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JB/SAIC/T&MSS QAPD

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Mr. Dwight E. Shelor, Acting Associate Director
for Systems and Compliance
Office of Civilian Radioactive Waste Management
U. S. Department of Energy, RW 30
Washington, D.C. 20585

Dear Mr. Shelor:

SUBJECT: TRANSMITTAL OF NRC COMMENTS ON SAIC/T&MSS QUALITY ASSURANCE PROGRAM DESCRIPTION DOCUMENT (QAPD)

The Department of Energy (DOE) requested that the Nuclear Regulatory Commission (NRC) review and accept the SAIC/T&MSS Quality Assurance Program Description (QAPD) document by letter from Shelor to Browning dated November 7, 1990. Attached, please find the NRC staff's comments on the above stated QAPD. These comments were previously discussed during a January 26, 1991 telephone conference between the NRC, DOE and State of Nevada.

If you have any questions regarding the contents of the attached document, please call John Buckley (FTS)492-0513 or Bill Belke (FTS)492-0513 of my staff.

Sincerely,

ORIGINAL SIGNED BY
John J. Linehan, Acting Director
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As Stated

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1. NRC REVIEW PLAN (RP) CRITERION

1.5 DOE and prime contractors describe major delegation of work involved in establishing and executing the QA program, or any part thereof, to other organizations.

NRC COMMENT

Section 1.6 of the QAPD states that T&MSS may delegate work to others but retains responsibility for the work. However, no mention is made of establishing and executing a QA program. Clarification should be provided to describe which QA program other organizations will be required to follow when performing activities affecting quality.

2. NRC RP CRITERION

1.10 Organization charts clearly identify all the "on-site" and "off-site" organizational elements which function under the cognizance of the QA program.

NRC COMMENT

The correlation matrix identifies this criterion as N/A. A chart should be provided identifying those T&MSS contractors which operate under the QAPD.

3. NRC RP CRITERION

1.11 The QA organization is involved in portions of the high-level waste repository program that affect safety and waste isolation. The extent of QA controls is determined by the QA staff, in combination with the line staff, and depends on the specific activity, its complexity, and its importance to safety or waste isolation, as defined in 10 CFR Part 60 Section 60.2.

NRC COMMENT

A description should be provided in the QAPD which indicates that QA controls are developed by the QA staff in combination with line staff.

4. NRC RP CRITERION

1.12 DOE and its prime contractors describe the QA responsibilities of each of the organizational elements noted on the organization charts.

NRC COMMENT

There does not appear to be a one-to-one correspondence between the written description of QA organization responsibilities expressed in QAPD Sections 1.3.1-1.3.5 with QA organizations depicted in Exhibit 1. Organizational responsibilities are missing for (1) Assistant PM, Technical Support, (2) Assistant PM, Project Management, (3) Project Office QA Liaison, and (4) Office of Institutional and External Affairs.

5. NRC RP CRITERION

2.13 Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.

NRC COMMENT

The correlation matrix shows that QAPD Sections 2.2.6, 2.2.7 and 2.2.12 address management assessments of QA programs for other organizations participating in QA program. These sections do not contain the desired information as requested in the above Review Plan criterion.

6. NRC RP CRITERION

2.14 Indoctrination, training, and qualification programs are established for personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained and that:

a. Personnel responsible for performing quality-related activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.

b. Personnel verifying activities affecting quality are qualified in the principles, techniques, and requirements of the activity being performed.

c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance.

d. Appropriate management monitors the performance of individuals involved in activities affecting quality and determines the need for retraining and/or replacement. A system of annual appraisal and evaluation can satisfy this criterion.

e. Qualified personnel are certified in accordance with applicable codes and standards.

NRC COMMENT

Although QAPD Section 2.2.11 adequately addresses most of the issues related to indoctrination, training and qualification programs, it does not mention specifically that personnel will be instructed as to the purpose, scope and implementation of manuals, instructions and procedures. In addition, Sections 2.2.11.1, 7.6.1, and 10.0 supposedly address certification of qualified personnel. Statements regarding this certification are not found.

7. NRC RP CRITERION

3.0 Section 3.0 of the NRC Review Plan requests that certain criteria be addressed for activities related to design control.

NRC COMMENT

Section 3.0 of the QAPD states that design activities shall be accomplished in accordance with written procedures which describe the process by which the specification of technical requirements are planned, controlled, and implemented. As such, design inputs, interfaces, outputs, reviews, changes, and deficiencies shall be controlled by approved procedures. Section 3.1 of the QAPD states that T&MSS is not assigned the responsibility to perform the design of structures, systems and components. There appears to be an inconsistency between the statements made in Sections 3.0 and 3.1 of the QAPD related to design control activities.

8. NRC RP CRITERION

5.4 Provisions are described for controlling changes to field and laboratory procedures associated with exploratory investigations within the site characterization program to assure that such changes are subsequently documented and verified in a timely manner by authorized personnel.

NRC COMMENT

Section 5.3 of the QAPD states that all changes will be "processed" in accordance with approved procedures. However, there is no description about documentation and verification of changes in timely manner by authorized personnel as requested in the Review Plan.

9. NRC RP CRITERION

6.3 Procedures are established to assure that correct and applicable documents are available at the location where the activity will be performed, before commencing the work.

NRC COMMENT

Section 6.2 of the QAPD does not indicate that procedures will be available at work stations prior to commencing the work as requested in the Review Plan.

10. NRC RP CRITERION

7.2 Organizational responsibilities are described for the control of purchased items, services and software.

NRC COMMENT

According to the correlation matrix, Section 7.0 of the QAPD is supposed to address the organizational responsibilities for the control of purchased items, services and software. This information appears to be missing.

11. NRC RP CRITERION

7.4 The organization providing items, materials, equipment, services, or software furnishes the following records to the purchaser:

a. Documentation that identifies the procurement and the specific procurement requirements met (e.g., codes, standards, and specifications).

b. Documentation identifying any procurement requirements that have not been met.

c. A description of those nonconformances from the procurement requirements dispositioned "accept as is" or "repair."

A procedure that assures that the review and acceptance of these documents, before installation or use of the procured item, should be described in the purchaser's QA program.

NRC COMMENT

The correlation matrix identifies Sections 7.6, 7.8 and 7.10 of the QAPD for information to address this Review Plan criterion. However, these sections do not indicate that the supplier will provide:

1. Documentation to identify procurement and specific procurement requirements met, and

2. Documentation of procurement procedures not met.

12. NRC RP CRITERION

7.5 Documents attesting to the acceptability of procured items shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased item, and retained in the records storage facilities for retrievability, as necessary.

NRC COMMENT

QAPD Sections 7.6, 7.9.5, 7.10, 7.11 does not contain the following item as requested by Criterion 7.5 of the Review Plan.

There are no statements describing that documents attesting to acceptability of procured items will identify specific requirements met by purchased item.

13. NRC RP CRITERION

7.7 Suppliers' certificates of conformance for items, services and software are periodically evaluated by audits, independent inspections, or tests to assure that they are valid and the results documented.

NRC COMMENT

QAPD Sections 7.4.1, 7.4.2 and 7.4.3 do not mention the periodic evaluation of suppliers certificates of conformance for items, services and software as requested by Criterion 7.7 of the Review Plan.

14. NRC RP CRITERION

8.3 Identification can be traced to the appropriate documentation such as drawings, specifications, purchase orders, technical reports, drilling locations and logs, (including well bore and depth), test records, installation and use records, inspection documents, and nonconformance reports.

NRC COMMENT

Sections 8.0, 8.1, 8.3 and 17.1 of the QAPD supposedly contain information to address this criterion of the Review Plan. However, there is no discussion about the types of documentation that items, services, and software must be traceable to.

15. NRC RP CRITERION

9.1 The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes is provided, which generally are those processes where direct inspection is impossible or disadvantageous, such as heat treatment, welding, nondestructive testing, data collection, and other site characterization activities.

NRC COMMENT

Section 9.0 of the QAPD states that scientific investigations are the only processes that apply to the T&MSS program. Provisions should be described for determining those processes which must be controlled as special processes as requested by Section 9.1 of the Review Plan.

16. NRC RP CRITERION

9.2 Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel.

NRC COMMENT

The correlation matrix identifies Sections 1.0, 9.0 and 20.6 of the QAPD as containing the information addressed in Criterion 9.2 of the Review Plan. However, these sections do not adequately describe the organizational responsibilities for qualification of special processes, equipment and personnel.

17. NRC RP CRITERION

9.3 Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. Acceptable methods for qualifying those special processes associated with scientific investigations are:

(1) the conduct of a prototype test, if possible, that demonstrates the process maintains quality or produces a quality product; or

(2) a technical review; or

(3) a peer review.

NRC COMMENT

The QAPD does not clearly state that procedures, equipment and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures and specifications.

18. NRC RP CRITERION

9.4 Procedures are established for recording evidence of acceptable accomplishment of special processes, using qualified procedures, equipment, and personnel.

NRC COMMENT

The QAPD does not explicitly state that procedures are established for recording evidence of acceptable accomplishment of special processes as requested by Criterion 9.4 of the Review Plan.

19. NRC RP CRITERION

10.1 The scope of the inspection program is described that indicates an effective program has been established to verify that items and services conform to documented instructions, procedures, drawings and specifications. Program procedures provide criteria for determining when inspections of each work operation are to be performed.

NRC COMMENT

The scope of the inspection program is identified in Section 10.0 of the QAPD. However, the QAPD does not state that inspection procedures will include criteria for determining when inspections will be performed.

20. NRC RP CRITERION

10.4 Inspection procedures, instructions, or checklists provide for the following:

a. Identification of characteristics and activities to be inspected.

b. A description of the method of inspection.

c. Identification of the individuals or groups responsible for performing the inspection operation.

d. Acceptance and rejection criteria.

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

f. Recording inspector or data recorder and the results of the inspection operation.

g. Specifying necessary measuring and test equipment, including accuracy requirements.

NRC COMMENT

Section 10.2 of the QAPD does not address several of the items identified in Criterion 10.4 of the Review Plan. Items which do not appear to be addressed include:

- identification of required procedures, drawings, and specifications and revisions
- recording inspector or data recorder
- necessary measuring and test equipment, including accuracy requirements

21. NRC RP CRITERION

10.5 Procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.

NRC COMMENT

The correlation matrix references Section 10.1 of the QAPD for information addressing Criterion 10.5 of the Review Plan. However, QAPD Section 10.1 says that T&MSS will incorporate requirements of NQA-1 and 10S-1. NQA-1 and 10S-1 do not require mandatory inspection hold points as required in Criterion 10.5 of the Review Plan.

22. NRC RP CRITERION

10.8 Inspection results are documented and evaluated, and their acceptability is determined by a responsible individual.

NRC COMMENT

Criterion 10.8 of the Review Plan requests inspection results to be documented and evaluated and their acceptability determined by a responsible individual. Neither Section 10.1 of the QAPD nor the referenced section in NQA-1 specifically address this topic.

23. NRC RP CRITERION

11.4 Test plans and procedures are reviewed in accordance with the verification requirements in Sections 3.15 and 3.17.

NRC COMMENT

Criterion 11.4 of the Review Plan requests that test plans and procedures be reviewed in accordance with the verification requirements in Sections 3.15 and 3.17 of the RP. The QAPD states that this criterion is N/A. However, this information should be contained in Section 20 if not in Section 3 of the QAPD. It appears that the QAPD is lacking in this area.

24. NRC RP CRITERION

11.6 Test procedures or instructions provide for the following:

a. The requirements and acceptance limits, including required levels of precision and accuracy, as appropriate, are contained in applicable documents.

b. Instructions for performing the test.

c. Test prerequisites such as: calibrated instrumentation; adequate test equipment and instrumentation; completeness of item to be tested; suitable and controlled environmental conditions; and provisions for data collection and storage.

d. Mandatory inspection hold points (as required).

e. Acceptance and rejection criteria, including required levels of precision and accuracy.

f. Methods of documenting or recording test data and results.

g. Provisions for assuring test prerequisites have been met.

NRC COMMENT

Section 11.2 of the QAPD addresses most of the requirements listed in Criterion 11.6 of the Review Plan. However, Section 11.2 does not include provisions for storage of data or provisions for assuring test prerequisites have been met.

25. NRC RP CRITERION

11.8 Items tested should be identified, controlled, and ultimately dispositioned, and samples should be archived as required by procedures.

NRC COMMENT

Criterion 11.8 of the Review Plan states that items tested should be identified, controlled, dispositioned, and samples archived per procedures. Although Sections 11.2k, 8.1 and 8.3 of the QAPD address these issues for equipment and instruments, this same information should be found in QAPD Section 20 to cover scientific investigations.

26. NRC RP CRITERION

12.3 Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) used for measurement, inspection, and monitoring. The review and documented concurrence of these functions is identified.

NRC COMMENT

Section 12.1 of the QAPD states that a calibration procedure for M&TE consistent with the OCRWM QARD will be implemented. The OCRWM QARD references Section 12 of NQA-1. NQA-1 does not specifically state that procedures must be described for calibration (technique and frequency), maintenance, and control of M&TE used for measurement, inspection, and monitoring. Further, NQA-1 does not mention that the review and documented concurrence of these functions should be identified.

27. NRC RP CRITERION

12.7 When measuring and test equipment is found to be out of calibration, evaluations are made and documented to determine the validity and acceptability of measurements performed since the last calibration. Inspections or tests are repeated on items determined to be suspect.

NRC COMMENT

Section 12.2G of the QAPD addresses most of the information requested by Criterion 12.7 of the Review Plan. However, the QAPD does not describe whether inspections or tests are repeated on items determined to be suspect.

28. NRC RP CRITERION

13.2 Procedures are established and described to control cleaning, handling, storage, packaging, and shipping of items and samples in accordance with design and procurement requirements and manufacturer's recommendations to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

NRC COMMENT

Section 13 of the QAPD does not specify that procedures for cleaning, handling, storage, packaging and shipping of items and samples will be in accordance with design and procurement requirements and manufacturer's recommendations as requested by Criterion 13.2 of the Review Plan.

29. NRC RP CRITERION

14.5 Procedures are established and described to control altering the sequence of required tests, inspections, and other operations important to safety. Such actions should be subject to the same controls as the original review and approval.

NRC COMMENT

Criterion 14.5 of the Review Plan requests controls for altering the sequence of tests inspections, and other operations important to safety to be the same as controls on original review and approval. A description on the control of alterations is not found in Section 14.2 of the QAPD.

30. NRC RP CRITERION

17.1 The scope of the records program is described which assures that sufficient records affecting quality are identifiable, retrievable, and maintained. QA records include scientific, engineering, and operational data and logs; geotechnical data; results of reviews, inspections, tests, audits, and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports, design review reports, peer review reports, nonconformance reports, and corrective action reports.

NRC COMMENT

Section 17 of the QAPD does not provide a list of or indicate the types of records to be included as QA records as requested in Criterion 17.1 of the Review Plan.

31. NRC RP CRITERION

17.3 Inspection and test records contain the following, where applicable:

a. Identification of procedure and item inspected or tested.

b. A description of the type of observation.

c. The date and results of the inspection or test.

d. Information related to conditions adverse to quality.

e. Inspector or data recorder identification.

f. Evidence as to the acceptability of the results, with signature and organization.

g. Action taken to resolve any discrepancies noted.

NRC COMMENT

Sections 10.1, 10.2 and 11.0 of the QAPD address most of the items requested for inspection and test records as presented in Criterion 17.3 of the Review Plan. However, these sections do not address (1) information related to conditions adverse to quality and (2) signing authority for person accepting the inspection results.

32. NRC RP CRITERION

17.6 Procedures are established describing methods of documenting/recording, reviewing, and confirming accuracy of records, which include laboratory and field notebooks and log books, data sheets, data reduction documents, and software.

NRC COMMENT

Section 17.2 of the QAPD is the section referenced to contain the information regarding the documenting/recording, reviewing, and confirming the accuracy of records. However, this section only contains a very broad statement about following approved procedures and instructions. In addition, such information is not found in Section 20 of the QAPD (Scientific Investigations).

33. NRC RP CRITERION

18.2 An audit plan is prepared identifying audits to be performed, their frequencies, and schedules, taking into consideration the complexity, safety, importance and degree of previous audits, inspections and surveillance. Audits are regularly scheduled, based on the status and safety importance of the activities being performed, and are initiated early enough to assure effective QA during design, procurement, site characterization, manufacturing, construction, installation, inspection and testing.

NRC COMMENT

The correlation matrix identifies Sections 18.1.1, 18.3.1, and 18.1.5 of the QAPD as the reference for information needed to address Criterion 18.2 of the Review Plan. These sections, however, do not discuss the basis for scheduling audits and do not address early QA involvement in design, procurement, etc...as stated in Review Plan.

34. NRC RP CRITERION

18.4 Audit results are documented and analyzed by the QA and technical staff organization, and the results are reported to responsible management for review, assessment, and appropriate action.

NRC COMMENT

According to the correlation matrix, Section 18.1.4 of the QAPD addresses the requirements of Criterion 18.4 of the Review Plan. However, this section does not indicate that the QA and technical staff organization will review and analyze the audit report and report results to management.