



Department of Energy
Washington, DC 20585

APR 24 1991

Mr. John J. Linehan
Director
Division of High-Level
Waste Management
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Linehan:

The Department of Energy (DOE) has completed its review and evaluation of the U.S. Nuclear Regulatory Commission (NRC) comments pertaining to Revision 1 of the Science Applications International Corporation/Technical and Management Support Services (SAIC/T&MSS) Quality Assurance Program Description (QAPD). Enclosed are the proposed DOE responses and resolutions to those comments.

The changes that are required to the QAPD will be incorporated in Revision 3 and will be forwarded for NRC review and acceptance. It is necessary to point out that Revision 2 of the SAIC/T&MSS QAPD had been approved by the DOE just prior to receiving the NRC comments to Revision 1 (these comments were previously discussed during a January 26, 1991, telephone conference between the NRC, DOE, and State of Nevada). As such, Revision 2 of the SAIC/T&MSS QAPD was never transmitted to the NRC.

Should you have any questions in this regard, please contact Linda Desell of my office at (202) 586-1462.

Sincerely,

Dwight E. Shelor
Acting Associate Director for
Systems and Compliance
Office of Civilian Radioactive
Waste Management

Enclosure:

DOE Responses to NRC Comments on SAIC/T&MSS QAPD, Revision 1

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cc:

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K. Hooks, NRC

March 12, 1991

RESPONSE TO NRC COMMENTS ON T&MSS QAPD, REV. 1

<u>NRC Comment No.</u>	<u>NRC Review Plan Criteria</u>	<u>Response</u>
1.	(1.5)	The T&MSS QA program was established and is executed by the T&MSS organization which consists of Science Applications International Corporation (SAIC), and its subcontractors, Harza Engineering Company and Westinghouse Electric Corporation. (Refer to policy statement and para. 1.0). To date there has been no major delegation of work outside the T&MSS organization with respect to establishing and implementing the QA program.
2.	(1.10)	Although T&MSS personnel perform work at the Yucca Mountain "site" location on a routine basis, there is no specific "onsite" vs. "offsite" organizational element. All work performed under the T&MSS QA program is directed and controlled by T&MSS management from the Las Vegas office location. A statement to this effect will be added to Section I of the QAPD. As explained above, there has been no major delegation of work to "contractors". If an on-site organization is warranted in the future, Section 1.0 will be revised accordingly.
3.	(1.11)	It should be noted that the extent of QA controls is determined by the "graded" approach (para. 2.2.9) which includes QA and line staff. Implementation of the controlling procedures results in an integration of QA and line staff input for the determination of the QA controls. The QAPD will be revised to reflect this concept.
4.	(1.12)	The four organizations noted in the NRC comment are a part of the overall T&MSS organization but were not responsible for activities within the scope of the QAPD. Exhibit 1 of Section I in the QAPD identifies (by asterisk and footnote)

those organizations with responsibilities within the scope of the QAPD. The four organizations in question were not identified as such, thus their responsibilities were not delineated in Section I. If these organizations are assigned activities within the scope of the QAPD, Section I will be revised accordingly.

5. (2.13) The requirements matrix will be revised to delete reference to paras. 2.2.6 and 2.2.7, they are not applicable to requirements for management assessment and only para. 2.2.12 applies. It is our determination that QAPD para. 2.2.12 is in compliance with the OCRWM QARD.
6. (2.14) Though QAPD para. 2.2.11 does not specifically state that "...personnel will be instructed as to the purpose, scope, and implementation of manuals, instructions, and procedures..." and that "...qualified personnel are certified..." these requirements have been correctly interpreted and implemented. However, QAPD para. 2.2.11 will be enhanced to clearly delineate the stated requirements.
7. (3.0) Section III, "Design Control" was not applicable to the scope of the QAPD, revision 1. Subsequently T&MSS scope of work was expanded to include control of design inputs. As a result, Section III of the QAPD has been revised to delineate the required control and responsibilities.
8. (5.4) The T&MSS QA program requires compliance with approved procedures. (See Section V) Prior to changing methodology a procedure revision is required. Therefore, the method of performance of T&MSS field and laboratory activities is in compliance with the requirements. However, a reference to para 6.1 will be added to the requirements matrix.

9. (6.3) Paragraph 6.2 of Section VI states "Document issuance and distribution shall be controlled to assure that correct, applicable, and current documents are available to personnel performing activities at work locations." It is our determination that this statement complies with the intended requirements.
10. (7.2) The organizational responsibilities are described in Section I and in detail in QA Program implementing procedures. A reference to Section I will be added to the requirements matrix. Section VII will be revised to read "Procedures describing the procurement shall be developed to ensure that delivered items, services, and software comply with purchasing documents and quality assurance requirements."
11. (7.4) The requirements matrix will be revised to provide the correct reference to paras. 4.5 and 4.7 of the QAPD which contain the required information.
12. (7.5) QAPD paras. 4.9 and 10.2 address the related requirements. The requirements matrix will be revised to provide the correct reference.
13. (7.7) The QAPD Section VII will be revised to include software and to specifically delineate the requirement for periodic evaluations of suppliers certificate of conformance. It should be noted that to date, T&MSS has not received a C of C for quality affecting items.
14. (8.3) The NRC comment that "...there is no discussion of the type of documentation..." does not appear as a requirement in the NRC review plan, para. 8.3. It is our determination that the QAPD paras. 8.1.C and 8.3.A provide adequate controls for traceability of samples and items as specified in NRC review plan; paras. 8.2 and 8.3.
15. (9.1) The OCRWM Quality Assurance Requirements Document (QARD) Rev. 4, Appendix A, Section 9.1 states in part: "The requirements for special processes apply to engineered items and do not apply to scientific investigation activities."

T&MSS scope of work does not include special processes of engineered items. The T&MSS QAPD Section IX will be revised to clearly specify that this section does not apply.

16. (9.2), 17. (9.3), and 18. (9.4) Refer to item 15.

19. (10.1) QAPD para. 10.0 does reference the OCRWM QARD for procedural development. The OCRWM QARD para. 10.1 requires inspection planning to include "criteria for determining when inspections of each work operation are to be conducted." It is our determination that the QAPD complies with the requirements.

20. (10.4) QAPD paras. 10.2.A and 10.2.C require identification of "the inspection procedure used" and "inspection criteria or reference documents used to determine acceptance". QAPD para. 10.2 requires identification of the "inspector" via reference to NQA-1. Based on this criteria, it is our determination that the requirements are adequately addressed. In regards to measuring and test equipment, QAPD para. 10.2.D does require identification of "equipment used during the inspection", which complies with the OCRWM QARD, however, this section will be revised to address "...including accuracy requirements."

21. (10.5) As noted, QAPD para. 10.1 specifies incorporation of requirements from NQA-1 and Supplement 10S-1. Para. 3 of NQA-1 Supplement 10S-1 states in part "...the specific hold points shall be indicated in appropriate documents." Since T&MSS inspection activities are limited to receipt and source inspection it was determined that the "appropriate" documents may include purchase orders, change notices, etc. and should not be limited to procedures. Therefore, it is our determination that the QAPD is in compliance with the intent of this requirement.

22. (10.8) The intent of complying with the NRC review plan criterion 10.8 was via the reference to NQA-1 Supplement 10S-1 in which para. 6.3 requires acceptance of an item to be documented and approved by authorized personnel. It is our determination that the QAPD complies with the OCRWM QARD.
23. (11.4) The NRC review plan criterion 11.4 states "Test plans and procedures are reviewed in accordance with the verification requirements in Sections 3.15 and 3.17". NRC review plan criterion 3.15 and 3.17 establish criteria for test program used for verifying; "...the adequacy of a specific engineering design feature..."; and "design change control" (respectively). The T&MSS QAPD para. 11.0 specifies that "Instructions and procedures shall be developed to ensure that equipment and instruments procured by T&MSS shall...". As noted previously in comment #7, engineering design is not in T&MSS' scope of work. It is therefore our determination that NRC review plan criterion 11.4 is not applicable to the T&MSS QAPD. Also, this requirement is not applicable to Section 20 (scientific investigation) as specified by the OCRWM QARD, Appendix A, Section 11.0.
24. (11.6) QAPD Paragraph 11.2. G, addresses test prerequisites. Paragraph 11.2, item J, indicates that test records are prepared in accordance with procedures. Section XVII provides the specific required QA records control measures including those for records (data) storage. However, the QAPD Section XI will be revised to include provisions for assuring that test prerequisites have been met.
25. (11.8) Section XI is not applicable to Section 20, "Scientific Investigation" (as discussed in comment #23). As for the control and storage of samples the T&MSS QAPD Section XIII has been revised to delineate the specified requirements.

26. (12.3) It is our determination that the T&MSS QAPD Section 12 is consistent with the OCRWM QARD.
27. (12.7) QAPD para. 12.2.G states in part "Results obtained from use of equipment found out of calibration will be re-evaluated." Para. 12.2.I states "Nonconformances resulting from defective M&TE or re-evaluation resulting in erroneous data shall be processed in accordance with Section 15 and 16 as appropriate." The QAPD will be revised to specify that inspections or testing be repeated as necessary on items determined to be suspect.
28. (13.2) QAPD Section XIII will be revised to clearly address the requirements of the NRC review plan criterion 13.2.
29. (14.5) QAPD para. 14.2 will be revised to specify that altering the sequence of tests, inspections, or other operations shall be subject to the same control as the original review and approval.
30. (17.1) QAPD para. 17.1 states in part "T&MSS procedures, and instructions, scientific investigation plans, procurement documents, and other quality related documents shall identify the quality records to be generated, supplied, or maintained..." It is our determination that this acceptably implements the intent of the NRC review plan criterion 17.1.
31. (17.3) QAPD Sections X and XI describe these requirements which are consistent with the OCRWM QARD.
32. (17.6) QAPD para 17.1 states:
"T&MSS procedures and instructions, scientific investigation plans, procurement documents, and other quality-related documents shall identify the quality records to be generated, supplied, or maintained. Those records shall be legible, identifiable, accurate, retrievable, and completed appropriately for the work or activity."

Also, QAPD para. 20.9 states:

"The original recorded data, reports, and scientific notebooks are all considered QA records and processed per Section 17 of this document. These records include technical reviews, peer reviews, technical reports, notebooks, logs, deficiency documentation, etc. Documentation resulting from scientific investigations shall be reviewed to assure that QA records for the investigation are adequate and complete."

However, to further clarify the requirements noted in the NRC comment, this section will be revised to state: "Documents are considered valid records only if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated in accordance with approved procedures. Authentication may take the form of a statement by the responsible individual or organization".

33. (18.2) The Requirements Matrix identifies paras. 18.1.1, 18.1.3, and 18.1.5 of the QAPD as containing the requirements of the NRC Review Plan Criterion 18.2. As currently written these paragraphs comply with the respective requirements of the OCRWM QARD.
34. (18.4) Audit results are reported to management as specified in the QAPD para. 18.1.4. This para. requires issuance of the audit report to "...the audited organization, the APM (Assistant Project Manager), or management of the supplier/contractor being audited, Project Office QA, and the T&MSS QA Manager. The Project Manager shall be copied on all T&MSS audit correspondence." The audited organization for internal QA audits of T&MSS is the "Technical staff." The audit program requires participation, i.e., reviews and responses, by the "technical staff". The requirements matrix will be revised to provide a reference to para. 16.3 which describes the analysis of audit results and audit reports.