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# TECHNICAL AND MANAGEMENT SUPPORT SERVICES

# QUALITY ASSURANCE PROGRAM DESCRIPTION

SCIENCE APPLICATIONS INTERNATIONAL CORPORATION (SAIC)

LAS VEGAS, NV

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TECHNICAL & MANAGEMENT SUPPORT SERVICES (T&MSS)

QUALITY ASSURANCE PROGRAM DESCRIPTION

APPROVAL/SIGNATURE PAGE

James B. Harper, Manager
T&MSS Quality Assurance

Date 10-26-90

John H. Nelson
T&MSS Project Manager

Date 10/26/90

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## POLICY STATEMENT

It is the Policy of Science Applications International Corporation (SAIC) Technical & Management Support Services (T&MSS) and its employees to provide the highest quality products, services, and management support to the Department of Energy (DOE) and its Yucca Mountain Project Office (YMPO). To assure the accomplishment of these critical activities, T&MSS has issued a Quality Assurance Program Description (QAPD) and implementing procedures which define the steps we will take to accomplish these activities. Compliance with the Quality Assurance Program by T&MSS personnel is mandatory.

The Project Manager of SAIC T&MSS is responsible for developing, maintaining, implementing, and verifying the activities accomplished under the QAPD. Each Assistant Project Manager (APM) whose organization performs quality-related activities is responsible for identifying those activities within his/her organization which are quality-related; establishing and clearly defining the duties and responsibilities of personnel within the organization who execute quality-related activities; planning, selecting, and training personnel; and establishing, maintaining, approving and following procedures and instructions for the accomplishment of these tasks.

The authority for defining the T&MSS QA Program and verifying its implementation is delegated to the T&MSS Quality Assurance Manager who is organizationally independent of the activities being accomplished and who reports directly to the Project Manager.

John H. Nelson
T&MSS Project Manager

INTRODUCTION

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The purpose of this document is to describe the quality assurance (QA) program of the Technical and Management Support Services (T&MSS) contractor to the Yucca Mountain Project Office (Project Office), describe responsibilities for achieving and assuring quality at T&MSS, describe the interfaces with T&MSS and the Project Office, and serve as the quality assurance program description for T&MSS. This document and the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements Document (QARD), reflect OCRWM policies and serve as the principle documents of the T&MSS QA program.

The T&MSS QA Program Description (QAPD) provided in this document covers activities affecting quality that are performed by T&MSS as a Yucca Mountain Project participant. Activities performed by T&MSS in a direct support capacity to the Project Office are described in, and controlled by, the OCRWM QAPD, and procedures of OCRWM and Project Office documents, as applicable.

The format and structure of this T&MSS QAPD provide a description of the T&MSS QA program in a manner that limits repetition of QA requirements found in the OCRWM QARD, its references and appendices. Each section of this document describes the provisions established by T&MSS to meet the requirements of the OCRWM QARD applicable to the T&MSS QA program as a Project participant.

The T&MSS Quality Assurance Program meets OCRWM QA requirements and those regulations and requirements promulgated by the Nuclear Regulatory Commission (NRC) as applicable to the Yucca Mountain Project. Attachment A, "T&MSS QA Program Basis," contains a listing of applicable QA regulations and requirements

Attachment B of this document describes the applicability of Project Administrative Procedures (APs) to T&MSS as a Participant.

The definitions provided in ANSI/ASME NQA-1, 1989 as supplemented by the OCRWM QARD are applicable to this document. Attachment C provides a listing of terms and definitions that are unique to the T&MSS QA Program.

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T&MSS QUALITY ASSURANCE PROGRAM DESCRIPTION

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## 1.0 ORGANIZATION

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The T&MSS organization consists of Science Applications International Corporation (SAIC), and its subcontractors, Harza Engineering Company and Westinghouse Electric Corporation. T&MSS has a participant role in the Yucca Mountain Project (YMP) as described in this section. T&MSS also has a support contractor role which is not within the scope of this document.

1.1 This section describes the T&MSS participant organization that executes the quality requirements in this program description. As work is assigned to T&MSS by the Yucca Mountain Project Office (Project Office), each T&MSS Assistant Project Manager and the T&MSS Quality Assurance (QA) Manager shall ensure that the scope of work assigned to them as delineated by the Project Office is executed under the requirements of this QAPD.

1.2 The T&MSS organization is depicted in Exhibits 1 through 5 of this section. These exhibits reflect the reporting relationships, titles and departments comprising the T&MSS organization and identifies those organizations to which this QAPD applies.

1.3 The T&MSS organizational components consisting of the following management positions listed below are responsible for those functions delegated specifically to T&MSS as a project participant. In addition, these managers establish the requirement for and provide training and indoctrination of assigned T&MSS personnel, and management assessments of the portions of their QA program, and the preparation and review of departmental procedures and instructions.

T&MSS Project Manager
T&MSS Deputy Project Manager
Assistant Project Manager, Programs and Operations
Assistant Project Manager, Resource Management
Assistant Project Manager, Regulatory & Licensing
T&MSS Quality Assurance Manager

NOTE: These Assistant Project Managers also have interfacing responsibilities with other T&MSS organizational components, and with the Project Office as defined in the Project Office QAPD.

### 1.3.1 T&MSS Project Manager

The T&MSS Project Manager is the Technical Project Officer for T&MSS with overall responsibility for implementation of the T&MSS QA program. He reports directly to the YMP Project Manager for technical direction and has authority over all T&MSS personnel

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assigned to work under the scope of services provided by T&MSS as a participant in support of the Yucca Mountain Project. The T&MSS Deputy Project Manager assists the T&MSS Project Manager as required and acts in the capacity of the T&MSS Project Manager during his absence or at the explicit direction of the T&MSS Project Manager. The T&MSS Project Manager's responsibilities include (but are not limited to) the following:

A. planning and directing work activities;
B. complying with quality requirements imposed by quality program documents;
C. satisfying staff resource needs, cost, and schedule objectives, and deliverable requirements;
D. approving and implementing the T&MSS QAPD and the T&MSS implementing procedures;
E. implementing the YMP procedures as they apply to the T&MSS scope of work;
F. implementing corrective actions for deficiencies identified within the T&MSS quality program;
G. providing periodic assessment to the Project Office regarding the adequacy and effectiveness of the T&MSS quality program; and
H. approving and implementing Stop Work Orders.

1.3.2 Assistant Project Manager (APM), Programs and Operations

The APM, Programs and Operations reports directly to the Project Manager and has overall responsibility for implementing the following activities in accordance with QA program requirements.

A. Regional Studies including:
- identifying potential repository related socioeconomic effects,
- assessment and monitoring of regional socioeconomic structure,
- strategies to mitigate adverse socioeconomic impacts, and
- socioeconomic support for financial assistance programs.

B. Transportation Studies including:
- rail and highway access,
- transportation safety risk, and
- transportation interface for repository/operation planning.

C. Records Management including:
- Local Records Center, and
- Document Control.

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D. Environmental Field Programs including:
- planning and coordination,
- site reclamation planning and coordination, and
- operation and maintenance of field equipment for air quality and meteorological monitoring.

E. Radiological Field Programs including:
- program planning and implementation,
- operation and maintenance of radiological field monitoring equipment,
- site analysis and reporting,
- field analysis and reporting,
- radiological laboratory analysis,
- radiological protection (safety), and
- radiological engineering requirements, implementation and support.

1.3.3 Assistant Project Manager, Resource Management

The APM, Resource Management reports directly to the Project Manager and is responsible for implementing the following activities in accordance with the QA program requirements:

A. Procurement of items and services in support of T&MSS participant, and
B. Verifying the education and experience of T&MSS personnel.

1.3.4 Assistant Project Manager, Regulatory and Licensing

The APM, Regulatory and Licensing reports directly to the Project Manager and is responsible for implementing safety and health-related sections of the Environmental Safety and Health Plan, as well as Environmental Compliance and Permitting in accordance with the QA program requirements.

A. The Safety and Health Compliance Department (SHCD)

SHCD is responsible for identifying project and management safety and health requirements applicable to T&MSS field activities through review of applicable Occupational Safety and Health Administration (OSHA) regulations, Department of Energy (DOE) orders, and Project Office plans and procedures. The SHCD coordinates the activities of a safety committee, reviews field activities procedures for compliance to health and safety requirements, coordinates inspections and abatement of identified deficiencies (Health & Safety), and coordinates responses to employee complaints and unsafe conditions. The SHCD

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also reviews and documents, as required, unplanned non-radiological events that have a potential for safety or health impact.

B. Environmental Compliance and Permitting

The Environmental Compliance and Permitting Department primarily performs Project Office support functions in the areas of environmental regulatory compliance and permitting including coordination with project participants, and will provide the T&MSS organization with regulatory surveillance support to ensure compliance with federal, state, and local environmental and land access requirements as they apply to T&MSS activities.

1.3.5 T&MSS Quality Assurance Manager

A. T&MSS QA Manager Responsibilities

The T&MSS quality assurance responsibilities are executed through the T&MSS Quality Assurance (QA) Manager. The T&MSS QA Manager reports directly to the T&MSS Project Manager with specific interface responsibilities with the YMP Project Office QA organization. He shall have unencumbered access to higher levels of management on quality issues. The T&MSS QA Manager is at the same or higher organizational level as the highest line manager responsible for quality-related activities. This position has the appropriate organization position, responsibilities and authority to exercise proper control over the T&MSS QA program. These controls include complete responsibility and authority to:

- identify quality problems;
- initiate, recommend or provide solutions to these problems;
- verify implementation of solutions;
- exercise stop work authority through established channels as required;
- assure control of processing, delivery, installation or operation until proper disposition of a condition adverse to quality has been achieved;
- directing and managing the T&MSS QA program;
- review, approval, and issuance of the QAPD including revisions, and review and approval of the associated implementing procedures;
- verifying the adequacy and effectiveness of the implementation of quality assurance requirements by conducting audits, surveillances, reviews and performing trend analyses;

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- coordinating T&MSS QA activities;
- initiating, reviewing, verifying and approving those documents used to identify QA program deficiencies; and
- indoctrination and training of the QA staff.

B. Independence

The QA organization shall have sufficient authority, organizational freedom, independence from cost and schedule (regarding quality issues) and access to work areas to carry out the duties and responsibilities previously described.

1.4 Quality Issues

1.4.1 T&MSS shall identify in procedures the methodology for elevating disputes regarding differences of opinion involving quality issues at any given organizational level where such disputes cannot be resolved at the working level.

1.4.2 Allegations of inadequate quality shall be resolved in accordance with procedures established by the Yucca Mountain Project Office.

1.5 Interfaces

Interfaces between the Yucca Mountain Project Office, other participants, and T&MSS shall be described in procedures, plans, or instructions, as appropriate.

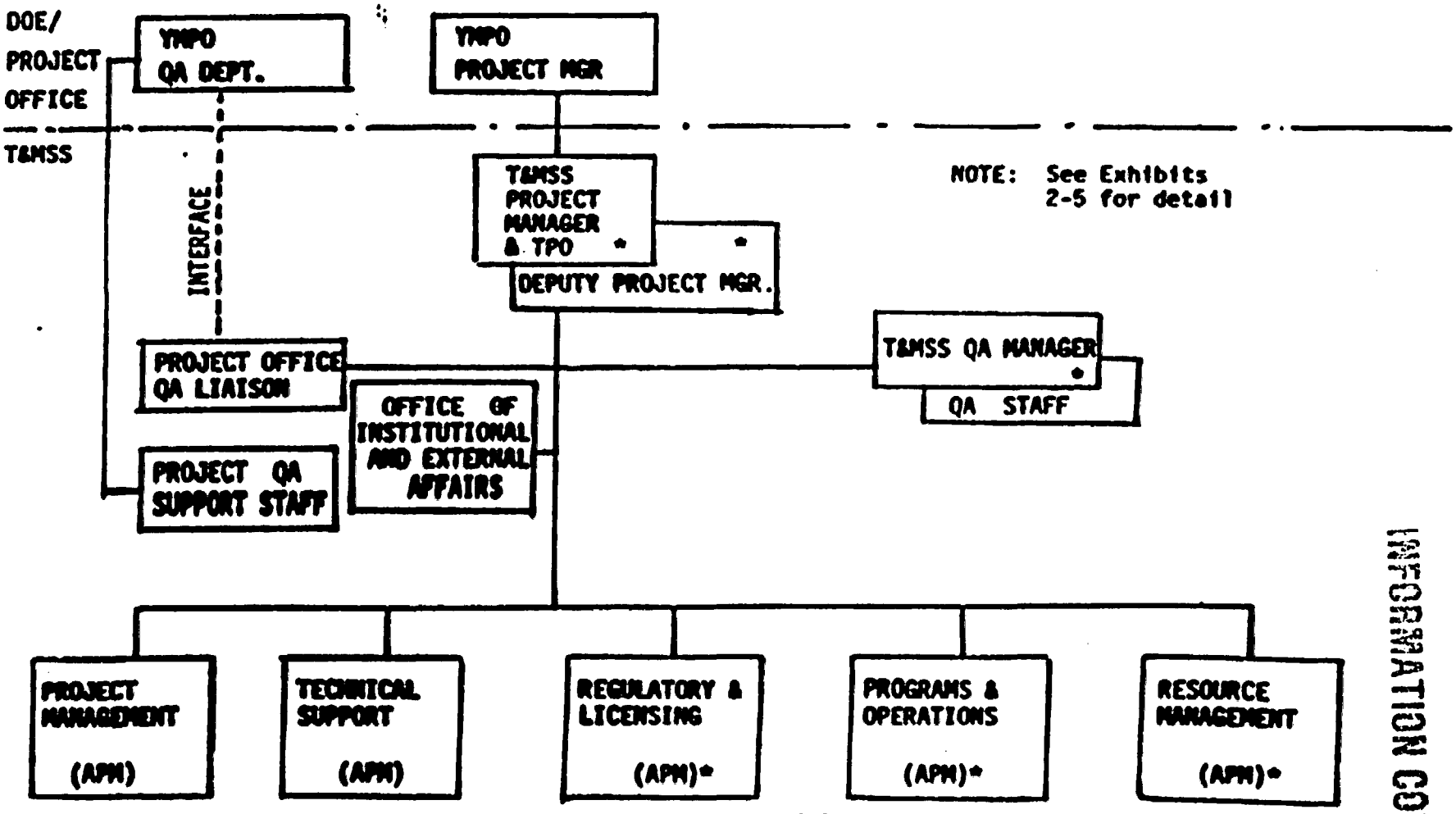
1.6 Delegation of Work

The T&MSS organization may delegate work to others but shall retain the responsibility for it. Where work is delegated, it shall be described and documented. T&MSS shall be responsible for evaluating any delegated work by audits and surveillances.

1.7 The T&MSS organization shall identify Procedures for issuing and lifting stopwork orders. Provisions shall include:

- o Criteria and methodology for stopping work and for lifting stopwork orders.
- o Exact definition of work being stopped.
- o Authorities and responsibilities.

EXHIBIT 1
SECTION 1




Asterick (*) Boxes Reflect Organizations in the Scope of the T&MSS Participant Organization

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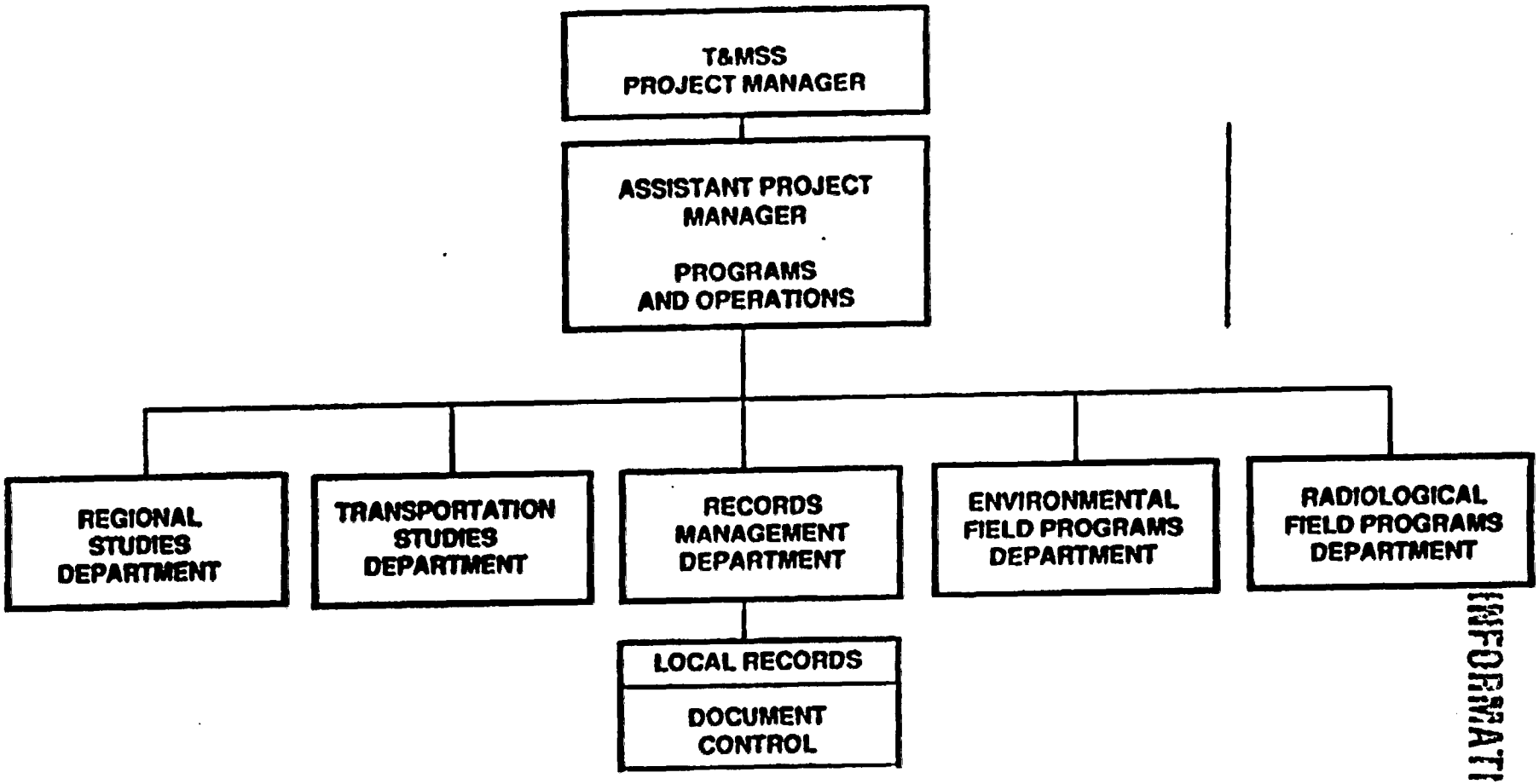


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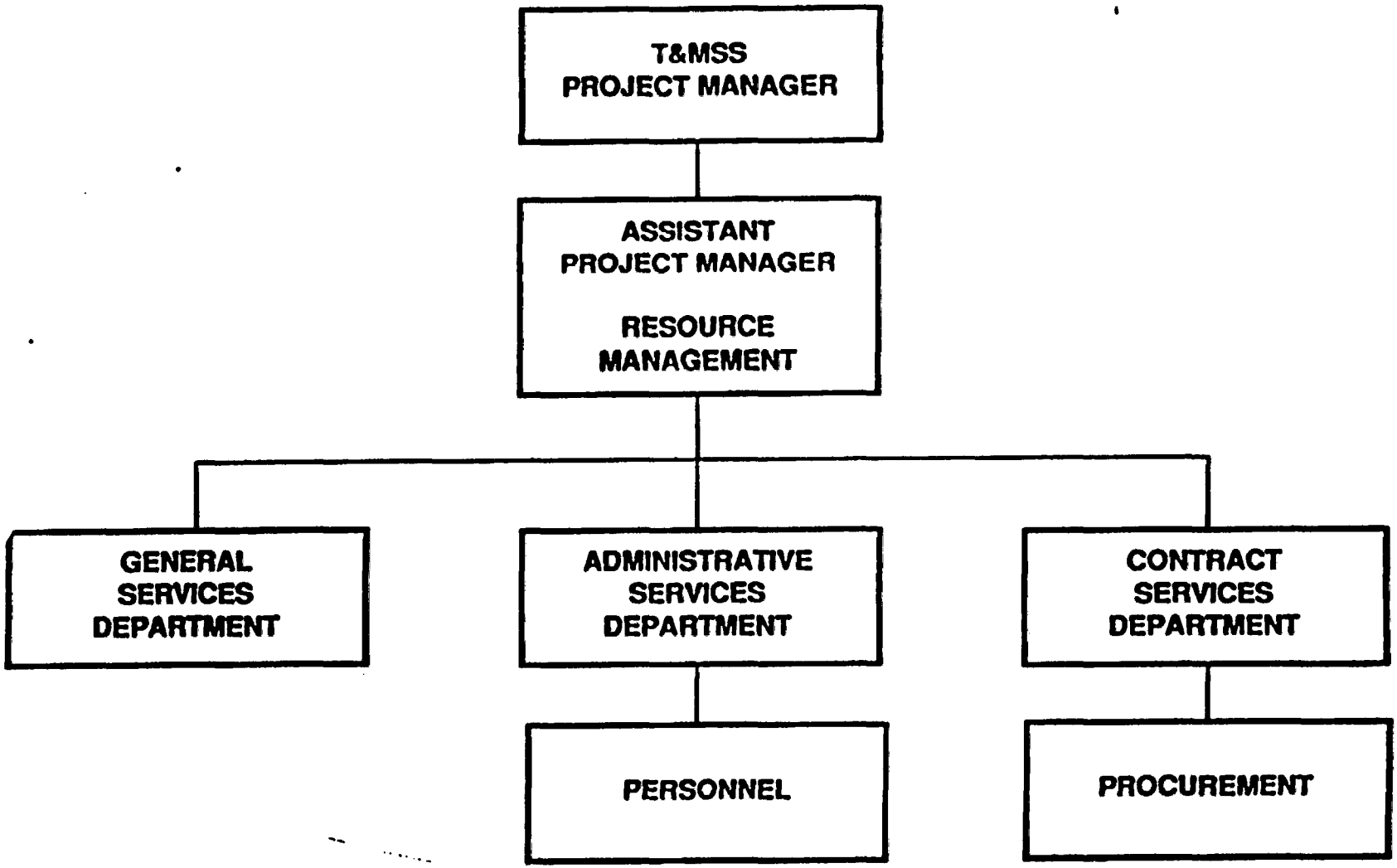

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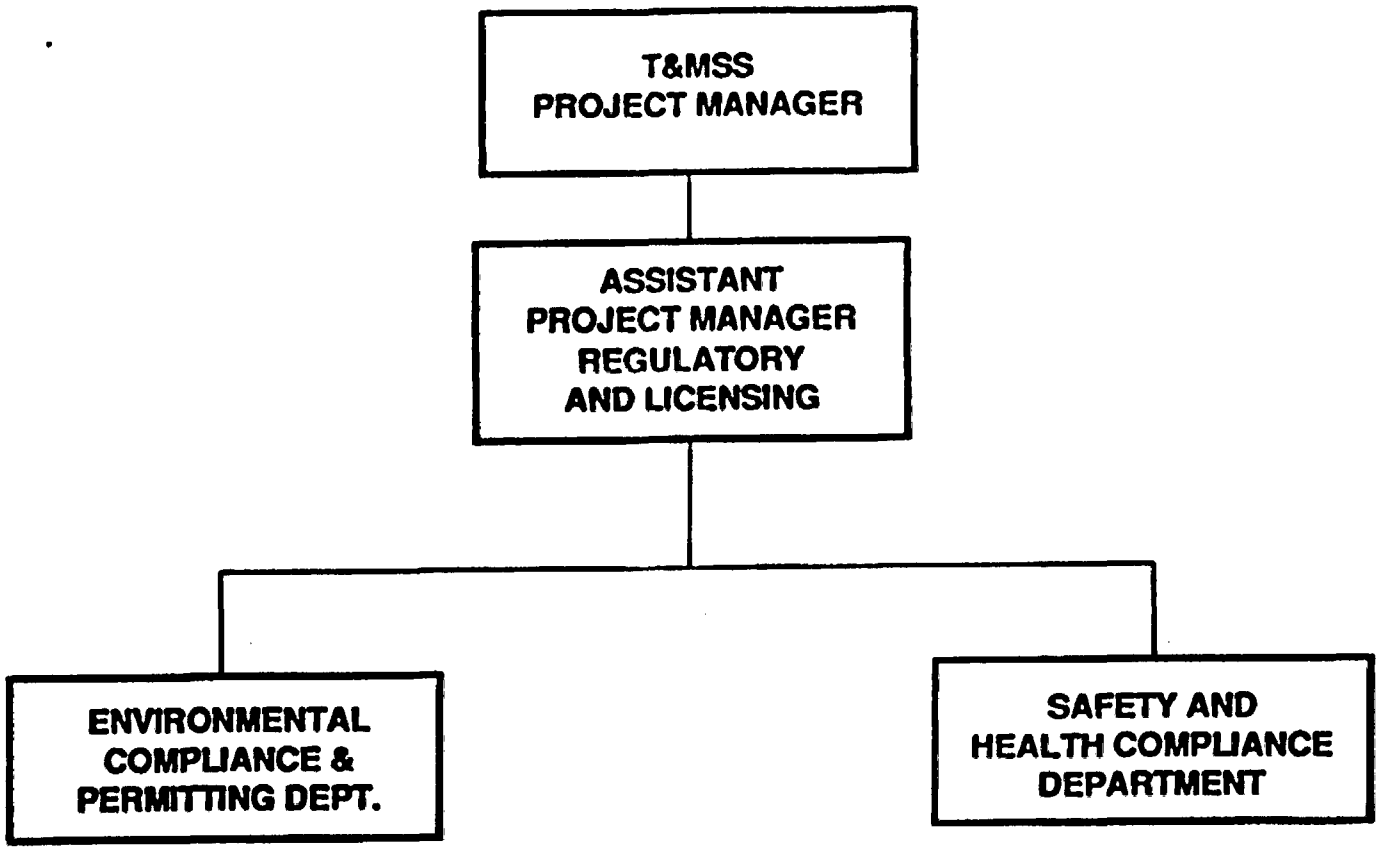


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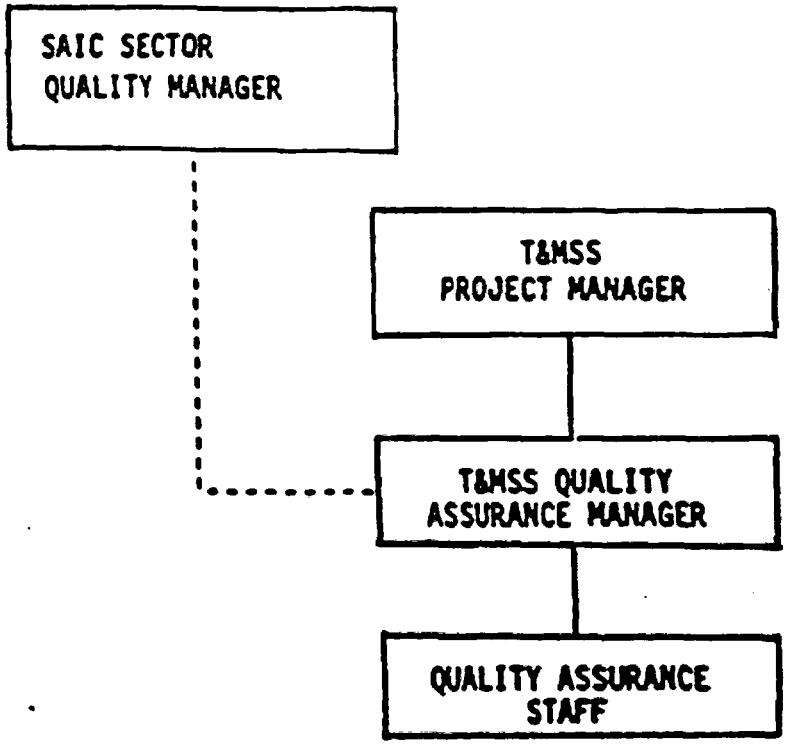
EXHIBIT 5




------- Access to Upper Management outside YMP on Quality Issues

## 2.0 QUALITY ASSURANCE PROGRAM

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The T&MSS organization has developed this document as its description of the quality assurance program that it shall implement. The T&MSS quality assurance program consists of the T&MSS QAPD and related procedures and instructions and complies with the OCRWM QARD requirements that are applicable to the T&MSS participant activities for the Yucca Mountain Project.

### 2.1 Scope

The scope of activities that constitute the T&MSS QA program includes Regional Studies, Transportation Studies, Environmental Field Programs, Radiological Field Programs, Procurement, Records Management, Document Control, Environmental Compliance and Permitting, Safety and Health Compliance, and Resource Management. Additional activities may be included at the direction of the YMP Project Office. Exhibit 1 of this section depicts the document hierarchy which sets forth requirements and guidance that the T&MSS QA Program must incorporate, as appropriate, to its scope of work. The T&MSS QA Program is implemented by line organization staff, management, and the quality assurance staff.

### 2.2 T&MSS QA Program

#### 2.2.1 QA Requirements

The quality assurance requirements for the T&MSS QA program are identified in the OCRWM QARD and its Appendix A, Amplifications of Quality Assurance Program Requirements for the Mined Geologic Disposal System (MGDS). Attachment A to this document lists the requirements documents upon which this program is based. When upper tier requirements, identified in the OCRWM QARD, are revised or changed, the T&MSS QAPD shall be revised to incorporate these changes within 20 working days and submitted to the Project Office for approval.

#### 2.2.2 YMP APQs

The quality-related YMP Administrative Procedures (APQs) provide the implementing interface controls utilized between the Project Office and the T&MSS participant organization activities. T&MSS procedures and instructions shall address the YMP APQs as necessary to implement its QA program. The applicability of APQs used directly by T&MSS participant activitie are identified in Attachment B to this document.

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2.2.3 T&MSS QAPD

The T&MSS QAPD describes the provisions established by T&MSS to implement the applicable requirements of the OCRWM QARD, the T&MSS organizational responsibilities and authorities for achieving and verifying quality, the interfaces between T&MSS and the Project Office, and the overall QA program. Provisions are described in the T&MSS QAPD to meet each section of the OCRWM QARD. The T&MSS QAPD is reviewed by appropriate T&MSS management, reviewed and approved by the T&MSS Project Manager and T&MSS QA Manager, and submitted to the Project Office for approval.

2.2.4 The T&MSS QA Department maintains QA Program Requirements Matrices that describe how T&MSS implements the NRC Review Plan, OCRWM QARD, ASME NQA-1 1989, and this QAPD. The Matrices link the requirement to implementing procedures or instructions.

2.2.5 T&MSS Implementing Procedures and Instructions

The T&MSS implementing procedures and instructions delineate the specific administrative and quality assurance controls used to implement the QA requirements. The three categories of implementing procedures are as follows:

A. Standard Practice Procedures (SP) - Procedures that assign responsibilities for action to personnel from more than one APM/Department Manager with the purpose being to tie together the activities into one flow relative to an activity or task. SPs are reviewed and approved by the T&MSS Project Manager and QA Manager.

B. Organizational Procedures (OPs) - Applies to activities and work associated with a requirement or responsibility contained within an organizational entity such as an Assistant Project Manager organization (can be used for Department/Divisions within an APM). OPs are reviewed and approved by the appropriate APM and QA Manager.

C. Work Instructions (WIs) - Implementing procedures that detail all essential work steps for the worker associated with a task or function. These procedures typically include step-by-step work instructions that may or may not require performer sign-off as each step is completed. WIs are reviewed and approved by the appropriate APM and QA Manager.

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As required, T&MSS shall implement YMP Project Office procedures as part of its QA program. Attachment B identifies the applicability of quality related Project Administrative Procedures (APQs).

2.2.6 Delegated Work

The delegation of work activities through consultants, subcontracts, etc. is controlled as described in Section 1.6 of this QAPD. The T&MSS QA organization reviews and approves subcontractor QA program documents.

2.2.7 Quality Assurance Program Controls

Quality assurance controls are applied to items and activities affecting quality under suitably controlled conditions that are performed by the T&MSS organization. The T&MSS QA program invokes controls over activities through procedures and instructions, internal audits and surveillances of the QA program by an independent QA staff, external audits and surveys of T&MSS suppliers of items and services, document reviews and management assessments. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied.

SHALL, SHOULD, and MAY have unique meanings as used in the QAPD and implementing procedures:

A. SHALL denotes an action required by a T&MSS commitment, by regulations, orders, or directive of T&MSS management. In playscript format, SHALL is implied when no specific adverb (should, may) is used.

B. SHOULD denotes an action to be completed unless there is (are) good reason(s) not to comply. Treated the same as SHALL by T&MSS personnel, but not subject to compliance auditing by NRC.

C. MAY denotes an action which is completed at the discretion of the person implementing the procedure.

2.2.8 Readiness Reviews

T&MSS management performs readiness reviews as deemed appropriate. Readiness reviews are used to ensure that specified prerequisites and programmatic requirements of major scheduled/planned activities have been satisfied prior to starting that activity.

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2.2.9 Determination of Importance and Graded QA for Items and Activities

The determination of importance of items and activities and the application of the "graded" approach to QA shall be consistent with the OCRWM QARD and Project Office procedures. T&MSS shall utilize Project Office procedures or develop T&MSS procedures as appropriate to identify items and activities important to radiological safety and waste isolation in accordance with NUREG 1318. These procedures shall enable T&MSS to identify controls for each item and activity; identify the scientific or technical information to be collected, analyzed, and/or used for design or site characterization; identify provisions for the identification of the required QA records related to these activities; and, identify QA program management controls.

2.2.10 "Qualified" Data

The T&MSS QA program provides for the acceptance of data or data interpretations for use in licensing activities that were not generated under the controls of the YMP Quality Assurance program. Once accepted, these data are classified as "qualified" for licensing purposes. Specific methods for acceptance of these data shall be described in T&MSS procedures and/or Project Office procedures consistent with the requirements of NUREG 1298.

2.2.11 Personnel Selection, Indoctrination and Training

T&MSS personnel assigned to perform activities that affect quality shall receive appropriate indoctrination or training prior to performing work. T&MSS procedures shall address the personnel selection, performance of indoctrination, training, and qualification activities.

An individual's manager is responsible for assuring that he(she) is trained and qualified. T&MSS management establishes job descriptions for each job position in the T&MSS scope of work. The extent and need of training for T&MSS personnel is based on an evaluation of the scope, complexity, and nature of the job position and associated activity and on the education, experience and proficiency of the person. The T&MSS Resource Management staff verifies the education and work experience of T&MSS personnel.

Personnel selected for T&MSS quality affecting positions shall have the education, experience, and training commen-

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surate with the functions associated with the job position description. Initial qualification shall be documented. Proficiency shall be maintained. Responsible managers shall evaluate and assess the need for additional indoctrination and training, as applicable, as assignments, position and procedures change. Retraining needs are determined by an annual evaluation.

2.2.11.1 Verification personnel such as lead auditors and inspectors shall be qualified in the principles, techniques, and requirements of the verification activity being performed (e.g., Audits, Inspections) in accordance with approved procedures and instructions which reflect the requirements established in the OCRWM QARD and ANSI/ASME NQA-1. Qualification records for these personnel shall be maintained.

2.2.11.2 Classroom training shall be performed in accordance with documented and approved lesson plans. Other forms of training include group instructions, on the job training, and procedural reading assignments.

2.2.11.3 Personnel shall receive annual proficiency evaluations which shall be documented and discussed with the person evaluated.

2.2.11.4 Records associated with indoctrination and training shall reflect attendance sheets, objective and content of the program material presented, and date(s) of attendance as applicable.

2.2.11.5 Indoctrination and training are evaluated through the audit, surveillance, and trend programs.

2.2.12 Management Assessments

T&MSS shall have management assessments of the T&MSS QA program conducted at least annually. The assessment shall be performed by management above or outside the T&MSS QA organization by, or at the direction of, the T&MSS Project Manager. The management assessment shall determine the effectiveness of the system and management controls that are established to achieve and assure quality, and the adequacy of resources and personnel provided to the QA program. These evaluations are performed, documented, and reported to upper management. Any conditions adverse to quality identified in these assessments shall be documented, tracked, and corrected.

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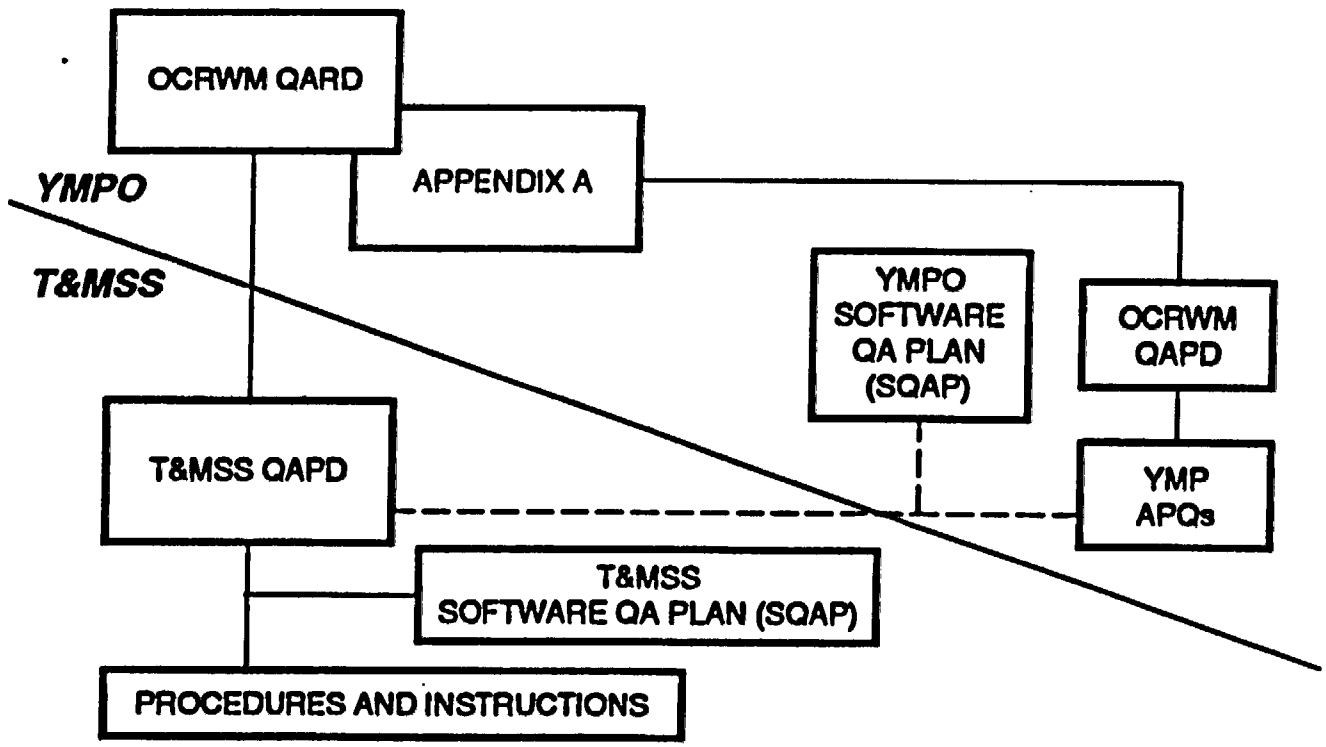
2.2.13 Management Information Reporting and Tracking

Communication and information systems shall be established to ensure timely reporting, dissemination, and tracking of quality assurance management information such as the status of QA program implementation, status of resolutions of significant conditions adverse to quality, and summaries of management overview results. This information may be found in meeting minutes, audits and surveillances reports, trending reports, and other doucments. It shall be furnished to T&MSS upper management and to the Project Office on at least a quarterly basis.

Exhibit 1
Section 2

QUALITY ASSURANCE PROGRAM
T&MSS DOCUMENT HIERARCHY




——— REQUIREMENTS CHAIN
– – – INTERFACE*

* Except where identified in Attachment B of this QAPD

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## 3.0 DESIGN CONTROL

Design activities shall be accomplished in accordance with written procedures. Those procedures shall describe the process by which the specification of technical requirements are planned, controlled, and implemented. Design inputs, interfaces, outputs, reviews, changes, and deficiencies shall be controlled by approved procedures.

### 3.1 Engineered Structures, Systems and Components.

T&MSS is not assigned the responsibility to perform the design of structures, systems and components.

### 3.2 Computer Software

The program description for Computer Software Controls is defined in Section 19 of this document.

### 3.3 Scientific Investigations

The program description for Scientific Investigations is defined in Section 20.

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## 4.0 PROCUREMENT DOCUMENT CONTROL

The procurement of items and services by the T&MSS organization shall be accomplished in accordance with approved procedures. These procedures shall describe the process by which procurement planning is accomplished, and the process by which procurement documents are prepared, reviewed and approved, revised and controlled. The following criteria shall be applied to all tiers of procurement as applicable and shall be set forth in the procurement documents.

4.1 T&MSS shall have a statement of the scope of work or services to be performed by the supplier.

4.2 Technical requirements as well as codes, standards, reference drawings, and specifications as applicable shall be specified.

4.3 Supplier QA programs shall be reviewed and approved by the T&MSS QA organization for quality-related purchases. To the extent necessary subcontractors quality programs shall be acceptable based on the scope, complexity, and importance to radiological safety or waste isolation of the item or service being procured. T&MSS may authorize some or all supplier activities to be performed under T&MSS's QA program when performance under a supplier's quality assurance program would be impractical. Material, items, and services shall be purchased from approved procurement sources.

4.4 Right of access shall be established by the procurement documents at each tier to assure that T&MSS can inspect, surveil, or audit the supplier facilities and records as necessary.

4.5 Requirements shall be established which identify the specific documentation to be furnished by the supplier (Certificates of Conformance, Calibration Certificates, etc.).

4.6 The quality assurance requirements for items and services shall be provided.

4.7 Requirements for control of nonconformances shall be established.

4.8 Controls shall be established for the evaluation, identification, and requirements for spare and replacement parts.

4.9 Acceptance criteria shall be identified for procured items and services and compliance with such criteria shall be verified by an approved acceptance, inspection, and verification program.

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4.10 Reviews of procurement documents shall be performed by the technical organization procuring the item/services and T&MSS QA as a minimum. Persons performing these reviews shall have access to pertinent information and an adequate understanding of the requirements and intent of the procurement documents. QA reviews shall assure that documents are prepared in accordance with procedures; that these documents reflect adequate and appropriate quality assurance requirements; and, include applicable regulatory, design basis, and related technical information, and that these requirements are correctly stated.

4.11 Changes to procurement documents shall be controlled in the same manner as the preparation and issuance of the original documents.

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## 5.0 INSTRUCTIONS, PROCEDURES, PLANS, OR DRAWINGS

The T&MSS participant organization implements its quality program through approved procedures, instructions, plans, or drawings that are appropriate to the work or activity. These instructions, procedures, plans, and drawings shall be consistent with the requirements of the documents identified in Attachment A and this QAPD. These instructions, procedures, plans, or drawings, as applicable, shall include or reference appropriate quantitative or qualitative acceptance criteria as required for determining that described activities have been satisfactorily accomplished, and have been reviewed and approved by T&MSS QA.

### 5.1 Preparation, Distribution, and Control

5.1.1 Instructions, procedures, plans, or drawings (as applicable) shall be prepared by the department or organization responsible for implementing the activity.

5.1.2 These documents shall be reviewed, approved, distributed, and controlled as described in Section 6 of this document.

5.1.3 When scientific notebooks are used to document scientific investigations, the requirements of Section 20 shall prevail.

### 5.2 QA Program Compliance

T&MSS shall demonstrate through a matrix system or other means that each of the applicable requirement of the OCRWM QARD, the NRC Review Plan, ANSI/ASMSE NQA-1, and this QAPD is properly documented and covered by implementing procedures and/or instructions.

T&MSS implements APQs. Attachment B identifies those APQs directly and indirectly implemented by T&MSS and those that do not apply to T&MSS participant activities.

### 5.3 Change Control

All changes to instructions, procedures, plans, and drawings are required to be processed in accordance with approved procedures.

### 5.4 Implementation Verification

Compliance with approved instructions, procedures, plans, and drawings by T&MSS personnel is required.

T&MSS QA shall verify appropriate implementation of T&MSS instructions, procedures, plans, or drawings through internal audits and surveillances.

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## 6.0 DOCUMENT CONTROL

T&MSS shall develop and implement procedures that describe the methodology for preparing, reviewing, approving, revising, and issuing quality related program documents in a controlled manner.

### 6.1 Document Preparation, Review, Approval, and Revision

Preparation of documents for quality related activities shall include as a minimum the following requirements:

A. Identification of the individuals or organizations responsible for the preparation, review, approval, revision, and release of the document.

B. Independent review of documents by qualified personnel, who were not materially responsible for the content of the document, for technical adequacy, completeness, correctness, and inclusion of appropriate quality requirements prior to approval and issuance.

C. Access by the reviewer to pertinent background information or data to assure a complete review.

D. Documented resolution of review comments for those comments considered mandatory by the reviewer prior to approval and issuance of the document.

E. An effective date shall be identified.

F. T&MSS QA shall provide appropriate reviews and concurrences of all quality related documents including revisions. Approvals shall be described in procedures appropriate to the work or activity.

### 6.2 Issuance and Distribution

Document issuance and distribution shall be controlled to assure that correct, applicable, and current documents are available to T&MSS personnel performing activities at work locations. Control shall either be through the Document Control Center at T&MSS or through established procedural controls. T&MSS Document Control shall perform the controlled document distribution, tracking, and maintenance functions for the Project Office. Documents such as Nonconformance Reports, Quality Finding Reports, Audit and Surveillance Reports, and Inspection Reports shall be controlled through their respective governing procedures.

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6.2.1 Controls for issuing quality related T&MSS documents include:

A. Identifying and marking of documents including documents that are released prior to the completion of the approval process. Any document that is released before approval shall be uniquely identified, controlled, authorized for release, and shall reflect the basis for release. The unverified (approved) portions of the document shall be identified and the use of the document shall be prescribed. Quality affecting work shall only be accomplished using approved documents.

B. Maintaining document distribution lists.

C. Marking, removal, or destruction of obsolete or superseded documents.

D. Maintaining of an index of the revision status for documents.

E. Assigning responsibility for document release.

6.2.2 Implementing procedures or instructions shall define the criteria for identifying documents that are to be controlled. Documents such as instructions, procedures, plans, drawings, etc. which have been identified as "CONTROLLED" shall be submitted to the T&MSS Document Control Center. The following provisions describe additional controls to 6.2.1 for these documents:

A. Use of a receipt acknowledgment system for controlled documents.

B. Maintaining a master list of controlled documents.

C. T&MSS personnel using "CONTROLLED" documents are responsible for acknowledging document receipt, using only the latest revision, and marking, returning, or destroying obsolete or superseded documents.

6.3 Change Control

All changes to documents except for "minor" changes shall be reviewed and approved by the same organization that approved the original, unless another organization is specified by the Project

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Manager. Minor changes such as inconsequential editorial changes do not require such a review and approval. T&MSS procedures shall identify the responsibility for authorizing, reviewing, and approving such changes. An evaluation of changes shall be conducted to determine any potential impact on the waste isolation capability of the site, or interference with other site characterization activities. Any impact on previous work shall be determined and evaluated, as required.

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## 7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

Procedures describing the procurement process shall be developed to ensure that delivered items and services comply with purchasing documents and quality assurance requirements. The T&MSS procedures and instructions shall comply with the following provisions:

### 7.1 Procurement Planning

T&MSS shall plan its procurement activities as early as practical to assure interface compatibility and a uniform approach to the procurement process. Procurement of items and services shall not be initiated until these requirements are satisfied. Procurement planning shall provide for the following as applicable:

A. procurement document preparation, review, and change control;

B. selection of procurement sources;

C. bid evaluation and award;

D. identification of minimum specifications;

E. T&MSS audits or surveillances of suppliers including the establishment of witness or hold points as necessary;

F. control of nonconformances;

G. corrective action;

H. acceptance of item or service; and

I. quality assurance records.

### 7.2 Supplier Selection

T&MSS QA is responsible for the evaluation and determination of acceptability of suppliers based on input from the technical personnel procuring items/services and on the capability of the supplier to furnish the required items or service in accordance with procurement document requirements. Acceptable suppliers shall be listed on a Qualified Suppliers List (QSL), maintained and controlled in accordance with T&MSS procedures. Measures for evaluation and selection of suppliers shall include one or more of the following:

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7.2.1 Documented evaluation of the supplier's history of providing an identical or similar product that performs satisfactorily in actual use.

7.2.2 Review of the supplier's current QA records supported by documented qualitative and quantitative information that can be objectively evaluated.

7.2.3 An evaluation by T&MSS QA and technical staff of the supplier's facilities, personnel, implementation of their QA program or the ability of the supplier to use the T&MSS QA program, as applicable, to ensure the adequacy of the supplier's technical and quality capability.

7.3 Bid/Proposal Evaluations

The procuring and technical organizations and QA participate in evaluating bids and proposals for conformance to procurement, technical, and quality assurance requirements.

7.4 Supplier Performance Evaluation

7.4.1 As required, T&MSS shall establish interface measures with the supplier to ensure that the performance evaluation methods are appropriate, adequate, and understood. These methods include:

A. requiring the supplier to identify planning techniques and processes,

B. reviewing supplier generated documents relative to the procurement activity,

C. providing change control criteria in procurement documents,

D. documenting information exchange between the supplier and T&MSS, and

E. establishing the extent of source surveillance and inspection activities necessary.

7.4.2 Verification of Supplier Performance

The extent of verification of supplier performance by T&MSS is dependent on the relative importance, complexity, and quantity of the item or services procured. Evaluation of established performance objectives, review of records,

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audits, surveillances, and inspections are methods by which verification of suppliers performance may be accomplished. The purchaser's verification activities shall not relieve the supplier of his responsibilities for verification of quality achievement.

7.4.3 When a supplier has an established QA program, T&MSS QA shall evaluate it to determine program adequacy prior to the supplier being qualified.

7.5 All technical and quality changes to procurement documents for items or services shall be initiated by a purchase requisition change notice and evaluated and processed in the same manner and with the same criteria as the original procurement documents.

7.6 Acceptance of Items or Services

T&MSS procedures shall establish criteria for accepting an item or service being furnished by a supplier. Supplier certificates of conformance, source verification, receiving inspection, or post installation testing at the T&MSS facility, or combinations of these methods are suitable means of acceptance. Certificates of conformance shall be traceable to items by purchase order number, part number, serial number, or some other approved method.

7.6.1 Receiving Inspection

Receiving inspection shall be performed by T&MSS personnel to verify conformance of supplied items to specified requirements per approved procedures. These inspection personnel shall be independent of the organization for which the item was procured, and assure problems are resolved prior to further use, processing, or delivery of an item. If these personnel are not part of the formal QA organization then this inspection activity shall be overviewed by the T&MSS QA organization. Inspection personnel shall be trained and qualified.

7.6.2 Post Installation Testing

When T&MSS elects to use post installation testing, test requirements, and acceptance criteria shall be established. Verification of the test performance, acceptance criteria, and results shall be documented.

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7.7 Acceptance of Services Only

When T&MSS procures only such services as third party inspections, engineering and consulting, installation, repair, overhaul, or maintenance work, acceptance activities shall consist of technical verification of data produced, or surveillance, audit, or both regarding the activity, and/or review of objective evidence for conformance to the procurement document requirements.

7.8 Control of Supplier Nonconformances

Nonconformances identified by T&MSS shall be identified and processed in accordance with Section 15 of this QAPD and approved T&MSS procedures. Where suppliers have a QA program, deficiencies identified in-process or at the supplier facility shall be identified per their program. Interfaces shall be established that ensure that supplier generated Nonconformance Reports with a "use-as-is" or "repair" recommendation for disposition are provided to T&MSS for approval.

7.9 Commercial Grade Items

Where scientific investigations or other T&MSS quality related activities require or provide for the use of commercial-grade items (as defined in this QAPD), then the following provisions are an acceptable alternative to the other requirements of this section. T&MSS procedures and instructions shall provide the detail for implementation of these requirements.

7.9.1 For an item to be considered a commercial-grade item, it must be described in the supplier or manufacturer's catalogue. This published product description shall be referenced in T&MSS procurement documents.

7.9.2 Scientific planning documents, study plans, or other documents, defining and planning the activity, shall identify the use of commercial-grade items (e.g. radiological and meteorological monitoring plans). The T&MSS department requiring commercial-grade items for its defined work activity shall determine if an alternate commercial-grade item can be used based on its intended function and application.

7.9.3 Source evaluation and selection requirements for commercial-grade items are applicable (see para. 7.2) as determined by T&MSS QA and the T&MSS procuring organization based on the complexity of the item and importance to safety or waste isolation.

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7.9.4 Commercial-grade software used to support quality affecting activities shall be acquired and controlled according to the requirements of the T&MSS Software QA Plan (SQAP).

7.9.5 After receipt of a commercial-grade item, it shall be determined that:

A. the item is not damaged;

B. the item received was the item ordered;

C. inspection, testing, or both are performed to ensure conformance to the manufacturer's published description; and

D. documentation, as applicable to the item, was received and is acceptable.

7.10 Control of Supplier Generated Documents

T&MSS procedures and instructions shall ensure that controls for documents that are provided by the supplier and furnished in accordance with procurement requirements include provisions for receipt, review, and evaluation. These documents include but are not limited to drawings, specifications, designs, and QA program plans.

7.11 QA Records

All procurement documentation required to demonstrate quality, including supplier generated documents, surveillance reports, receiving inspection reports, purchase orders/requisitions, and change requests associated with procuring items or services, evaluating and approving suppliers, or receiving and evaluating items and services are QA records. They shall be processed and controlled in accordance with Section 17 of this QAPD.

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## 8.0 IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES, AND DATA

T&MSS procedures and instructions shall describe the methods for ensuring that only correct and accepted items, samples, and data are utilized in accordance with the requirements established in OCRWM'S QARD. Control of software is identified in Section 19.

### 8.1 Samples

The T&MSS procedures and instructions for the identification and control of samples shall be generated by the organization responsible for the activity and shall ensure that the following provisions are met.

A. Samples shall be identified and controlled in a manner consistent with their use.

B. Interfaces with the Sample Management Facility and other organizations shall be established to define responsibilities for the collection, identification, handling, storage, transportation, traceability, testing, and disposition of samples. Records generated from these activities shall be identified.

C. T&MSS shall either physically identify samples or identify samples on records traceable to the sample. Traceability of samples from acquisition to final disposition is required, including traceability to appropriate documentation.

D. Controls shall be established to preclude the mixing of samples or the contamination of samples. Verification of identification of samples shall be performed prior to the transfer or release by T&MSS or the receipt from other organizations. Samples whose identification or integrity cannot be verified shall not be used in quality related or quality affecting activities.

### 8.2 Data

T&MSS procedures shall establish measures ensuring that data resulting from T&MSS activities are properly identified and traceable to the source from which it was generated. This identification and traceability shall be maintained through final disposition. Unacceptable data shall be controlled to prevent inadvertent use; its disposition shall be justified and documented.

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Data gathered under a QA program that does not meet the requirements of the OCRWM QARD shall be qualified per the requirements of Section 2.2.9 of this QAPD and NUREG 1298.

8.3 Items

Items shall be controlled as follows:

A. Materials, parts, components, and equipment shall be identified either by physical markings or by records traceable to the items at all times during the life of the item.

B. Marking materials and methods shall be applied using materials and methods which provide a clear and legible identification and do not detrimentally affect the function or service life of the item marked.

C. Marking or identification requirements shall be identified in procurement documents or specifications as necessary.

D. Identification of items shall be verified and documented as appropriate prior to use or release.

E. Items having limited calendar or operating life or cycle shall be identified and controlled to preclude inadvertent use of items whose shelf life or operating life has expired.

F. The provisions for control of item identification shall be consistent with the planned duration and conditions of storage

G. Plans, Procedures, or Instructions shall identify items necessary to support scientific investigations.

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## 9.0 CONTROL OF PROCESSES

While the requirements for process control apply to both scientific investigations and engineered items (special processes), only processes relating to scientific investigations apply to T&MSS activities. The control of these processes are described in procedures and instructions which ensure that the collection, preparation, and analysis of data are controlled and maintained. Process controls for laboratory and field processes use standard techniques for which reliability has been previously demonstrated, and new techniques requiring qualification as addressed in Section 20 of this QAPD and in OCRWM's QARD. T&MSS procedures and instructions shall address qualification and documentation requirements for personnel and processes.

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## 10.0 INSPECTION

Inspection criteria apply only to engineered items and not to scientific investigation activities. As such, inspection for T&MSS activities is limited to "receiving and source inspection" as described in Sections 7.6 and 7.6.1 of this QAPD. Procedures describing these activities shall be developed and implemented in accordance with OCRWM QARD requirements as follows:

### 10.1 Inspection Procedures and Instructions

- T&MSS procedures and instructions developed for receiving inspection activities shall incorporate the requirements of ANSI/ASME NQA-1 Basic Requirement 10 and Supplement 10S-1 as applicable.

### 10.2 Inspection Records

In addition to NQA-1 requirements, inspection records generated from these procedures and instructions shall identify:

A. the inspection procedure used,

B. characteristics inspected,

C. inspection criteria or reference documents used to determine acceptance,

D. equipment used during the inspection, and

E. any special expertise used.

## 11.0 Test Control

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Test Control for T&MSS activities shall be limited to equipment and instruments that apply to engineered items only. Scientific investigation activities are controlled under the provisions of Section 20. Instructions and procedures shall be developed to ensure that equipment and instruments procured by T&MSS shall perform satisfactorily in service as determined by testing and that the items conform to specified requirements. These procedures and instructions for tests shall establish controls as described in the OCRWM QARD.

11.1 T&MSS tests shall include prototype qualification tests as necessary.

11.2 Test procedures shall provide for the following, as appropriate:

A. test objectives, methods, and characteristics.

B. criteria for determining when a test is required.

C. mandatory inspection hold points (as required).

D. test requirements and acceptance limits.

E. trained and qualified personnel.

F. instructions for performing the test.

G. test prerequisites and other inspection points (witness points) as necessary. Prerequisites shall consider the following, as applicable; calibrated instrumentation, appropriate equipment, condition of test equipment, item to be tested, suitable environmental conditions, and provisions for data acquisition.

H. acceptance and rejection criteria, including required levels of precision and accuracy.

I. recording of test data and results and evaluation of data to insure that test requirements have been satisfied

J. test records that include description of item tested, date of test, identification of tester or data recorder, type of observation, results and acceptability, action taken and in connection with any deviations noted, identification of person evaluating test results.

K. required tests shall be controlled in accordance with approved procedures.

L. identify potential sources of uncertainty and error and that parameters affected by potential sources of uncertainty shall be identified and controlled.

11.3 In lieu of test procedures, T&MSS may utilize appropriate sections of American Society for Testing and Materials (ASTM) documents, supplier manuals, drawings, and other such documents where adequate instructions exist to assure the required quality of work.

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## 12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

T&MSS procedures shall describe the methods by which tools, gauges, instruments, and other measuring and test equipment used for quality related activities are controlled, calibrated, recalled, and adjusted at specific intervals to maintain accuracy within established limits. Devices such as rulers, tape measures, levels, watches where normal commercial practices provide adequate accuracy do not fall within the scope of this section.

### 12.1 M&TE Program

A procedure shall be implemented which describes an M&TE program for T&MSS consistent with OCRWM QARD requirements. The T&MSS procedure shall specify and establish a M&TE custodian, recall system, a master log of M&TE including calibration due dates, M&TE usage logs, and a history file for each M&TE used by T&MSS.

The T&MSS QA organization shall monitor the implementation of the M&TE program through audits and surveillances.

### 12.2 Calibration Systems

In addition to the requirements described in Para. 12.1 the M&TE program established by T&MSS shall provide for the following:

A. Use of calibration standards traceable to nationally recognized standards or reviewing and documenting the basis for calibration when no standard exists.

B. Unless limited by state of the art, calibration standards shall have accuracy greater than the equipment being calibrated. Calibration standards with the same accuracy may be used if they can be shown to be adequate for the requirements, and the basis for acceptance is documented by management. The management authorized to perform this function shall be identified.

C. Application requirements shall determine selection of M&TE.

D. Identification of calibration status by tagging or other appropriate means.

E. Repairing or replacing damaged equipment or equipment consistently out of calibration.

F. When accuracy is suspect, M&TE shall be calibrated. Otherwise, M&TE will be calibrated at specified intervals based on the intended use, type of equipment, degree of usage, etc.

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G. Devices out of calibration shall be identified and not used. Results obtained from use of equipment found out of calibration will be re-evaluated.

H. Calibration records shall identify the procedure and revision used to perform the calibration.

I. Nonconformances resulting from defective M&TE or re-evaluations resulting in erroneous data shall be processed in accordance with Sections 15 or 16 as appropriate.

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## 13.0 HANDLING, STORAGE, AND SHIPPING

T&MSS procedures shall describe the methods for handling, storage, cleaning, packaging, shipping and preservation of items to prevent loss or damage and to minimize deterioration. T&MSS QA shall monitor implementation of the procedures and instructions through audits and surveillances. QA shall also perform technical document reviews as necessary for special equipment and/or equipment requiring protective environments. These procedures and instructions shall provide for the following criteria:

13.1- Implementation by suitably trained personnel. Operators of special handling and/or lifting equipment shall be experienced or trained in the use of that equipment. This experience and/or training shall be documented.

13.2 Special handling tools and equipment shall be inspected and tested, as necessary, to assure that equipment is properly maintained. Any inspection or test shall be documented. Use of this equipment shall be controlled as necessary to assure safe and adequate handling.

13.3 Procedures shall describe measures (e.g. environmental controls, special containers, etc.) appropriate to the circumstances for sensitive items or samples. Storage provisions for any item or sample shall consider the planned duration and intended use of the item or sample. Its integrity shall be maintained as appropriate.

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## 14.0 INSPECTION, TEST, AND OPERATING STATUS

Although the scope of this section does not include scientific investigations, the following activities shall comply with the provisions of this section: receiving inspection activities, post installation testing and use of environmental and radiological monitoring equipment by T&MSS. Procedures and instructions shall provide for identifying the status of inspection and test activities to ensure that required inspections and tests are performed and to ensure that unacceptable items are not inadvertently installed, used, or operated.

14.1 Provisions shall be made for the use of status indicators as appropriate (tags, markings, inspection records, etc.). Authority for application and removal of such status indicators shall be defined. T&MSS shall provide examples of these indicators in the appropriate procedures.

14.2 Procedures shall control altering the sequence of tests, inspections, and other operations important to safety or waste isolation, as necessary.

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## 15.0 CONTROL OF NONCONFORMING ITEMS

T&MSS procedures and instructions shall describe the methods used to identify and control nonconforming items (e.g., damaged, improperly installed, etc.) to prevent inadvertent use or installation. Replacement, adjustment, and repair of items due to routine maintenance and operations of equipment shall be described and controlled through maintenance procedures and are not required to be addressed on nonconformance reports. Programmatic or procedural deficiencies, software, and documentation discrepancies shall be identified and processed as described in Section 16. T&MSS procedures and instructions shall include the following provisions for the control of nonconformances:

### 15.1 Identification and Control

T&MSS personnel shall identify any nonconforming item immediately upon detection to the organization responsible for the item or associated activity and to T&MSS QA. The nonconformance shall be documented in accordance with approved procedures requiring the identification of the nonconforming condition, item description and location. The nonconforming item shall be tagged or segregated to prevent inadvertent use. Further use or work relating to this item is prohibited pending disposition of the nonconformance.

### 15.2 Tracking

A nonconformance control log shall be utilized to track and status the nonconformance.

### 15.3 Conditional Releases

Prior to disposition, a request for conditional release may be made contingent on four conditions: (1) the subject item can be corrected at a later date without impairing other items or facilities or further damage to itself, (2) it remains accessible for inspection or examination, (3) its limitations for use are defined and documented, and (4) traceability and identification of the item is maintained. Responsible T&MSS technical and QA personnel must approve this conditional release.

### 15.4 Evaluation and Disposition

Nonconformances shall be documented on a report form with a unique identifier and submitted to the applicable APM for review, evaluation, and disposition. T&MSS QA shall evaluate the identified condition prior to disposition and document

their concurrence with the proposed disposition. The APM responsible for the disposition or a designee having the technical expertise to evaluate the nonconformance shall provide a disposition of accept, use-as-is, reject, repair or rework. Rejected items may be returned to vendor or scrapped. This disposition shall be signed by the responsible authority. Instructions for carrying out the disposition shall be provided as necessary and technical justification provided for use-as-is or repair dispositions.

15.5 Verification and Closure

T&MSS shall verify satisfactory disposition of the nonconformance and document the verification activity. Repaired or reworked items shall be re-examined in accordance with the original acceptance criteria unless the disposition establishes alternate acceptance criteria. Upon satisfactory verification of nonconformance dispositions, the nonconformances shall be closed.

15.6 Trending

Nonconformances shall be trended and reviewed for significance per Section 16 of the QAPD and analyzed by T&MSS QA to identify quality trends and root causes of nonconformances. Results of these trend analyses shall be reported to the Project Manager for review and assessment.

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## 16.0 CORRECTIVE ACTION

T&MSS procedures and instructions shall be implemented to assure that conditions adverse to quality, such as malfunctions, deficiencies, nonconforming and defective items, samples, procedures, software and records are promptly identified and corrected. Significant conditions adverse to quality as determined by criteria established in T&MSS procedures require the root cause to be determined, investigative action to evaluate the deficiency including generic implications to the QA program, and corrective actions to prevent recurrence. A trend analysis program shall also be established to measure the achievement of quality. Significant conditions adverse to quality and adverse trends shall be identified to the T&MSS Project Manager for evaluation and subsequent corrective action.

16.1 Hardware or engineered items that are deficient, damaged, or malfunctioning shall be processed in accordance with nonconformance control criteria in Section 15. Programmatic and procedural anomalies associated with these nonconformances shall be addressed in accordance with this section of the QAPD as necessary, based on the nature and extent of the problem.

16.2 Programmatic, procedural, documentation, and data deficiencies shall be processed by T&MSS QA in accordance with procedures describing the T&MSS deficiency document reporting system. These procedures shall incorporate the following provisions:

A. Describing the deficiency in the deficiency reports such that the full extent, scope, and nature of the problem is fully defined.

B. Providing criteria for evaluating the significance of the deficiency and identifying the adverse condition to the responsible T&MSS organization for a response.

C. Require remedial actions to correct the identified deficiency and corrective action to prevent recurrence if necessary.

D. Determination of root cause and investigative actions as necessary relative to the significance of the deficiency.

E. Concurrence of the proposed response from the responsible organization by T&MSS QA.

F. Verification by T&MSS QA that all corrective action commitments have been satisfactorily accomplished and that the corrective actions resolved the adverse conditions.

G. Concurrence with proposed corrective action or verification of corrective actions shall be within prescribed time limits.

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H. Providing to responsible management at all levels, copies of documentation of corrective actions that involve significant conditions adverse to quality.

16.3 Procedures for trend analysis shall assure that the results of audits, surveillances, inspections and other activities which produce results (e.g. QFRs, NCRs) of an evaluation of quality related items and activities are utilized in the analysis of the QA program and help identify root causes at specified intervals. T&MSS QA shall perform trend analyses in a timely manner such that any adverse trends shall be promptly identified and corrected.

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## 17.0 QUALITY ASSURANCE RECORDS

T&MSS shall process Quality Assurance Records in accordance with approved procedures and instructions. T&MSS generated records shall be processed through the T&MSS Local Records Center (LRC) or Yucca Mountain Site Office (YMSO) LRC. T&MSS procedures and instructions shall provide interfaces for submittal of these records to the Central Records Facility (CRF). The following provisions apply to T&MSS and shall be reflected in procedures and instructions.

### 17.1 Generation of Records

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. These records shall be legible, identifiable, accurate, retrievable, and completed appropriately for the work or activity.

### 17.2 Record Validation

T&MSS documents that furnish documentary evidence of quality become a valid QA record when authenticated in accordance with approved procedures or instructions. Originals or copies may be furnished as records.

### 17.3 Index, Identification, Distribution

T&MSS QA records shall be indexed, identified, and distributed by CRF in accordance with T&MSS procedures and instructions. The location of indexed records shall be identified, and records shall be identified by a unique number that is traceable to controlling programmatic information. Procedures and instructions shall control in-process records and provide for the timely submittal of completed records into the records system.

### 17.4 Records Correction

Provisions for correcting records shall ensure that corrected records are reviewed and approved by the originating organization. Such corrections shall include the date and the identification of the person making the correction. Previous information shall not be obliterated by the correction. Provisions shall be established for supplementing or amending records. Controls shall be established for transcribing and authenticating illegible or un-reproducible data or documents.

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17.5 Local Records Center

17.5.1 T&MSS QA records shall be submitted to the LRC for processing. Submittal of records to the CRF shall be in accordance with T&MSS procedures and instructions. Records submitted to the LRC shall be stored in dual facilities or in a two-hour rated safe. One-of-a-kind records shall be stored in a two-hour fire rated safe or vault. Where dual facilities are used, such facilities are located sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard.

17.5.2 Procedures and instructions shall identify the LRC receipt control system for identifying the records received, receipt and inspection of incoming records, and submittal to the storage facility.

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## 18.0 AUDITS AND SURVEILLANCES

The T&MSS Quality Assurance organization shall implement an audit and surveillance program in accordance with this section and OCRWM's QARD. Both internal audits and surveillances of the T&MSS quality program and external audits and surveillances of T&MSS suppliers and/or contractors that furnish quality related items or services shall be performed by the T&MSS QA organization. This program shall provide independent verification of the status, adequacy, compliance, and implementation of the T&MSS QA program and its elements. T&MSS procedures and instructions for this program shall include the following provisions:

### 18.1 Audits

T&MSS shall implement procedures which define responsibilities and methods for conducting planned and scheduled quality assurance audits by qualified personnel to accomplish the following:

- o verify compliance and determine effectiveness of the program;
- o provide objective evaluation of program implementation;
- o determine effectiveness of achieving quality objectives;
- o involve T&MSS management at all levels in the audit process, and
- o evaluate the technical adequacy of procedures, plans, software, test data, items and activities.

#### 18.1.1 Audit Scheduling

The audit schedule shall address all quality-related activities and criteria under T&MSS responsibility and the evaluation shall consider results of previous surveillances and audits, and the impact of significant changes in personnel, organization or quality assurance program. Each area of activity shall be audited at least annually or during the life of the activity whichever is shorter, except for supplier audits. The audit schedule shall be reviewed periodically and updated as necessary. Supplemental audits may be performed as necessary to provide adequate coverage. Copies of the T&MSS audit schedule shall be furnished to APMs and Project Office QA.

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18.1.2 Audit Team

A. An audit team comprising one or more auditors (one of whom shall be qualified as a Lead Auditor) shall be identified prior to each audit in an audit notification letter/memo to the organization to be audited. Technical specialists shall be utilized where necessary, e.g. to audit scientific investigations and experiments. The Lead Auditor is responsible for directing and organizing the audit, determining that the audit team is qualified to conduct the audit, preparing and issuing the audit report, and evaluating the responses.

B. Lead Auditor qualifications shall comply with requirements established in ANSI/ASME NQA-1, Supplement 2S-3 and Appendix 2A-3.

C. Technical members of the audit team shall be indoctrinated in audit techniques. Auditors shall not have had any direct responsibility for the activity being audited.

18.1.3 Audit Plan and Process

A. Planning shall involve the review of previous audits for the activity/area being audited and shall address previous findings (deficiencies, concerns, corrective actions etc.) surveillances, and assessments. Reviews of appropriate documents, procedures, and instructions shall also be performed.

B. An audit plan shall be developed which identifies the audit scope, requirements, audit personnel, activities to be audited, organizations being audited, applicable documents, schedule, and written procedures or checklists.

C. T&MSS shall conduct pre-audit and post-audit conferences with the audited organizations to identify the scope and methodology of the audit, establish interfaces, and identify audit findings, observations, and overall results of the audit.

D. Requirements from the audit checklist or procedures shall be used to evaluate the elements selected for the audit.

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18.1.4 Audit Report

The audit report is prepared and signed by the Lead Auditor and issued to the audited organization, the APM of the audited organization, 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.

Documentation of identified deficiencies that are not corrected during the course of the audit shall be in accordance with Sections 15 and 16 of this QAPD as shall be the review, verification, and closure of deficiencies.

18.1.5 Supplier Audits and Evaluations

A. Audits of suppliers shall be conducted as necessary based on the scope, complexity, importance to safety or waste isolation, procurement document and/or contractual requirements. When T&MSS determines that an external audit of a supplier is required, the supplier shall be audited on a triennial basis, as a minimum. The controls and responsibilities previously described in this section shall be utilized.

B. Regardless of audit requirements, all T&MSS suppliers on the Qualified Suppliers List shall be evaluated on an annual basis. The results of previous audits and previously identified deficiencies and nonconformances shall be considered in this evaluation. This evaluation shall be based on some combination of: reviews of supplier documents; results of previous source verifications, audits and receiving inspections; or, demonstrated reliability of an item in service; and results of audits from other sources.

C. After award of the contract and based on the determination of the quality assurance program applicability of each item or service to be procured, the need for external audits shall be evaluated. A determination may be made that external audits are not necessary for procuring items that are:

1. Relatively simple and standard in design, manufacture, and test;

or

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2. Adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery. The rationale for not performing an external audit shall be documented and maintained as part of the QA records.

18.2 Surveillances

T&MSS QA shall be responsible for implementing the surveillance program. Surveillance functions by non-QA personnel may be conducted in accordance with approved work instructions for a specific activity (e.g. Radiation Monitoring) as long as the personnel do not directly report to the supervisors responsible for the activity. T&MSS QA shall implement a surveillance program described in T&MSS procedures which assesses in-process work or activities through observation and/or examination. Technical adequacy and quality implementation of the activity shall be evaluated. QA Surveillance personnel shall be knowledgeable in the activity being surveiled, and shall not be directly responsible for the work/activity under surveillance. Surveillances shall be planned and documented and shall identify acceptable and deficient conditions. Surveillances shall be conducted at times commensurate with work schedules and shall be relevant to project milestones. Deficiencies that are not corrected during the course of the surveillance shall be evaluated and handled in accordance with Sections 15 and 16 of this QAPD as appropriate.

Surveillance reports shall be issued to the department or organization being surveilled and to the appropriate APM. The Project Manager shall be copied on all such reports.

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## 19.0 SOFTWARE QUALITY ASSURANCE

For quality related software, T&MSS shall develop a software development and control program to meet the applicable requirements of Section 19 of the OCRWM QARD. The program shall be consistent with guidelines contained in NUREG-0856 and will be designed based on a Software Life Cycle (SLC) model tailored to T&MSS activities.

Application of software QA requirements shall be graded according to software function, nature, and other characteristics of each software type. Criteria shall be established that result in the application of different controls depending upon software relative importance, intended end-use, regulatory significance, degree of complexity, requirement relevance, software origin and the type of software to be employed by T&MSS organizations. Software controls are graded depending on criteria such as:

1. Whether the software is to be used to support Project safety and licensing activities (i.e., does the software support "Activities Affecting Quality" as defined in the OCRWM QARD).

2. Whether the software function is considered scientific or engineering in nature, as defined by NUREG-0856.

3. Whether the software is developed for and by participating organizations (i.e., developed per the OCRWM QARD).

4. Whether the software is procured or otherwise acquired for the T&MSS from sources other than project participating organizations.

5. Whether the software is relatively complex in nature and will require extensive effort to verify and/or validate.

6. Whether the quality of a software product will depend upon SLC controls employed during design, development, and testing.

7. Whether the software will be used to generate primary data.

### 19.1 SOFTWARE QUALITY ASSURANCE PLAN (SQAP)

T&MSS shall implement the software quality assurance requirements contained in OCRWM's QARD, when applicable, in a manner commensurate with the methods, criteria, and controls described in the T&MSS Software QA Plan (SQAP).

The T&MSS SQAP shall establish administrative controls to be used by T&MSS organizations that use quality-related software to perform analysis to support a high-level nuclear waste repository license application. The SQAP shall govern the

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SLC, including the process of software planning, determination of software type, requirements development, structured analysis and design, coding and documentation, testing, verification and validation, installation, certification for release, operational use and change for all quality-related software.

This SQAP shall prescribe controls and a systematic process to reduce the likelihood of software defects entering executable computer software during development. It also ensures that the end-product software implements software quality assurance requirements for the intended application, and reduces the likelihood that software defects will be introduced into executable code during maintenance.

T&MSS Organizations shall control specific software types in accordance with the applicable Standard Practice Procedures (SPs), Organizational Procedures (OPs), or Work Instructions (WIs).

The main objective of the SQAP is to define a structured, disciplined process that controls the acquisition, design, develpment, qualification, documentation, usage, and maintenance of quality-related software. Specific software management objectives to be met by the SQAP include the following:

1. Establishment of a SLC approach to development, acquisition, testing, and use of quality-affecting software.

2. Definition of a prescribed set of software products to be generated and maintained as QA records.

3. Establishment of controlled software libraries which form a baseline for a software configuration management system.

4. Creation of a software development library for control of unverified or invalidated software.

5. Creation of a software production library for use of verified and validated software that is developed, acquired, and modified according to the controls of the SQAP.

The SLC process as described in the SQAP shall contain several phases that apply to specific software types which are distinct and separate. Each phase contains specific tasks, activities, and work that contributes to the control of computer program acquisition, development, use and maintenance. T&MSS organizations will adhere to the following SLC phases, as applicable:

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| SLC Phase | Title Used |
|---|---|
| I | Software Classification |
| II | Requirements Development |
| III | Software Acquisition |
| IV | Software Design |
| V | Code Development |
| VI | Installation and Operational Use |
| VII | Software Verification/Validation |
| VIII | User Application |

The SQAP shall apply to quality-related software used for primary data analysis, data reduction, data acquisition, data generation, or quality-affecting activities that produce or manipulate primary data that is used directly to perform technical calculations in support of site characterization, repository design, design analysis, performance assessment, and operation of repository structures, systems, and components.

This SQAP also applies, in part, to system software (high-level software languages, etc.), acquired software, and proprietary off-the-shelf commercial software packages developed outside the Project.

The SQAP shall contain descriptions of processes employed, requirements established, methodologies used, and criteria to be met for quality-related software in the following areas:

a. Software Quality Management Program
b. Organization and Responsibilities
c. Software Requirements Applicability
d. Software Life Cycle Management Process
e. Software Documentation, Control and Review
f. Software Verification and Validation Process
g. Software Configuration Management System
h. Qualification and Acquisition of Existing Software
i. Software Use and Application.

## 19.2 SOFTWARE VERIFICATION AND VALIDATION

Software may be used extensively in quality related scientific and engineering computations. Since error in such software could have serious impacts on activities affecting safety and waste isolation, it is necessary that computer programs exhibit a high level of reliability.

Verification and validation is a systematic process for improving reliability that includes:

- Computer software verification - a process that demonstrates that the computer software performs correctly, that software

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requirements are implemented in software design, and that the software design is implemented in the computer code.

- o computer model verification - an independent assessment that software performs the operations specified in a numerical model correctly.

- o computer model validation - an independent assessment for a specific computer software application that demonstrates that the mathematical model embodied in the software is an adequate representation of the process or system for which it is intended.

The T&MSS SQAP shall describe the processes used to assure software verification and validation is planned, performed, documented, and justified consistent with NUREG-0856 requirements and the SLC.

## 19.3 SOFTWARE CONFIGURATION MANAGEMENT

In order to satisfy configuration management program requirements of the OCRWM QARD, a Software Configuration Management System (SCMS) shall be established by T&MSS and described in the SQAP. The SCMS shall be controlled and managed by the T&MSS Information Systems Department (ISD) according to implementing procedures or instructions. The purpose and scope of the SCMS is to:

- o Uniquely identify, control, and track T&MSS organization computer software products.

- o Control and record change to software products during development and maintenance of quality-related software.

- o Control the transfer of T&MSS organization computer software between the software production library, the software development library, and outside organizations.

- o Maintain the status of T&MSS organization quality-related software and any changes made to software products.

The SCMS shall provide for six basic functions which shall be described in the T&MSS SQAP. These include:

1. Identify each software product.

2. Enter software products into the SCMS.

3. Provide change control over the baseline.

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4. Facilitate software discrepancy reporting.

5. Assure that software defects are corrected.

6. Identify and maintain status of the baseline.

Two software libraries shall be established and maintained by T&MSS for the purpose of controlling software with different status. The software libraries utilized are:

A. The Software Production Library. This library contains System Software and software approved for use in Project license application activities. User access to the library is controlled by the ISD Manager. Software in this library must have completed all applicable phases of the SLC and must be verified and/or validated.

B. The Software Development Library. This library contains software approved for use which shall be controlled until verification and/or validation is completed. Access to the library is controlled by the ISD Manager. Once verified and validated, computer programs in this library will be transferred to the Software Production Library. The computer results obtained from use of computer programs in the Software Development Library shall be marked or stamped to identify and control the use of such data in quality-affecting activities.

## 19.6 QUALIFICATION OF EXISTING SOFTWARE

All T&MSS software that is acquired from commercial or non-Project sources is considered existing software and shall be evaluated or qualified prior to use in quality affecting activities. The qualification process for existing software ensures that the software and associated documentation can meet applicable technical and QA requirements.

System software is a special software type that is procured based on proven commercial use without qualification.

## 19.7 SOFTWARE DOCUMENTATION

T&MSS quality related software shall be documented in accordance with the SLC control process and procedures. Each SLC phase results in the preparation of one or more software products documenting the tasks, activities, and work conducted during the phase. These software products are prepared, reviewed, and approved according to the criteria provided in the T&MSS SQAP.

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Computer programs are documented and controlled during each phase of SLC. The documentation shall meet the minimum acceptable levels established by the SQAP. The documentation of scientific and engineering software shall be consistent with the guidance contained in NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management."

## 19.8 SOFTWARE REVIEWS

Reviews of computer software and associated documentation shall be performed in accordance with a T&MSS software review procedure. Reviews shall be performed for each software product completed during the SLC as specified in the T&MSS SQAP. Reviews shall be performed according to a document review process that includes T&MSS comment resolution prior to entry of documentation into the SCMS.

## 19.9 DISCREPANCY REPORTING AND CORRECTIVE ACTION

A formal software operational problem and defect reporting system shall be established and integrated with the SCMS. Software problems shall be evaluated to determine their potential impact and whether or not a software defect exists. The evaluation considers the following:

1. Does the software problem involve a condition adverse or potentially adverse to quality?

2. Could the software problem, if not corrected, affect the quality of primary data?

3. Is the software product used to perform scientific and engineering computations in support of the Project license application?

4. Is the software product in use in the Software Production Library?

Once a software defect is identified and affected users are notified, it is the responsibility of the prime user to take corrective action. This includes documentation of the software defect, determination of its impact on any prior user applications, and correction of the software defect by modification of the software.

A software defect shall be cause to withdraw the software from either the Software Production or Development Library.

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19.10 MEDIA CONTROL AND PHYSICAL SECURITY

Master copies of physical media containing the images of software shall be physically protected to prevent their inadvertent damage, degradation or loss. Media control and security is ensured by the Yucca Mountain Project computer center, the magnetic tape storage system, the software library, and the Project Office computer program protection system.

19.11 ACQUIRED COMPUTER SOFTWARE

T&MSS shall establish procedures or instructions to control the following software acquisition activities:

1. Acquisition of system software
2. Acquisition of existing software
3. Conversion of existing software
4. Transfer of existing software
5. Change to acquired software

19.12 COMPUTER SOFTWARE APPLICATION

Each T&MSS organization using software installed in the Software Production or Development Library to perform technical calculations in support of site characterization, design analysis, performance assessment and operation of repository structures, systems, and components, shall follow approved technical procedures or instructions to:

1. Control the application, documentation, review and verification of scientific and engineering computations.
2. Control electronic calculations as required by the SQAP.
3. Control the use of unverified or unvalidated software.

19.13 T&MSS SOFTWARE QA PROCEDURES AND INSTRUCTIONS

T&MSS shall develop specific implementing procedures or instructions to control the software activities described in the SQAP, as appropriate.

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If specific software activities are anticipated, planned, or expected to be conducted, and the initiation date of such activities is uncertain, implementing procedures or instructions may be deferred until the activities are defined and their need is certain.

T&MSS organizations developing software QA procedures or instructions will adhere to the following provisions, as appropriate:

1. A series of procedures or instructions based on any hierarchial relationship that is consistent with the T&MSS SQAP.

2. Issuance of one or more procedures or instructions only when they are needed to perform specific activities.

3. The complete freedom to refer, cite, apply, specify, and utilize information or criteria contained in the SQAP.

4. Avoid, wherever feasible, duplication and redundancy between the SQAP and its implementing procedures and instructions.

5. Preclude, whenever possible, the introduction of new acceptance or rejection criteria not specified, defined, or provided in the SQAP.

6. Clarifications, explanations, definitions and interpretations of the SQAP will be documented by the T&MSS Information Systems organizations in memoranda and correspondence to primary users and affected parties.

7. The software quality assurance analyst reporting to the T&MSS Information Systems organization will be responsible for concurring with clarifications, explanations, definitions and interpretations of the T&MSS SQAP.

8. If the SQAP does not require the use of standards, conventions, techniques, or methodologies, implementing procedures, or instructions may reference such methods and assure compliance by a memorandum stating those portions of the reference to be followed.

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## 20.0 SCIENTIFIC INVESTIGATION CONTROL

T&MSS shall develop and implement instructions, procedures, and plans as required by the activity to control scientific investigations. These instructions, procedures, and plans shall implement the requirements described in the OCRWM QARD and reflect the following provisions.

### 20.1 Scientific Investigation Planning

Scientific investigations for T&MSS participant activities shall utilize appropriate plans, including study plans as the scientific planning documents. The YMP Radiological Monitoring Plan shall be utilized by Radiological Field Programs and the YMP Meteorological Monitoring Plan shall be utilized by the Environmental Field Programs as planning documents.

T&MSS shall develop scientific planning documents prior to initiating the scientific investigations. Plans previously developed and utilized by T&MSS under the Project Office Quality Program may be used in lieu of developing replacements. Planning documents shall contain as a minimum:

- a description of the work to be performed;
- rationale and justification for the information to be obtained;
- proposed methodology;
- rationale and justification for the proposed methodology;
- references to applicable documents;
- identification, explanation, and justification for areas where scientific notebooks are to be used;
- description of constraints;
- description of the application of the results;
- descriptions of schedules and milestones;
- identification of mandatory hold points for monitoring prerequisites;
- intended use of data with alternate uses being justified and evaluated for appropriateness;
- suitable laboratory conditions are maintained;

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- o description of equipment used, including range and accuracy;
- o established equipment performance parameters;
- o assurance of compatibility of scientific investigations with any conceptual or mathematical models used;
- o provisions for the evaluation of data quality;
- o provisions for deviations from national standards or development of specially prepared procedures to be subject to peer or technical review;
- o explanation of the change control process;
- o disposition of facilities after completion of scientific investigation activities; and
- o environmental compliance and land access approval

20.2 Planning Document Review and Approval

T&MSS shall conduct either a technical review or peer review of the scientific planning document with qualified personnel who did not develop the original planning document. In exceptional cases, the originator's immediate supervisor may perform the review if he or she is the only technically qualified individual and if the need is documented and approved. T&MSS QA must concur. The results of the technical or peer review and the resolution of any comments shall become QA records in accordance with Section 17.

All changes in scientific investigation planning documents shall go through the same review and approval process as the original planning documents.

The intended use of data shall be documented as part of the planning for scientific investigations. Any alternate use of the data shall be evaluated for appropriateness and the justification documented.

The range, accuracy, and precision of equipment used for scientific investigations shall be specified in order to be commensurate with requirements. In developing quality assurance program requirements for equipment, consideration shall be given to whether proper performance of a scientific investigation can be determined during or after the scientific investigation (that is, whether failure or malfunction

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of equipment can be detected). Where special quality assurance program requirements are found to be necessary, specific performance verification requirements shall be established and described to govern the use of the equipment.

20.3 Technical Procedures

The use of technical procedures is one method by which scientific investigations are controlled. This method is used to perform repetitive work that does not require a high degree of professional judgment or trial and error methods, or when it is not possible to deviate from a prescribed sequence of actions without endangering the validity of the expected results. These procedures shall provide for the following as appropriate:

- o Requirements, objectives, methods, and characteristics to be tested or observed;
- o Prerequisites such as calibrated instrumentation, adequate equipment, readiness of facilities, controlled environments, etc.;
- o Mandatory verification points, as applicable;
- o Acceptance and rejection criteria including required levels of accuracy and precision as appropriate;
- o Methods of documenting or recording data and results including precision and accuracy;
- o Methods of data reduction if it is part of a test, or reference to procedures containing the information;
- o Provisions for ensuring that prerequisites have been met, special training or qualification requirements for personnel performing scientific investigations are met, and personnel responsibilities are defined;
- o Procedures are detailed to the extent that the investigation can be repeated by personnel who are skilled in the state of the art of the field of investigation.
- o Potential sources of uncertainty and error in technical procedures are controlled as required; and
- o Suspect input data are identified and controlled as required.

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20.4 Scientific Notebooks

The scientific notebook system is another method for controlling scientific investigations where a high degree of professional judgment or trial and error methods are used or a methodology is required to be developed to accomplish an activity. When this system is used, the scientific investigation planning document or study plan shall control the activities. The notebook shall contain specific detail such that the investigation can be repeated by another qualified individual and achieve the same results. Logbooks or notebooks are used to document the activities undertaken and comprise the scientific notebook system. Requirements are established in OCRWM's QARD for initial and subsequent entries into the scientific notebook regarding title of research, names of persons performing the research, objectives, methodology, etc. The initial entries may be modified as necessary by authorized personnel and subsequent entries shall be detailed step-by-step implementation of the prescribed methodology. The final entries in the record shall have as a minimum the signature of the experimenter and the signature of a technical reviewer.

20.5 Interface Controls

T&MSS shall identify ongoing field investigations to preclude inadvertent interruption and to assure operational compatibility. The location of field investigations shall be clearly identified.

20.6 New Methods, Procedures, or Processes

If the nature of a scientific investigation or experiment is such that a new method, procedure or process is required to accomplish it, then the method, procedure or process shall be documented. This documentation requires that these processes, equipment, and personnel be qualified prior to obtaining data for scientific investigations.

20.7 Data Interpretation and Analysis

T&MSS procedures, instructions, and plans shall ensure that the data interpretation and analysis are documented in sufficient detail as to purpose, method, assumptions, input references and units such that technically qualified personnel are able to review, understand, and verify the analysis without recourse

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to the originator. Because these verifications may not be examined and used for an extended period of time the documentation of the analysis shall include the following:

- o statement of objectives;
- o identification of input, input sources, and assumptions;
- o listing of applicable references;
- o results of literature searches or other background data;
- o identification of any computer calculation including computer type, program name and subject, revision, input, output, evidence of program verification, and the bases of application to the specific problem;
- o calculations identifiable by subject, originator, reviewer and dates;
- o signatures and dates of reviews and approval by appropriate personnel; and
- o description of the methods of control of erroneous, rejected, superseded, or otherwise unsuitable data.

T&MSS is responsible to assure that equipment and methods used to obtain and analyze data are technically adequate and properly selected. Data transfer and reduction controls shall, as appropriate, be such that errors are held within prescribed limits and not lost in the outputs. Any computer programs utilized are controlled as described in Section 19 of this document.

20.8 Scientific Investigation Results

T&MSS shall document and summarize the results of all scientific investigations in a technical report. The documentation results shall include a discussion as to whether or not the research or experiment objectives were achieved. The following shall be included as appropriate:

- o Unreviewed data and data with unresolved questions shall be clearly identified when used or reported, and uncertainty limits shall be assigned prior to use.

- o Peer reviews or technical reviews shall be performed on the results of these investigations by T&MSS in accordance with approved procedures.

- o Data collection and analysis are to be technically reviewed by qualified T&MSS personnel other than those who performed the investigation. Questions shall be resolved before the results are used as a baseline.

Any procedural deficiencies or nonconformances identified during or subsequent to the scientific investigations shall be handled in accordance with the requirements of Sections 15 and 16 of this QAPD.

20.9 Records of Scientific Investigations

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.

20.10 Peer and Technical Reviews

Peer reviews and technical reviews utilized in the activities associated with scientific investigations shall be performed in accordance with T&MSS procedures and instructions.

- o Technical reviews shall be performed when the information or document under review is within the state of the art and is based on accepted standards, criteria, principles, and practices.

- o Technical reviews shall be used when documents, activities, material, or data require technical evaluation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

- o Technical reviews shall be performed by individuals with sufficient technical knowledge of the area under review.

- o Results shall be documented.

ATTACHMENT A

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T&MSS QA Program Basis

The regulations, NUREGS, guides, and NRC and OCRWM QA related documents and the leading industry standard NQA-1 as listed below represents the basis for the T&MSS QA Program. These basis documents are implemented by this QAPD and related procedures.

| | Document | Rev/Issue Date |
|---|---|---|
| 1. | 10 CFR 60, Subpart G, "Quality Assurance" | Current |
| 2. | 10 CFR 50, Appendix B, "Quality Assurance" Criteria for Nuclear Power Plant and Fuel Reprocessing Plants" | Current |
| 3. | 10 CFR 71, Packaging and Transportation of Radioactive Material | Current |
| 4. | 10 CFR 72, Licensing Requirements for the Storage of Spent Fuel in an Independent Spent Fuel Storage Installation (ISFSI) | Not Applicable To T&MSS |
| 5. | "NRC Review Plan" | Rev 2, March, 1989 |
| 6. | NUREG - 1318, Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements. | April 1988 |
| 7. | NUREG - 0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management" | June 1983 |
| 8. | NUREG - 1297, "Peer Review for High-Level Nuclear Waste Repositories" | February 1988 |
| 9. | NUREG - 1298, "Qualification of Existing Data for High-Level Nuclear Waste Repositories" | February 1988 |

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| Document | Rev/Issue Date |
|---|---|
| 10. ANSI/ASME NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities" including all Supplements except for Supplement 11S-2, Section 2.2, "In-Use-Tests;" Section 3, "Test Procedures," item (e) Section 5, "Test Records," items (3), (4), (5), and (6). See Section 19.0 of Appendix A of the OCRWM QARD for specific requirements. The provisions of Appendix 2A-1, "Non-mandatory Guidance for the Qualification of Inspection and Test Personnel" is included as a basis document. | 1989 Edition |
| 11. "OCRWM Quality Assurance Requirements Document" (QARD) (DOE/RW-0214) including Appendix A - Amplification of Quality Assurance Program Requirements for the Mined Geologic Disposal Systems and Attachment I, "Glossary" | Rev 4, 1990 |
| 12. YMP Administrative Procedures See Attachment B for specific applicability. | |
| 13. YMP Software Quality Assurance Plan (YMP/89-12) | Rev 0, July 1990 |
| 14. OCRWM "Records Management Policies and Requirements" (DOE/RN-0194) | Rev 1, May 1989 |
| 15. YMP "Records Management Plan" (YMP/89-15) | Rev 1, April 1990 |
| 16. DOE Order 5700.6B, "Quality Assurance" | NA-9/23/90 |

ATTACHMENT B

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## APPLICABILITY OF YMP APQS

I. APQs Directly Implemented by T&MSS as a Participant

| | |
|---|---|
| AP-1.3Q | Publication Review and Approval |
| AP-1.6Q | Release of Unpublished Information |
| AP-1.10Q | Preparation, Review and Approval of SCP Study Plans |
| AP-3.6Q | Configuration Management |
| AP-5.1Q | Control and Transfer of Technical Data on the Yucca Mountain Project |
| AP-5.2Q | Technical Information Flow to and from the Yucca Mountain Project Technical Data Base |
| AP-5.3Q | Information Flow into the Project Reference Information Base |
| AP-5.9Q | Qualification of Data or Data Analyses not Developed Under the Yucca Mountain Project Quality Assurance Plan |
| AP-5.19Q | Interface Control |
| AP-5.20Q | Hold Control |
| AP-5.21Q | Field Work Activation |
| AP-5.28Q | Quality Assurance Grading |
| AP-6.3Q | Interaction of Participants and Outside Interests with Yucca Mountain Project Sample Management |

II. APQs Implemented by T&MSS through T&MSS Participant Procedures

| | |
|---|---|
| AP-1.5Q | Issuance and Maintenance of Controlled Documents |
| AP-4.1Q | Procurement |
| AP-5.13 | Readiness Review |
| AP-5.27Q | Control of Nonconformances |
| AP-6.1Q | Project Office Document Development, Review, Approval, and Revision Control |

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III. APQs Not Applicable to T&MSS as a Participant, but may be implemented by T&MSS personnel performing direct support to the Project Office under the OCRWM QA Program.

| | |
|---|---|
| AP-3.3Q | Change Control Process |
| AP-5.10Q | Use of NTS Contractors on the NNWSI Project |
| AP-5.14Q | Design Review |
| AP-5.18Q | ESF Design Control |
| AP-6.2Q | Management and Operation of Sample Handling Activities at Borehole Sites |
| AP-6.4Q | Procedure for the Submittal, Review, and Approval of Requests for Yucca Mountain Project Geologic Specimens |
| AP-6.6Q | Field Collection, Documentation, and Specimen Removal of Exploratory Shaft and Drift Rock |
| AP-6.17Q | Determination of the Importance of Items and Activities |

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ATTACHMENT C

T&MSS QA GLOSSARY

This Glossary contains only those terms and definitions that are unique to the T&MSS QA Program. The terms and definitions of NQA-1 Supplement S-1, the Yucca Mountain Glossary, and the OCRWM QARD shall also apply to all T&MSS participant activities. Where differences exist between this document and others, the definitions in this document shall take precedence.

Acceptance - An act performed after methods for verifying that items and services being furnished comply with the procurement requirements have been satisfied.

Computer Program - A sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution as well as to execute it.

Commercial Grade Item - An item satisfying all of the following:

a. Not subject to design or specification requirements that are unique to Mined Geologic Disposal System, and
b. Used in applications other than Mined Geologic Disposal System, and,
c. Is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g. a catalog).

Controlled Document Information System (CDIS) - A computerized data base system which stores the controlled document master list of documents, controlled document distribution lists, and controlled document log and performs search and retrieval of controlled document information.

Deficiency - A deviation from established requirements, which, if left uncorrected could have an impact on the quality of item or activity.

Document Control Center (DCC) - A facility dedicated to the processing, distribution, recall, and storage of documents and their protection from loss, damage, or deterioration.

Facility Survey - A direct evaluation of the supplier's facility, personnel, and implementation of his program to determine the capabilities of the supplier to satisfy the requirements of the purchase order or contract.

Form Custodian - The person who is responsible for creating, revising, or maintaining a form(s) associated with a T&MSS procedure or T&MSS activity.

Functional Change - A change in the title, functions, responsibilities, or lines of reporting authority of an organization.

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Job Position Description - Documentation of the duties to be performed and the minimum qualifying experience, education, and professional training required for a position.

Major Revision - Changes to a document that affect a process within the document, the basic content, or a major change in concept.

Minor Revision - Changes such as department name changes; typographical errors; minor wording changes for clarity; and editorial corrections in grammar, punctuation, or spelling where the basic content of the document does not change.

Mandatory Comment -Comments that identify significant problems or weaknesses regarding technical content, concept, practice, implementation, or responsibilities that render a document unacceptable for implementation or out of compliance with established requirements. All comments designated as mandatory must be resolved with the reviewer and the resolution documented.

Management Assessment - Determination of effectiveness of establishing, planning and implementing quality requirements which conform to applicable regulations, standards, procedures, and related program requirements. It verifies that responsible managers have defined the quality objectives and requirements for their activities; planned and established the organizations resources and means for performing their activities; communicated their objectives, requirements, plans, procedures and assignments to involved organizations and individuals; and monitored the performance of activities to verify that objectives are being achieved.

Nonmandatory Comment - Suggestions regarding the organization or content of a document that provide helpful additions or deletions, typographical corrections, punctuation, etc., but do not constitute a significant problem or weakness. Nonmandatory comments may be incorporated at the discretion of the author.

Non-technical Document - A document that does not contain technical subject matter. A description of Yucca Mountain Project technical activities and technical documentation are defined in the Systems Engineering Management Plan, NNWSI/88-3.

Organization Chart - A graphic representation of the structure of the T&MSS organization that illustrates organizational titles, lines of reporting authority, names of individuals assigned to the organization, and remarks about the current status of the organization or individuals within the organization.

Organizational Change - A change in the functional structure or personnel of an organization, which is reflected in the T&MSS organization chart.

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Organization Procedure (OP) - Applies to activities and work associated with a requirement or responsibility contained within an organizational entity such as an Assistant Project Manager organization (can be used for Department/Divisions within an APM).

Obsolete Document - An obsolete document is a document that is no longer required for use, will not be superseded, and is removed from controlled distribution.

One-over-One Approval - The approval, by signature, of the originator of a document and originator's immediate manager or higher tier manager.

Occurrence - Any deviation from planned or expected behavior or course of events in connection with any Department of Energy or Department of Energy-controlled operation if the deviation has environmental protection, safety, or health protection significance.

Position Description - Documentation of the duties to be performed and the minimum qualifying experience, education, and professional training required for a position, synonymous with job position description.

Provisional Status - An asterisk on the organization chart that indicates that procedures/controlled documents are being revised to reflect a functional change or that training is still being conducted in response to a personnel change.

Personnel Change - The addition, deletion, or transfer of an individual within an organization.

Procedure Category - Identification and numbering of procedures and instructions based on groups or categories that best satisfy task requirements. Categories are typically determined by subject, frequency, or criteria.

Procurement Record - Consists of those procurement documents (pre-award and post-award) necessary to adequately delineate procurement, requester, and Quality Assurance (QA) requirements for procurement.

Procurement Package Table of Contents - An open-ended document initiated upon generation of a PR Package which lists each document as it is added to the PR Package and Procurement Record.

Qualified Supplier List (QSL) - A controlled list of qualified suppliers determined to have the capability to supply items or services meeting the requirements of procurement documents.

Qualified Supplier List Change Notice - The form used to modify the QSL during the period between required revisions of the QSL. (e.g., additions, deletions, or adjustments to the existing list).

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Qualified Supplier List Index - The index is a compilation of suppliers which features a matrix which provides a quick reference to vendor capabilities.

Qualified Supplier - A supplier which has been evaluated and determined to be capable of fulfilling the quality and technical requirements applicable to the actual or anticipated scope of work.

Quality-Affecting Items - Those manufactured or engineered structures, systems, and components which could impact the safety, reliability, or operability of the repository within the context of 10CFR60 Subpart G.

Quality Affecting Items and Services - Items and activities on the Q-List, Quality Activities List.

Quality Assurance Program Description (QAPD) - The document that describes T&MSS' Quality Assurance (QA) Program as a participant, the organizational responsibilities for achieving and assuring quality at T&MSS, and defines how compliance with QA criteria will be accomplished for T&MSS' scope of work that is performed as a participant.

Quality Finding/Management Corrective Action Report (QF/MCAR) - A pre-formatted form used to document identified conditions adverse to quality (programmatic or implementation), significant conditions adverse to quality and their associated follow-up.

Receipt - Activities conducted upon receipt of items to check such elements as the quantity received, part number and the general condition of the freight package.

Receiving Inspection Report - The document used to identify items to be received, the inspection method(s) used to accept the item(s), the characteristics to be inspected, and the results of the inspections.

Receiving Office - Any designated receiving function approved to perform receipt inspection.

Off-site - Any designated drop shipment point, other than the standard T&MSS on-site receiving function, that has approved procedures for receipt and control of quality affecting items or services which have been reviewed and accepted by T&MSS Quality Assurance (QA).

On-site - The receiving function located at Office Services, Room 407, 101 Convention Center Drive, Las Vegas, Nevada.

Resolution - Agreement between staff member and reviewer that disposition of a mandatory comment is mutually satisfactory or has been reconciled by appropriate management personnel.

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Responsible Manager - The manager to whom the assigned staff member reports administratively and has one-over-one approval authority.

Senior Manager - For the purpose of this procedure, a Senior Manager includes the Project Manager and any manager with direct reporting responsibility to the Project Manager (e.g., Assistant Project Managers, T&MSS Quality Assurance Manager, Manager of the Office of Institutional and External Affairs, and the Project Office QA Liaison).

Service - The performance of activities such as design, fabrication, inspection, nondestructive examination, investigation, site characterization, calibration, repair, installation, or other service as defined in the procurement document.

Software Requirements Specification - The Software Product resulting from the software requirements phase of the Software Life Cycle. A definition of User needs and Computer Program functions.

Standard Practice Procedure (SP) - A procedure that assigns responsibility for action to Personnel from more than one APM Organization with the purpose being to tie together the activities into one system or flow relative to an activity or task.

Stop Work Action - An action documented on a Stop Work Order (SWO) and issued as a directive to cease and desist the identified activity when, in the view of the Quality Assurance Manager and T&MSS Project Manager, continuing work could result in:

Failure to adequately control the processing, delivery, installation, modification, or operation of a nonconforming item.

Serious failure or breakdown of the T&MSS Quality Assurance Program.

Significant hazard to those items or activities that are important to safety and/or waste isolation.

Superseded Document - A superseded document is a previously released document, which has been replaced in its entirety by another controlled document.

Supplemental Audit - Audits which are conducted in addition to regularly scheduled audits. They cover specific subjects deemed necessary by the T&MSS QA Manager or Lead Auditor.

Technical Coordinator (TC) - The staff member with functional responsibility for a specific DOE Order area (e.g., managers of T&MSS Quality Assurance, Radiological Field Programs, Safety and Health Compliance, Information Systems, etc.). Functional responsibility is generally determined by the current T&MSS Organization Chart.

Technical Document - A document of technical subject matter other than institutional materials developed for one-time use for specialized audiences, or financial, property control, management, or contractual information that is administrative in nature. Technical documents may include (but are not limited to) the following:

- topical reports, final reports, and letter reports;
- technical data for programmatic decisions;
- conceptual designs, schematics, block diagrams, drawings, and maps;
- any nonadministrative documents (e.g., regulatory, socioeconomic, or environmental) required or developed to support project objectives.

Testing - an element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

Unplanned Event - A situation that occurs outside of normal planned activities and occurrences. Examples of unplanned events include serious injury, fire, release to the environment of radioactive materials or hazardous chemical, loss or theft of hazardous or radioactive material, and other significant events which may concern the public.

Unusual Occurrence (UO) - The term UO applies only to such occurrences as are reportable to DOE under applicable DOE Orders.

Work Instruction (WI) - Implementing procedure that details all essential work steps for the worker associated with a task or function. These procedures typically include step-by-step work instructions that may or may not require performer sign-off as each step is completed.