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United States Government | Department of Energy

memorandum

HQO.871102.0036

DATE: OCT 30 1987

REPLY TO ATTN OF: RW-24

SUBJECT: Transmittal of NRC's Comments on LANL QA Plan

TO: Carl Gertz, WMPO

Attached are the NRC comments to the LANL QA Plan (LANL-NNWSI-QAPP, Revision 1). We would appreciate WMPO coordinating with LANL, a review of the NRC comments and we request your providing HQ-OGR proposed disposition to these comments by 11/30/87.

In the attached letter, Linehan to Knight dated October 9, 1987, the NRC requests that a meeting be held on this matter. If such a meeting is agreeable, arrangements can be made at a later date.

If you have any questions, please contact Karl Sommer at FTS 896-1639.

Sincerely,

James P. Knight, Director
Siting, Licensing and Quality
Assurance Division
Office of Geolgic Repositories

Attachment

WM Record File
405

WM Project 1
Docket No.
PDR ✓
LPDR

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

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HQO.871102.0037

OCT 0 9 1987

Mr. James Knight, Director
Siting, Licensing, and Quality
Assurance Division
Office of Geologic Repositories
U.S. Department of Energy
RW-20
Washington, DC 20585

Dear Mr. Knight:

In preparing for the audit of the Los Alamos National Laboratory (LANL) in June, the NRC staff conducted a review of the LANL Quality Assurance Program Plan for Nevada Nuclear Waste Storage Investigations, LANL-NNWSI-QAPP, R1 (LANL QA Plan). The purpose of this letter is to provide the Nuclear Regulatory Commission (NRC) staff comments on the LANL QA Plan so that the Plan can be made to conform to the Commission's requirements as quickly as possible. The LANL QA Plan has been reviewed against the criteria in the NRC QA Review Plan. We recognize that the LANL QA Plan was developed and will continue to meet the Nevada Nuclear Waste Storage Investigations Quality Assurance Plan, NVO-196-17. However, that document does not yet conform to the NRC QA Review Plan.

Certain information requested in our comments may be contained in the implementing procedures. It is advantageous, however, to include this information in the plan so that a relatively stable baseline plan and any changes after baselining can be approved by the staff. The staff will review selected detailed implementing procedures in its audits and other reviews but cannot review all of them nor their numerous revisions.

It is our understanding that the LANL QA Plan will be revised to meet the newly revised NVO-196-17, Rev.5. We believe a working meeting between LANL QA, DOE QA, and NRC QA personnel before that revision is made would be beneficial to

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reduce the time necessary to develop a plan which fully meets our requirements.

Should you have any questions regarding our review or establishing a meeting date and time, please contact K. Stablein of my staff on (301) 427-4796.

Sincerely,

John J. Linehan, Section Leader
Operations Branch
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Staff Comments on LANL QA Plan

cc w/encls:
C. Sommer, OGR
J. Blaylock, NNWSI
D. Oakley, LANL
P. Guthels, LANL
R. CLARK, WESTON, 10-16-87

LANL QAP REVIEW

1. Position 1.5 of the NRC QA Review Plan (RP) states that individuals or organizations are to be identified as responsible for the quality of delegated work. Section 1.0 of the LANL QA Plan (QAPP) however, only addresses the responsibilities for QA functions, not all activities which may affect the quality of work important to waste isolation. Additional information on these responsibilities should be provided in the QAPP.

2. Position 1.6 of the RP requests a commitment for a description of the management controls and lines of communication that exist for QA activities between DOE and its contractors, to assure direction of the QA program. The QAPP does not address this issue. Information should be provided in the QAPP describing the management controls that exist between LANL and DOE to assure quality-related activities will be properly implemented. Figure 1-1 should also identify the interface and reporting relationship of the Technical Project Officer (TPO).

3. Position 1.8 of the RP requests a commitment for a description of the involvement of the QA organization with the line staff for the purpose of determining the extent of the QA controls that will be applied to the high level waste repository program based upon the specific activity, complexity and importance to safety or waste isolation as defined in 10 CFR Part 60.2. The Introduction section of the QAPP describes what activities the QAPP will apply to in accordance with the three-level QA approach, but does not address the QA organization and line staff involvement in this process. This information should be provided in the QAPP.

4. Position 1.9 of the RP requests that the QA responsibilities of the organizational elements noted on the organizational charts be described. Table 1.1 in the QAPP lists the function of the organizational element

but does not provide the details of what the function involves. Additional information in equivalent detail is needed in the QAPP, in order for the NRC staff to gain an understanding of the specific QA responsibilities of the organizational elements shown in Figure 1.1 and Table 1.1.

5. Position 1.10 of the RP requests the QAPP to identify a management position that retains overall authority for the QA program. This is not identified in the QAPP. Additional information is needed in the QAPP to identify the management position retaining overall authority for the QAPP. This position should be occupied by an individual with appropriate management and QA knowledge and experience and have the following characteristics:

   a. Reports to 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.

6. Position 1.11 of the RP requests verification of conformance to established requirements be accomplished by individuals or groups within the QA organization. (Certain exceptions for: design, RP position 3.7; inspections, RP position 10.2; and test data evaluation, RP position 11.3.) Section 1.1 of the QAPP states in part that, "The persons performing QA functions...." but does not identify whether they are part of the QA organization. Additional information on this RP position should be provided in the QAPP.

7. Section 1.1 of the QAPP identifies the Quality Assurance Implementation Manager (QAIM) as having the authority to resolve disputes involving quality. Clarify whether this authority includes the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel and whether the QAIM has ultimate authority for this resolution.

8. Position 1.14 of the RP requests a commitment describing whether policies regarding the implementation of the QA program are documented and made mandatory. Additional information on this RP should be provided in the QAPP.

9. Position 1.15 of the RP requests the persons responsible for directing and managing the overall QA program be identified. These individuals are not identified in the QAPP. Additional information is needed in the QAPP to identify these individuals and whether they have appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. These individuals should be free from non-QA duties and can thus give full attention to assuring that the QA program is being effectively implemented.

10. Position 2.1 of the RP requests the items and activities covered by the QAPP be identified. Section 2.1 of the QAPP states that this list is covered by the Work Breakdown Structure and is maintained at the TPO's office. The QAPP should list the items and activities covered by the QAPP that are identified in paragraph 2.1.

11. Position 2.2 of the RP requests a commitment that computer activities will meet the guidance of NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High Level Waste Management." Sections 3.1.4 and 3.2.2 of the QAPP address computer programs but do not indicate whether it meets the guidance of NUREG-0856. Additional information is needed in the QAPP on whether it meets the guidance in NUREG-0856.

12. Position 2.3 of the RP requests a commitment regarding provisions for the establishment of technical and quality assurance procedures. Section 2.1 of the QAPP however, only addresses that the LANL NNWSI Project will be carried out in accordance with the QAPP and identified implementation procedures. Additional information is needed to assure that technical and quality assurance procedures required to implement the QA program are consistent with QA program requirements and are properly documented, controlled, and mandated through a policy statement or equivalent document signed by a responsible official.

13. Position 2.5 of the RP requests a commitment that the QA and appropriate technical organizations participate in the QA program definition stage and apply a graded approach to items and activities. Section 1.2 of the QAPP indicates that the QA and technical staff do participate but there is no information on the graded approach. Additional information is needed in the QAPP to assure that the QA and necessary technical organizations participate early in the QA definition stage to determine and identify the extent QA controls apply to specific items and activities. The information should include the effort of applying a defined graded approach in accordance with importance to safety or waste isolation as defined in 10 CFR Part 60.2 and affects such disciplines as described in the Appendix B to 10 CFR Part 50 criteria.

14. Position 2.6 of the RP requests a list which identifies the existing or proposed QA procedures and detailed technical procedures reflecting that each criterion of 10 CFR Part 50, Appendix B, appropriate to specific items and activities, will be met. This list was not provided and should be included as part of the QAPP.

15. Position 2.7 of the RP requests a commitment for management to assess the QAPP. This position is not addressed in the QAPP. Additional information is needed to provide a description of how LANL NNWSI Project Management regularly assesses the scope, status, adequacy,

and compliance of the QA program to 10 CFR Part 50, Appendix B. These measures should include:

a. Frequent contact with program status through reports, meetings, and/or audits.

b. Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked.

16. Position 2.8e of the RP requests a commitment that qualified personnel be certified in accordance with applicable codes and standards. Sections 2.1 and 2.2 of the QAPP do not address this position. Additional information is needed in the QAPP to clarify whether indoctrination, training, and qualification programs include measures to assure that qualified personnel are certified in accordance with applicable codes and standards.

17. Appendix A in the QAPP should include the definitions of position 3.1 of the RP for design, design information, design activities, and data analysis to be consistent with regulations as follows:

Design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. It includes designs at each stage of design development (i.e., from conceptual design to final design). Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses and related information such as test results and analysis. Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters.

18. Position 3.3 of the RP requests a description of the organizational responsibilities for preparing, reviewing, approving, and verifying

design and design information documents. Section 3.0 of the QAPP does not address these responsibilities. Additional information on these responsibilities should be provided in the QAPP.

19. Position 3.4 of the RP requests a commitment for corrective action in design documents. Section 3 of the QAPP does not address this position. Additional information should be provided in the QAPP and describe measures which assure errors and deficiencies in approved design and design information documents are documented, and action is taken to assure that all errors and deficiencies are corrected.

20. Position 3.6 of the RP requests a commitment to assure design documentation is reviewed by the QA organization. Section 3.1.3 of the QAPP minimally addresses this position for the scientific investigation planning (SIP) and quality assurance level assignment (QALA) phases. Additional information should be provided in the QAPP to assure that design drawings, specifications, criteria, and analyses are reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements.

21. Position 3.7.b of the RP requests a commitment for QA concurrence in those cases where design verification is performed by the design supervisor. This position is addressed in Section 3.1.3 of the QAPP for the SIP and QALA phases but not for Section 3.2, "Design Control." Additional information should be provided in the QAPP to assure that in those exceptional cases, in which the designer's immediate supervisor performs a design verification, the need is individually documented and approved in advance with concurrence of the quality assurance manager.

22. Position 3.8 of the RP requests a commitment for a peer review for certain designs or design activities. Section 3.1.3 of the QAPP states that a peer review of the SIP will be conducted if the WMPO deems it necessary. The QAPP does not state the conditions when a peer review will be conducted, nor does it address peer reviews of

tests, reports, etc. other than the SIP. Additional information should be provided in the QAPP to describe measures which assure that for design or design activities which involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed, a peer review will be conducted. The procedures defining the selection process for a peer group, and the process by which the peer group conducts its review should be described. A peer review is a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work. See 57 below for the NRC position on peer review.

If peer review responsibility has been assumed by WMPO for LANL work, the staff will review and audit that area in its review of WMPO.

23. Position 3.9 of the RP requests a commitment for procedures to identify the reviewer's responsibilities, features to be verified, and the documentation required. Section 3.0 of the QAPP does not address this issue. Additional information should be provided in the QAPP to describe whether procedures prescribe the responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation.

24. Position 3.10 of the RP requests a commitment to analyze design changes to verify they are necessary and train affected groups or individuals on these changes when necessary. Section 3.0 of the QAPP does not address this position in specific detail. Additional information should be provided in the QAPP and describe whether a configuration control system is in place such that design changes, including field changes, are analyzed to assure 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.

25. Position 6.5 of the RP requests a commitment that a master list or equivalent document control system be established to identify how current revisions to documents are controlled. Section 6.1 in the QAPP states that a master list or equivalent method will be used. The equivalent method is not described in the QAPP. The QAPP should describe the equivalent method established in Section 6.1 to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents.

26. Position 6.6 of the RP requests a commitment concerning release of documents prior to verification. Section 6.0 of the QAPP does not address this position. Additional information should be provided in the QAPP to describe measures to assure that when documents which require verification are released prior to verification, they are so identified and controlled.

27. Position 7.1 of the RP requests organizational responsibilities to be described for the control of purchased materials, parts, and services. The QAPP does not have this description. Additional information should be provided in the QAPP to describe who is responsible for purchasing, source evaluation, procurement document requirements, receipt inspection and QA involvement.

28. Position 7.2 of the RP requests a commitment that the QA organization be involved in supplier selection and receiving inspections. Section 7.0 of the QAPP implies this is being performed but does not describe the QA organization's involvement. Additional information should be provided in the QAPP to clarify whether procedures governing procurement of items or services, including appropriate QA organization participation, provide for: (a) evaluation and selection of suppliers; (b) verification of supplier's activities; and (c) receiving inspections.

29. Position 8.1 of the RP requests a commitment to identify and control samples including the organizational responsibilities for doing so. Additional information is needed in the QAPP to address this position.

30. Position 8.4 of the RP requests a commitment to verify and document the correct identification of samples prior to release for use or analysis. The QAPP does not address this position and additional information should be provided in the QAPP to describe whether correct identification of samples is verified and documented prior to release for use or analysis.

31. Position 9.1 of the RP requests the QAPP to identify a listing of special processes. Appendix A in the QAPP identifies what a special process consists of, but Section 9.0 in the QAPP does not include the listing of special processes that would fall within the category of the definition. Additional information is needed in the QAPP to provide as complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous.

32. Position 9.2 of the RP requests the QAPP to identify the organizational responsibilities including those for the QA organization for qualification of special processes, equipment and personnel. Section 9.0 in the QAPP indicates the QA organization is involved but does not identify the specific QA position or other positions involved. Additional information is needed in the QAPP to provide a description of the organizational responsibilities including those for the QA organization for qualification of special processes, equipment, and personnel.

33. Position 9.3 of the RP requests that the QA organization be involved in the qualification activities associated with special processes to assure they are satisfactorily performed. Section 9.2.5 of the QAPP indicates that the QA organization surveys the program for compliance but does not provide any specifics on the QA organizations involvement. Additional information should be provided in the QAPP which identifies the specific QA organization involvement in the qualification activities of procedures, equipment and personnel associated with special processes to help assure they are satisfactorily performed.

34. Position 9.4 of the RP requests a commitment that procedural controls be established to provide documentary evidence of acceptability for special processes. This position is not addressed in Section 9.0 of the QAPP. Additional information should be provided in the QAPP and describe measures for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

35. Position 10.1 of the RP requests the scope of the inspection program to be described. Section 10.1 of the QAPP indicates "one-of-a-kind items of hardware or equipment developed and built to support research activities are subject to the controls described herein." It is not clear as to the degree and extent of the LANL inspection program scope. Additional information should be provided in the QAPP to provide a description of the scope of the LANL inspection program to indicate an effective inspection program has been established, what items or activities will be subject to LANL inspection and the LANL QA organization's involvement in these functions.

36. Position 10.3 of the RP requests a commitment in the QAPP to establish a qualification program for inspectors. Section 10.2.6 of the QAPP indicates that inspection and surveillance personnel shall be qualified to perform the assigned inspection. Section 10.2.6 does not address provisions for an inspector qualification program. Additional information in the QAPP should be provided to describe whether a qualification program for inspectors and surveillance personnel is established and documented, and whether the qualifications and certifications of inspectors are kept current.

37. Position 10.4 of the RP requests a commitment that inspection procedures, instructions, or checklists contain certain provisions. Section 10.2.7 in the QAPP does not contain provisions to indicate records provide for the following:

    a. Identification of required procedures, drawings, and specifications and revisions.

b. Specifying necessary measuring and test equipment including accuracy requirements. Additional information in needed in the QAPP to address this position.

38. Position 11.2 of the RP requests a commitment to describe measures to assure test plans and procedures are reviewed in accordance with the verification requirements in Review Plan Sections 3.7, 3.8, and 3.9. Additional information should be included in the QAPP to address this issue since it is not addressed in Section 11.0 of the QAPP.

39. Position 11.3 of the RP requests a commitment to control the potential sources of error and uncertainty in test plans, procedures, and parameters. Section 3 in the QAPP does not address this position. Additional information should be provided in the QAPP to assure requirements and acceptance limits are included in applicable documents, including identifying required precision and accuracy, potential sources of uncertainty in test procedures, plans, and parameters.

40. Position 11.5 (the last position in Section 11 of the RP identified as 11.3 should be 11.5) of the RP requests a commitment for the evaluation of test results by a responsible individual or group as described in Section 3 of the QAPP. Section 11.2.3 of the QAPP states the evaluation of test results is being done by a responsible authority. Additional information is needed in the QAPP to identify the responsible authority.

41. Position 17.1 of the RP requests a commitment that the scope of the records program include geotechnical samples. This position is not addressed in the QAPP. Additional information is needed in the QAPP to describe whether QA records include geotechnical samples and data.

42. Position 17.4 of the RP requests that suitable facilities for the storage of records be described. Section 17.2.10 of the QAPP states that records will be stored at dual facilities which are not required to satisfy the requirements of single storage facilities but "shall meet the other requirements of this document." Additional information

should be provided in the QAPP to explain what "the other requirements of this document" mean.

43. Position 18.8 of the RP requests a commitment for the resolution of audit findings and that root causes and corrective actions be described. The QAPP does not address this position. Additional information should be provided in the QAPP to describe measures which assure that in the resolution of findings, the root cause of each finding is also identified and corrective action for it described.

44. In various sections of the QAPP, there are certain ambiguous phrases such as, "may include", "where appropriate," "where necessary" etc. These phrases are listed below by the appropriate page and paragraph number. Clarify the intent of these phrases.

Page	Paragraph	Phrase
18	4.1	as necessary
18	4.2.1	may include
18	4.2.1	where necessary
18	4.2.1	as appropriate
19	4.2.1	where required
20	5.1	appropriate to the circumstances
20	5.1	appropriate quantitative
20	5.2.2	appropriate to the circumstances
20	5.2.3	appropriate quantitative
20	5.2.3	appropriate for determining
20	5.2.3	appropriate design documents
23	7.1	provisions as appropriate
24	7.2.4	measures may include the following
27	7.2.10	when required
27	7.2.10	if applicable
27	7.2.10	shall be considered
28	8.1	or other appropriate means
28	8.2	identified as appropriate
28	8.2	or other appropriate identification

Page	Paragraph	Phrase
29	9.1	or other appropriate means
29	9.2.1	or other appropriate means
31	10.2.2	where necessary
31	10.2.2	if required
34	11.2.1	controlled including, as appropriate
34	11.2.2	include the following as applicable
36	11.2.5	periodically or as appropriate
39	13.4	as necessary
39	13.6	as necessary
39	13.3	as required
39	13.2	when required
40	1st paragraph	where required
41	15.1	as appropriate (twice)

45. Editorial: Pg. 9, paragraph 2.1 - 1st sentence should be NWO-196-17
Pg. 13 paragraph 3.2.1 - App. E now App. B.

The following comments are from the LANL NNWSI QA Procedures Manual:

46. In the "Contents" section of the QA Manual, under the heading of "Quality Assurance Procedures," a "Quality Assurance Program Index," QA procedures TWS-MSTWA-QP-02, R10 and TWS-MSTWA-QP-11 are listed but not included in the QA Manual. These procedures should be provided in the QA Manual.

47. TWS-MSTQA-QP-02 R10, pg. 1, paragraph 4 lists MST-9 QAS - Additional information should be provided to identify this reporting relationship in the QA organization.

48. TWS-MSTQA-QP-03, R6, Pg. 1, paragraph 3.2 lists a QASM - Additional information should be provided to identify this position on QAPP organizational chart.

49. TWS-MSTQA-QP-03, R6, Pg. 9, Attachment A, contains instructions for using a lab notebook. However, Attachment A states in part, "It is recommended that the procedure addressed below be followed when using this book." The conditions of where or when not to follow the procedure should be explained.

50. TWS-MSTQA-QP-06, pg. 2, paragraph 3.5, additional information should be provided to identify who approves the purchase request. In the same procedure, pg. 6, paragraph 4.3, additional information should be provided to identify the QA position responsible for reviewing the purchase request.

51. TWS-MSTQA-QP-09, pg. 4 paragraph 4.4 classifies records as Lifetime, Nonpermanent, and Convenience. This appears contrary to the requirements of section XVII-2, paragraph 4 of NVO-196-17 which classifies all NNWSI Project Records as lifetime.

52. TWS-MSTQA-QP-09, RO, paragraph 4.2.1 on page 3 does not appear to correlate with the NNWSI organizational chart in Figure 1.1 of the QAPP. Also, paragraph 4.2.2 does not meet the requirements for record storage contained in NQA-1. Additional information should be provided to correlate these organizational charts. Additional information should also be provided to describe whether the LANL QA records storage facility complies with the requirements of the records storage facility in Supplement 17S-1, Section 4.4 in NQA-1.

53. TWS-MSTQA-QP-12, RO, page 4, paragraph 4.1 states that Quality Level 1 or Quality Level 2 items shall be inspected by the requester. Additional information is needed to explain who the "requestor" is and whether the individual is part of the QA organization and qualified in accordance with applicable QA program requirements.

54. TWS-MSTQA-QP-12, RO, page 6, paragraph 4.1.3, contains information regarding the receipt of commercial grade items. Additional information should be provided to explain how commercial grade items that are to be used as Quality Level 1 or 2 are dedicated.

55. TWS-MSTQA-QP-15, page 4, paragraph 6.0, contains requirements for operator calibrated instruments. Additional information should explain whether QA or other organizations involvement in operator calibrated instruments for QA Level 1 or 2 work assures the quality assurance aspects of the calibration programs are properly implemented.

56. Enclosed are two Generic Technical Positions (GTPs) the NRC staff has developed for the high-level waste repository program. Enclosures 1 and 2 were published in their final form on June 30, 1987 and deal with Peer Review and Qualification of Existing Data respectively. It is the NRC staff position that LANL provide a commitment to comply with the two enclosures or provide equivalent alternatives in sufficient detail for our review.