. Describe the scope of the record program. That is, identify by type of data what records will be maintained within the records management system. (17.1)

34. Describe the responsibilities of the prime contractors' QA organizations in the records management system. Also, identify (by position title) who in the SRPO organization is responsible for meeting the requirements of Section 17.4 of the plan. (17.2)

35. Supplement 4 of the OGR QA Plan addresses QA records, and it introduces the concept of "post-closure" records. Address SRPO requirements for maintaining records after closure of the repository.

36. Section 18.4.11 of the plan addresses follow-up activities by auditing organizations. Clarify that these include analysis of audit data by the QA organization with the results being reported to responsible management for review, assessment, and appropriate action. (18.4)

37. Clarify that technical audits which provide a comprehensive independent verification and evaluation of procedures and activities affecting quality are included in the audit program, that audit team membership includes personnel (not necesarily from the QA organization) having technical expertise in the areas being audited, and that audit team leaders are from the QA organization. (18.9)

38. The last sentence of Section 18.4.9 of the plan requires that the audit team leader obtains agreement from the audited organization regarding the validity of audit findings. Clarify what is required when such agreement cannot be obtained.

Department of Energy
Salt Repository Project Office
110 North 25 Mile Avenue
Hereford, Texas 79045

HQO.871015.0205

September 3, 1987

Stephen H. Kale, Associate Director
Office of Geological Repositories, HQ
RW-20

SUBJECT: SRPO DEVELOPED MATRIX REFLECTING RESOLUTION OF NRC COMMENTS TO REVISION 0 OF THE SRPO QA PLAN

Please find attached the proposed Revision 1 of the SRPO QA Plan and a matrix providing direction as to where and how the NRC's comments to Revision 0 of the subject Plan were resolved.

This submittal satisfies the verbal commitment made by the QA Manager, Mr. T.J. Reese, of this office, to Mr. Gary Faust (Weston) on August 11, 1987.

Revision 1 of the SRPO QA Plan is currently going through the internal review and approval process, prior to submittal to OGR for approval.

Should you have any questions, please contact Mr. T.J. Reese at (806) 374-2320.

for J.O. Neff
Project Manager
Salt Repository Project Office

SRPO:JON:max:1238SG

Enclosure:
As Stated

cc: J. Reese, SRPO
K. Sommer, RW-242
G. Faust, Weston

261-87-0M

SRPO QA PLAN (rev. 1) -VS- NRC COMMENTS TRANSMITTED TO SRPO ON 6/1/87 VIA J. KNIGHT.

NRC COMMENT	WHERE COMMENT RESOLUTION CAN BE FOUND AND COMMENTS
1.	Subject of comment is not currently addressed in OGR/B-3. SRPO will address when addressed by B-3.
2.	Delagated authority is noted in Attachment B (section 1) and further explanation of "who" is found in Chapter 8.6 of the SCP.
3	Section 1 clarifies this.
4.	Section 1.3.1
5.	Section 1.3.5.1 d, also QAAP 18.2, rev. 0, section 5.1.1.
6.	Attachment A in section 1.
7.	Sections 2.3.3 and 2.3.4, also QAAP 1.5, rev. 0.
8.	Section 15.3.2.1 d; section 16.3.2.1 c and Qaap 15.2, rev. 0.
9.	See section 2.2 which also references OGR/B-3.
10.	Section 2.4.1.
11.	Section 1.3.5.1 g, also QAAP 5.1, rev. 0, section 4.2.4.
12.	See QAAP 5.1 (Responsibility Matrix).
13.	See section 3.3.2 (The RD is baselined).
14.	See sections 3.3.1, 3.3.2, 3.3.3 and 3.3.4.
15.	See section 3.3.3.1.
16.	See section 3.4.5.
17.	See sections 3.4.9 and 3.4.10.
18.	See section 4.3.2. Section 7 refers to Primes (all inclusive)
19.	See sections 5.3.1 and 5.3.2.
20.	See sections 3.0, 6.2 and 7.0.

SRPO QA PLAN (rev. 1) -VS- NRC COMMENTS TRANSMITTED TO SRPO ON 6/1/87
VLA J. KNIGHT.

NRC COMMENT	WHERE COMMENT RESOLUTION CAN BE FOUND AND COMMENTS
21.	Section 7.3.1.1 e clarifies delivered item (s) and responsibility. Section 7.3.3 explains QA Manager.
22.	See sections 7.4.4, 7.4.5 and 7.4.6.
23.	See sections 9.2, 9.3.2 and 9.4.
24.	Rev. 1 of the QA Plan shows that SRPO still approves and overviews (audit surveillance etc.).
25.	See section 10.3.
26.	See section 10.3, 10.3.2 and 10.4.5.
27.	See section 10.3.2.1.
28.	See section 11 in its entirety, activity delegated to Primes.
29.	See section 15.1 and 15.3.2.1 a, 1st bullet, also 15.3.2.1 c.
30.	See sections 16.4.1.2 and 16.4.1.5.
31.	See sections 16.4.2, 16.4.3 and 16.3.4.
32.	See sections 16.3.2 gives responsible position title.
33.	See sections 17.1, 17.2, 17.3.1 and 17.4.2.
34.	See sections 17.3.2.1, 17.3.3.1 and 17.3.5.
35.	Post closure is beyond the scope of SCP activities.
36.	See section 18.4.1 d.
37.	See section 18.4.7 - our issued "Standard Review Plan" does not contain 18.9.
38.	See section 18.4.9 (wording changed). The NRC viewed this as a requirement and it was not intended as such.

Attachment #1

Status of DOE Response to NRC Comments and Requests for Additional Information on Headquarter's and Project Office QA Programs

QA Plan	Title	Scheduled Date of DOE Comment Disposition Submittal to the NRC	Scheduled Date of DOE/NRC Comment Resolution Meeting	Scheduled Date of DOE Submittal of Revised QA Document(s) to the NRC
OGR/B-3 (8/85)	Quality Assurance Plan for High-Level Radioactive Waste Repositories	Complete	Complete	1/31/88
BQARD (Rev. 0 1/86)	Basalt Quality Assurance Requirements Document	Complete	Complete	Complete
BWIP/QAP (Rev. 1, 4/15/86)	Basalt Waste Isolation Project-Quality Assurance Plan	Complete	Complete	Complete
NVO-196-17 (1/14/86)	Nevada Nuclear Waste Storage Investigations-QA Plan	11/30/87	TBD	1/22/88
NNWSI-SOP-02-01 (1/31/86)	Nevada Nuclear Waste Storage Investigations Project Quality Assurance Program Plan Requirements for Participating Organizations and NTS Support Contractors	11/30/87	TBD	1/22/88
SRPO QA Rev. 0 (12/4/85)	Quality Assurance Plan-Salt Repository Project Office	10/30/87	TBD	12/31/87

EQO.870928.0058

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

HQO.871015.0207

MAR 9 1987

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

Dear Mr. Knight:

Your letter of July 17, 1986 to the NRC provided a number of DOE QA plans for NRC staff review. Several of these reviews have been furnished to you in letters dated August 25 and November 21, 1986 (NNWSI QA Plan NVO-196-17), and January 28, 1987 (OGR QA Plan OGR-B-3). The purpose of this letter is to transmit staff review comments on the remaining plans, which are in the following attachments:

Attachment 1	Basalt Waste Isolation Division QA Plan, Revision 1, April 15, 1986
Attachment 2	Basalt Quality Assurance Requirements Document (BQARD), Revision 0, January 1986
Attachment 3	Salt Repository Project Office QA Plan, Revision 0, November 26, 1985

As part of our overall review of the QA program prior to site characterization, we have commented or will be commenting on the QA plans for OGR, the project offices, Rockwell, Battelle, and several NNWSI participants. Novel or unique QA procedures will also be reviewed in detail. In order for the DOE to achieve a fully qualified program prior to the start of site characterization, it will be necessary that these staff reviews be completed and comments resolved. We believe it would be helpful if a planning meeting could be held in the near future to discuss the status of the DOE QA Plans and NRC reviews of them.

As we have noted in the past, it is important to recognize the limits of the review of the QA program plans. The extent that the program is actually used throughout the high-level waste repository program as a management tool as opposed to being put in place merely to satisfy the 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 10 CFR 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

Enclosures:
As stated

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

REQUEST FOR ADDITIONAL INFORMATION
SALT REPOSITORY PROJECT OFFICE QUALITY ASSURANCE PLAN
REVISION 0, December 4, 1985

1. The SRPO Quality Assurance Plan was written prior to the following NRC June 1986 draft generic technical positions (GTPs):

   a. Peer review.

   b. Qualification of existing data.

   c. Items and activities subject to QA requirements.

   An evaluation should be made against the draft guidance of these GTPs, and differences between the plan and the draft GTPs should be addressed.

2. Section 1.3 of the plan indicates that SRPO delegates some authority for the QA program to Prime Contractors. Identify the SRPO Prime Contractors and describe the major delegation of work involved in establishing and implementing the QA program. (1.2)*

3. Clarify whether the Prime Contractors and other participants under direct contract to DOE for Salt Repository Project work report to DOE-HQ, DOE-CH, or DOE-SRPO. (1.3)

4. Section 1.3.1 of the plan states: "The Project Manager, SRPO executes his QA responsibilities by approving this QA Plan and the implementing Quality Assurance Administrative Procedures (QAAPs) which set forth the requirements of the SRPO QA Program." Revise this sentence to clarify that the Project Manager, SRPO also performs other activities to execute his QA responsibilities, as discussed in the remainder of the section.

5. Section 1.3.3 of the plan indicates the SRPO verifies effective implementation of the QA program. Clarify that this includes at least an annual audit of the Prime Contractors. (1.4)

6. Show the location (e.g., onsite or offsite) of the organizational elements shown on Attachments A and B to Section 1.0 of the plan. This should also be required of other SRP organizations. (1.7)

7. Describe how the extent of SRPO QA controls is determined. (1.8)

---

* The number in parenthesis after an RAI refers to the specific guidance in the NRC review plan.

8. Sections 1.3.3. and 1.4.1.2 of the plan address stop work. Describe how stop work requests are initiated and completed, and clarify the retention time of records of stop work requests. (1.12)

9. Identify items and activities covered by the QA program. Clarify whether importance to safety and importance to waste isolation are defined as numerical performance objectives and standards. Justify why not if not. (2.1)

10. Section 2.4.1 of the plan addresses computer software control. Provide a commitment in the plan that SRPO computer activities will meet the commitments of Section 2.4.1 and the guidance of NUREG-0856. (2.2)

11. Section 1.3.3.1 of the plan indicates the Chief, Quality Assurance, is responsible for the development, maintenance, issue, and control of Quality Assurance Administrative Procedure (QAAPs). Clarify that these responsibilities include the review and documented concurrence with all SRPO quality-related procedures relative to QA requirements. (2.4)

12. Identify existing and proposed SRPO QAAPs and detailed technical procedures reflecting that each criterion of 10CFR50, Appendix B, appropriate to specific items and activities will be met. (2.6)

13. Describe measures by SRPO which ensure that applicable regulatory requirements and design bases are reflected in design, procurement, and procedural documents. Also, describe measures which ensure that performance goals are specified for repository subsystems and components to support the establishment of data gathering and analysis needs. Discuss the timeliness of specifying these requirements. At the latest, planned performance allocation should be addressed in the SCP consistent with agreements reached in NRC/DOE meetings of April 17, 1981 and September 26 and 27, 1985 on this matter. (3.2)

14. Describe organizational responsibilities for preparing, reviewing, approving, verifying, and validating design and design information documents. (3.3)

15. Describe measures which ensure that design drawings, specifications, criteria, and analyses are reviewed by a QA organization to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and QA requirements. Also clarify what is meant by "design reports" in Section 3.3.2.4.a of the plan. (3.6)

16. Section 3.4.5 of the plan addresses design verification. Describe measures which ensure that design checking, which includes such things as confirmation of the numerical accuracy and computations and the accuracy of data input to computer codes, will be performed. (Confirmation that the correct computer code has been used is part of design verification.) Design verification should be performed by persons other than those performing design checking. Clarify whether personnel performing design verification can be associated with the responsible design organization. (3.7)

17. Section 3.4.9 of the plan addresses design changes. Clarify whether a configuration control system is in place such that design changes, including field changes, are analyzed to ensure they are required, are subject to the same design controls as the original design, are communicated to all affected groups and individuals, and are considered for changes to procedures and training. (3.10)

18. Section 4.3.2.1 of the plan requires that integrated contractor task agreements include the "applicable requirements of this Section," while Section 4.3.2.1 requires that procurement documents and interagency agreements are in accordance with the " applicable requirements of Section 4.4." Similarly, Section 4.3.2.1 indicates the Chief, Budget and Project Control, is responsible for preparation and implementation of QAAPs, while the Chief, Contracts and Administration, shall ensure that QAPPs are developed and implemented. Clarify the significance of these differences in handling the different types of procurement documents. Also clarify why Section 7.3.1.2 of the plan requires incorporation of applicable requirements of Section 7.4 in procurement QAAPs while Section 7.3.1.3 does not have a comparable requirement for integrated contractor task agreement QAAPs.

19. Section 5.3 of the plan indicates that SRPO retains overall responsibility for assuring that the doers implement the instructions, procedures, and drawings which prescribe activities that affect quality. Identify who (by position title) within SRPO has this responsibility and describe how this responsibility is met. (5.1)

20. Section 6.4.1.a of the plan gives examples of the types of documents controlled in accordance with the document control system. Clarify that the responsible QA organization reviews and concurs with these documents with respect to quality-related aspects. (6.2)

21. Section 7.3.1.e of the plan indicates that SRPO Chiefs are responsible for accepting delivered items. Clarify the responsibilities of the SRPO Chiefs (including the Chief, Quality Assurance) for receipt inspections. (7.2)

22. Describe measures which ensure that suppliers' certificates of conformance are periodically evaluated by audits, inspections, or tests to assure they are valid and the results documented. (7.4)

23. Section 9.2 of the plan includes a number of processes. Differentiate items in the list between processes that will be classified as special processes and those that will not. If necessary, expand the list to provide such examples. (9.1)

24. Sections 10.3, 9.3, and 8.3 of the plan state that SRPO retains the overall responsibility for ensuring that "documents... are controlled... . " Clarify each of these sections to show that SRPO has more-than document control responsibilities in the areas of inspection, process control, and item identification and control.

25. Section 10.3.1.2 of the plan indicates involvement of SRPO QA in the QA planning function. Clarify whether SRPO requires similar QA involvement in the inspection planning activities required by Section 10.4.1 of the plan. (10.1)

26. Section 10.4 of the plan addresses inspection requirements. Clarify that Section 10.4 is met by SRPO in its inspection activities. Section 10.4.5 of the plan addresses inspector qualification and permits inspections by personnel outside QA organizations. The inspection 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. Clarify section 10.4.5.c accordingly. (10.2)

27. Section 10.4.5 also refers to personnel with "special" expertise. Describe QA's involvement in determining the expertise required commensurate with the technical complexity of the inspection function and the acceptability of the qualifications of the inspector. (10.3)

28. Describe measures which ensure that, when practicable, tests of structures, systems, and components shall be at conditions which simulate both normal and anticipated off-normal operations. (11.5)

29. Section 15.1 of the plan refers to activities and items which do not conform to the SRPO QA Program requirements. Clarify that the purpose of Section 15.0 is to also address activities and items which do not conform to SRPO technical requirements. Also clarify the first sentence of Section 15.3.2.1.b of the plan which indicates that "use-as-is" and "repair" dispositions will correct the nonconforming condition.

30. Describe measures which ensure that the significance of each nonconformance is assessed to determine whether corrective action is required to prevent recurrence. Identify the organization responsible for this assesment, and identify the management level of DOE responsible to review and assess significant results of nonconformance trend information. (15.4)

31. Clarify that the SRPO responsibilities regarding corrective action (Section 16.3 of the plan) include the verification of activities to preclude recurrence and the establishment of root causes. Identify (by position title) who is assigned these responsibilities for CARs issued to or received by SRPO. Also clarify in section 16.4.1.1 of the plan that significant quality problems are documented. (16.4)

32. Section 16.0 of the plan uses the following terms:

    a) Significant condition adverse to quality (defined in Section iii)
    b) Condition adverse to quality
    c) Significant quality problem
    d) Trends adverse to quality
    e) Significantly adverse trend

    Clarify the meaning of and the relationship between these terms. Identify (by position title) who is responsible to determine when something adverse or a problem is significant and thus requires formal, documented, Corrective Action Reports.

33. Describe the scope of the record program. That is, identify by type of data what records will be maintained within the records management system. (17.1)

34. Describe the responsibilities of the prime contracture' QA organizations in the records management system. Also, identify (by position title) who in the SRPO organization is responsible for meeting the requirements of Section 17.4 of the plan. (17.2)

35. Supplement 4 of the OGR QA Plan addresses QA records, and it introduces the concept of "post-closure" records. Address SRPO requirements for maintaining records after closure of the repository.

36. Section 18.4.11 of the plan addresses follow-up activities by auditing organizations. Clarify that these include analysis of audit data by the QA organization with the results being reported to responsible management for review, assessment, and appropriate action. (18.4)

37. Clarify that technical audits which provide a comprehensive independent verification and evaluation of procedures and activities affecting quality are included in the audit program, that audit team membership includes personnel (not necesarily from the QA organization) having technical expertise in the areas being audited, and that audit team leaders are from the QA organization. (18.9)

38. The last sentence of Section 18.4.9 of the plan requires that the audit team leader obtains agreement from the audited organization regarding the validity of audit findings. Clarify what is required when such agreement cannot be obtained.

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