TRW Environmental
Safety Systems Inc.

Civilian Radioactive Waste Management System

Management & Operating Contractor

B&W Fuel Company
Duke Engineering & Services, Inc.
Fluor Daniel, Inc.

INTERA Inc.
JK Research Associates, Inc.
E. R. Johnson Associates, Inc.

Morrison Knudsen Corporation
R&D Associates
Woodward-Clyde Federal Services

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Civilian Radioactive Waste Management System Management and Operating Contractor

Quality Assurance Program Description

Contract No. DE-AC01-91RW00134

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Revision 3

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11-30-92
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QA POLICY STATEMENT

The U.S Department of Energy (DOE) has been authorized by the Nuclear Waste Policy Act, as amended in 1987, to site, license, construct, and operate a geologic repository and a monitored retrievable storage facility, and to provide for safe transportation of radioactive waste to those locations.

The DOE Office of Civilian Radioactive Waste Management has contracted with TRW Environmental Safety Systems Inc., herein referred to as the Civilian Radioactive Waste Management System (CRWMS) Management and Operating (M&O) Contractor for systems engineering, development, and management of the Civilian Radioactive Waste Management System.

The M&O has committed to implement an effective quality assurance program, which is in compliance with the applicable DOE and federal regulatory requirements. The M&O Quality Assurance Program is based on achievement of quality as a line responsibility where each performer is accountable for the quality of the work assigned. The M&O Quality Assurance organization, reporting directly to the M&O General Manager, verifies the achievement of quality through audits, surveillances, and reviews.

The M&O conducts its activities in accordance with the highest standards of integrity, openness, technical expertise, and professional excellence, employing technical resources of the highest caliber and integrity. This Quality Assurance Program shall be implemented for the planning and implementation of all M&O quality affecting activities. Compliance with the provisions of this Quality Assurance Program Description Document is mandatory.

R.L. Robertson
General Manager, CRWMS M&O

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INTRODUCTION

The Civilian Radioactive Waste Management System, Management & Operating Contractor Quality Assurance Program Description Document (QAPD) is applicable to CRWMS M&O quality affecting activities at all organizational levels from the General Manager to M&O teammates and M&O subcontractors. This document and the DOE/RW-0214, Quality Assurance Requirements Document (QARD) for the Civilian Radioactive Waste Management Program, serve as the principal documents defining the CRWMS M&O Quality Assurance Program.

This QAPD satisfies the requirements of the following higher level quality assurance requirements documents:

a. U.S. DOE, OCRWM, "Quality Assurance Requirements Document (QARD)," DOE/RW-0214

b. ANSI/ASME NQA-1 (1989), "Quality Assurance Program Requirements for Nuclear Facilities" with its supplements and appendices, as identified in the QARD.

Sections 1 through 19 of this document describe the quality management controls established to meet the requirements of all applicable OCRWM QARD sections and appendices for the scope of work assigned to the M&O. These controls apply to all M&O and subcontractor personnel performing quality affecting activities on the Civilian Radioactive Waste Management System elements consisting of the Mined Geologic Disposal System (MGDS), Monitored Retrievable Storage (MRS), and Nuclear Waste Transportation unless specifically stated otherwise. Section 20, Scientific Investigations, in Appendix A to the QARD is not addressed as the present M&O scope of work does not include this activity. Other exceptions to M&O scope of work are also indicated in the appropriate QAPD sections and noted in the QA Requirements Matrix. The Quality Assurance Program elements that follow are sequenced and numbered to be consistent with the QARD for direct correlation with its requirements. This QAPD is implemented through M&O quality administrative and implementing line procedures.

For consistency with the OCRWM QA Program, the terms and definitions of NQA-1 Supplement S-1 and Appendix E of the OCRWM QARD apply to this document. Terms not contained in the referenced documents are defined in the applicable M&O procedures.

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SECTION 1

ORGANIZATION

1.0 GENERAL

This section describes the M&O organizational structure, functional responsibilities, authorities, and interfaces for quality affecting activities. Within the M&O, the line organizations achieve quality while the quality assurance organization performs overview activities through audits, surveillances, and reviews to verify the achievement of quality.

The M&O Quality Assurance Program described in this section and associated procedures implement the committed requirements of QARD Section 1.

1.1 M&O ORGANIZATION

The M&O consists of the following team members and their respective primary roles in the organization (Note: An asterisk signifies lead responsibility):

TRW	-	Program Management,* Systems Engineering*
Duke Engineering and Services, Inc	-	Licensing,* Outreach,* MRS Design,* Quality Assurance*
Fluor Daniel, Inc.	-	MGDS Surface Facility Design and Development*
Morrison Knudsen	-	MGDS Underground Facility Design and Development*
Babcock & Wilcox	-	Waste Package Design and Development,* Training*
Woodward-Clyde	-	Site Characterization*
INTERA Technologies	-	Performance Assessment*
JK Research Associates, Inc.	-	Senior Staff
ER Johnson Associates, Inc.	-	Storage and Transportation
R&D Associates	-	Systems Engineering, Licensing

Most of the team members provide Quality Assurance personnel to the M&O QA organization with Duke Engineering and Services, Inc., having the lead.

A single M&O Quality Assurance Program Description addresses the entire M&O scope of responsibility. The organizational structure for carrying out the QA Program extends from the M&O Headquarters in Vienna, Virginia to the sites and all subcontractors to ensure communication and interface control in the implementation of this standard, and effective quality assurance program.

Figure 1 details the M&O organizational structure. This organizational structure is based on a bicameral management concept where the systems organization is the "concept manager" and the operations organization is the "concept executor."

The M&O Quality Assurance organization is detailed in Figure 2. The M&O line organizations are responsible for performing quality affecting activities. The functional and quality assurance responsibilities for key positions within the M&O organization are described in the following sections.

1.1.1 General Manager

The General Manager reports to the TRW Systems Integration Group Vice President and General Manager and has the overall management responsibility and authority as Chief Executive Officer for the M&O organization. The key management positions reporting to the General Manager having quality assurance responsibilities are the Quality Assurance Manager, the Human Resources Manager, the Assistant General Manager for Systems, the Nevada Site Manager, and the Assistant General Manager for Operations.

The quality assurance responsibilities of the General Manager are to:

a. Establish M&O quality assurance policy direction and controls that are commensurate with CRWMS program requirements, and M&O goals and objectives

b. Establish and execute a quality assurance program that ensures compliance with the QARD

c. Approve the M&O Quality Assurance Program Description (QAPD)

d. Approve M&O Quality Administrative Procedures (QAPs)

e. Provide adequate funding and resources to effectively support the quality assurance objectives of the program

f. Interface with OCRWM and through OCRWM with: NRC; Federal regulatory agencies; the nuclear industry; and affected states, local governments, Indian tribes, and the general public on quality assurance matters related to their areas of interest

g. Maintain awareness of quality assurance issues, problems, and ensure their resolution

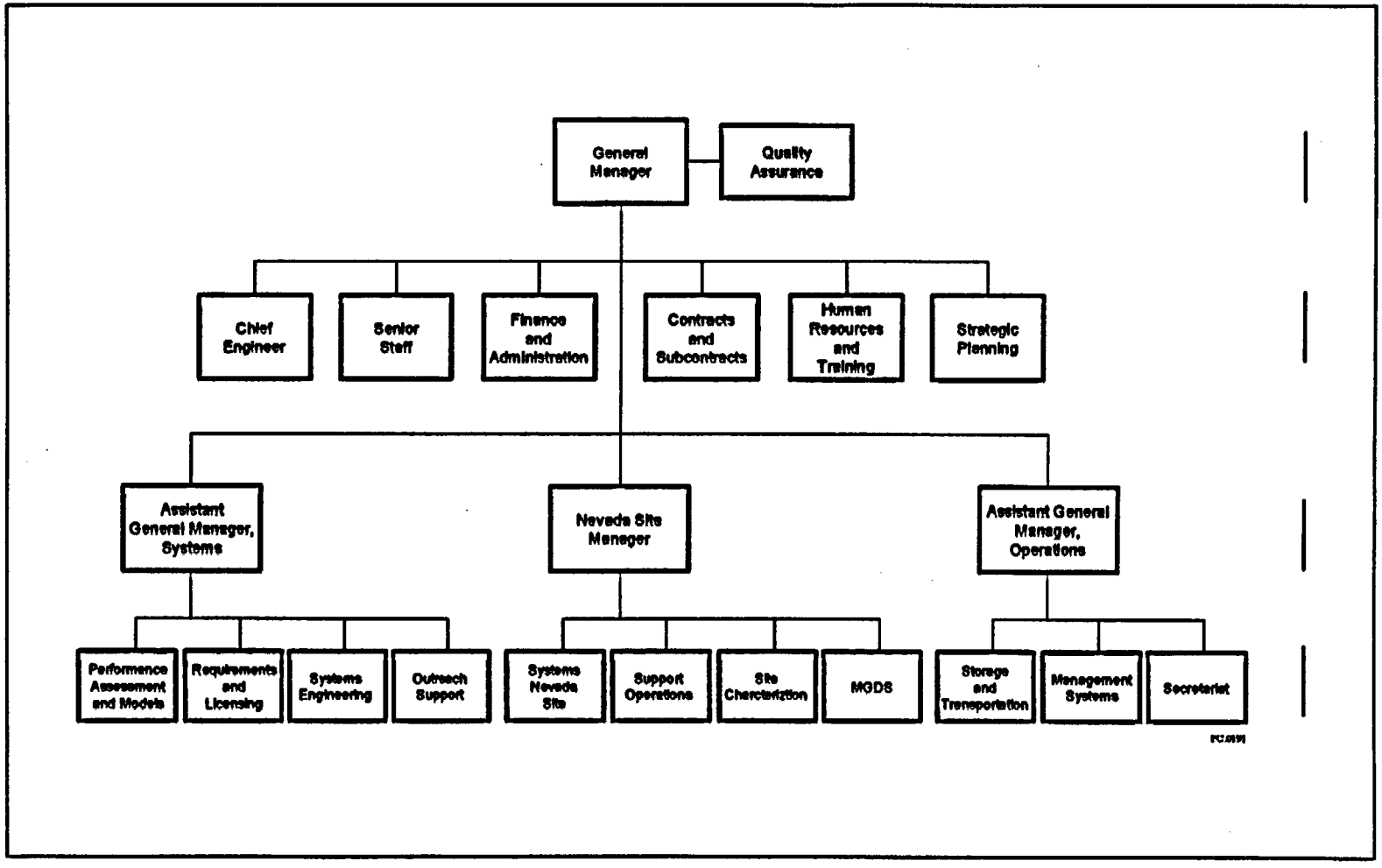

Figure 1. Civilian Radioactive Waste Management System M&O

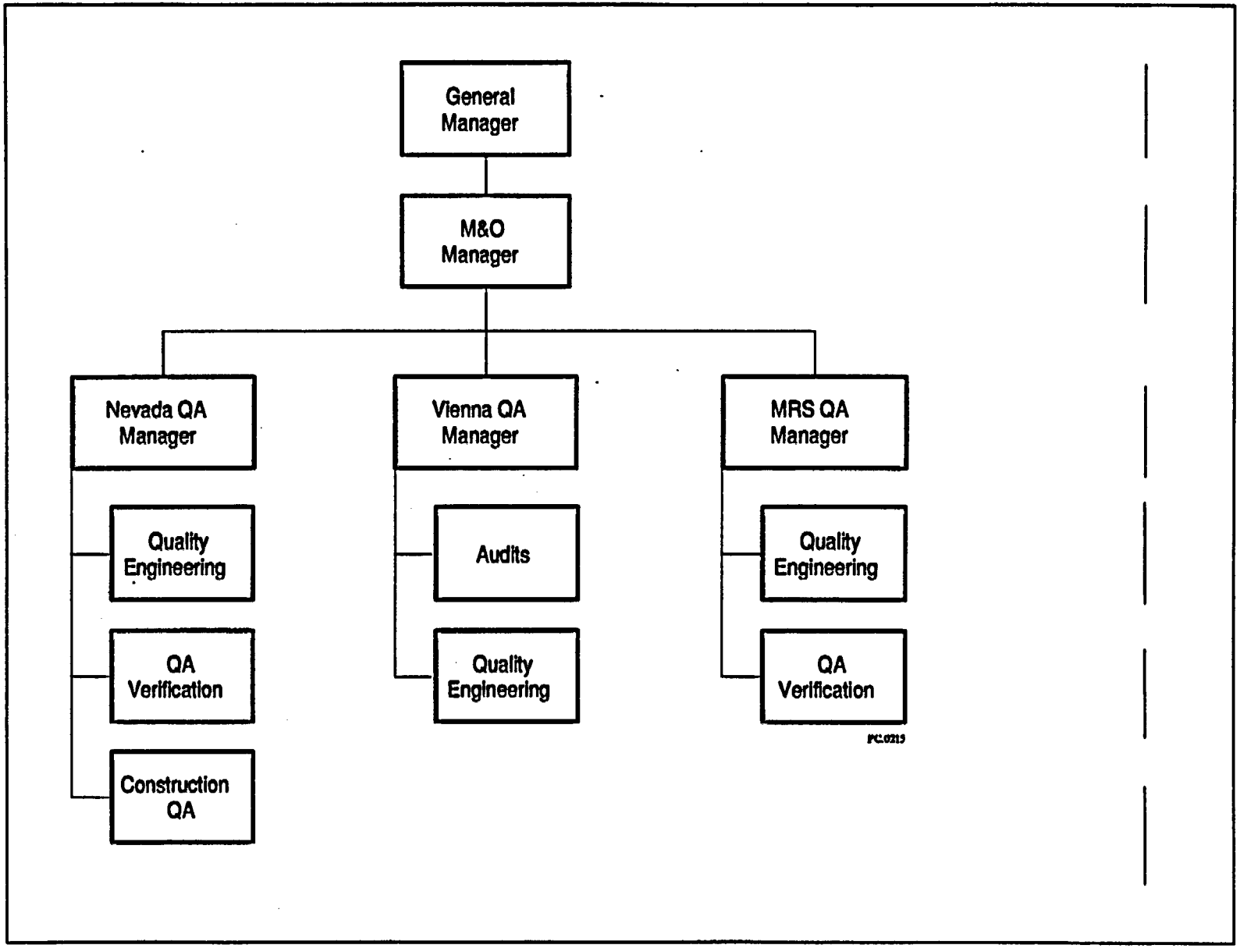

Figure 2. Quality Assurance

h. Provide for annual independent management assessment of the scope, adequacy, and requirements compliance of the M&O Quality Assurance Program.

1.1.2 Quality Assurance Manager

The Quality Assurance Manager reports to the General Manager, thereby providing direct access to the highest management level and assuring appropriate independent control over the Quality Assurance Program. The key management positions reporting to the Quality Assurance Manager are the Nevada QA Manager, the Vienna QA Manager, and the MRS QA Manager.

The responsibilities of the Quality Assurance Manager are to:

a. Incorporate the policy direction and controls established by the General Manager and the requirements of the QARD into the M&O Quality Assurance Program

b. Develop, approve, issue, and maintain this QAPD

c. Assist in the development, review, and approval of all Quality Administrative Procedures (QAPs) and implementing line procedures

d. Ensure that an adequate quality assurance program, responsive to governing DOE and regulatory requirements, is established and implemented

e. Verify through audits, surveillances, and reviews that quality affecting activities are performed effectively and in accordance with the established program

f. Provide interpretations of quality assurance program requirements

g. Obtain DOE acceptance of this QAPD

h. Identify quality-related problems; initiate, recommend, provide solutions; verify implementation of effective corrective action; and, when necessary, stop unsatisfactory work

i. Develop and conduct quality assurance indoctrination, training, and certification programs

j. Review quality affecting documents to ensure compliance with quality assurance requirements

k. Interface with OCRWM and through OCRWM with: NRC; Federal regulatory agencies; the nuclear industry; and affected states, local governments, Indian tribes, and the general public on quality assurance matters related to their areas of interest.

1.1.2.1 Nevada Quality Assurance Manager

The Nevada Quality Assurance Manager reports to the M&O Quality Assurance Manager. This position manages the Quality Engineering, QA Verification, and Construction QA activities in

support of the M&O Nevada Site Manager in implementing the M&O QA Program on M&O assigned quality affecting activities.

The responsibilities of the Nevada Quality Assurance Manager are to:

a. Perform Quality Engineering reviews as delineated in applicable QAPs of M&O site-generated quality affecting documents, implementing line procedures, reports, and records for verification of compliance with the requirements of the QARD

b. Provide M&O Quality Assurance personnel to serve on site program change control boards and task forces as requested

c. Provide program compliance verification of M&O Nevada Site quality affecting activities through surveillances

d. Provide assistance to M&O QA Audits organization in auditing M&O activities

e. Provide data to Vienna QA Manager for the Quality Management Information System

f. Perform QA activities in support of the M&O A/E functions of the Exploratory Studies Facility (ESF)

g. Provide and maintain a certification training program for the M&O inspectors assigned to the Nevada Quality Assurance Manager.

1.1.2.2 Vienna Quality Assurance Manager

The Vienna Quality assurance Manager reports to the M&O Quality Assurance Manager. This position manages the Audits and Quality Engineering (QA) activities headquartered in Vienna, Virginia.

The responsibilities of the Vienna Quality Assurance Manager are to:

a. Manage the training, qualification and certification of lead auditors and auditors

b. Implement the QA Audit Program to verify program compliance spanning the entire scope of M&O quality affecting activities

c. Perform quality engineering reviews as delineated in applicable QAPs of quality affecting documents, implementing line procedures, reports, and records for verification of compliance with the requirements of the QARD

d. Provide M&O Quality Assurance personnel to serve on program change control boards, task forces, and source selection boards as needed

e. Support the Assistant General Manager, Systems by providing QA program compliance verification and reviews of performance assessment, modeling, licensing, and system engineering quality affecting activities

f. Support the Assistant General Manager, Operations by providing QA Program compliance verification and reviews, of MGDS, waste package, storage and transportation designs and associated documentation to verify compliance with QARD requirements

g. Provide quality assurance reviews of procurement documents

h. Maintain the Quality Management Information System database and provide periodic reports to management

i. Track corrective action reports and perform trend analysis

j. Provide document control and records management interface between Vienna QA and the M&O Secretariat.

1.1.2.3 MRS Quality Assurance Manager

The MRS Quality Assurance Manager reports to the M&O Quality Assurance Manager. This position manages the Quality Engineering and QA Verification activities in support of the MRS design activities in Charlotte, NC.

The responsibilities of the MRS Quality Assurance Manager are to:

a. Perform Quality Engineering reviews as delineated in applicable QAPs of MRS Design group generated quality affecting documents, implementing line procedures, reports, and records for verification of compliance with the requirements of the QARD

b. Perform investigations and reviews of quality issues

c. Provide program compliance verification of MRS Design group quality affecting activities through surveillances

d. Provide assistance to M&O QA Audits organization in auditing M&O activities

e. Provide M&O QA personnel to serve on change control boards and task forces as requested

f. Provide data to Vienna QA Manager for the Quality Management Information System.

1.1.3 Human Resources Manager

The Human Resources Manager reports to the General Manager. The key individual reporting to the Human Resources Manager having quality assurance responsibilities is the Training Manager. The Training Manager is responsible for developing and implementing a training program that meets the quality assurance requirements of Section 2 of this QAPD.

1.1.4 Assistant General Manager for Systems

The Assistant General Manager, Systems reports to the General Manager. The key positions reporting to the Assistant General Manager for Systems having quality assurance responsibilities are the Performance Assessment and Models Manager, the Requirements and Licensing Manager, and the Systems Engineering Manager.

The quality assurance responsibilities of the Assistant General Manager for Systems are to:

a. Develop and implement CRWMS quality assurance control requirements through engineering specifications and procedures for quality affecting structures, systems and components

b. Approve quality affecting procedures where the Assistant General Manager for Systems is designated as the development implementing manager

c. Develop, maintain, and control CRWMS technical baselines

d. Control CRWMS system level interfaces

e. Manage the review of existing and proposed system designs for technical adequacy and compliance with baseline and quality assurance requirements

f. Provide review authority responsibilities over direct reports, Strategic Planning, and Systems, Nevada Site

g. Ensure systems integration and optimization of the CRWMS

h. Establish procedures for the development, documentation, control, and implementation of system engineering and scientific models, and for related technical databases

i. Control the verification and validation of quality affecting software used by the M&O

j. Chair the M&O CRWMS Change Control Board (CCB)

k. Interface with OCRWM and through OCRWM with: NRC; Federal regulatory agencies; the nuclear industry; and affected states, local governments, Indian tribes, and the general public on quality assurance matters related to their areas of interest.

1.1.5 Nevada Site Manager

The Nevada Site Manager reports to the General Manager. The positions reporting to the Nevada Site Manager having quality assurance responsibilities are the Systems Manager, Support Operations Manager, Site Characterization Manager, and the MGDS Manager.

The quality assurance responsibilities of the Nevada Site Manager are to:

a. Approve quality affecting procedures where the Nevada Site Manager is designated as the implementing manager

b. Serve as the principal interface between the M&O and the Yucca Mountain Site Characterization Project Office

c. Serve as the M&O Technical Project Officer to the Yucca Mountain Site Characterization Project Office

d. Integrate all M&O activities in support of the Yucca Mountain Site Characterization Project Office

e. Function as the M&O Site Secretariat

f. Provide administrative and support services for all M&O personnel on permanent or temporary assignment in Nevada

g. Coordinate with the Nevada Site QA Manager on quality assurance activities in support of the M&O Site Office and the Yucca Mountain Site Characterization Project Office

h. Manage the MGDS design activities

i. Provide review authority over the activities of direct reports

j. Interface with OCRWM and through OCRWM with: NRC; Federal regulatory agencies; the nuclear industry; and affected states, local governments, Indian tribes, and the general public on quality assurance matters related to their areas of interest.

1.1.6 Assistant General Manager for Operations

The Assistant General Manager, Operations reports to the General Manager. The positions reporting to the Assistant General Manager for Operations having quality assurance responsibilities are the Storage and Transportation Manager, the Management Systems Manager, and the Secretariat.

The quality assurance responsibilities of the Assistant General Manager for Operations are to:

a. Approve quality affecting procedures where the Assistant General Manager for Operations is designated as the implementing manager

b. Manage the overall direction, integration, and coordination of Storage and Transportation, Management Systems and Secretariat activities

c. Provide review authority over the activities of the MGDS design in Nevada, Management Systems, Storage and Transportation, MRS design in Charlotte, NC, Waste Acceptance, and the Secretariat

d. Manage M&O document control and record management activities to the requirements of the QARD

e. Serve as Deputy Chairman for the M&O CRWMS Change Control Board (CCB)

f. Control the program baselines

g. Manage the design of the MRS

h. Interface with OCRWM and through OCRWM with: NRC; Federal regulatory agencies; the nuclear industry; and affected states, local governments, Indian tribes, and the general public on quality assurance matters related to their areas of interest.

1.2 INDEPENDENCE OF QUALITY ASSURANCE PERSONNEL

The Quality Assurance Manager is charged with no other duties than to manage the Quality Assurance organization described in this QAPD. The Quality Assurance organization has been charged with sufficient authority, access to work areas, sufficient freedom from cost and schedule considerations, and organizational independence to:

a. Identify quality problems

b. Initiate the process to correct problems

c. Recommend or provide solutions

d. Obtain resolutions through the proper quality administrative procedure

e. Verify the completion of corrective actions to correct problems.

It is stressed that the identification of quality problems in a timely manner is the responsibility of all M&O personnel.

1.3 ORGANIZATIONAL INTERFACES AND DELEGATION OF WORK

The organizational interfaces between OCRWM, M&O sites, and subcontractors are identified in this document, plans, and applicable implementing procedures. Major M&O interfaces with OCRWM offices are shown in Figure 3.

The delegation of work between OCRWM M&O sites and subcontractors are also identified in this document, plans, and applicable implementing procedures. In all cases of delegation, M&O retains the overall responsibility for all work performed under the direction of the M&O. All M&O quality affecting work shall meet requirements as described in the OCRWM Quality

Assurance Requirements Document and directed by this QAPD. Responsible individuals may delegate some or all assigned work to another individual unless such delegation is restricted by M&O policy or by specific constraints (if any) in the applicable implementing procedures. All delegations shall be in writing.

1.4 RESOLUTION OF DISPUTES

Disputes involving differences of opinion on quality assurance matters or issues are brought to the attention of management, and if not resolved, are elevated progressively to the Quality Assurance Manager. If satisfactory resolution cannot be obtained at that level, the matter is then elevated to the General Manager.

1.5 RESOLUTION OF ALLEGATIONS

Resolution of allegations registered within the M&O organization shall be investigated, resolved, documented, and completely handled in accordance with the DOE OCRWM Quality Concerns Program.

1.6 STOP WORK AUTHORITY

Stop work authority within the M&O is vested in management whenever the health and safety of workers and/or the public is involved, or when continued work will produce results that are not in compliance with the M&O QA Program. This process is controlled by a Quality Administrative Procedure that details the authorities and responsibilities for stopping work, the criteria and documentation required to process the stop work order, and actions required before work may resume. This process ensures that quality affecting activities are controlled until the deficiency, or unsatisfactory condition, has been resolved. Stop work is further discussed in Section 16.8 of this QAPD.

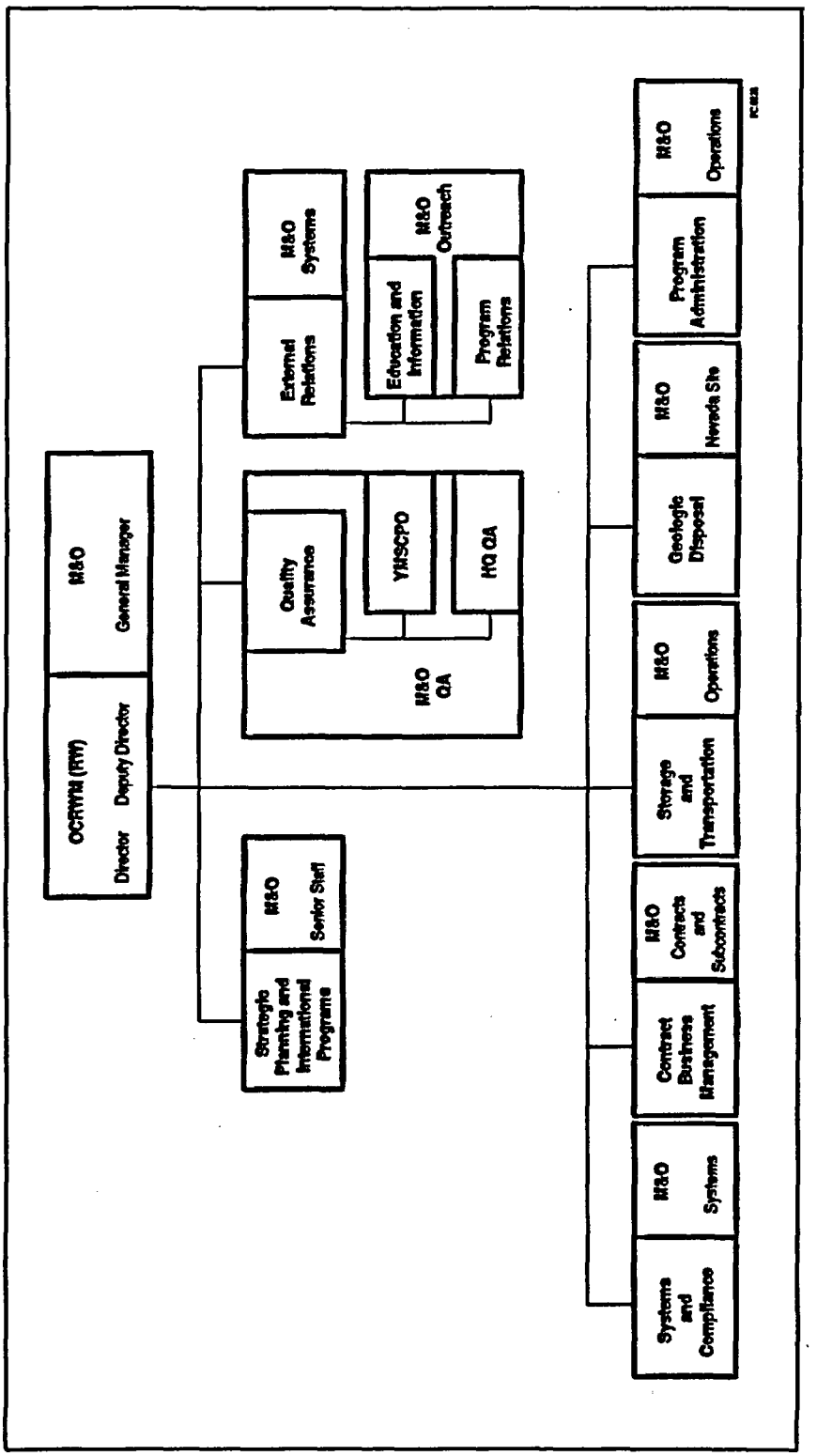

Figure 3. M&O/OCRWM Organizational Interface

SECTION 2

QUALITY ASSURANCE PROGRAM

2.0 GENERAL

The M&O QA Program complies with applicable requirements of the OCRWM QARD and applies to all levels of the organization, including subcontractors.

The M&O Quality Assurance Program is applied in a manner that emphasizes precluding conditions adverse to quality and ensures prompt detection, identification, and corrective action if such conditions occur.

The M&O Quality Assurance Program described in this section and associated procedures implements the committed requirements of QARD Section 2 with the exception of NQA-1 Supplement 2S-2. The scope of work at this time does not require the M&O to have nondestructive examination personnel. If the M&O scope of work changes to require such personnel, then the QA Program shall be revised accordingly.

The M&O Storage and Transportation activities will eventually require the need for certified receiving inspectors. Prior to receiving any items, the receiving inspector certification program shall be established and inspectors shall be trained, tested and certified in accordance with the requirements of NQA-1 Supplement 2S-1 and the requirements of the QARD. When M&O work requires inspector certifications then the necessary certifications programs shall also be established, personnel trained, tested and certified in advance of needing the certified inspectors.

2.1 QUALITY ASSURANCE PROGRAM

2.1.1 Quality Assurance Requirements and Hierarchy of Applicable QA Documents

The quality assurance requirements for the M&O QA Program are derived from the OCRWM QARD. The hierarchy of QA documents that govern and control the quality affecting activities of the M&O and its subcontractors are:

a. DOE OCRWM Quality Assurance Requirements Document (QARD)

b. M&O Quality Assurance Program Description (QAPD)

c. M&O Quality Administrative Procedures (QAPs)

d. M&O Implementing Line Procedures

2.1.2 Quality Assurance Program Description

This QAPD details the M&O organizational structure, quality affecting responsibilities, interfaces, and management controls necessary to meet the requirements of the QARD for the scope of work

assigned by OCRWM to the M&O. This QAPD is approved by the M&O General Manager and Quality Assurance Manager and is required to be submitted to DOE OCRWM for review and acceptance.

2.1.3 Quality Administrative Procedures

M&O Quality Administrative Procedures (QAPs) are used to control quality affecting activities including technical activities (i.e. Design) performed across the entire M&O organization. These procedures are written to implement specific administrative and quality assurance management controls as required by the QARD. Preparation of QAPs is generally assigned to the functional discipline or group with lead responsibility for the activity or area but can be assigned to a group or an individual who has expertise in the activity. All affected M&O groups are to review and concur with the initial (Revision 0) issue of the QAPs and subsequent revisions prior to submittal for approval by the Quality Assurance Manager and the General Manager. QA review and approval of the QAPs ensures that QARD requirements have been included and enables QA to update the QA Requirements Matrix in a timely manner. Once approved, these procedures are contained in the Quality Administrative Procedures Manual, which is issued and controlled by the M&O Secretariat as a controlled document in accordance with the requirements of Section 6 of the QARD.

2.1.4 Implementing Line Procedures

M&O Implementing Line Procedures (ILPs) are used to control quality affecting activities where detailed implementing instructions are restricted to an M&O geographic location or an individual M&O functional area. These procedures include the technical, management, and operating instructions necessary to ensure implementation of the requirements for the individual functional disciplines or groups within the line organization. ILPs are prepared, reviewed, and approved by the management of the line organization responsible for performing the quality affecting work. Interfacing groups provide review and concurrence. QA review and approval of these procedures ensures that QARD requirements have been included and enables QA to update the QA Requirements Matrix in a timely manner. Where needed, these procedures are contained in Implementing Line Procedure (ILP) manuals, which are distributed and controlled by the M&O Secretariat or his designee as in the case of remote locations (i.e., MGDS Nevada Site and MRS Charlotte, N.C. design activities).

2.1.5 QA Requirements Matrix

M&O QA shall maintain a QA Requirements Matrix which shows where QARD requirements are addressed in the M&O QAPD and where implementing controls to meet the requirements are covered in QAPs and in implementing line procedures. If exceptions are taken to the QARD requirements then justification for not implementing the requirements is included in the matrix and is provided to DOE QA for approval prior to starting quality affecting work.

2.2 PROGRAM PLANNING

M&O program planning is to incorporate the elements of Section 2 of the QARD into the development of M&O plans and procedures. Planning efforts are to allow sufficient time for

plans and procedures preparation, review, resolution of comments, approval, distribution, training, and if applicable the performance of readiness reviews prior to the start of quality affecting work.

2.3 READINESS REVIEWS

Readiness reviews are to be performed prior to the start of critical milestones of M&O quality affecting activities as determined by OCRWM direction or by the M&O General Manager. Such reviews are to be performed to the applicable quality administrative procedure prior to the start of quality affecting activities or prior to resuming work that has been stopped by management. The results of such reviews are reported to M&O and DOE management and all open items are tracked to closure. The reviews are performed to confirm that the requirements of Section 2 of the QARD have been satisfied prior to starting or resuming the quality affecting activity.

2.4 CLASSIFYING ITEMS AND APPLYING QA CONTROLS

Classification of items and their associated activities is controlled by the applicable quality administrative procedure (QAP). This QAP implements a methodology for classifying items consistent with Section 2 of the OCRWM QARD and the guidance provided in NUREG-1318, Technical Position on Items and Activities in the High Level Waste Geologic Repository Program Subject to Quality Assurance Requirements, April 1988, as well as other regulations as they apply to the CRWMS program elements for which the M&O is performing quality affecting work. The basis for classification is centered around the item's importance to: radiological safety; waste isolation; control and management of site-generated liquid, gaseous, and solid radioactive waste (other than spent fuel and high-level radioactive waste); safety from the hazards of fire or explosion; seismic interactions; and worker radiological protection. Items in these classifications are placed on a recommended Q-List which is submitted by procedure to OCRWM for approval and control of the Q-list. Quality assurance controls are applied for items on the Q-list and their associated activities commensurate with the factors addressed in Section 2 of the QARD. The applicable controls are placed in the controlling plans and procedures during the natural application of the QA program. The QAP to control this is submitted to DOE QA for review and approval of initial issuance and subsequent revisions.

2.5 PERSONNEL SELECTION, INDOCTRINATION AND TRAINING, AND QUALIFICATION

2.5.1 Personnel Selection

The M&O employs personnel thoroughly trained and experienced in the functional disciplines to which they are assigned. Generally, these individuals only need indoctrination and training in M&O Program requirements, specific methods, procedures, organizational relationships, personnel, and equipment applicable to M&O activities.

Qualifications of personnel employed by M&O are detailed in applications or resumes. These qualifications are matched against position descriptions that establish the minimum education level and experience requirements for the position as well as quality affecting responsibilities. The required education and experience are verified.

2.5.2 Indoctrination and Training

Indoctrination and training needs for individuals are identified based on their job assignment, education and experience. Required indoctrination and training for each individual is established and assigned by the individual's manager or supervisor, except for the General Manager who establishes his own training assignments with concurrence of the M&O Training Manager and QA Manager.

Applicable procedures control indoctrination and training as well as training preparation, lesson plan approvals, content of training, training objectives, conduct of training, and documentation of completed training. Training is conducted to keep pace with new requirements or changes in methods, procedures, and job responsibilities.

Indoctrination and training on the QAPD is required of all personnel performing quality affecting activities. Personnel shall receive indoctrination and training on the general criteria, applicable codes, standards, DOE documents, and procedures for their particular job assignments as determined by their supervisor. Proficiency of personnel performing quality affecting activities shall be maintained through additional training as required by supervision.

Indoctrination and training of M&O personnel are planned, conducted, and coordinated by the M&O Training organization. Records of indoctrination and training are maintained in accordance with the applicable Quality Administrative Procedures. The implementation of indoctrination and training is verified by M&O QA through audits, surveillances, and reviews.

2.5.3 Certification

M&O personnel qualified to perform certain quality affecting activities shall be certified. Certification involves initial certification and periodic recertification, as specified in applicable certification procedures. The only assignments presently requiring certification within the M&O QA Program are instructors, Quality Assurance Lead Auditors and Auditors, and overview inspectors. The M&O Training Manager certifies instructors and the Quality Assurance Manager certifies Lead Auditors and Auditors in accordance with the requirements of NQA-1, Supplement 2S-3, and Appendix 2A-3. Other personnel shall be certified when required by specifications governing activities that they are performing.

2.5.4 Qualification of M&O Personnel to Perform Work to OCRWM QA Program

M&O personnel assigned by DOE to perform quality affecting work under the DOE OCRWM QA Program receive QA Indoctrination Training and the applicable procedure training as required by the OCRWM QA Program. These personnel are also required to have their personnel qualifications verified in accordance with the applicable OCRWM procedure prior to the start of quality affecting work.

2.6 SURVEILLANCE

The M&O QA Program utilizes surveillances to evaluate effective implementation of quality affecting work activities performed by M&O personnel.

Surveillances are relatively narrow-scoped observations of activities or documentation to evaluate compliance with approved procedures. Surveillances are conducted by M&O Quality Assurance personnel, trained in the applicable QAP, who are independent of the work activity. Technical experts, when used, must not be directly responsible for the activities under surveillance, and will be accompanied by a member of the QA organization trained in performing surveillances.

Surveillances are controlled by the appropriate Quality Administrative Procedure. This administrative procedure details the planning, preparation, performance, documentation, reporting, and tracking of surveillance results. The results of surveillances are formally documented and reported in a timely manner to the M&O management. The timely notification of findings allows for prompt initiation of necessary corrective actions. The procedure also allows for immediate correction of findings during performance of the surveillance. Deficiencies identified during surveillances are documented and processed in accordance with Section 16 of this QAPD. All surveillance findings are tracked to ensure completion of corrective actions and are trended to evaluate the need for further corrective action to prevent recurrence. Records of surveillances are maintained in the M&O Record Management System.

2.7 MANAGEMENT ASSESSMENTS

An independent management assessment of the implementation and effectiveness of the M&O QA Program is conducted annually at the direction of the General Manager. Management Assessments are performed to the applicable Quality Administrative Procedure, which incorporates the requirements of Section 2 of the QARD for these assessments. Findings are reported to management and tracked to completion of all corrective actions.

2.8 QUALITY ASSURANCE PROGRAM MANAGEMENT INFORMATION REPORTING AND TRACKING

The M&O Quality Assurance organization is responsible for reporting, tracking, and disseminating quality assurance program management information. The following types of quality assurance program management information are reported quarterly to the General Manager, his staff having responsibility for implementing the M&O QA Program, and DOE:

a. Status of development of the M&O QA Program

b. Status of resolution of significant conditions adverse to quality, QA issues, and quality trends

c. Summary of required management and QA overview results.

The administration of reporting, tracking, and disseminating this information is documented in the appropriate Quality Administrative Procedure. The resulting information is used to inform senior management of program progress and provide a management tool for program evaluation and improvement.

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SECTION 3

DESIGN CONTROL

3.0 GENERAL

The quality assurance controls described in this section are applicable to Conceptual, Title I, Title II, and Title III Design activities commensurate with the structure's, system's or component's classification as discussed in Section 2 of this QAPD. Major activities include preparation of design inputs and outputs, design analyses, design verifications, design change control, interface control, and design documentation including conceptual and final design reports, drawings, specifications, engineering study reports, and major interdisciplinary engineering reports.

The M&O Quality Assurance Program described in this section and associated procedures implements the committed requirements of QARD Section 3.

3.1 M&O CONTROL OF DESIGN ACTIVITIES

M&O implements a systems engineering approach to control and manage the development of the technical baseline for which the M&O has design responsibilities. Control of M&O quality affecting design activities are through QAPs and ILPs written to meet the requirements of the OCRWM QARD. These procedures include measures for documenting, reviewing, and approving applicable design inputs, design criteria, performance requirements, regulatory requirements, codes and standards identification, and appropriate quality assurance standards.

Changes from approved design inputs, including the reason for the change are identified, approved, documented, and controlled in the same manner as the original design. The configuration management process controls the iterative process of developing an integrated design, and documenting, maintaining, and controlling the technical baseline through a Change Control Board. The M&O Assistant General Manager Systems is responsible for the development and control of the system technical baselines.

3.2 DESIGN RESPONSIBILITIES

The M&O Assistant General Manager for Operations, Assistant General Manager for Systems, and the Nevada Site Manager are responsible for the control of design activities assigned to their organizations. Each Design Manager has the authority and responsibility to prescribe, accomplish, and document design control activities within their assigned area of design. QAPs and implementing line procedures for design activities are written in accordance with the M&O QAPD and the OCRWM QARD.

Procedures specify how the originators of design documents are responsible for including, either directly or by reference, the applicable quality assurance requirements. Quality assurance requirements are applied throughout the design process according to potential impacts on safety to the public, waste isolation, and program objectives as determined by the cognizant engineering document originators with the concurrence of QA.

The M&O Assistant General Manager for Systems is responsible for the conduct of review and verification of design packages to ensure that they are in compliance with system and regulatory requirements.

3.3 DESIGN INPUTS

Design inputs for each CRWMS element (MGDS, MRS, Storage and Transportation) are provided in a design basis document. The design basis document identifies all applicable federal, state, and local regulations. Regulatory requirements affecting design, such as 10CFR60, 10CFR70, 10CFR71, environmental regulations, applicable consensus standards, etc., have been identified by OCRWM Headquarters. State and local requirements are identified by the project office or OCRWM Headquarters. These requirements are baselined and maintained in the DOE approved design requirement documents. Other information included in the design basis documents are:

1. Design codes and standards

2. Design data

3. Design assumptions

4. Results of studies specifying configuration

The design basis documents are controlled design requirements documents and are generated under the M&O QA Program controls contained in this document. The design basis documents are to be approved by DOE OCRWM Headquarters.

3.4 DESIGN PROCESS

Overall planning of M&O quality affecting design activities is accomplished and controlled by the appropriate QAPs or implementing line procedures. The priority for procedure development and implementation supports the program element schedule. Procedures are generated, approved, and implemented to allow sufficient time for design analysis and verification that the design meets requirements. Final approved design documents are completed as appropriate to accommodate Title I, Title II, and Title III Design activities for each CRWMS program element.

3.4.1 Design Analyses

Design analysis documents address the purpose, method, assumptions, design inputs including their sources, design units, and references such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. Calculations are identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date. For any computer calculation the computer type, computer program name, revision identification, inputs, outputs, evidence of or reference to the program verification and the bases reference supporting the application of the computer program to the specific physical problem is also included. Design analysis documents are legible, reproducible, and retrievable.

The design is traceable by reference to the pertinent documents in sufficient detail to permit design verification.

3.4.2 Design Verification

Procedures used for design verification ensure the following:

a. The method and results of verification are documented

b. The reviewers and their qualifications are identified

c. The specific item being verified is clearly identified and traceable

d. The method to identify, track, and resolve the resolution of comments is delineated

e. The criteria for determining the method of verification is established

f. Responsibilities of persons performing the verification are defined

g. The procedure clearly defines the documents required for completion of the verification process.

The extent of required design verification is a function of the importance to safety or to waste isolation of the item under consideration, the critical nature of the item's performance in relation to system performance and mission objectives, the complexity of the design, the degree of standardization, the state of the art, and similarity with previously proven designs. Known problems affecting standard or previously proven designs are evaluated and documented.

Design verification is accomplished by one or more of the following methods:

1. Design reviews, which verify the following, as a minimum:

    a. Design inputs are correctly selected

    b. Assumptions necessary to perform the design activity are clearly documented and identified for subsequent verification when the detailed design activities are completed

    c. An appropriate design method was used

    d. Design inputs were correctly incorporated into the design

    e. Design output is reasonable compared to design inputs and meets system functional and performance requirements

    f. The necessary design input and verification requirements for interfacing organizations are specified in the design documents or in supporting procedures.

2. Calculations or analyses are performed using alternative methods to verify the results of the original calculation or analysis. The appropriateness of assumptions, input data used, and the computer program or other calculation methods used is reviewed.

3. Qualification Tests. When design adequacy is verified by qualification testing, the tests and test configuration are clearly identified, defined, and documented. Qualification testing demonstrates the adequacy of performance under conditions that simulate the most adverse design conditions.

   Test results are reviewed by the responsible design group to assure that test requirements have been met.

Design verification is performed prior to release for procurement, manufacturing, construction or use in other design activities. Any unverified portions of the design are appropriately identified and controlled. The results of design verification are clearly documented, with the identity of the verifier clearly indicated. Activities are performed and outputs are used for formal reference, procurement, or other M&O uses only to completed "released" documents.

3.4.3 Technical Reviews

Technical reviews are performed for designs that are within the state of the art. These reviews shall be performed by a qualified individual, or individuals, other than those who performed the original design. Technical reviews may be performed by the originator's supervisor, provided the supervisor did not specify a single design approach or rule out certain inputs used in the design. If the original supervisor does not meet this test, and is the only individual in the organization competent to perform the verification, the originating supervisor may be selected to verify the design if the Assistant General Manager for Operations or the Nevada Site Manager or their designees approves and documents the selection, with QA concurrence, in advance.

Technical reviews shall assure that the document being reviewed is applicable, correct, complete and meets established requirements. The results of the technical review are required to be documented.

3.4.4 Peer Review

Peer reviews are conducted for studies and designs outside the state of the art. Because of the investigative nature of studies that are beyond the state of the art, it is required that a review of designs, procedures, tests, data acquisition and reductions, analysis, and interpretation of data for each investigation activity be conducted by a technically qualified peer group other than those who performed the original study or design. Cognizant office managers shall specify items to be reviewed and, when requested by DOE, will designate peer review candidates for consideration and endorsement by DOE. Peer reviews are performed to the applicable M&O Quality Administrative Procedure which is written to implement the guidance provided in NUREG-1297, Peer Review for the High-Level Waste Repositories Generic Technical Position, February 1988. DOE may also request that M&O personnel conduct peer reviews under the OCRWM QA Program. These reviews are then performed to the applicable OCRWM procedure.

3.4.5 Design Changes

Verification of design is performed for all changes (including field changes) to previously verified designs. Design changes are evaluated for need as well as impact on the overall design, affected procedures and training. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure are reviewed and modified as necessary. Design changes are reviewed and approved using the same methods applied to the preparation of the original design.

3.4.6 Computer Programs

Computer programs used for the design of quality affecting structures, systems and components are controlled by the M&O Computer Software Quality Assurance Plan. Software configuration, verification, and validation processes are controlled by the applicable QAPs. Section 19 of this QAPD addresses this plan.

3.5 DESIGN DEFICIENCY CONTROL

Errors and deficiencies in approved design and design input documentation are documented and resolved in accordance with Section 16 of this QAPD. The impact of such design deficiencies on work previously performed using the affected documents is evaluated and corrective measures applied.

3.6 DESIGN DOCUMENTATION

Design drawings, specifications, criteria, and analyses are reviewed by the line organization responsible for the design to ensure the documents are prepared, reviewed, approved, and released in accordance with procedural requirements. The M&O QA organization verifies compliance with the QA Program through audits, surveillances, and reviews.

3.7 DESIGN INTERFACES

Internal and external design interfaces are identified by an interface control document and controlled in accordance with the M&O Configuration Management Plan and approved procedures.

3.8 CONFIGURATION MANAGEMENT

Configuration control is accomplished in accordance with applicable M&O QAPs and implementing line procedures. This system ensures there is a consistent and current M&O-wide understanding of configuration control.

3.9 READINESS REVIEWS FOR DESIGN ACTIVITIES

Readiness reviews of design activities are performed to confirm the following:

a. Design schedules and related planning documents have incorporated the applicable design development, review, and baseline factors

b. Applicable regulatory requirements, codes, standards, and controls have been identified. Procedures and procurement documents reflect required design inputs.

c. Design and interface responsibilities are clearly defined in applicable procedure and procurement documents

d. Design schedules identify milestone design reviews, and technical performance measurement points and parameters

e. Configuration management procedures for baselining design documents and controlling subsequent changes are generated, approved, and personnel trained in their use prior to start of design activities

f. The activity is mature enough to proceed to the next implementation phase.

SECTION 4

PROCUREMENT DOCUMENT CONTROL

4.0 GENERAL

Quality assurance controls specified in this section are applicable to procurement document control activities at all levels throughout the M&O organization where quality affecting items and services are procured. This section addresses the requirements for the preparation, review, and approval of procurement documents and subsequent changes.

The M&O Quality Assurance Program described in this section and associated procedures implements the committed requirements of QARD Section 4.

4.1 PROCUREMENT DOCUMENT PLANNING, PREPARATION, REVIEW AND REVISION, AND APPROVAL

4.1.1 Planning

The applicable Quality Administrative Procedure details the generation, review, and approval of procurement documents. Planning includes the detailing of the identification of the need for the specific item or service, determining the specific service and deliverables to be accomplished, identifying the appropriate technical and quality assurance requirements, and evaluating the potential sources for the item or service. Planning preparation also allows for sufficient time for training of personnel on the applicable procedures prior to the time the item or service is needed.

4.1.2 Document Preparation

In preparing the M&O issued procurement documents for items or services, the following is included in the procurement document package, as appropriate:

a. A statement of the scope of work to be performed or provided by the supplier

b. Technical requirements to include, as necessary, reference to specific drawings, specifications, codes, standards, regulations, procedures or instructions including revisions

c. Quality assurance program requirements:

   1. Reference to, and/or inclusion of, quality assurance program requirements of the QARD commensurate with the importance of the item or service to safety or waste isolation, etc., as determined by the procurement requestor through the application of the classification process

   2. A statement allowing the supplier to perform quality affecting work to the M&O QA Program or instructions to incorporate the applicable QARD requirements into the supplier implementation procedures

3. A statement requiring the supplier to incorporate appropriate provisions of the QARD requirements in subtier procurement documents and supplier procedures

4. The right of access by the M&O to supplier and subtier facilities and records for QA verification purposes

5. Documentation and submittal of reports and records to be included in the procurement document

6. Identification of M&O requirements for reporting and approving the disposition of nonconformances and corrective action documentation

7. Verification that the supplier has received the applicable indoctrination and training on the M&O QA Program and M&O procedures to perform a service if the M&O QA Program is to be used

8. Identification of appropriate spare and replacement parts or assemblies and the technical and quality assurance related data required for ordering these parts or assemblies

9. Identification of test, inspection, and acceptance requirements for monitoring and evaluating the supplier's performance.

4.1.3 Review and Revision

Procurement documents are reviewed by the M&O technical discipline requiring the item or service and the quality assurance organization prior to contract award to ensure that the applicable technical and quality assurance program requirements are included. If the procurement document requires revision, it shall undergo the same level of review as the original procurement document. Personnel performing the review receive training in the applicable Quality Administrative Procedure and have access to pertinent information and an adequate understanding of the technical and quality assurance requirements imposed on the supplier.

4.1.4 Approval

Once the procurement document is approved by the technical and quality assurance representatives, it is submitted to the M&O Contracts and Subcontracts Manager for final approval.

4.2 DOCUMENT CONTROL AND DOCUMENTATION

Control of the procurement document to the supplier is the responsibility of the M&O Contracts and Subcontracts Manager. A copy of the procurement document is forwarded to the M&O Quality Assurance Records System in accordance with Section 17 of this QAPD.

SECTION 5

PLANS, PROCEDURES, AND DRAWINGS

5.0 GENERAL

M&O quality affecting activities are prescribed by plans, procedures, and drawings. Procedures include or reference the appropriate quantitative and qualitative acceptance criteria for determining the acceptance of prescribed activities. The planning, preparation, review, approval, issuance, and training of personnel to these documents is accomplished prior to the start of quality affecting work.

The M&O Quality Assurance Program described in this section and associated procedures implements the committed requirements of QARD Section 5.

5.1 M&O PLANS, PROCEDURES, AND DRAWINGS

Plans, when required, are developed, reviewed, and approved in accordance with the applicable Quality Administrative Procedure. The M&O Quality Administrative Procedures (QAPs) and Implementing Line Procedures (ILPs) incorporate the committed requirements from the applicable sections of the QARD. QA ensures that all applicable quality assurance requirements are addressed prior to approval. QAPs and ILPs are developed using the applicable M&O Quality Administrative Procedure. These procedures are reviewed by those groups that have actions in the procedures; comments are resolved; and documentation of resolutions of mandatory comments are retained as QA records. All QAPs and ILPs are required to identify what documents generated by the procedures are to be retained as QA records. Further discussion on QAPs and ILPs is found in Section 2 of this QAPD.

The generation, review, and approval of drawings is also controlled by a M&O Quality Administrative Procedure. Any revision to these documents undergo the same approval process as the original.

5.2 PERIODIC REVIEW

Quality Administrative Procedures and implementing line procedures are reviewed by an individual knowledgeable in the area affected by the procedure at a frequency not to exceed 2 years. The M&O Manager responsible for the development of the procedure has the responsibility for performing this review. This review verifies the procedure remains consistent with current requirements. The results of these reviews are documented and retained in the QA Records Management System.

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SECTION 6

DOCUMENT CONTROL

6.0 GENERAL

M&O develops documents that provide direction for M&O quality affecting activities. This QAPD section addresses the preparation, issue, and change controls for such documents. The M&O Secretariat has overall responsibility for M&O document control except for procurement documents as detailed in Section 4 of this QAPD.

The M&O Quality Assurance Program described in this section and associated procedures implement the committed requirements of QARD Section 6.

6.1 CONTROL SYSTEM

6.1.1 Document Preparation and Change

Preparation, issue, and changes to plans, procedures, drawings and other documents specifying activities affecting quality are controlled by the applicable Quality Administrative Procedure to ensure that correct documents are being used. The documents to be controlled are identified, distribution established, and responsibilities identified, for the preparation, review, approval, and issuance. Documents, including changes, are reviewed for impact on program elements (i.e., waste isolation capability, interference with other site characterization activities, transportation system impacts on MRS or MGDS, etc.), adequacy, completeness, and correctness by authorized personnel prior to approval and issuance.

Major changes to documents are reviewed and approved by the same organization that performed the original review and approval unless other organizations are specifically designated. The reviewing organization has access to pertinent background data or information upon which to base their approval.

Major changes are those changes that constitute a modification to a QA program document changing previously established M&O policy, Quality Assurance Program requirements, technical requirements, or a substantive change in a previously established level of control.

Minor changes, such as inconsequential editorial corrections, do not require the same review and approval. Persons authorized to implement a minor change are clearly delineated.

6.1.2 Issuance and Distribution

Document issuance and distribution is controlled to ensure that correct, applicable, and current documents are available to M&O personnel performing quality affecting activities. Relevant documents are issued prior to commencing quality affecting work. Documents are issued and distributed in accordance with the applicable Quality Administrative Procedure.

The Quality Administrative Procedure for document control addresses the following provisions:

a. Identification and marking of documents are described

b. A receipt acknowledgement is maintained documenting receipt of issued documents

c. Distribution lists are maintained for controlled documents

d. For documents that require verification, but need to be released prior to verification, the unverified portions are clearly identified as "verification pending." In such instances, these documents are restrictively controlled and authorized for release only by appropriate signature authority, and the basis for their release is documented

e. Procedures detail the timely marking, removal, or destruction of obsolete or superseded controlled documents to prevent inadvertant use

f. Controlled document lists are maintained that provides the current revision status for all controlled documents

g. Resolution of review comments is accomplished for comments considered mandatory prior to approval and issuance of the document. The process to control this is addressed in the applicable QAPs used to generate quality affecting documents.

SECTION 7

CONTROL OF PURCHASED ITEMS AND SERVICES

7.0 GENERAL

Quality assurance controls specified in this section are applicable to control of purchased items and services at all levels throughout the M&O organization. This section addresses the requirements for the evaluation and selection of suppliers of quality affecting items and services and the acceptance of such items and services.

The M&O Quality Assurance Program described in this section and associated procedures implement the committed requirements of QARD Section 7.

7.1 SUPPLIER QUALITY ASSURANCE PROGRAMS

Prospective suppliers of quality affecting items and services shall submit their QA program documents showing evidence that their QA program meets the imposed QARD requirements on the procurement document. M&O QA shall review and assure that any deficiencies found with the program are corrected prior to the initiation of quality affecting work. Procurements are prepared and contracts placed in accordance with the Federal Acquisition Regulations (FAR) and Department of Energy Acquisition Regulations (DEAR) as applicable.

7.2 M&O CONTROL OF PURCHASED ITEMS AND SERVICES

The applicable Quality Administrative Procedure describes the methods used to evaluate and document a supplier's ability to meet M&O's expectations for providing quality affecting items or services.

7.2.1 Procurement Planning

Procurement planning is accomplished and documented as early as practicable to provide the appropriate interface compatibility and ensure a systematic approach to the procurement process. Procurement planning addresses the following:

a. The quality affecting items or services being procured

b. Identification of M&O organizations having responsibilities and interfaces with the procurement

c. Establishment of schedule for the procurement

d. Provisions for the integration of: procurement document preparation, review, and change control; selection of sources; bid evaluation and award; purchaser hold and witness points; evaluations of supplier's performance; control of nonconformances/ corrective actions; acceptance of the item or service; and quality assurance records.

7.2.2 Supplier Selection

Methods and criteria for evaluating supplier capabilities and selecting suppliers is in accordance with the applicable Quality Administrative Procedure. The cognizant M&O requisitioning manager, the Contracts and Subcontracts Manager, and Quality Assurance participate in the selection process.

7.2.3 Supplier Performance Evaluation

Once the contract is placed and the supplier's QA program is verified to meet the applicable QARD requirements then performance evaluations, including reviews, audits, and surveillances, as appropriate, will begin commensurate with the relative importance and complexity of the procured items or services and the supplier's past quality performance. For subcontracted work, the primary supplier is required to impose all applicable QARD requirements to subtier suppliers. The supplier is required to perform performance evaluations of subtier suppliers however the M&O retains the right to also evaluate subtier suppliers. Evaluations are implemented to ensure conformance with procurement document requirements.

7.2.4 Change Control

Changes to purchased items and services are evaluated in the same manner and with the same criteria as the original procurement documents.

7.2.5 Acceptance of Items and Services

Acceptance of purchased items and services is based on one or more of the following techniques:

a. Technical review of the purchased service's data and report

b. Surveillance or audits of the supplier

c. Review of objective evidence for conformance to the procurement document requirements

d. Evaluation of quality assurance documentation required by the procurement document

e. Receipt inspections of supplied items.

7.3 RECEIVING INSPECTIONS

When required by the M&O scope of work, receiving inspectors shall be trained and certified in accordance with Section 2 of this document. Receiving inspection procedures shall be written, reviewed, and approved in accordance with the requirements of Sections 5 and 10 of the QARD and training shall be conducted prior to quality affecting receiving inspections being performed.

SECTION 8

IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

8.0 GENERAL

Under the present scope of work, the M&O QA Program does not necessitate the establishment of management controls for Section 8 of the QARD. If the M&O scope of work changes to require this, then the QA Program shall be revised accordingly. This would require a revision to the QAPD, the generation, approval, and controlled issuance of implementing procedures and personnel training to the QAPD revision and implementing procedures prior to any quality affecting work being performed in this area.

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SECTION 9

CONTROL OF PROCESSES

9.0 GENERAL

Under the present scope of work, the M&O QA Program does not necessitate the establishment of management controls for Section 9 of the QARD. If the M&O scope of work changes to require this, then the QA Program shall be revised accordingly. This would require a revision to the QAPD, the generation, approval, and controlled issuance of implementing procedures and personnel training to the QAPD revision and implementing procedures prior to any quality affecting work being performed in this area.

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SECTION 10

INSPECTION

10.0 GENERAL

Quality Assurance controls specified in this section are applicable to inspection activities at all levels throughout the M&O organization where quality affecting items and activities are inspected by the M&O. This section addresses the requirements for inspection on an item or activity to verify conformance to specified requirements and to demonstrate satisfactory performance for service. This section also controls overview inspections as required by applicable DOE orders.

The M&O Quality Assurance Program described in this section and associated procedures implement the committed requirements of QARD Section 10.

10.1 INSPECTION PERSONNEL

The applicable M&O Procedures requires that inspection personnel who perform an inspection to verify conformance of an item/activity to specified acceptance criteria are qualified to perform the assigned inspection task.

Prior to obtaining certification, inspections are performed by personnel during on-the-job training for qualification under the direct observation and supervision of a qualified inspector.

Inspection personnel do not report directly to the immediate supervisor of the organization/crew performing the work being inspected.

10.2 INSPECTION PLANNING

The planning for inspection activities is accomplished and documented in the applicable M&O Procedures, and the following is included:

a. Identification of the implementing documents to be used to control and perform the inspections including procedures, drawings, and specifications and their revisions

b. Identification of the characteristics to be inspected and when, during the work process, inspections are to be performed

c. Identification of the inspection or process monitoring methods to be employed

d. Specification of applicable measuring and test equipment, including accuracy requirements

e. Identification of the qualification level of inspection personnel

f. Identification of acceptance criteria

g. Methods to record inspection results

h. Identification of recognized standard practices and sampling requirements as applicable when a sample is used to verify acceptability of a group of items.

10.3 INSPECTION HOLD POINTS

Specific hold points are indicated in implementing documents when it is necessary to control work that should not proceed without the specific consent of the organization placing the hold points. Consent to waive specified hold points is documented prior to continuation of work beyond the designated hold points.

10.4 OVERVIEW INSPECTIONS

Overview inspections are conducted as required by applicable DOE orders on existing inspection processes or construction activities to evaluate the effectiveness of a contractor's inspection program. Overview inspections are performed by certified inspectors working to the applicable inspection implementing procedures. These inspections are documented in accordance with the applicable inspection procedures.

10.5 IN-PROCESS INSPECTION AND MONITORING

The requirement that items and work activities in-process or under construction are inspected when necessary to verify quality is prescribed by procedure. Where inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel is performed.

Both inspection and process monitoring are performed when control is inadequate without both. The procedure requires that when a combination of inspection and process monitoring methods are used, they are performed in a systematic manner to ensure that the specified requirements for control of the process and the quality of the item are met throughout the duration of the process.

Controls are established and documented for the coordination and sequencing of the work activities at established inspection points during successive stages of the conducted process or construction.

10.6 FINAL INSPECTIONS

The applicable M&O Procedures requires final inspections on completed items and work activities that include inspections for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item or work activity to specified requirements. If not previously accomplished, quality records are examined for adequacy and completeness.

Final inspections include a records review of the results and resolution of nonconformances and/or Corrective Action Reports (CARS) identified by earlier inspections. The final inspection is planned to arrive at a conclusion regarding conformance of the item or work activity to specified requirements.

The acceptance of the item or work activity under the total control of the M&O is documented and approved by authorized M&O personnel and reviewed by M&O QA.

The acceptance of items/activities under contractor control are accepted by the contractors and/or OCRWM.

Modifications, repairs, or replacements of items performed subsequent to final inspection are required to be reinspected or retested, as appropriate, to verify acceptability.

10.7 INSPECTION RECORDS

The applicable M&O Procedure requires that inspection records, as a minimum, identify the following:

a. Item or work activity inspected

b. Date of inspection

c. Name of the inspector, or the inspector's unique identifier, who documented, evaluated, and determined acceptability

d. Type of observation or method of inspection

e. Inspection criteria, sampling plan, or reference documents used to determine acceptance

f. Results or acceptability

g. Measuring and test equipment used during the inspection including the identification number and the most recent calibration date

h. References to information on action taken in connection with nonconformances/CARS.

The M&O completed inspection records are reviewed by M&O QA and maintained in accordance with Section 17 of this QAPD.

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SECTION 11

TEST CONTROL

11.0 GENERAL

Under the present scope of work, the M&O QA Program does not necessitate the establishment of management controls for Section 11 of the QARD. If the M&O scope of work changes to require this, then the QA Program shall be revised accordingly. This would require a revision to the QAPD, the generation, approval, and controlled issuance of implementing procedures and personnel training to the QAPD revision and implementing procedures prior to any quality affecting work being performed in this area.

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SECTION 12

CONTROL OF MEASURING AND TEST EQUIPMENT

12.0 GENERAL

Under the present scope of work, the M&O QA Program does not necessitate the establishment of management controls for Section 12 of the QARD. If the M&O scope of work changes to require the M&O to establish its own calibration program, then the QA Program shall be revised accordingly. This would require a revision to the QAPD, the generation, approval, and controlled issuance of implementing procedures and personnel training to the QAPD revision and implementing procedures prior to any quality affecting work being performed in this area.

If during the course of performing overview inspection of constructor activities and measure and test equality activities is needed, then the M&O inspectors shall use M&TE that is controlled under an OCRWM approved QA program.

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SECTION 13

HANDLING, STORAGE, AND SHIPPING

13.0 GENERAL

Under the present scope of work, the M&O QA Program does not necessitate the establishment of management controls for Section 13 of the QARD. If the M&O scope of work changes to require this, then the QA Program shall be revised accordingly. This would require a revision to the QAPD, the generation, approval, and controlled issuance of implementing procedures and personnel training to the QAPD revision and implementing procedures prior to any quality affecting work being performed in this area.

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SECTION 14

INSPECTION, TEST, AND OPERATING STATUS

14.0 GENERAL

Under the present scope of work, the M&O QA Program does not necessitate the establishment of management controls for Section 14 of the QARD. If the M&O scope of work changes to require this, then the QA Program shall be revised accordingly. This would require a revision to the QAPD, the generation, approval, and controlled issuance of implementing procedures and personnel training to the QAPD revision and implementing procedures prior to any quality affecting work being performed in this area.

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SECTION 15

CONTROL OF NONCONFORMING ITEMS

15.0 GENERAL

The requirements addressed in QARD Section 15 are not addressed. The identification of nonconformances with the requirements and commitments of the M&O QA Program shall be identified, evaluated, corrected, and documented as described in Section 16 of this document. If the scope of work for the M&O changes and requires the M&O to write nonconformance reports, then this section of the QAPD shall be revised, an implementing procedure shall be generated, approved and issued, and training of personnel shall be completed prior to the implementation of the revised program.

If during overview inspections a nonconformance is observed, then the appropriate OCRWM procedure shall be used to identify the nonconformance.

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SECTION 16

CORRECTIVE ACTION

16.0 GENERAL

Conditions adverse to quality are promptly identified, documented, evaluated to determine the degree of significance, and corrected in a timely manner. Such conditions are reported on Corrective Action Reports. These Corrective Action Reports are routinely reported to keep management apprised of status and closely tracked to closure. M&O personnel are required to identify such conditions in accordance with the applicable Quality Administrative Procedure. Identification of such deficiencies is not limited to the QA organization, but is the responsibility of all M&O personnel.

The M&O Quality Assurance Program described in this section and associated procedures implements the committed requirements of QARD Section 16.

16.1 CONDITIONS ADVERSE TO QUALITY

Conditions adverse to quality exist wherever program requirements are not met and are reported on Corrective Action Reports. Examples of conditions adverse to quality are programmatic deficiencies such as defective software, procedures, records, unverified computer codes, activities, or actions that result in failure to comply with established procedures, plans, and other requirements.

16.2 SIGNIFICANT CONDITIONS ADVERSE TO QUALITY

Significant conditions adverse to quality are those conditions determined to be repetitive in nature, or any condition adverse to quality that, were it to remain uncorrected, could adversely affect safety or waste isolation, or the validity or credibility of site characterization conclusions. These conditions are evaluated to determine root cause, generic implications to the program, immediate remedial corrective action, and action taken to preclude recurrence. When a condition is determined to be a significant condition adverse to quality, appropriate management is immediately notified.

16.3 IDENTIFICATION OF CONDITIONS ADVERSE TO QUALITY

Conditions adverse to quality are identified as a result of audits, surveillances, and reviews of the performance of normal work activities of line personnel and suppliers working to the M&O QA Program. Conditions adverse to quality are documented on Corrective Action Reports in accordance with the applicable Quality Administrative Procedure and, as such, are uniquely identified with a report number, used to track the deficiency to completion of corrective actions.

16.4 EVALUATION

Conditions adverse to quality are evaluated to determine the degree of significance, root cause, and actions required to correct deficiencies and preclude recurrence.

16.5 CORRECTIVE ACTION

After conditions adverse to quality are evaluated, planned corrective action is documented by the responsible organization for resolving the deficiency. QA then reviews the planned corrective action to ensure that QA requirements are satisfied. This is required for the remedial actions and corrective actions to preclude recurrence. Upon satisfactory review of the plan, corrective actions are implemented.

16.6 VERIFICATION OF COMPLETED CORRECTIVE ACTIONS

QA verifies the satisfactory completion of all corrective actions and, if the condition was significant, also verifies the actions taken to preclude recurrence. This verification document is part of the close-out process.

16.7 TRENDING

Audit reports, surveillance reports, corrective action reports, and management assessments are analyzed for possible trends and identification of root causes for repetitive deficiencies. Adverse trends are evaluated to determine program impact and subsequent corrective actions. Any significant adverse trends are promptly reported to senior M&O management.

The applicable Quality Administrative Procedure for trending includes the following considerations:

a. The quality indicators trended

b. The methods of data handling such as gathering, collecting, sorting, grouping, and coding

c. The statistical processes used to analyze and report the data

d. The actions taken when an adverse trend is identified

e. The type, distribution, and frequency of issue of trend reporting.

16.8 STOP WORK

If it is determined that a condition adverse to quality presents a serious negative impact on the M&O Program, a Stop Work order will be issued by M&O management. This order will remain in effect until the conditions causing the Stop Work have been alleviated. The implementation of the Stop Work process is governed by the appropriate Quality Administrative Procedure. Stop Work authority is also discussed in Section 1.6 of this QAPD.

SECTION 17

QUALITY ASSURANCE RECORDS

17.0 GENERAL

The QA Records Program for the M&O is accomplished in accordance with written plans and procedures. These documents describe the integrated set of activities for creating, identifying, collecting, controlling, processing, organizing, distributing, storing, preserving, retrieving, and disposing of Program QA records. These documents identify responsibilities of the Quality Assurance organization, Secretariat, and other organizations generating QA records

This section describes provisions established by M&O to implement QA records program activities.

The M&O Quality Assurance Program described in this section and associated procedures implements the committed requirements of QARD Section 17.

17.1 M&O QA RECORDS SYSTEM

The M&O Records Management System is decentralized in that Record Centers (RCs) are established at the M&O Headquarters, the Las Vegas, Nevada, Office, and the MRS office in Charlotte, North Carolina, which serve as record collection points.

The QA records system is a subset of the overall records management system. The M&O Secretariat retains responsibility for the total QA records system, while delegating records collection for work performed by the Las Vegas office and the MRS office to the two offices.

Control and maintenance of QA records are delegated to the M&O Secretariat by M&O General Manager. Control and maintenance of QA records generated or received by Las Vegas or Charlotte are retained by them. Controlled documents and technical baseline documents, as appropriate, specify records to be generated, supplied, or maintained.

17.2 RECORD DEFINITION

M&O Quality Administrative Procedures and implementing line procedures define minimum QA records generated as a result of QA Program implementation. In general, the following documents are considered QA records:

a. Individual documents that are executed, completed, and authenticated that furnish evidence of the quality and completeness of data (including raw data) and activities affecting quality

b. Documents prepared and maintained to demonstrate implementation of the Quality Assurance Program

c. Procurement documents subject to quality assurance controls

d. Other documents, such as plans, drawings, correspondence, specifications, technical data, books, maps, papers, photographs, and data sheets that are part of the technical baseline

e. Other materials that provide data and document quality, regardless of physical form or characteristic including magnetic media.

A complete record is a document that has been completed or whose revision would normally consist of the reissue of the document, and is signed and dated by the originator and by the person authorized to approve the record.

17.3 RECORD GENERATION

The applicable design specifications, procurement documents, procedures, and other controlled documents specify the records to be generated, supplied, or maintained by M&O.

Documents designated to become records shall be legible, identifiable, accurate, complete, reproducible, microfilmable, and appropriate to the work accomplished. Documents are considered valid records only if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated in accordance with approved procedures. These records may be originals or legible reproductions. M&O RCs maintain lists that contain the signatures and initials of personnel authorized to authenticate records.

Completed records are suitably protected by the record initiator prior to turnover to the appropriate RC.

17.4 RECEIPT OF RECORDS

The M&O Records Center is responsible for organizing and implementing a system of control for records for permanent and temporary storage in accordance with the requirements of the QARD. The receipt control system is structured to permit a current and accurate assessment of the status of records during the receiving process. The receipt control system includes:

a. The method for designating the required records to be maintained

b. The method for identifying the records received

c. Procedures for receipt and inspection of incoming records.

M&O Records Center personnel receiving QA records provide protection from damage, deterioration, or loss during the time that the records are in their possession.

17.5 RECORDS IDENTIFICATION

The Records Information System provides sufficient information to permit timely retrieval. It identifies the relationship between records and the items and activities to which they apply. Records are directly traceable to programmatic information, such as project, contract number, WBS number, preparing organization, author, date, title, subject, etc. The Records Information System provides for location identification of the record within the system.

17.6 RECORDS STORAGE

Records are controlled from the time they are completed until they are stored in predetermined locations that meet the requirements of the OCRWM QARD. The storage procedure includes:

a. The description of the storage facility

b. The filing system to be used

c. The method for verifying that the records received are in agreement with the transmittal documents and the records are legible

d. The method for verifying that the records are those designated

e. Rules governing access to and control of the files

f. The method for maintaining control of and accountability for records removed from the storage area

g. The method for filing supplemental information.

17.7 PRESERVATION AND SAFEKEEPING

Provisions have been made to prevent damage from moisture, temperature, and pressure. Document records are firmly attached in binders or placed in folders or envelopes for storage in steel filing cabinets or on shelving in containers. If used, special processed records (e.g., radiographs, photographs, negatives, microfilm, magnetic material, etc.) are protected to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity. Measures to provide for replacement, restoration, or substitution of lost or damaged records are detailed in the applicable Quality Administrative Procedure.

17.8 CORRECTED INFORMATION

Records are corrected as specified in the applicable Quality Administrative Procedure. All corrections include the date and the identification of the person authorized to issue such corrections and do not obliterate the corrected data.

17.9 RETRIEVAL

The storage system provides for retrieval of information in a timely manner.

17.10 ACCESS CONTROL

Lists are maintained of designated personnel who may access the files in the M&O Records Center. These lists are maintained and dated with the current authenticated issue of the list posted in the entrance to the Records Centers or on the top drawer of any appropriately approved fireproof filing devices that are used for temporary storage.

17.11 RECORDS CLASSIFICATION

For records retention purposes, all M&O QA records are classified as lifetime and retained until turnover to DOE OCRWM.

SECTION 18

AUDITS

18.0 GENERAL

The M&O audit program provides an independent verification of the status, adequacy, compliance, and implementation effectiveness of the M&O QA Program. Audits are performed to verify conformance with QA Program requirements, procedures, and technical adequacy of procedures and techniques used to perform quality affecting activities.

The M&O Quality Assurance Program described in this section and associated procedures implements the committed requirements of QARD Section 18.

18.1 AUDIT PROGRAM IMPLEMENTATION

The applicable Quality Administrative Procedure establishes the system for planned audits to verify compliance with quality and technical requirements. Audits include objective evaluation of work areas, quality affecting activities, processes, and items; reviews of documents and records, quality related practices, procedures, and instructions to determine the effectiveness of implementation of the QA program and the technical adequacy of the work being performed.

The M&O QA Manager is responsible for development, implementation, and maintenance of the M&O audit program. The M&O QA organization plans and conducts audits of M&O quality affecting activities, observes DOE audits of selected contractors and national laboratories, and performs audits as requested by DOE OCRWM.

18.2 AUDIT SCHEDULING

Quality assurance audits are scheduled to provide maximum coverage of ongoing quality assurance program activities for which M&O is responsible. Audit schedules are established, based on the status, safety, and mission importance of the work being performed by M&O. Audits of M&O quality affecting activities are scheduled to ensure that applicable elements of the M&O QA Program are audited at least once a year. The frequency of the audits of a given area is also governed by previous findings, procedure changes, requirements, work scope, or management direction. The annual audit schedule includes audits to be performed, activities to be audited, frequency, and schedule dates. The schedule is periodically reviewed and revised as necessary to ensure that coverage is maintained.

Suppliers' quality assurance programs are audited on a triennial basis. These programs are evaluated for audit at least annually and when major changes to contract scope or work methodology occur.

18.3 AUDIT TEAMS

Each M&O audit is led by a certified lead auditor. Lead auditors and auditors are certified in accordance with the applicable Quality Administrative Procedure. The M&O QA Audits Manager selects and assigns each audit team.

The assigned audit team members are independent of the activities being audited. Technical experts assigned to the audit teams will not have management or technical responsibilities for the activities being audited. The audit team members are assigned by QA management based on programmatic and technical expertise in the work area being audited, by virtue of prior experience, education, and/or specific documented training. Technical experts receive training and indoctrination in the applicable Quality Administrative Procedure for audits.

18.4 AUDIT PREPARATION

The lead auditor develops and documents the audit plan for each audit. This plan identifies the audit scope, requirements, audit team, activities to be audited, organizations to be notified, applicable documents, schedule, and marked up procedures or checklists to be used. The development of the audit checklist considers the results of previous audits as well as the impact of significant changes in scope of work, personnel, organization, or requirements. The audit plan is approved by the appropriate quality manager prior to performance of the audit. The team consists of one or more auditors. The lead auditor organizes and directs the audit, coordinates preparation and issuance of the audit report, and evaluates responses. The lead auditor ensures that the audit team is prepared prior to initiation of the audit.

18.5 AUDIT PERFORMANCE

Audits are performed in accordance with the applicable Quality Administrative Procedure and approved checklists or marked-up procedures as early in the life of the activity as practical and shall continue at intervals consistent with the schedule of accomplishing the activity. Elements that have been selected for audit are evaluated against specified requirements that include an objective evaluation of the quality related practices, procedures, instructions, activities, and items. Objective evidence such as documents and records are examined to the depth necessary to determine if the quality assurance program is effective and properly implemented. Appropriate document reviews, personnel interviews, and in-progress activities shall be conducted under the direction of the lead auditor. Audit results are documented and reported to management having responsibility for the area audited for review, assessment, and appropriate action. The management of the audited organization is actively involved in following the progress of the audit, attending the exit interview, and in directing any required corrective actions. Conditions requiring prompt corrective action are reported immediately to the management of the audited organization.

18.6 AUDIT REPORTING

Audit reports, signed by the lead auditor and his Audit Manager, are issued to the management of the audited organization and will include the following information:

a. Executive Summary

b. Description of the audit scope

c. Identification of the auditors

d. Identification of persons contacted during audit activities with designation of persons who attended the pre-audit and post-audit conferences

e. Summary of audit results, including a statement regarding the effectiveness of the quality assurance program elements audited

f. Description of each audit finding in sufficient detail to enable corrective action to be taken by the audited organization. If the findings meet the criteria for issuing a corrective action report, the applicable Quality Administrative Procedure is used to report the findings, and copies of the corrective action reports are attached.

g. A date by which the response is due back to QA for evaluation.

Management of the audited organization or activity will investigate the audit findings; determine the root cause of the condition identified in the finding; define and schedule corrective action focused on the cause and measures to prevent recurrence; evaluate the impact of the finding on completed work; and notify Quality Assurance in writing of action taken or planned. The adequacy of audit responses are evaluated by the M&O Quality Assurance Audits Group. A tracking system for audit findings is established to ensure all audit findings are appropriately addressed, prioritized as to their significance and need for timely resolution/correction, and to maintain a trend analysis of conditions adverse to quality. Follow-up action, including re-audit of deficient areas, are undertaken to verify that effective corrective actions are implemented.

18.7 AUDIT RECORDS

Audit records include, as a minimum, audit plans, audit notifications, audit reports, written responses to audit reports, applicable corrective action reports, and records of completion of corrective action. These records are submitted to the M&O Records Center for processing and storage.

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SECTION 19

COMPUTER SOFTWARE DESIGN AND CONTROL

19.0 GENERAL

The design and control of computer software developed by M&O, as well as the control and qualification of acquired software, to be used for quality affecting activities shall be controlled in accordance with the M&O Computer Software Quality Assurance Plan (CSQAP). The CSQAP implements the requirements of Section 19 of the QARD and the applicable management controls from Sections 1, 2, 3, 4, 5, 6, 7, 16, 17, and 18 of this document. The M&O Computer Software Quality Assurance Plan is consistent with the guidance specified in NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management," dated June 1983. The CSQAP is reviewed and approved by DOE OCRWM prior to any quality affecting work being performed under the plan.

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APPENDIX A

LIST OF ABBREVIATIONS

APPENDIX A. LIST OF ABBREVIATIONS

ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
CCB	Change Control Board
CFR	Code of Federal Regulations
CSQAP	Computer Software Quality Assurance Plan
DOE	Department of Energy
ILP	Implementing Line Procedure
M&O	Management and Operating Contractor
MGDS	Mined Geologic Disposal System
MRS	Monitored Retrieval Storage
NQA-1	ANSI/ASME Standard NQA-1-1989 "Quality Assurance Program Requirements for Nuclear Facilities"
NRC	Nuclear Regulatory Commission
OCRWM	Office of Civilian Radioactive Waste Management
QA	Quality Assurance
QAP	Quality Administrative Procedure
QAPD	Quality Assurance Program Description
QARD	Quality Assurance Requirements Document
RCs	Record Centers
TESS	TRW Environmental Safety Systems Inc.
WBS	Work Breakdown Structure
YMSCPO	Yucca Mountain Site Characterization Project Office