

DEPARTMENT OF ENERGY
OCRWM
OFFICE OF QUALITY ASSURANCE
QUALITY ASSURANCE SURVEILLANCE REPORT

1.0 Surveillance Number
HQ-SR-92-001

2.0 Dates of Surveillance
October 1-3, 1991

3.0 Organization and Location
TRW Environmental Safety Systems, Inc. (TESS)
Charlotte, NC

4.0 Surveillance Team Members
Louis Wade, Team Leader (WESTON)
John Marchand, Team Member (WESTON)
Ram Murthy, Observer (DOE-OQA-RW 3.1)
Prasanna Kumar, Observer (DOE-OS&T-RW 421)

5.0 Personnel Contacted
Alden Segrest, MRS Design Manager (TESS/DE&S)
Frank Nash, QA Audits Manager (TESS/DE&S)
Ken Ashe, MRS Designer (TESS/DE&S)
Diane Whitley, MRS Designer (TESS/DE&S)
O.J. Gilstrap, MRS Engineer Supervisor (TESS/DE&S)

6.0 Scope
This surveillance was limited to determining what quality affecting activities, associated with the conceptual design of the MRS, are currently being performed and verification that a quality assurance program is in place to perform those activities.

7.0 Requirements

7.1 NWMS M&O Quality Assurance Program Description (TSO.910410.0001)
Rev. 2, dated June 14, 1991 (QAPD)

8.0 Results

8.1 Executive Summary

The surveillance was performed to determine what quality affecting activities, related to the conceptual design of the MRS, were being conducted and to verify that those activities were being performed using approved procedures by trained personnel. As a result of interviews with personnel it was determined that no quality affecting activities, directly related to MRS conceptual design, are being performed in the Charlotte office. However, some quality affecting activities, indirectly related to the conceptual design, have been performed. These activities include the development of procedures and the training of personnel. The surveillance concluded that the M&O does not yet have a quality assurance program in place for performing all quality affecting conceptual design activities.

8.2 Discussion

8.2.1 The surveillance team reviewed Quality Administrative Procedures (QAP), Quality Assurance Implementing Procedures (QAIP), interviewed personnel, reviewed indoctrination and training records of personnel and evaluated the organization. To date only five QAPs and ten QAIPs have been developed and approved. The surveillance determined that the conceptual design efforts, currently in progress, are limited to a review/study phase which is not considered quality affecting. The QAIPs for design control are limited to the preparation of design specifications and engineering calculations/analysis. Other procedures to specifically address the conceptual design process or the preparation of the Conceptual Design Report (CDR), which is a quality affecting activity, are not in place.

An evaluation of the organization and interviews with personnel determined that there are no quality assurance personnel located in the Charlotte office. The MRS Engineering Supervisor, who reports to the Manager, MRS Engineering, has been designated as the "QA Coordinator." This position is an administrative function that interfaces with the M&O QA Organization in Fairfax, VA. The QA Coordinator does not have approval or signature authority for the QA organization but rather serves a coordinating function such as interfacing in the resolution of comments on procedures per QAIP 06-10, and processing Design Nonconformances per QAIP 16-10. Several of the QAIPs specify responsibilities of the QA Manager. It

is questionable that these responsibilities can be effectively or efficiently executed when the QA Organization is located in Fairfax, VA, and the MRS Design Group in Charlotte, NC.

8.2.2 The following objective evidence was reviewed during the surveillance.

A. Quality Administrative Procedures (QAP) as follows:

- 2.1, Rev. 0 - Indoctrination & Training
- 2.2, Rev. 0 - Verification of Personnel Qualifications
- 5.1, Rev. 0 - Preparation of Procedures
- 6.1, Rev. 0 - Document Control
- 17.1, Rev. 0 - QA Records Management

B. Quality Assurance Implementing Procedures (QAIP) as follows:

- 01-10, Rev. 0 - MRS Design Group Organization
- 02-10, Rev. 0 - Graded Quality Assurance
- 03-10, Rev. 0 - Design Specifications
- 03-20, Rev. 0 - Engineering Calculations Analysis
- 01-30, Rev. 0 - Procurement of Services
- 05-10, Rev. 0 - Engineering Drawings
- 06-10, Rev. 0 - Control of QAIPs
- 06-20, Rev. 0 - Document Control (Design documents)
- 16-10, Rev. 0 - Design Nonconformances
- 19-10, Rev. 0 - Computer Software Validation & Verification

C. Indoctrination and Training Records for:

- OCRWM QARD, M&O QAPD and NQA-1
(dated 9-12-91)
- Workshop for Initial Instructor Development Training
(dated 9-20-91)
- Quality Assurance Implementing Procedures
(dated 9-26-91)
- M&O QA Program I&T Requirements
(dated 9-27-91)
- Trainer Certification for C. Denton, D. Whitley, and K. Ashe
(dated 9-20-91)

D. Other:

Duke Power Document Transmittal Form
(dated 9-26-91)
Duke Engineering Services Organizational Chart
(dated 10-1-91)

8.2.3 The following observations were identified during the surveillance. Observations do not require a written response, however, it is expected that management will take appropriate action. OCRWM will follow up on action taken during future verification activities.

- A. Several concerns were identified in the preparation, review, approval and control of QAIPs. QAIPs were developed to an earlier "Draft" version of the M&O QAPD instead of the currently approved version, Rev. 2. The review and approval of the QAIPs were performed prior to the approval of QAP 5.1 "Preparation of Procedures" which governs the preparation, review and approval of procedures. QAIPs have been approved and issued without having the applicable QAPs in place (ie: QAIP 03-10,03-20,04-30, etc.) Additionally, the QAIP Manuals were not being controlled as required by QAIP 06-10 "Control of the Quality Assurance Implementing Procedures." This was documented by the M&O on a Design Nonconformance report as discussed in B below. The proposed resolution includes to withdraw all the manuals issued, correct the content, and assure that they are properly issued and controlled. Per the Manager-MRS Design, the procedures will also be reviewed for compliance to the QAPD and QAP 5.1. Considering that no quality affecting design activities are being performed this observation is not considered to be a condition adverse to quality, however, if gone undetected it could have a significant impact on future quality affecting activities.
- B. The M&O initiated a Design Nonconformance (DN), in accordance with QAIP 16-10 "Design Nonconformances," to address the fact that QAIPs were not being controlled as required. At the time of the surveillance the DN was the only vehicle the M&O had in place to document deficiencies. A review of the M&O QAPD, regarding Nonconformances and Corrective Action (Sections 15 & 16) implies that

conditions adverse to quality be addressed on Corrective Action Reports in accordance with the applicable QAP. At the time of the surveillance no such QAP existed but is in the development stages. Since QAIP 16-10 permits the use of the DN to document procedural noncompliances the surveillance team considered this to be minimally acceptable.

- C. Indoctrination and Training (I&T) records were reviewed and it was determined that training is being conducted in accordance with QAP 2.1 with one exception. QAP 2.1 requires that Managers/Supervisors designate I&T requirements for each individual on the I&T Assignment form (I&TA), Attachment II of the procedure. Although I&T has been conducted, the I&TAs had not been completed for the individuals identified as having received I&T. Prior to the completion of the surveillance the M&O presented the surveillance team with completed I&TAs for several employees. A review of the I&TAs determined that training previously received by the individuals, was specified with additional I&T assignments identified for procedures currently in the development stages. The remedial action taken satisfies the requirement, however, emphasis was placed on the necessity to identify and conduct I&T prior to an individual performing any quality affecting activities.
- D. QAIP 06-10 identifies Duke Power Co. Technical Services Division (TSD) as having responsibility and action. No interface, either organizationally or contractually could be established between the M&O and TSD. The activities being performed by TSD appear to be limited to the distribution of QAIPs. However, if TSD is to perform quality affecting activities in accordance with the M&O program, the interfaces and responsibilities must be defined.

8.2.4 An exit meeting was held on October 3, 1991, to present the results of this surveillance to the M&O-MRS Design Organization. During the meeting the surveillance team presented the observations identified and expressed the importance of having the appropriate controls in place prior to performing quality affecting activities. The M&O representatives were informed that had this surveillance been a qualification audit, their program and its implementation to date would have been considered unacceptable and ineffective to perform

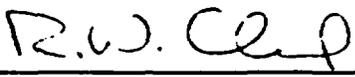
quality affecting activities. Strong emphasis was placed on expediting the issuance of the remaining QAPs, reviewing and revising the existing QAIPs to assure compliance to the QAPD and the applicable QAP requirements and assuring that personnel performing quality affecting work are appropriately trained and qualified. Also, Quality Assurance personnel must be assigned to the Charlotte office to support and overview the MRS design related activities.

8.2.5 In conclusion the MRS Design Group does not yet have a quality assurance program in place to commence quality affecting activities related to conceptual design. Considering that no quality affecting design activities are being performed the concerns previously identified do not, at this time, have an adverse effect on quality. It is further understood that prior to the MRS Design Group commencing any quality affecting design activities a readiness review will be conducted to assure that an acceptable QA Program is in place.

9.0 Corrective Action Request

9.1. No Corrective Action Request were issued during this surveillance.

Prepared by:  11-26-91
Surveillance Team Leader Date

Approved by:  12/3/91
Director, OQA Date