

FORM 1
1-80
Approved by NRC June 1978

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Cori Macaluso
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PDR WASTE
HM-11 PDR

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RESPONSE TO NRC COMMENTS ON TAMSIS QAPD, REV. INRC
Comment No.NRC Review
Plan Criteria

- | | | |
|----|--------|--|
| 1. | (1.5) | The TAMSIS QA program was established and is executed by the TAMSIS 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 TAMSIS organization with respect to establishing and implementing the QA program. |
| 2. | (1.10) | Although TAMSIS 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 TAMSIS QA program is directed and controlled by TAMSIS management from the Las Vegas office location. If an off-site organization is warranted in the future, Section 1.0 will be revised accordingly. As explained above, there has been no major delegation of work to "contractors". |
| 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. |
| 4. | (1.12) | The four organizations noted in the NRC comment are a part of the overall TAMSIS organization but were not responsible for activities within the scope of the QAPD. Exhibit I 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. |

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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 QAP para. 2.2.12 is in compliance with the OCRM of QAP.

6. (2.14)

Though QAP 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, QAP 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 QAP, revision 1. Subsequently TAMSS scope of work was expanded to include control of design of inputs. As a result, Section III of the QAP has been revised to delineate the required control and responsibilities.

8. (5.4)

The TAMSS QA program requires compliance with compliance with approved procedures. (See Section V) Prior to changing methodology a procedure revision is required. Therefore, the method of performance of TAMSS field and laboratory activities is in compliance with the requirements.

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.

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10. (7.2)

The organizational responsibilities are described in Section I and in detail in the Program implementing procedures. Section VII states "Procedures describing the procurement process shall be developed to ensure that delivered items and services comply with purchasing documents and quality assurance requirements." A reference to Section I will be added to the requirements matrix.

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. 4.8 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 specifically delineate the requirement for periodic evaluations of suppliers certificate of conformance. It should be noted that to date, TAMS 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 8.2.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 OCSRM 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." TAMS scope of work does not include special processes of engineered items. The TAMS QARD 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.

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19.

(10.1)

QAPD para. 10.0 does reference the OCRM QAPD for procedural development. The OCRM QAPD 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 MOA-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 OCRM QAPD.

21.

(10.5)

As noted, QAPD para. 10.1 specifies incorporation of requirements from MOA-1 and Supplement 105-1. Para. 3 of MOA-1 Supplement 105-1 states in part "...the specific hold points shall be indicated in appropriate documents." Since TASS 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 NAC review plan criterion 10.8 was via the reference to MOA-1 Supplement 105-1 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 OCRM QAPD.

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 TAMSS QAPD para. 11.5 specifies that "Instructions and procedures shall be developed to ensure that equipment and instruments procured by TAMSS shall...". As noted previously in comment #7, engineering design is not in TAMSS' scope of work. It is therefore our determination that NRC review plan criterion 11.4 is not applicable to the TAMSS QAPD. Also, this requirement is not applicable to Section 20 (scientific investigation) as specified by the OCRM QAPD, Appendix A, Section 11.0.

24.

(11.6)

QAPD Paragraph 11.2.6, addresses test prerequisites. Paragraph 11.2, item J, indicates that test records are prepared in accordance with procedures. Section XVII provides the specific required QAPD records control measure including those for records (data) storage. It is our determination that the Review Plan is satisfied.

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 TAMSS QAPD Section XIII has been revised to delineate the specified requirements.

26.

(12.3)

It is our determination that the TAMSS QAPD Section 12 is consistent with the OCRM QAPD.

27.

(12.7)

QAPD para. 12.2.2 states in part "Results obtained from use of equipment found out of calibration will be re-evaluated." Para. 12.2.1 states "Nonconformances resulting from defective NITE or re-evaluation resulting in erroneous data shall be processed in accordance with Section 15 and 16 as appropriate." It is our determination that the paragraphs comply with the intent of NRC review plan criterion 12.2.

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 "TMS 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 OCRM QAPD.

32. (17.6)

QAPD para 17.1 states:

"TMS 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. 20.4 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."

It is our determination that the NRC Review Plan has been acceptably translated into the QAPD.

33. (18.2)

The Requirements Matrix identifies paras. 18.1.1, 18.1.3, and 18.1.5 of the QAP as containing the requirements of the NRC Review Plan Criterion 18.2. As currently written these paragraphs comply with the respective requirements of the CCROM QAP.

34. (18.4)

Audit results are reported to management as specified in the QAP para. 12.1.4. 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&MS QA Manager. The Project Manager shall be copied on all T&MS audit correspondence." The audited organization for internal QA audits of T&MS is the "Technical staff." The audit program requires participation, i.e., reviews and responses, by the "technical staff". It is our view that the QAP meets QAPD requirements.