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405/JK/87/03/09/KNIGHT LTR

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

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WM Project 10, 11, 16
Docket No.
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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,

Original Signed By:
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
BASALT WASTE ISOLATION PROJECT QUALITY ASSURANCE PLAN
REVISION 1, APRIL 15, 1986

1. The BWI Project 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. Expressions such as "are expected to" or "is expected that" are found throughout the plan. Change these expressions to "shall" or justify not doing so.

3. Section 1.3 and Appendix A of the plan describe QA responsibilities within the BWI Division. Identify who (by position title) in the Richland Operations Office is responsible for the overall BWI program. Clarify the meaning of the dashed lines, arrowheads, and ellipses on Figure 1.3 of the plan. Also indicate what ES&H stands for on Figure 1.3 and in Section 1.5 of the plan. (1.1)*

4. Discuss how the Integrating Contractor avoids conflict of interest in its roles of project management and project participant. Clarify whether the Integrating Contractor, the Architect/Engineer, the Construction Manager, and other participants under direct contract to DOE for BWI Project work report to DOE-HQ, DOE-RL, or DOE-BWI Division. (1.3)

5. Section 1.2.2 of the plan indicates the BWI Division verifies effective implementation of the QA program. Clarify that this includes at least an annual audit of the Integrating Contractor. (1.4)

6. Sections 1.4 and 1.5 of the plan discuss QA interface with DOE-HQ and interdivision interface within DOE-RL respectively. Similarly, discuss the DOE-RL interface with Project participants. (1.6)

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

7. Clarify whether the Director, BWI Division, reports through the Office of Commercial Nuclear Waste (Section 1.3.1) or the Office of Civilian Nuclear Waste (Figure 1-2). Identify the onsite and offsite organizational elements which function under QA program controls or justify not doing so. Show the ES&H Division, the Procurement Division, and the Personnel Division on an organization chart. (1.7)

8. Describe measures which ensure that DOE-RL's BWI Division Quality Systems Branch Chief is involved in the aspects of the BWI Project that affect safety and/or waste isolation and how the extent of DOE-RL QA controls is determined. (1.8)

9. Identify a management position within DOE-RL, the Integrating Contractor, Architect/Engineer, and Construction Manager organizations that retains overall authority and responsibility for the applicable QA program. Describe the management, QA, and technical experience and knowledge requirements for these positions. Verify that each of these positions 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. (1.10)

10. Describe measures which ensure that persons and organizations performing QA functions have direct access to management levels which will assure the ability to:

    a. Identify quality problems.

    b. Initiate, recommend, or provide solutions through designated channels.

    c. Verify implementation of solutions.

    Describe how these actions are accomplished. (1.12)

11. Section 1.2.6 of the plan addresses stop work. Clarify the retention time of records of stop work requests. (1.12)

12. Identify items and activities covered by the QA program. Section 2.0 of the plan indicates that analytical processes are used to determine importance to safety and/or waste isolation. 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)

13. Section 3.2 of the plan indicates that Supplement 6 of the OGR QA plan addresses computer software control. Update Section 3.2 to reflect the fact that Supplement 6 of the OGR plan no longer addresses computer software. (2.2)

14. Section 2.4 of the plan indicates a management team assesses effectiveness of the overall Project QA program. Clarify that the management team is composed of personnel above or outside the DOE-RL QA organization. (2.7)

15. Section 3.1 of the plan indicates that design controls include those used to ensure the correct translation of design inputs into designs. Describe the controls 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)

16. Describe measures which ensure that (1) errors and deficiencies in approved design and design information documents are documented and (2) action is taken to ensure that all errors and deficiencies are corrected. (3.4)

17. Section 3.4 of the plan addresses design verification, and it includes in Section 3.4.4, "Design Verification by Similarity, " an addition to the 3 methods of 10 CFR 50 Appendix B. This method would by acceptable if a fourth condition was added: (4) the design characteristics (attributes, features) that are not identical are identified and verified in a manner other than by similarity. Add such a condition or justify not doing so. Also, 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)

18. Clarify whether procedures prescribe the extent of documentation required for design verification. (3.9)

19. Section 3.6 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)

20. Section 5.0 of the plan refers to personnel "who meet the independence criteria specified in Section 3.4 of this QAP." Clarify what these criteria are.

21. Section 5.2 of the plan requires review of technical procedures by QA personnel. Clarify whether DOL-RL requires such review of administrative procedures (Categories 1 and 2 per Section 5.1 of the plan), instructions, and drawings. Also clarify whether "each participating entity in the Project" as specified in Section 5.0 of the plan is the same as "each Project participant" which is used elsewhere in the plan. (5.1)

22. Describe the scope of the DOE-RL document control program and identify the types of documents controlled by this program. Section 6.1 of the plan describes what the BWI Division requires of all Project participants in the area of document control. Clarify that the BWI Division requires the same of DOE-RL. This clarification should be made, as appropriate, throughout the plan since page v of the plan indicates that "all project participants" does not include the BWI Division of DOE-RL. (Section 4.1 and 7.0 are examples where clarification is required.) (6.1)

23. Describe measures which ensure that obsolete or superseded documents are removed and replaced by applicable revisions at work areas in a timely manner. (6.4)

24. Section 7.3.1 and 10.4 of the plan address mandatory hold points for inspection or witnessing and use the term "where appropriate." Identify the organization(s) that determine when these (and similar) activities are appropriate. (7.1 and 10.5)

25. Describe the BWI Division Quality Systems Branch and other DOE-RL organizational responsibilities for qualification of special processes, equipment, and personnel. Provide examples of processes during site characterization that will be classified as special processes and those that will not. (9.2)

26. Clarify that special processes (standard or not standard) are required to be in conformance with applicable codes, standards, QA procedures, and specifications. The last sentence of Section 9.2 of the plan requires that participant's QA Plan describes QA's role in special processes. Clarify whether the BWI Division requires involvement of QA organizations. (9.3)

28. Section 7.5 of the plan indicates that DOE-RL's BWI Division is responsible for ensuring that delivered items and materials comply with applicable QA requirements, but Section 10 assigns inspection to Project participants. Describe how the BWI division meets the responsibility noted from Section 7.5 without performing inspections. Indicate how the BWI Division participates in determining when inspections are required and in defining how and when inspections are performed. (10.1)

29. Section 10.2 of the plan addresses inspector qualification and permits inspections by personnel outside QA organizations. Clarify that inspections are accomplished by individuals or groups who do not have direct responsibility for performing the work being inspected. 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. (10.2)

30. Section 10.2 also refers to personnel with "particular" or "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. Also clarify that the qualifications and certifications of inspectors (both in and outside QA) are documented and kept current. Section 10.2 uses the term, "participant's QA inspection function." Clarify whether this is the same as the participant's QA organization. (10.2)

31. 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)

32. Describe the scope of the QA program for the control of M&TE and identify the types of equipment to be controlled. (12.1)

33. Sections 12, 13, and 14 of the plan appear somewhat inconsistent. Sections 12 and 13 make the Integrating Contractor responsible for the controls, but 14 doesn't. Sections 13 and 14 address each Project participant, but 12 doesn't. Section 12 addresses cognizant QA organizational responsibilities, but 13 and 14 don't. Sections 12 and 13 specify surveillance and audit by DOE BWI Division QS, but 14 doesn't. Clarify these sections to eliminate these apparent inconsistencies, and describe how the involved organizations will meet their assigned responsibilities.

34. Describe measures which ensure that nonconforming items and samples are segregated from those which are acceptable. (15.1)

35. Section 15.2 of the plan requires that "use-as-is" and "repair" dispositions receive technical review and approval at the next higher level of project participation. Describe QA responsibilities regarding this review and approval. (15.2)

36. Section 15.1 of the plan requires that each nonconformance be documented. Clarify that nonconformance documentation identifies the item, describes the nonconformance, shows the disposition of the nonconformance, and includes signature approval of the disposition. (15.3)

37. Section 15.4 of the plan states that "The Project" will monitor and analyze nonconformance trends on a Project-wide basis. Identify what organization is responsible for these activities. Clarify that the trend analyses are used to help identify root causes of nonconformances. Identify the management level of DOE responsible to review and assess significant results of the nonconformance trend information. (15.4)

38. 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 assessment. (16.2)

39. 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)

40. Describe the responsibilities of the project participants' QA organizations in the records management system. (17.2)

41. Section 17.3 of the plan addresses an archival facility for long-term storage of project records. Describe record storage facilities to be used prior to the availability of such a facility. (17.4)

42. Section 18.3 of the plan addresses audit scheduling. Clarify that audit scheduling considers the safety importance of the activities being performed. (18.2)

43. Section 18.13.2 of the plan addresses follow-on 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)

44. Describe measures which ensure that audited organizations describe in a formal report the corrective action to be taken to address adverse audit findings and that this report is submitted to responsible management and the auditing organization. (18.7)

45. 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 necessarily from the QA organization) having technical expertise in the areas being audited, and that audit team leaders are from the QA organization. (18.9)

46. Appendix A of the plan gives exceptions/clarifications to the NRC review plan. The following comments result from the staff review of Appendix A:

    a. The last sentence of clarification item 1 states that QA program controls are exercised by line functions. Clarify whether "line functions" refer to BWI Division personnel. If so, identify these line functions with the organization shown in Figure 1-2 of the plan. If not, identify what is meant by "line functions." Also clarify whether the "QA program controls" are the surveillances performed by BWI Division technical personnel as described in Section 18 of the plan. If not, clarify what is meant by QA program controls.

    b. Clarification item 2 states that qualified individual(s) or organizational element(s) will be identified within DOE's organization, prior to initiation of activities, as responsible for assuring that delegated work meets established quality standards. Identify such individual(s) or organizational element(s) with this responsibility for ongoing delegated work. (1.5)

    c. Clarification item 3 indicates that DOE will identify a DOE management position that retains overall authority and responsibility for: (1) performing QA functions relative to direct quality affecting activities within DOE, (2) verifying effectiveness of quality-related controls applicable to quality affecting work performed by DOE personnel, and (3) verifying proper performance of QA functions within contractor QA programs. Clarify who (by position title) has these responsibilities within DOE-RL for the BWI Project.

    d. Clarification item 4 indicates that both DOE and contractor verification of conformance to established requirements may be performed by people outside the QA organization. When this is the case, clarify that the QA organization performs periodic surveillance to confirm sufficient independence from the individuals who performed the activity.

    e. The last sentence of clarification item 7 states: "Geological data acquisition "testing" is not considered to belong to the "special process" category for purposes of process demonstration. Explain the QA significance of this statement.

    f. Clarification item 9 is acceptable if only "samples" will require handling, preservation, storage, etc; i.e., if no structures, systems, components, or other materials are involved. If this is not the case, delete this clarification or justify not doing so.

g. Section 16.0 of the plan defines significant problems, and Appendix A of the plan describes significant conditions adverse to quality. Rectify these terms and their definitions or justify not doing so. (16.4)

REQUEST FOR ADDITIONAL INFORMATION
BASALT QUALITY ASSURANCE REQUIREMENTS DOCUMENT (BQARD)
REVISION 0, January 1986

1. A statement used throughout BQARD is: "Therefore, the intent of this requirement will be met if implemented as stated." As a requirements document, BQARD should address meeting a requirement rather than meeting "the intent" of a requirement. Also, requirements document should use "shall" instead of "will" or "may". Further, the term "if implemented" should be clarified as was done on Sheet 3 under Criterion 3. Therefore the quoted statement should read: "Therefore, this requirement shall be implemented as stated," or words to that effect.

2. Sheet 10 under Criterion 2 addresses requirements for personnel performing quality-related activities. For these personnel (the "doers"), reference is made to NRC's Review Plan items 2.8a, c, and d. Item 2.8e, "Qualified personnel are certified in accordance with applicable codes and standards," should also be referenced as some of these personnel (welders, for example) require certification. The second sentence under item 1 should read: "Therefore, this requirement shall be met by implementing the requirements of 2.8a, c, d, and e as stated."

3. The note on Sheet 12 under Criterion 2 indicates that test inspectors (i.e., inspectors of testing activities) can be "... assigned to the testing organization and designated by the testing supervisor to be an in-process Inspector...." Clarify that "in-process Inspectors" do not have direct responsibility for performing the work being verified. The quality control 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.

4. The note on Sheet 7 under Criterion 3 limits the use of the word "validating" to the context of computer codes. The definition of validation from NUREG-0856 should be expanded to: "Assurance that a model is a correct representation of the process or system for which it is intended." Note that the definition of verification in ANSI N45.2.11 expands the definition in NUREG-0856 in a similar fashion.

5. The first paragraph on Sheet 1 under Criterion 4 states that site characterization participants have the option of controlling procurement activities per the requirements of either Criterion 4 or Criterion 7. While there may be some duplication in these criteria, there are also differing requirements, and the requirements of both criteria should be met.

6. The last paragraph on Sheet 2 under Criterion 4 states that construction participants have the option of using either the Site Characterization Criterion 4 or NQA-1 Basic Requirement 4 and Supplement 4S-1. Here again there are differing requirements, all of which should be met. The

proviso at the end of this paragraph does not appear to address this. A comparable comment applies to Criteria 5 through 18.

7. Supplements 4S-1 and 7S-1 of NQA-1 do not address the involvement of the QA organization in the various activities. The NRC Review Plan Sections 4.2 and 7.2 do. BQARD should require that these sections of the review plan be met. (See Sheet 3 under Criterion 4 and Sheet 3 under Criterion 7.)

8. The second paragraph on Sheet 1 under Criterion 9 implies that tests conducted per Criterion 11 do not require qualified procedures, qualified equipment, qualified personnel, and monitoring of process variables. This implication should be eliminated.

9. The first sentence under BWIP Project Implementation on Sheet 2 under Criterion 9 indicates that the NRC has "reworded" Criterion 9. The NRC has not reworded Criterion 9, and this sentence should be deleted or revised. A similar problem exists on Sheet 10 under Criterion 10, Sheets 7 and 9 under Criterion 11, Sheet 2 under Criterion 12, Sheet 2 of Criterion 14, Sheet 4 of Criterion 16, and on Sheets 5 and 6 under Criterion 18.

10. The discussion of inspection on Sheets 1 and 2 under Criterion 10 needs clarification. The first sentence indicates inspection is an "independent verification," but the third paragraph indicates that in-process inspections may be performed by the supervisor of the activity. We agree that the doer's supervisor is directly responsible for the work, and we believe that supervisors can and should make (or have made) in-process checks (i.e., nonindependent verification) and final checks before having work inspected. We do not agree that a doer's supervisor has the independence required to perform inspections, and the discussion should be revised to reflect this. Note that some work may require inspection during processing, some may require checking, and some may require neither.

    The first sentence on Sheet 2 under Criterion 10 states: "Final (General) Inspection provides independent confirmation of the adequacy of the supervisor's conclusion," indicating a personal inspector vs. line supervisor relationship which is not desirable. The inspector's responsibility is neither to confirm nor deny "the adequacy of the supervisor's conclusion," and the sentence should be deleted or revised. Finally, clarify the significance of the parenthetical words in the third and fourth paragraphs under Criterion 10.

11. Sheet 6 under Criterion 10 indicates that Section 8 of 10S-1 of NQA-1 will be implemented to ensure that inspection results are documented and evaluated and that their acceptability is determined by a responsible individual. Beyond documentation, Section 8 does not appear to address this guidance. Clarify.

12. Explain the last sentence on Sheet 10 under Criterion 10 which states: "For the BWIP project, refer to the PMP/SEMP for identification of the BWIP designated inspectors."

13. Item C on Sheet 4 under Criterion 11 addresses the fact that QA should, as a minimum, audit the test program. Item C should specify that this will be done.

14. Under Criterion 11, BQARD should address whether testing will test the item under conditions which will be present during normal and anticipated off-normal operation when practicable.

15. The last paragraph on Sheet 8 under Criterion 11 states, "The requirement for test records will be met by implementing the requirements of the NRC Review Plan Section 17.3, in lieu of the requirements of NQA-1-1983, Supplement 11S-1, paragraph 5." Test records should meet both Section 17.3 of the NRC Review Plan and paragraph 5 of supplement 11S-1 of NQA-1, and the paragraph should be so clarified.

16. Under criterion 18, clarify that both technical and QA programmatic audits are performed and that audit team membership includes personnel (not necessarily from the QA organization) having technical expertise in the areas being audited.

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)

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 OA 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.