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ERD UMTRA PROJECT QUALITY ASSURANCE PROGRAM PLAN

September 1995

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ERD UMTRA PROJECT
QUALITY ASSURANCE PROGRAM PLAN

September 1995

This report supersedes Revision 6

UMTRA DOE/AL-185
Revision 7

Environmental Restoration Division
Uranium Mill Tailings Remedial Action Project
Albuquerque Field Office
U.S. Department of Energy
Albuquerque, New Mexico 87115

ERD UMTRA PROJECT

QUALITY ASSURANCE PROGRAM PLAN

September 1995

APPROVED BY: _____ 9/26/95

ERD UMTRA PROJECT QUALITY ASSURANCE MANAGER — DATE

ERD UMTRA PROJECT DEPARTMENT OF ENERGY
QUALITY ASSURANCE PROGRAM PLAN

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REVISION 7 performed by Paul Pehrson, Sr. QA Specialist/TAC

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ATTACHMENT A DOE ORDER 5700.6C, *Quality Assurance*, criteria versus ASME NQA-1 Quality Assurance Program for Nuclear Facilities
ERD UMTRA Project Quality Assurance Program Plan

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LIST OF ACRONYMS

Acronym	Definition
DOE	U.S. Department of Energy
DOE-AL	DOE Albuquerque Field Office
DOE-EML	DOE Environmental Measurement Laboratory
DOE-HQ	DOE Headquarters
DQC	data quality controls
DQO	data quality objectives
EM	Office of Environmental Restoration and Waste Management
EPA	U.S. Environmental Protection Agency
EPM	Environment/Project Management
ER	Environmental Restoration
ERD	Environmental Restoration Division
ES&H	Environment, Safety and Health
GRS	General Records Schedule
JEG	Jacobs Engineering Group Inc.
LAN	Local Area Network
MTSO	Management and Technical Services Office
NARA	National Archives and Records Administration
NEPA	National Environmental Policy Act
NRC	U.S. Nuclear Regulatory Commission
OEPM	Office of Environmental Project Management
ORE	operational readiness evaluation
ORR	operational readiness review
PDCS	Project Document Control System
QA	quality assurance
QAPP	Quality Assurance Program Plan
QC	quality control
RAC	Remedial Action Contractor
RAIP	remedial action inspection plan
SOP	standard operating procedures
TAC	Technical Assistance Contractor
TMO/PAD	Technical Management and Operations/Performance Assessment Division
UMTRA	Uranium Mill Tailings Remedial Action
UMTRCA	Uranium Mill Tailings Radiation Control Act of 1978
UPDCC	UMTRA Project Document Control Center

FOREWORD

Because of the recent realignment at the U.S. Department of Energy (DOE) Albuquerque Field Office, a number of offices referenced in Revision 6 of the DOE Uranium Mill Tailings Remedial Action (UMTRA) Quality Assurance Program Plan (QAPP) were renamed or incorporated in newly created offices. The former UMTRA Project Office was absorbed by the newly created Environmental Restoration Division (ERD). The former Operations Management Division/Performance Assessment Branch responsibilities are now performed by the Technical Management Operations Performance Assessment Division. The Office of Energy and Special Programs no longer exists.

The UMTRA Project was established to accomplish remedial actions at inactive uranium mill tailings sites in accordance with Public Law 95-604, the Uranium Mill Tailings Radiation Control Act of 1978. The UMTRA Project's mission is to stabilize and control the residual radioactive materials at designated sites in a safe and environmentally sound manner so as to minimize or eliminate radiation health hazards to the public.

The DOE's ERD directs overall UMTRA activities. Because these efforts may involve possible risks to public health and safety, a quality assurance (QA) program that conforms to the applicable criteria (set forth in the reference documents) has been established to control the quality of the work. This document, the QAPP, brings into one document the essential criteria to be applied on a selective basis, depending upon the nature of the activity being conducted, and describes how those criteria shall be applied to the UMTRA Project.

QA requirements for the ERD UMTRA Project QAPP are based on the criteria outlined in DOE Order 5700.6C or applicable sections of 10 CFR 830.120. QA requirements contained in this QAPP shall apply to all personnel, processes, and activities, including planning, scheduling, and cost control, performed by the ERD UMTRA Project and its contractors.

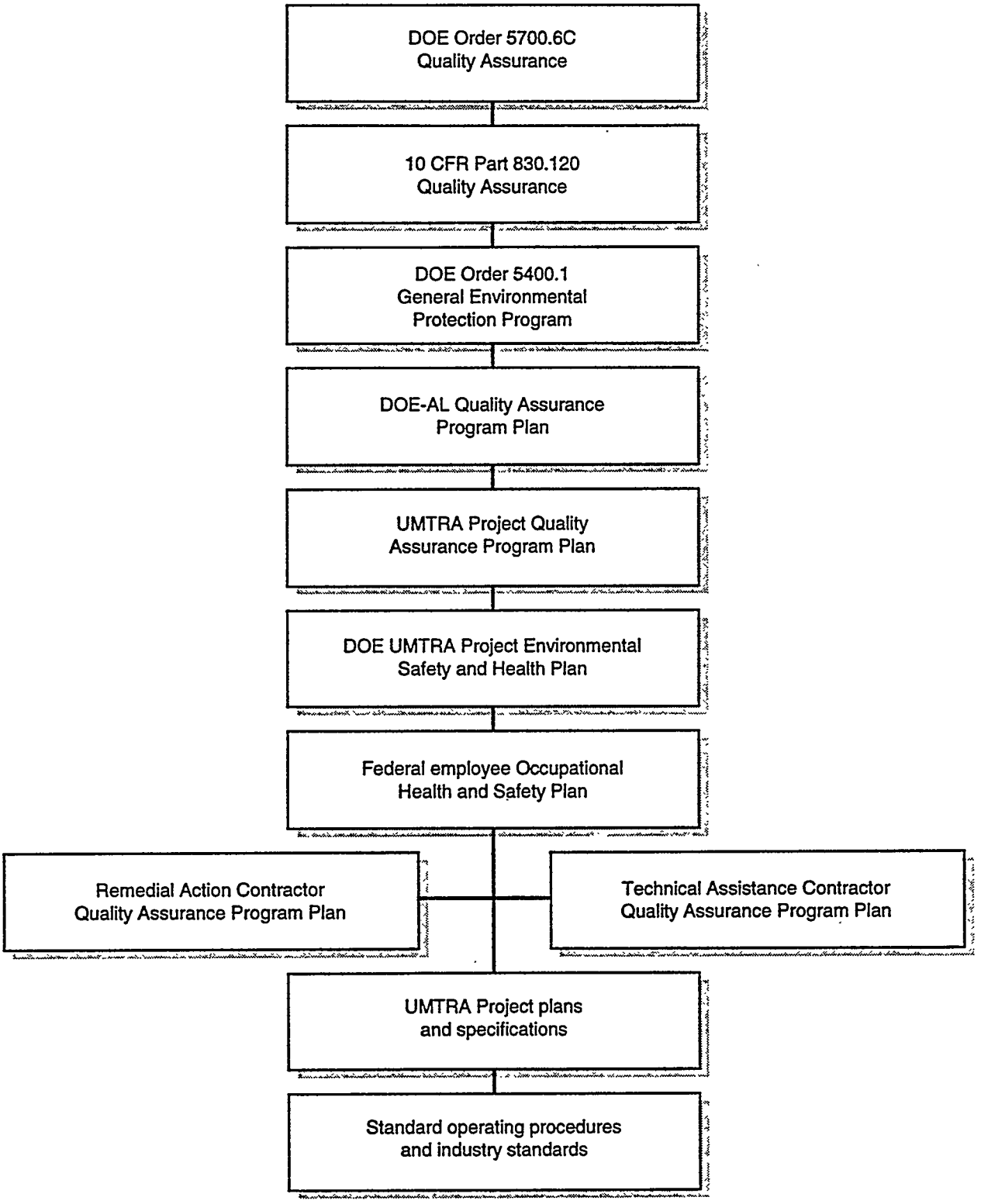
EXCEPTION: Umetco Mineral Corporation's Engineering Services for the design of the Naturita disposal cell will follow the QA requirements of NQA-1 instead of the QA requirements of DOE Order 5700.6C. The exception is allowed because NQA-1 meets all of the nuclear safety requirements of DOE Order 5700.6C and conforms to the standards that are familiar to the private industry.

The ERD UMTRA Project shall require each Project contractor to prepare and submit for approval a more detailed QAPP that is based on the applicable criteria of this QAPP and the referenced documents. All UMTRA Project QAPPs shall fit within the framework of this plan or an industry standard format that has been approved by the DOE ERD.

DOE Order 5700.6C, *Quality Assurance*, criteria versus ASME NQA-1 (ANSI/ASME, 1989) Quality Assurance Program for Nuclear Facilities matrix is shown in Attachment A.

A hierarchy of documents for the UMTRA Project QA program is presented in Figure 1.

Figure 1
UMTRA Project Hierarchy of Quality Assurance Documents



POLICY

The Environmental Restoration Division (ERD) Uranium Mill Tailings Remedial Action (UMTRA) Project management considers quality assurance (QA) an essential element of all UMTRA Project activities. The ERD UMTRA Project QA program is applicable to all activities that could compromise successful Project implementation. It is the policy of the ERD UMTRA Project, as described in this Quality Assurance Program Plan (QAPP) and implemented by appropriate procedures, to satisfy the applicable QA criteria of all reference documents. It is the policy of the ERD management that this QAPP applies only to UMTRA activities. The goal is to instill a culture in which there is a commitment to achieving a rising standard of quality. This demands that processes and methods employed to achieve quality be continuously improved.

QA programs for the UMTRA Project are based on applicable portions of the reference documents. These documents shall be used by the ERD to evaluate the QAPPs of the participating organizations, the UMTRA Project contractors, and task contractors. Not all elements of these documents are applicable in every case, and this is taken into account in the evaluation process.

It is also ERD UMTRA Project policy to apply a graded approach to QA which acknowledges that public health and safety are not always affected, and that an adequate level of quality is also needed for such aspects of the Project as operational reliability and maintainability. Applicable portions of this document shall be implemented to the maximum degree for quality-related functions that are identified as safety-related. A less stringent but still viable quality level shall be maintained for other UMTRA Project activities.

ERD UMTRA Project policy requires that U.S. Department of Energy contractors shall ensure that their subcontractors who perform chemical analyses under a radiochemical analysis subcontract shall participate in the interlaboratory Quality Assurance Program, Environmental Measurements Laboratory Radiological Intercomparison Study. The results of these intercomparisons shall be tracked and trended and reported to the appropriate level of management.

Since UMTRA Project activities also involve research, development, and investigative activities, it is necessary to adapt the criteria to fit the context of the work environment. Such adaptation is the responsibility of each organization preparing a QAPP for the UMTRA Project, with the principal thrust being the assurance that the results of its activities are properly validated, documented, and available for use as a basis for task-related decision making.

1.0 MANAGEMENT

1.1 GENERAL

1.1.1 This section describes the organizational structure, responsibilities, levels of authority, and lines of communication for activities affecting quality for the Uranium Mill Tailings Remedial Action (UMTRA) Project activities and the Project contractors. Interface between the Environmental Restoration Division (ERD) and Project contractors shall be described in the Quality Assurance Program Plan (QAPP) of these respective organizations, including technical quality requirements for work to be performed, coordinated, and satisfactorily completed.

1.1.2 The Uranium Mill Tailings Radiation Control Act (UMTRCA) authorized the U.S. Department of Energy (DOE) to select and execute a plan of remedial action that satisfies standards set forth by the U.S. Environmental Protection Agency (EPA) and other applicable laws and regulations. Under requirements established by the UMTRCA, the DOE oversees all remedial action activities, from site conceptual design to disposal site selection, determination and mitigation of environmental impacts, remedial action construction, site certification, and initiation of disposal site surveillance, licensing, and maintenance activities.

1.1.3 Within DOE Headquarters (DOE-HQ), the Assistant Secretary for the Office of Environmental Restoration and Waste Management (EM) is assigned primary responsibility in the UMTRCA, supported by the Office of General Counsel and the assistant secretary for the Office of Environment, Safety and Health. EM program management responsibilities are assigned to the Office of Environmental Restoration, with policy direction and guidance provided by the Off-Site Remediation Division.

1.1.4 The majority of UMTRA Project functions are EM's responsibility. Management of the UMTRA Project is assigned by EM to the DOE Albuquerque Field Office (DOE-AL) in the Project charter. Authority for field operations is delegated to DOE-AL and the ERD. DOE-AL is delegated day-to-day authority to manage and execute UMTRA Project activities within established procurement, real estate, and other approved operational thresholds.

1.1.5 The ERD is responsible for ensuring that the appropriate quality assurance (QA) requirements, procedures, and specifications are reviewed, approved, and implemented to provide confidence that activities or systems will protect public health and safety and ensure successful completion of the UMTRA Project. UMTRA Project QA controls are established and maintained in a top-down management approach from the DOE-AL Office of the Manager in coordination with the DOE-AL Technical Management and Operations/Performance Assessment Division (TMO/PAD), the Technical Assistance Contractor (TAC),

and the Remedial Action Contractor (RAC). The Project's organizational relationship is illustrated in Figure 1.1.

1.1.6 The objectives of the ERD UMTRA QA program are to ensure the following occurs:

a. Management provides planning, organization, direction, control, and support to achieve the UMTRA program objectives.

b. Every employee participates in contributing to improve the quality of products and services.

c. Overall performance is reviewed and evaluated using an assessment process.

1.2 UMTRA PROJECT ORGANIZATION

1.2.1 Organizational relationships

The DOE-AL is the headquarters for UMTRA Project activities. The DOE-AL responsibility chain includes the Office of the Manager, the assistant manager for TMO/PAD, the assistant manager for Environment/Project Management (EPM)/ERD, and the director of ERD. The director of ERD reports to the assistant manager for EPM. The directors for the PAD and Occupational Safety and Health Division report to the assistant manager for TMO. Both assistant managers report to the Office of the Manager, DOE-AL. This organizational relationship is illustrated in Figure 1.2. The QA responsibilities for UMTRA staff are contained in Section 1.3 of this QAPP.

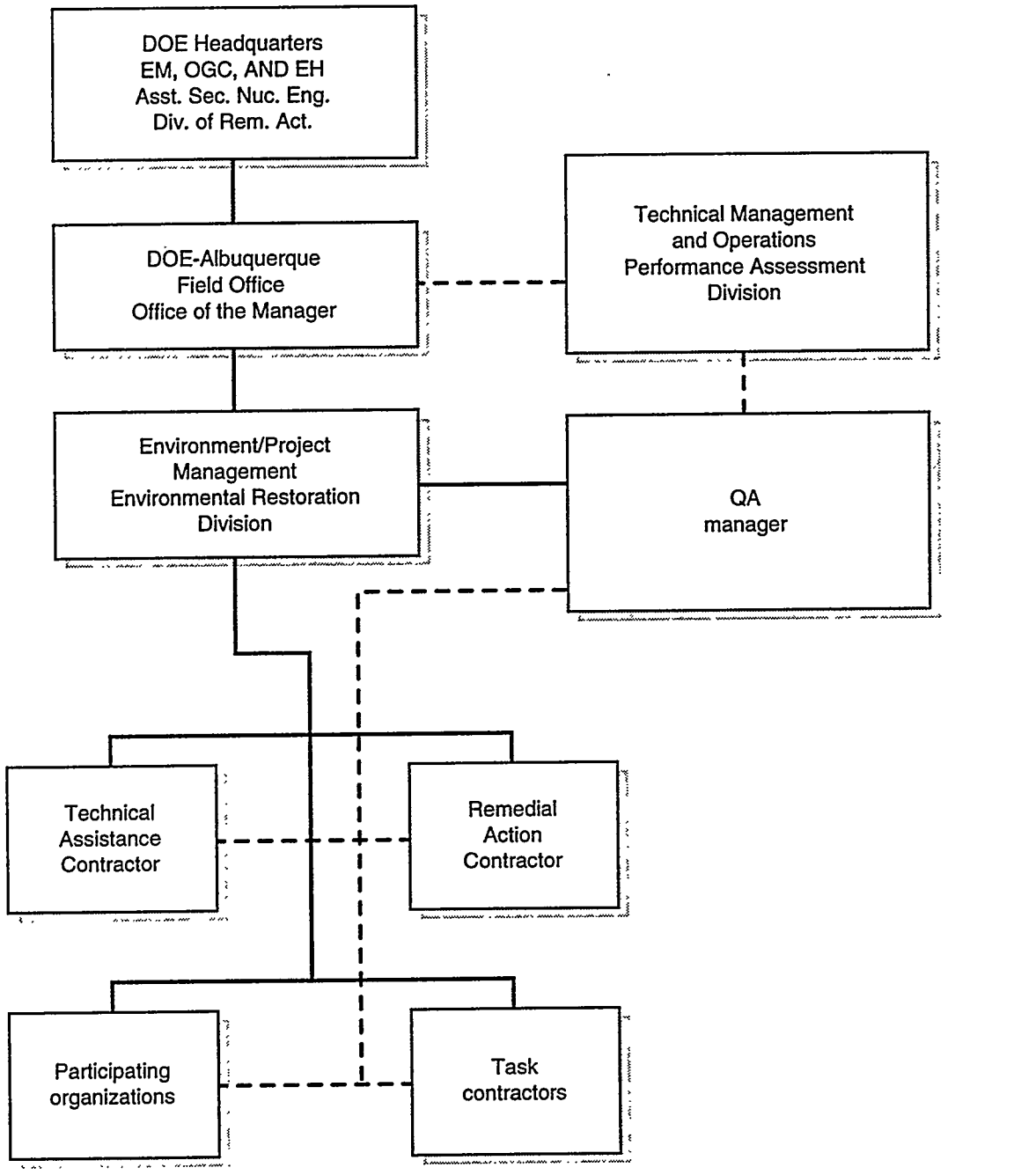
1.2.2 UMTRA Director of ERD

a. Responsibility for management of UMTRA activities is assigned to the director of the ERD, who is supported by the Environmental Restoration Management and Management and Technical Services offices of the ERD. Management of UMTRA Project activities is conducted in accordance with overall program policy and guidance provided by DOE-HQ. The ERD organization is shown in Figure 1.3. The UMTRA Project Charter (DOE, 1986) specifies the ERD director's responsibilities. This individual shall:

   1. Implement DOE-HQ policy and overall program guidance and recommend changes to DOE-HQ, as appropriate.

   2. Negotiate, execute, and administer cooperative agreements with state and local governments and Indian tribes.

Figure 1.1
UMTRA Project
Quality Assurance Interface/Administration



EH Office of Environment, Safety and Health
OGC Office of General Counsel

Figure 1.2
DOE Albuquerque Field Office
UMTRA Project Functional Interface

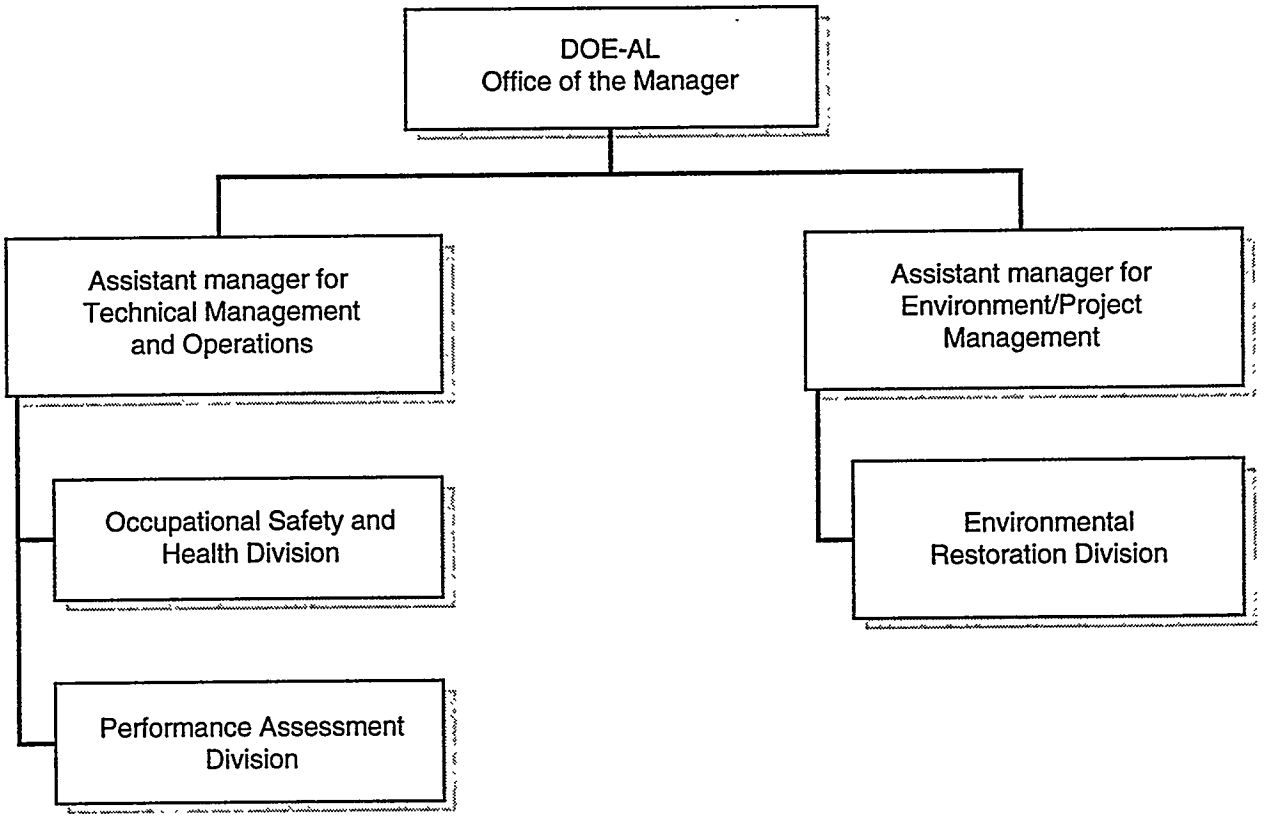
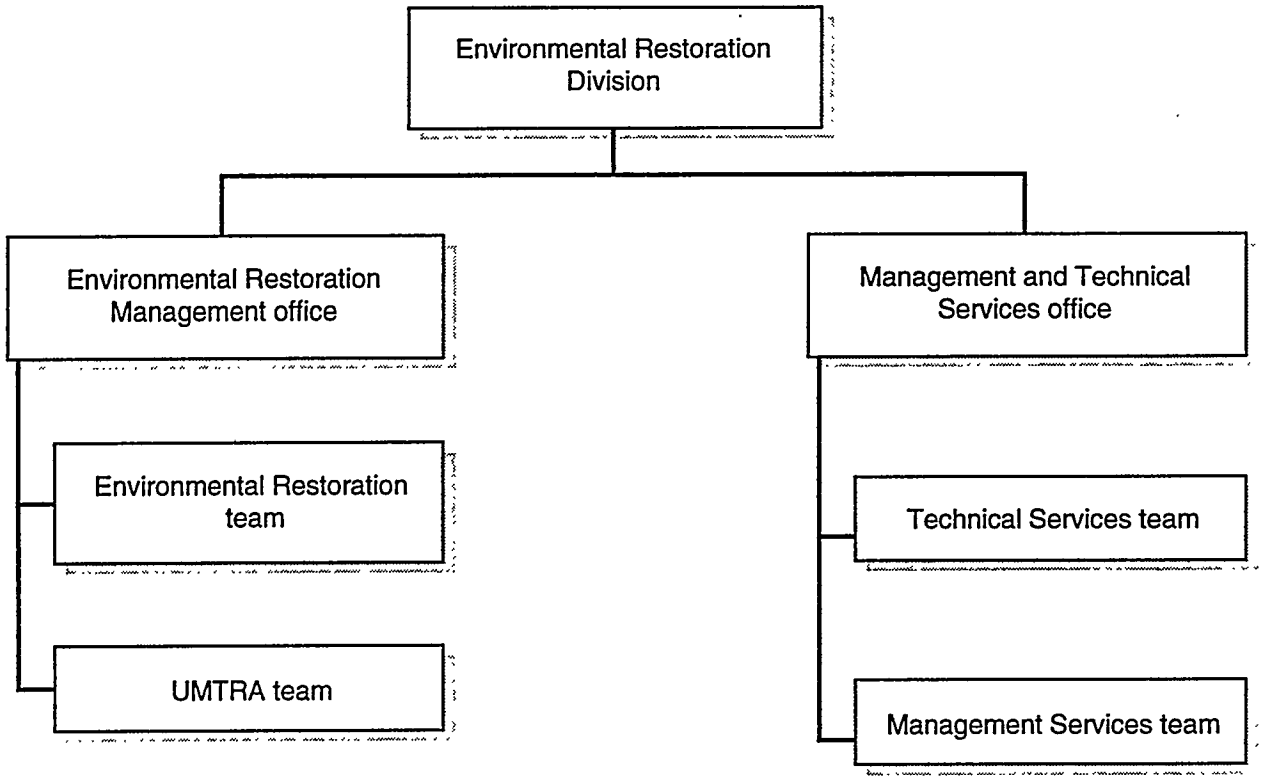


Figure 1.3
Environmental Restoration Division Organization



3. Establish and execute (in coordination with DOE-HQ) public participation and information programs, acting as liaison with state/local government officials and Indian tribes, and coordinating with DOE regional offices.

4. Establish a technology development effort in accordance with DOE-HQ guidelines and in coordination with other DOE offices and Federal agencies (the U.S. Nuclear Regulatory Commission [NRC] and the EPA).

5. Manage the survey and inclusion processes for designated vicinity properties, and determine which of those properties require remedial action.

6. Manage mill site characterization, develop site conceptual designs, and prepare remedial action plans.

7. Manage the preparation of environmental impact documentation, provide logistics support of the National Environmental Policy Act (NEPA) process, and support DOE-HQ NEPA review and decision-making activities.

8. Manage mill site engineering and design development and vicinity property engineering.

9. Recommend for DOE-HQ approval:

   a. Decisions to acquire designated processing sites.

   b. Determination that removal of tailings from a processing site is necessary in accordance with DOE policy stated in the Project Plan (DOE, 1989).

   c. Decisions to acquire lands to be used as disposal sites.

10. Manage radon monitoring programs at each site before, during, and after remedial action.

11. Manage mill site and vicinity property remedial action.

12. Implement and manage interim and final mill site surveillance and maintenance programs.

13. Prepare and maintain a Project Plan (DOE, 1989) that describes schedule and resource requirements for overall UMTRA Project and supplemental UMTRA documents identifying site-specific schedule and resource requirements.

14. Prepare and maintain a Project management plan that delineates roles and responsibilities for UMTRA Project activities, other supporting field offices, contractors, and the involved states and Indian tribes.

15. Establish and implement UMTRA Project control and management systems in accordance with DOE-HQ guidance to monitor cost, schedule, and technical status to ensure that UMTRA Project objectives are achieved within budget and on schedule; in accordance with established change control procedures, recommend for DOE-HQ approval changes in baseline schedules and budgets; organize and present UMTRA Project reviews semiannually and at other times as agreed with DOE-HQ.

16. Monitor, evaluate and report on UMTRA Project technical, schedule, cost progress and accomplishments, and the performance of all contractor participants; institute or recommend appropriate changes to improve progress, efficiency, and public acceptance.

17. Prepare budget plans and execute information in accordance with established procedures and DOE-HQ guidance; use allotted UMTRA Project funds within the limitations of the financial plan.

18. Serve as the focal point for contact with the NRC on implementation of UMTRA Project activities.

19. Advise and otherwise assist DOE-HQ in the promulgation of regulations by DOE pursuant to the UMTRCA.

20. Review international activities involving uranium mill tailings remedial action and make recommendations to DOE-HQ concerning possible United States participation.

1.2.3 ERD UMTRA Team team leader

a. The ERD UMTRA Team team leader reports directly to the Manager of the ERD Environmental Restoration Management office and the ERD director, and is responsible for overall management of UMTRA Project activities. This individual shall supervise and oversee the following UMTRA Project activities:

Site Design and Planning
Remedial Action Site Management
Vicinity Property Management
Ground Water Management/Transition
Completion Report/Certification
Real Estate
Site Licensing
NRC and State Liaison

RAC Contract Interface
Lead Stakeholder Interface
Change Control - Review/Approval
Line Responsibility (QA and Environment, Safety and Health [ES&H])
Title X Support
Funds Management
Cooperative Agreements
Budget Exercises/Actions Support
Hydrology and Ground Water Program Activities
Value Engineering

This individual shall also perform the following:

1. Review and approve site planning activities.

2. Coordinate review and approval of baseline schedules.

3. Review and approve site remedial action activities.

4. Coordinate site status assessments.

5. Manage vicinity property remedial action.

6. Coordinate Project activities with tribes, states, local governments, property owners, and the public.

b. The ERD UMTRA Team team leader shall review all UMTRA site manager correspondence with controversial, policy, or legal implications.

1.2.4 ERD Technical Services team leader

a. The ERD Technical Services team leader reports directly to the ERD Manager of the Management and Technical Services Office and the ERD director, and is responsible for supporting the UMTRA team. This individual shall oversee and supervise the following UMTRA Project activities:

Compliance Support
Safety Advancement Field Effort
ES&H Program Management
Technical Document Coordination
NEPA Coordination
Environmental Restoration (ER) Program Assessment
Contract Support
QA - Surveillance of Construction Activities, QAPP, Remedial Action Inspection Plans (RAIP), Review/Update
UMTRA Rad Verification
Office of Environmental Project Management Cost Estimating

Conduct of Operations Assessment - operational readiness reviews (ORR) and operational readiness evaluations (ORE)
Occurrence Reporting

This individual shall also perform the following:

1. Manage the NEPA process and prepare associated documents.

2. Coordinate QA program activities (specific QA manager responsibilities are listed in Section 1.3.3 of this QAPP).

3. Coordinate radiological monitoring and ES&H program activities.

4. Supervise completion report and site certification activities.

5. Review site licensing criteria.

6. Coordinate and approve surveillance and maintenance plans.

7. Certify vicinity properties.

1.2.5 ERD Title 10

a. The ERD Management Services team leader is responsible for supervising Title 10 Reimbursement with support from the UMTRA team. The Management Services team leader reports directly to the ERD Manager, Management and Technical Services Office, and the ERD director. The Management Services group shall:

1. Supervise Title 10 financial management planning activities.

2. Coordinate Title 10 Project planning and estimating activities.

3. Control and integrate Title 10 Project cost and schedule activities.

4. Report Title 10 Project performance.

5. Coordinate review and approval of Title 10 Project procurement activities.

6. Coordinate Title 10 office administration support.

1.2.6 Environmental Restoration Team and Management Services Group

The ER Team and Management Services of the ERD support UMTRA activities on an as-needed basis. Most UMTRA activities are performed by the UMTRA Team and Technical Services Team group.

1.2.7 The DOE-AL Office of the Manager

a. The DOE-AL Office of the Manager has programmatic responsibility under the assistant secretary for Defense Programs. The Assistant Secretary for the EM, Division of Remedial Action Programs, has overall programmatic responsibility for UMTRA Project activities. The administration of UMTRA Project activities is the responsibility of the DOE-AL Office.

1.3 UMTRA QA RESPONSIBILITIES

1.3.1 The ERD director

a. The ERD director reports directly to the DOE-AL Office of the Manager and is responsible for the quality of work and for directing the QA program. This individual shall:

1. Ensure that the ERD UMTRA Project QAPP is developed, implemented, and provided to the director of TMO/PAD for review.

2. With the assistance of the TMO/PAD, determine quality objectives and ensure the establishment of appropriate quality requirements under the UMTRCA.

3. Ensure that quality requirements are included in contractual documents.

4. Ensure that UMTRA QAPPs are developed by contractors.

5. Ensure contractor QAPP implementation and compliance.

6. Ensure that applicable quality requirements are included in procurement documentation.

7. Ensure that adequate funding for QA activities and labor requirements is included in the UMTRA Project budget.

8. Provide written responses to the director of TMO/PAD regarding actions taken in connection with recommendations included in QAPP reviews.

9. Coordinate QA reviews of UMTRA Project activities.

10. Issue stop-work orders for deficient quality operations.

11. Approve design criteria, conceptual design, and final design.

12. Assess the adequacy of the contractor's quality programs.

13. Assess the quality of work performed by the contractors.

14. Ensure that readiness reviews are performed prior to major scheduled or planned work.

15. Perform management self-assessments of the UMTRA QA program and ensure that applicable corrective actions are promptly implemented.

16. Implement continuous improvement processes.

1.3.2 The ERD Technical Services Team team leader

a. The ERD Technical Services Team team leader reports directly to the manager of the Management and Technical Services Office (MTSO) and the ERD director and is responsible for QA activities. This individual shall:

1. Assist the ERD director and MTSO manager in implementing the QA Program for UMTRA activities.

2. Review contractor quality program activities, report results to the MTSO manager and ERD director, and request follow-up and corrective actions, as necessary.

3. Review stop-work recommendations from the ERD Technical Services Team QA manager for noncompliance, investigate each situation, and report findings to the MTSO manager within 1 business day.

4. Supervise QA activities for the UMTRA Project.

5. Determine that audit findings are corrected promptly.

6. Assist the ERD director in implementing the continuous improvement process.

7. Recommend to the ERD director, independent of RAC and TAC recommendations, that stop-work orders be issued for deficient quality operations.

1.3.3 The ERD Technical Services Team QA manager

a. The ERD Technical Services Team QA manager (ERD QA manager) reports to the ERD director through the Technical Services Team team leader and MTSO. This individual shall:

1. Develop the ERD UMTRA QAPP and establish, implement, and maintain the QA program.

2. Review contractor QAPPs and RAIPs.

3. Review contractor quality program activities, report results to the ERD director through the Technical Services group team leader and MTSO, and request follow-up and corrective actions, as necessary.

4. Conduct QA audits and in-process surveillances, approve audit and in-process surveillance reports, and review the status of associated action.

5. Review stop-work recommendations from the TAC and RAC program managers for noncompliance, investigate each situation, and report findings to the ERD director through the Technical Services group team leader and MTSO within 1 business day.

6. Supervise and direct TAC and RAC QA activities.

7. Review and approve audit and surveillance schedules associated with RAC site operations.

8. Ensure access to work areas and records to identify problems associated with quality requirements.

9. Initiate, recommend, or provide solutions in establishing corrective action.

10. Verify implementation of corrective actions and solutions.

11. Ensure that processing, delivering, installing, or using deficient material or workmanship is controlled until corrective action has occurred. Corrective action includes withholding payment for deficient operations on firm-fixed contracts and reporting to the MTSO manager and ERD director progress payments made for deficient operations under cost-reimbursable contracts.

12. Recommend to the MTSO manager and ERD director, independent of RAC and TAC recommendations, that stop-work orders be issued for deficient quality operations.

1.3.4 TMO/PAD director

a. The TMO/PAD director reports to the DOE-AL Office of the Manager through the assistant manager for TMO. This individual shall:

1. Serve as a focal point and provide consultation to the ERD director on matters related to the DOE-AL QA program.

2. Assist the ERD director in determining quality objectives and requirements.

3. Review the implementation of both DOE and contractor quality program activities for UMTRA Project activities, report quality review results to the ERD director, and request follow-up reports and corrective actions, as necessary.

4. Report to the DOE-AL Office of the Manager through the TMO manager the results of QA audits and the status of associated actions. The TMO/PAD director has direct access to the Office of the Manager concerning QA matters that are not satisfactorily resolved at the assistant manager level.

5. Provide quality policy guidance, document review, and audit/surveillance assistance.

1.4 UMTRA PROJECT CONTRACTORS

1.4.1 General

a. The ERD interfaces between UMTRA Project contractors and other participating organizations by providing technical and quality requirements for work to be developed, performed, and coordinated until remedial action is completed. Programmatic QA requirements are imposed by the ERD on all UMTRA Project contractors and participating organizations. The ERD conducts quality audits of each of these organizations with the assistance of the DOE-AL TMO/PAD or the TAC QA Department with the cognizance and participation of UMTRA Project contractors and participating organizations. Interorganizational interface shall be further described in the UMTRA Project contractors' respective QAPPs.

b. QA personnel for UMTRA Project contractors and participating organizations shall report to a management level that provides the authority and organizational freedom to conduct the following activities:

1. Access work areas to identify problems associated with quality requirements.

2. Initiate, recommend, or provide solutions in establishing corrective action.

3. Verify implementation of corrective actions and solutions.

4. Ensure that processing, delivery, installation, or use of deficient material or workmanship is controlled until corrective action has occurred. Corrective action includes withholding payment for deficient progress on firm-fixed contracts and reporting to the ERD director progress payments made for deficient progress under cost reimbursable contracts.

c. The ERD Technical Services Team shall direct and control the UMTRA Project. Verification of UMTRA activities associated with quality is achieved through QAPP reviews, in-process surveillance and monitoring activities, and QA audits.

1.4.2 TAC organization

a. The TAC organization is currently made up of the contract team: Jacobs Engineering Group Inc. (JEG); Geraghty & Miller, Inc.; Roy F. Weston, Inc.; and AGRA Earth & Environmental, Inc.. The TAC's organizational structure provides adequate organizational autonomy for the QA function. The program TAC QA manager reports to the JEG Albuquerque Operations Manager and to the JEG corporate QA organization and provides support to the UMTRA QA manager. The program includes the TAC Project Manager, TAC QA manager, and TAC QA specialists, in addition to various disciplinary department managers. This TAC organizational relationship is illustrated in Figure 1.4. Functional relationships and QA program responsibilities are described in the following paragraphs.

1.4.3 TAC Project Manager

a. The TAC Project Manager is responsible for overseeing the overall effort of all TAC technical and administrative activities and interfaces with the ERD director and the TAC QA manager. The TAC Project Manager is responsible for organizing, administering, planning, budgeting, and coordinating the program. Also, the TAC Project Manager is responsible for ensuring that the TAC staff implement and comply with the applicable requirements of the TAC QAPP. All site, department, and assistant project managers report to the TAC Project Manager.

1.4.4 TAC QA manager

a. The TAC QA manager is responsible for overseeing and controlling all TAC QA activities in support of UMTRA Project activities. The TAC QA manager shall interface directly with the ERD QA manager and the TAC Project Manager and report to the JEG Albuquerque Operations Manager and the JEG corporate QA organization.

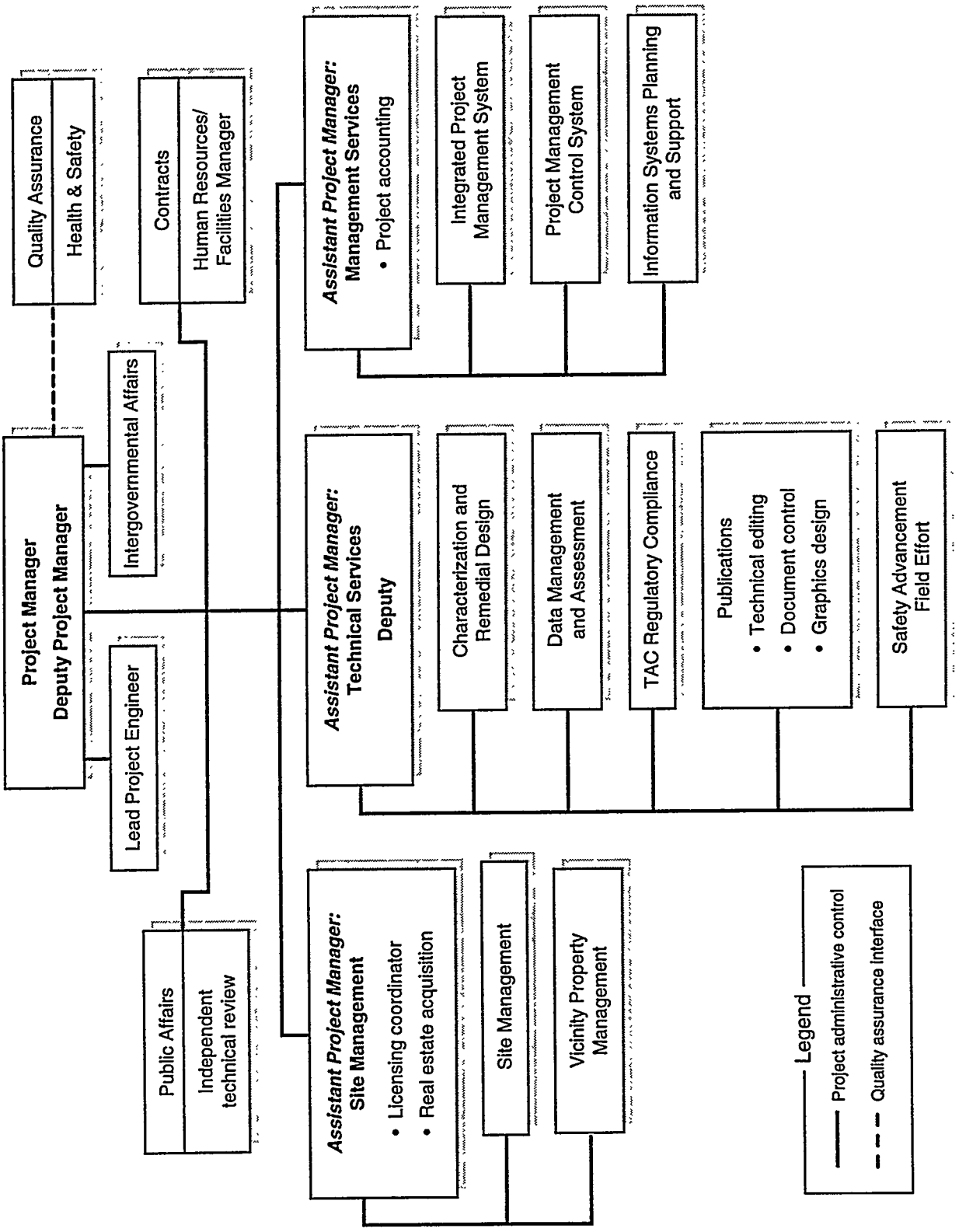
b. The TAC QA manager shall have the authority to carry out the following responsibilities:

   1. Support the ERD UMTRA QA manager.

   2. Develop and implement the TAC QA program.

   3. Develop and organize the QA Department and administrative staff.

Figure 1.4
UMTRA Project Technical Assistance Contractor Organization



4. Establish and implement a QA training program.

5. Establish and implement audit and surveillance programs and schedules.

6. Review all TAC standard operating procedures (SOP).

7. Evaluate the effectiveness of the QA program, report to management, and establish and maintain interface between the TAC and the ERD.

8. Recommend to the TAC Project Manager that work be stopped when activities are not in compliance with contract documents or when unsatisfactory work is performed. Oral recommendations shall be followed by written recommendations.

9. Establish plans, schedules, and methods to ensure that QA procedures are followed.

10. Represent the TAC on UMTRA QA matters and in the resolution of QA problems.

11. Review deficiency reports, nonconformance reports, and corrective action reports.

12. Monitor QA personnel activities, schedules, and assignments.

1.4.5 TAC quality assurance specialist

a. The TAC QA specialist reports directly to the TAC QA manager. This individual shall:

1. Support the ERD UMTRA QA manager in performing QA audits, OREs, and QA in-process surveillances.

2. Establish QA audit, ORE, and QA in-process surveillance techniques and procedures.

3. Develop QA audit, ORE, and QA in-process surveillance schedules, select team members, and conduct audits, OREs, and in-process surveillance under direction from the ERD UMTRA QA manager.

4. Develop QA audit, ORE, and QA in-process surveillance checklists and prepare QA audit, ORE, and QA in-process surveillance reports.

5. Perform QA audit, ORE, and QA in-process surveillance follow-up activities.

6. Maintain records of QA audit, ORE, and QA in-process surveillance activities.

7. Prepare and maintain records of QA audits, OREs, and QA in-process surveillances and an audit/surveillance tracking system.

8. Provide assistance in developing TAC QAPP and associated SOPs.

9. Participate in trend analysis.

10. Support the TAC QA manager in tracking and trending results from the Systems Performance Advancement Measurement and Training Records and Administration Information Network programs.

11. Develop management reports on lessons learned from root cause analysis reports.

12. Identify and use the benefits of data base management systems and track performance improvements.

13. Prepare reports for UMTRA Project management on performance improvements, and coordinate and participate in conducting total quality management training.

14. Support the TAC Quality Council by tracking outstanding quality improvement suggestions, developing correspondence, and maintaining records.

15. Support TAC internal QA audits.

b. Refer to Section 10.0, Independent Assessment, of this QAPP, for methods to accomplish QA audits and QA in-process surveillances.

1.4.6 RAC organization

a. The RAC contractors consist of MK-Ferguson and the state of Utah. The remedial action work at the Salt Lake City site has been completed. Accordingly, the state of Utah's functions and responsibilities are not included in the UMTRA QAPP. The RAC organizational structure provides the RAC QA department adequate organizational freedom to perform QA activities as required by the ERD. The RAC organization consists of a Project director, site managers, Project quality manager, site quality supervisors, and quality inspectors. This organizational relationship is illustrated in Figures 1.5 and 1.6. The RAC's functional relationships and QA program responsibilities are described in the following paragraphs.

Figure 1.5
UMTRA Project Remedial Action Contractor Project Functional Diagram

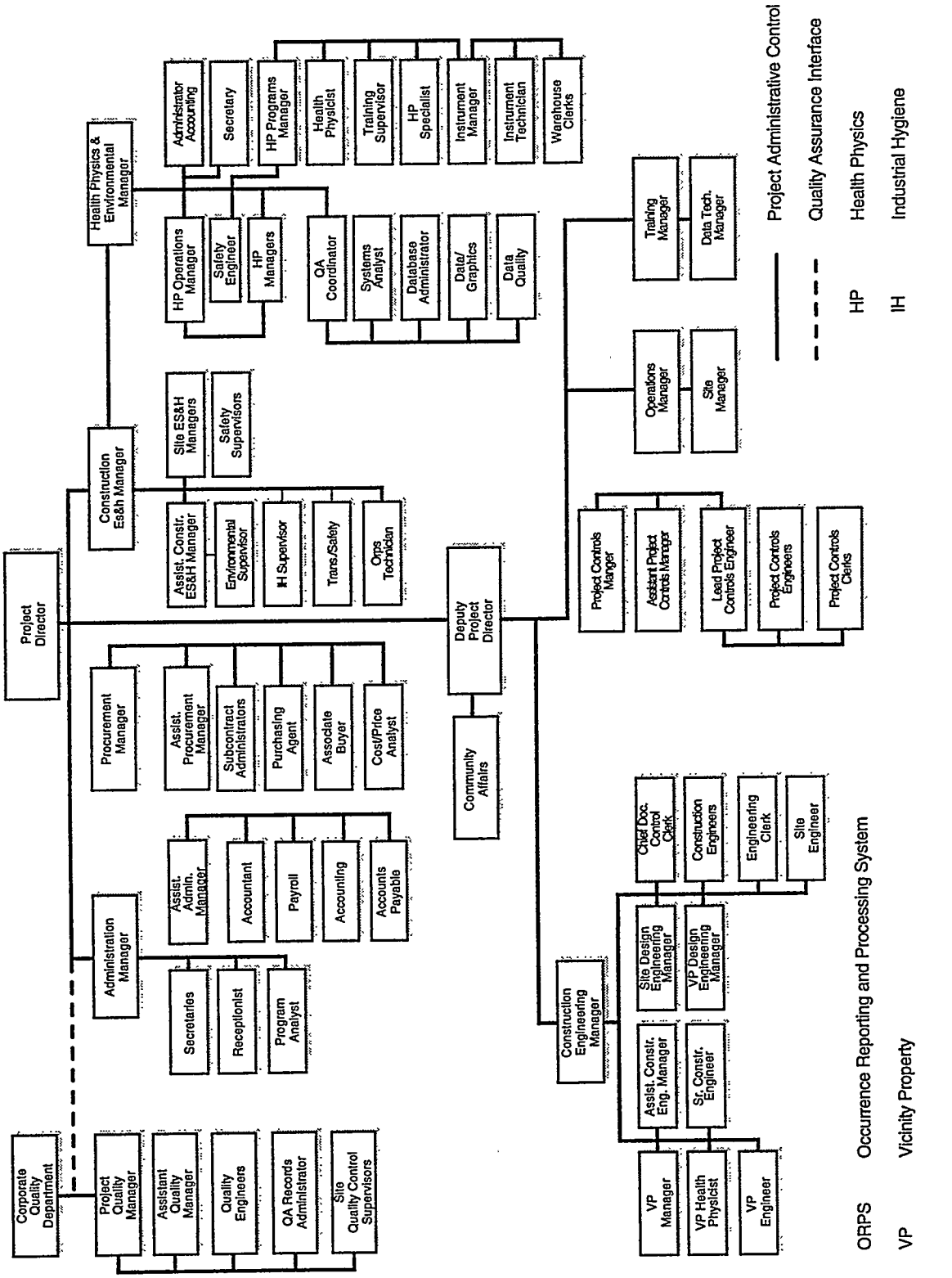
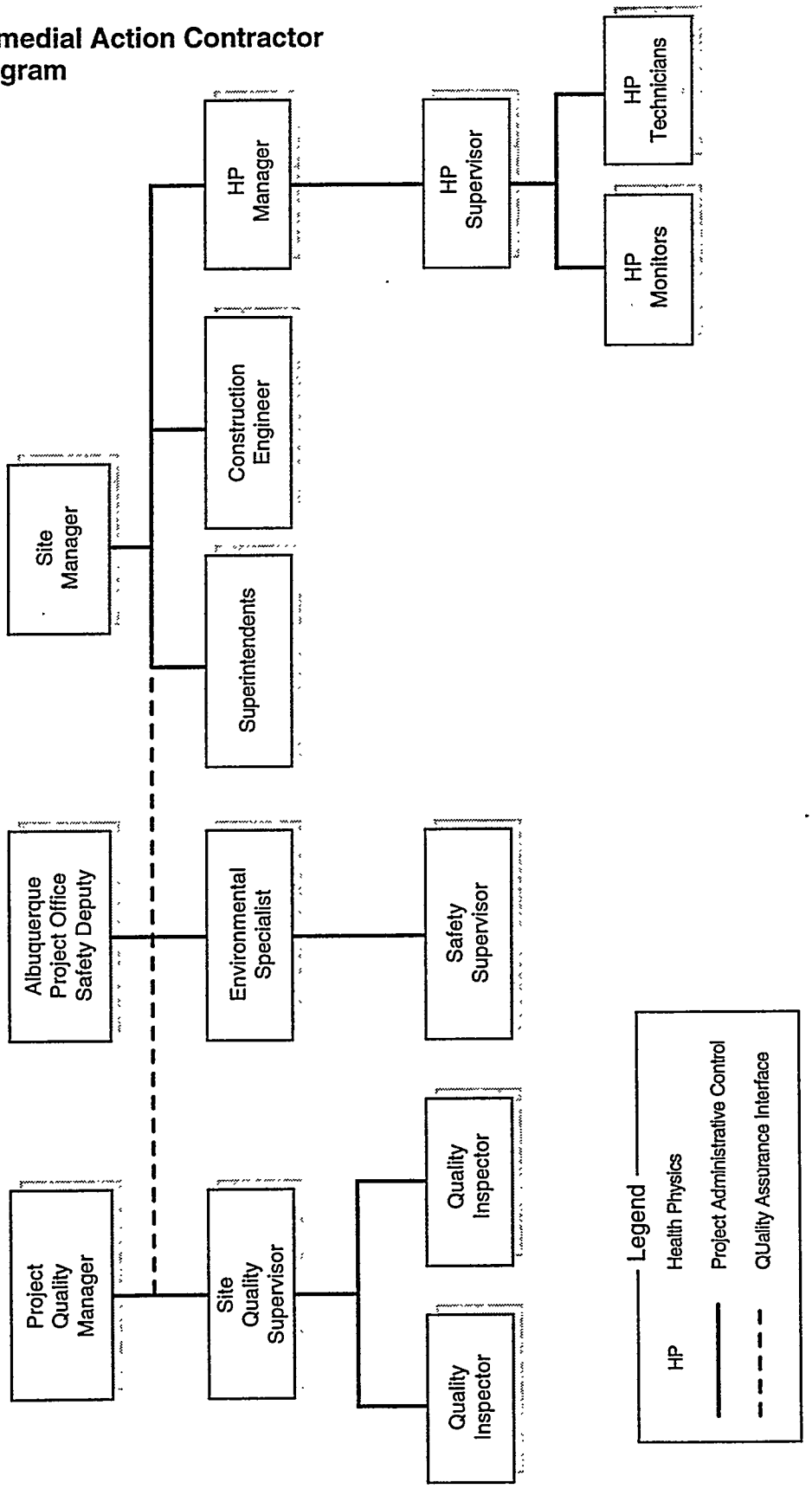


Figure 1.6
UMTRA Project Remedial Action Contractor Site Functional Diagram



1.4.7 RAC Project director/contracting officer

a. The RAC Project director has overall responsibility for the successful completion of remedial action construction activities at all assigned UMTRA Project sites as directed by the ERD. The Project director's responsibilities include organizing, administering, planning, budgeting, and coordinating UMTRA Project activities. All RAC site managers, department managers, and task managers report to the RAC Project director. The contracting officer has the authority to issue stop-work orders for deficient quality operations.

1.4.8 RAC quality manager

a. The RAC quality manager is responsible for establishing and implementing the RAC QA program, under the direction of the ERD. The RAC quality manager reports directly to the corporate QA manager; site quality supervisors report to the RAC quality manager. The quality manager shall:

1. Respond to and support the ERD.

2. Develop and implement the RAC QA program and supporting procedures.

3. Develop and organize the RAC QA Department and administrative staff.

4. Establish and implement an indoctrination and training program.

5. Develop and implement an audit program and respective schedules.

6. Stop work and initiate corrective action when activities are not performed in accordance with UMTRA Project requirements.

7. Identify the need for corrective action.

8. Initiate, recommend, and/or provide solutions to issues requiring corrective action.

9. Verify implementation of solutions and corrective action.

10. Evaluate the effectiveness of the QA program, report to management, and establish and maintain interface between the RAC and ERD.

11. Represent the RAC on UMTRA Project QA matters, in meetings, and in the resolution of QA problems.

12. Monitor QA personnel activities, schedules, assignments, and administrative details.

13. Sign certificates of compliance/conformance when required and ensure the quality of site activities.

1.4.9 RAC site quality supervisor

a. The RAC site quality supervisor reports directly to the RAC quality manager and supervises the site quality inspection staff. The site quality supervisor shall:

1. Implement the site RAIP.

2. Control remedial action quality control (QC) testing and processing, and control nonconforming items and materials to preclude delivery and installation.

3. Ensure the quality of all site activities.

1.4.10 Site quality inspectors

a. Site quality inspectors report directly to the site quality supervisor. All inspectors are trained and qualified to perform QC activities and tests in accordance with approved requirements, plans, and procedures.

1.5 ORGANIZATION INTERACTIONS

1.5.1 Interactions between the ERD UMTRA Project and other organizations are conducted in accordance with the following paragraphs. Interactions between organizations other than the ERD UMTRA Project shall be described in the participants' UMTRA QA program descriptions.

a. U.S. Nuclear Regulatory Commission

1. The ERD UMTRA QA manager, with the assistance of the TAC QA manager, advises the ERD director on matters affecting Project quality prior to communication or meetings with the NRC. The ERD director shall provide direction regarding the course of appropriate action, type of communication, and/or meetings necessary to comply with and respond to NRC quality issues.

b. State, local, and tribal governments

1. The ERD directs, as necessary and with the active support of the TAC, all scheduling of meetings and other communications, including community awareness programs, between the ERD and participating state, local, and tribal governments.

c. Other participating organizations

1. The interactions with other organizations concerning activities affecting UMTRA Project QA are coordinated by the ERD director with the assistance of the ERD QA manager and the TAC QA manager when required.

1.6 UMTRA PROJECT WORK DELEGATION

1.6.1 The responsibility for the overall UMTRA Project is retained by DOE-AL. The responsibility for establishing and implementing tasks and selected portions of the QA program has been delegated to the ERD. Further work has been delegated to UMTRA contractors and UMTRA participants under the approval and direction of the ERD. These responsibilities and tasks are documented using action memos and approved plans and procedures.

1.7 DISPUTE RESOLUTION

1.7.1 All UMTRA Project concerns and differences of opinion involving technical and quality issues presented at any management level shall be addressed to the managers at that level. If an issue or concern cannot be resolved, it will be presented progressively to the next management level and up to the DOE-AL Office of the Manager.

1.8 STOP-WORK AUTHORITY

1.8.1 The overall authority to stop work on all levels of the UMTRA Project rests solely with the DOE contracting officer, who shall be fully informed by the ERD director, the contracting officer's representative. Direction to stop work can be issued by any DOE representative when imminent danger to personnel health and/or safety is involved.

1.8.2 Personnel responsible for issuing the stop-work order shall, in all cases, notify the responsible supervisor or task manager, who in turn shall notify the next level of management, QA, and health and safety personnel as necessary, and the ERD. The ERD shall, with the assistance of the TAC QA manager, investigate all stop-work orders to identify causes for the order and to adequately resolve the problems. The ERD director shall be responsible for issuing orders to resume work.

1.9 QUALITY ASSURANCE PROGRAM PLANS AND PROCEDURES

1.9.1 QAPPs, site-specific RAIPs, and associated operating procedures shall be developed, reviewed, and approved by the UMTRA Project contractors. The contractors' QAPPs shall be submitted to the ERD for review and approval prior to implementation. The ERD shall provide each site-specific RAIP to the NRC for concurrence. All updates to the plans shall go through the same review and approval process as new documents.

1.10 UMTRA PROJECT QUALITY ASSURANCE PROGRAM

1.10.1 QA requirements

a. The QA requirements for the UMTRA Project are identified in DOE Order 5700.6C and applicable sections of 10 CFR 830.120. QA requirements contained in this QAPP shall apply to all personnel, processes, and activities, including planning, scheduling, and cost control performed by the UMTRA Project and its contractors. It is UMTRA Project policy to apply a graded approach to QA acknowledging that public health and safety are not always affected, and that an adequate level of quality is needed to ensure the Project's operational reliability and maintainability. Applicable portions of this document shall be implemented to the maximum degree for quality- and safety-related functions, and a less stringent but still viable quality level shall be used for other Project activities. This QAPP incorporates the 10 criteria contained in DOE Order 5700.6C. EXCEPTION: Umetco Mineral Corporation's Engineering Services for the design of the Naturita disposal cell will follow the QA requirements of NQA-1 instead of the QA requirements of DOE Order 5700.6C. The exception is allowed because NQA-1 meets all of the nuclear safety requirements of DOE Order 5700.6C and conforms to the standards that are familiar to the private industry.

b. This QAPP describes 1) the provisions established by the ERD to implement the applicable requirements of the documents listed in Section 11.0, 2) the ERD organizational responsibilities for achieving and verifying quality, and 3) the interface between the ERD, the TAC, and the RAC. Organizational charts are provided and the provisions that are implemented to meet each section of the applicable requirements of the documents referenced in Section 11.0 are described. This QAPP shall be reviewed by the ERD Technical Services Team and approved by the ERD QA manager. The approved QAPP shall be issued as a controlled document.

c. This QAPP shall be reviewed once each calendar year. The review shall be accomplished not sooner than 6 months and not later than 18 months following the last review. Reviews shall be documented, including the reviewer's name, date, and comments, if no update of the text is required.

d. The UMTRA Project QA program shall be implemented at each level by all contractor management, QA staff, and personnel. Organizational personnel are responsible for achieving a minimum specified level of quality. Performance objectives shall be established to ensure that quality is achieved. Initial estimates used in planning shall be based on verified data and assumptions relating to personnel, material/service, cost, availability, and productivity.

e. The RAC shall develop a checklist and perform and document an ORR for each UMTRA site or substantial construction activity. The TAC shall assist

the ERD in performing an ORE of the RAC's ORR. Readiness reviews shall be performed before start-up after winter shutdowns, any prolonged shutdown, or any major scheduled or planned work. The readiness reviews shall be performed to verify the following:

1. Work prerequisites are satisfied.

2. Detailed technical and QA procedures are reviewed for adequacy and appropriateness.

3. Personnel are suitably trained and qualified.

4. The proper equipment, material, and resources are available.

f. The ERD QA staff shall evaluate the adequacy of the ERD contractor's QA program and technical products through verification techniques such as reviews, audits, surveillances, and ORRs. The ERD QA staff may use the expertise of the TAC in making these evaluations. The ERD QA manager shall assist in developing and implementing the QA program, overseeing activities to verify achievement of quality, and evaluating and reporting on QA program compliance and implementation effectiveness. Organizational managers supervising the work shall ensure that the specified quality is achieved by using appropriate means of verification such as review, inspection, or observation.

g. Verification of the achievement of quality for each organization's internal activities shall be provided by QA personnel who are independent of the item or activity being verified. Verification personnel shall have sufficient authority, access to work areas, and organizational freedom to 1) identify quality problems; 2) initiate, recommend, or provide solutions to quality problems through designated channels; 3) verify implementation of the solutions; and 4) ensure that further processing, delivery, installation, and use of nonconforming items are controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. QA personnel shall oversee and monitor activities by conducting independent QA reviews, audits, and surveillances. A detailed description of QA audit and surveillance controls is identified in Section 10.0 of this QAPP.

h. Direction and oversight of the UMTRA Project contractor's QA activities shall be provided by ERD QA personnel. Adequate direction and oversight shall be achieved by establishing UMTRA QA requirements in the DOE UMTRA QAPP and by performing quality verification through QA reviews, audits, surveillances, and OREs.

1.10.2 Environmental data operations

a. All activities involving the generation, acquisition, and use of environmental data shall be planned and documented. The type and quality of

environmental data needed shall be determined with respect to their intended uses. Data quality objectives (DQO) will document the types of data required and data quality controls (DQC) will document the quality of data required. Determining the type and quality of environmental data needed shall involve all data users as well as those responsible for activities that affect data quality. DQOs and DQCs are defined and implemented by the TAC Quality Assurance Implementation Plan.

b. The data collection process for characterizing environmental processes and conditions shall be defined, controlled, verified, and documented. The data collection design process includes the design of field sampling events, sample handling and custody, analytical operations, data validation methods, techniques for assessing limitations on data use, and data reporting requirements. The design process also applies to data compilation for modeling or additional studies.

c. The intended use of the data, including the potential for litigation, shall determine the extent of validation and documentation required during each sampling and analysis cycle. Any variables that determine or affect the quality of results shall be identified and controlled.

d. The data collection process shall ensure that data are traceable to the sampling and analytical procedures, performance standards, analysts, and measuring and test equipment. Data transfer, reduction, and validation requirements shall be determined and specified. Data interpretation and analysis needs shall also be determined and specified.

e. Procedures shall be established and implemented to ensure that only qualified and accepted services, equipment, or supplies are used in the environmental data operations and to maintain identification of the accepted equipment and supplies (i.e., chemicals, parts, and the like) in documents traceable to the items.

1.10.3 Management information reporting and tracking

a. Communication and information systems will be established to ensure timely reporting, dissemination, and tracking of QA management information, such as the status of the implementation of QA programs, status of the resolutions of conditions adverse to quality, and status of QA overview results. Applicable reports shall be provided to management promptly.

1.11 UMTRA PROJECT CONTRACTORS

1.11.1 The UMTRA Project contractors shall develop a QA program that complies with the requirements contained in this QAPP applicable to the work delegated to them. The QA program requirements shall be reviewed and approved by the ERD manager. Contractor QA organizations will review lower-tier QA program descriptions and recommend approval or disapproval to the management.

2.0 PERSONNEL TRAINING AND QUALIFICATIONS

2.1 GENERAL

2.1.1 Personnel shall be qualified to perform their assigned work according to UMTRA Project-specific requirements. Management shall identify those work functions requiring special skills. Management shall establish procedures to ensure that personnel demonstrate and maintain proficiency in performing their assigned work, and the results shall be documented. Required training shall be accomplished and documented as required to ensure satisfactory job proficiency.

2.1.2 The ERD UMTRA Project shall develop and implement the necessary instruction and training activities to ensure that its personnel are properly qualified and trained. The ERD UMTRA Project has also delegated the responsibility to each UMTRA contractor to develop and implement instruction and training activities for their personnel.

2.1.3 The UMTRA Project contractors shall establish and implement a system to ensure that their employees are properly qualified and trained. The requirements for this system, including methods and responsibilities, shall be specified in their individual QAPPs.

2.2 REQUIREMENTS

2.2.1 All personnel shall be capable of performing their assigned tasks and shall receive the appropriate instruction and training before performing their assigned tasks. Personnel shall have the appropriate education, experience, and training commensurate with the functions associated with their work.

2.2.2 Training should ensure that personnel understand the fundamentals of the process or activity that they are performing and the requirements associated with that process or activity. Training should focus on the process or activity quality requirements, the individual's responsibilities for quality, and the importance of doing it right the first time.

2.2.3 Training shall cover the purpose, scope, objectives, and applicable requirements associated with the ERD UMTRA Project QAPP.

2.2.4 Training shall be documented to ensure that personnel understand the fundamentals of the processes or activities they perform and the requirements and regulations associated with these processes or activities.

2.3 TRAINING PLANS

2.3.1 Supervisors shall review the job functions or tasks of personnel under their supervision and determine the extent of training required.

2.3.2 Training plans shall promote and stimulate professional development. Training plans shall provide for maintenance of proficiency and progressive improvement, and shall not be limited to attainment of initial qualification.

2.3.3 Training requirements for management personnel shall include professional, managerial, communication, and interpersonal skills.

2.3.4 Persons verifying activities (such as lead auditors, auditors, or personnel conducting surveillances) shall be qualified in the principles, techniques, and requirements of the activity being performed. Specific qualification requirements shall be documented.

2.3.5 Training may involve on-the-job training, self-accomplished reading assignments, and courses given by qualified instructors.

2.4 PROFICIENCY EVALUATION

2.4.1 Training shall be subject to ongoing review to determine program and instructional effectiveness. Training should be upgraded as additional requirements or improvements are identified.

2.4.2 Supervisors shall evaluate at least annually the proficiency of their personnel in the performance of their assigned duties. Appropriate training shall be provided to maintain or improve proficiency.

2.5 DOCUMENTATION/RECORDS

2.5.1 Documentation of qualification and training requirements and records of required indoctrination and training accomplished shall be maintained. A copy of the training records shall be provided to the ERD UMTRA Project Document Control Center (UPDCC).

2.6 ERD UMTRA PROJECT EVALUATION

2.6.1 The ERD UMTRA Project shall evaluate the adequacy of the Project contractor's indoctrination and training systems through verification techniques such as audits, in-process surveillances, and reviews conducted in compliance with Section 1.0, paragraph 1.10.1(f).

3.0 QUALITY IMPROVEMENT

3.1 GENERAL

3.1.1 Organizations shall establish and implement procedures to prevent or detect problems that adversely affect quality during the planning, implementation, and assessment of technical and management activities. Deficiency and corrective action data shall be evaluated for their impact and application. Processes shall also be established and implemented to promote and conduct continuous quality improvement in technical and management processes, including the identification of performance measures of success and standards of excellence.

3.1.2 The ERD UMTRA Project shall cultivate and implement a system that promotes quality improvement objectives. Also, the ERD UMTRA Project has delegated responsibility to each UMTRA Project contractor to develop and implement a system that promotes quality improvement objectives within their operations. The UMTRA Project contractors shall establish and implement their own quality improvement systems. Their quality improvement activities shall be specified, including methods and responsibilities, in their individual QAPPs.

3.2 REQUIREMENTS

3.2.1 The objectives of a quality improvement system are to prevent problems and improve quality, performance standards, and associated performance measures. The focus of quality improvement should be to reduce the variability that influences quality. Examples of planning and problem prevention approaches include, but are not limited to, peer reviews, design reviews, probabilistic risk assessments, safety analysis reports, reliability/availability/maintainability analyses, audits, in-process surveillances, and ORRs.

3.2.2 Performance data, prevention and failure costs, nonconformance reports, and other quality-related information should be used to identify trends that adversely impact quality and to identify opportunities to improve items, processes, and services. Managers of the Project contractors shall be informed of these quality improvement results.

3.3 NONCONFORMANCES

3.3.1 A nonconformance is a variance from regulations, approved requirements, or SOPs that adversely affect safety, durability, performance, or any other basic objective that impacts quality.

3.3.2 The reporting of a nonconformance shall not be considered in a negative manner, but rather shall be considered an important tool that allows for and results in improved quality. Procedures shall be established that provide for reporting, controlling, and dispositioning of conditions which are not, or are suspected of not being, in conformance with approved requirements.

3.3.3 Nonconforming material shall be promptly identified, marked or tagged and, where practical, segregated to prevent inadvertent installation or use, further processing, or delivery. Nonconforming services and processes shall be curtailed until approved disposition is provided.

3.3.4 Nonconformances shall be documented and the documentation provided to the organization responsible for disposition. The justification for disposition shall be documented.

3.3.5 Modifications, repairs, rework, and replacements shall be inspected or tested to verify acceptability in accordance with the original requirements and specifications.

3.3.6 The ERD UMTRA Project shall approve corrective action on nonconforming items, processes, and services that may affect site licensing.

3.4 CORRECTIVE ACTION

3.4.1 All conditions adverse to quality shall be promptly identified, documented, and corrected as soon as practical.

3.4.2 Adverse conditions shall be evaluated including trend analysis, identification of the root cause, extent, and effects on the UMTRA Project.

3.4.3 When the evaluation is complete, the applicable corrective action shall be identified. This corrective action shall address the root cause, identify the action necessary to preclude recurrence, and define a schedule for the action. The corrective action shall be reviewed by the appropriate manager to ensure that proper focus is given, adequate resources are allocated, and difficult issues are resolved.

3.4.4 A follow-up investigation shall be conducted to verify implementation of the corrective action. Additional reviews may be performed to verify that corrective action has been effective in preventing a recurrence of the adverse condition.

3.5 ADVERSE CONDITIONS IDENTIFIED BY THE ERD UMTRA PROJECT

3.5.1 All adverse conditions identified by the ERD UMTRA Project that are applicable to UMTRA Project contractors shall immediately be brought to the attention of the affected contractor Project manager. The contractor Project manager shall take immediate corrective action and report corrective action progress within the time period designated by the ERD.

3.6 DOCUMENTATION

3.6.1 Reporting of nonconformances, disposition activities, evaluations of adverse quality activities, corrective actions, and verification of corrective actions shall be documented.

3.7 ERD UMTRA PROJECT EVALUATION

3.7.1 The ERD UMTRA Project shall evaluate the adequacy of the UMTRA Project contractors' quality improvement systems, including the nonconformance and corrective action activities. The evaluation process is intended to verify quality achievement and to evaluate and report on compliance and effectiveness of implementation. The ERD's evaluation of the adequacy of the quality improvement systems shall be conducted through verification techniques such as audits, in-process surveillances, and reviews that will be conducted in compliance with Section 1.0, paragraph 1.10.1(f).

4.0 DOCUMENTS AND RECORDS

4.1 DOCUMENTS

4.1.1 General

a. The preparation, issue, and revision of documents that specify quality requirements or prescribe activities affecting quality shall be controlled to ensure that correct documents are used. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.

b. The ERD UMTRA Project shall establish a system for controlling its documents. Additionally, the ERD UMTRA Project has delegated responsibility to the Project contractors to develop a system for controlling their documents.

c. Each UMTRA Project contractor shall develop and implement procedures to ensure that UMTRA Project documents are prepared, revised, reviewed, approved and issued in a prescribed and controlled manner, as specified in their individual QAPPs.

4.1.2 Documentation preparation, revision, review, and approval

a. Procedures for preparing and revising plans, manuals, procedures, instructions, reports, and other documents shall address at least the following requirements:

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

2. Review of the document by individuals or organizational elements responsible for implementation.

3. Review of the document by individuals other than the preparer of the document.

4. Access by reviewing organizations to pertinent background data or information to ensure adequacy, completeness, and correctness prior to approval and issuance.

5. Resolution of review comments that are considered mandatory by the reviewing organization before a document is approved and issued. Review comments and resolutions shall be documented and maintained in accordance with approved procedures.

4.1.3 Issuance and distribution

a. Document issuance and distribution shall be controlled to ensure that correct, applicable, and current documents are available to personnel at the location

where the work is performed before work begins. Document control procedures include the following provisions:

1. Identifying and marking documents, including documents released before the approval process is completed.

2. Maintaining document distribution lists.

3. Marking or removing obsolete or superseded documents.

4. Maintaining an index that includes document revision status.

4.1.4 Controlled documents

a. Controlled documents meet all requirements associated with document preparation, approval, and issuance, and are considered important enough that only the latest issues of the documents should be used.

b. Provisions for controlled documents include:

1. Identifying documents to be controlled and their specified distribution, including documents released before the approval process is completed.

2. Acknowledging receipt of document transmittal forms.

3. Maintaining controlled document distribution lists.

4. Controlling superseded and canceled documents. This should include measures to ensure that only correct documents are in use. Record copies should be marked "Superseded" or Canceled" and kept for a specified retention period.

5. Maintaining an index giving revision status for controlled documents. Project contractors may place controlled documents on a local area network (LAN), if the system is available.

6. Locating controlled copies on a LAN, provided the latest revision of the document is available. Additionally, an individual shall be designated as the custodian for the controlled documents that are on the LAN, to ensure they remain current.

4.1.5 Document changes

a. Minor changes

1. Minor changes to UMTRA Project documents, such as typographical or editing errors of no consequence, do not require that the revised documents receive the same review and approval process as the original

documents. Each Project contractor shall document in its procedures the types of minor changes that do not require a review and approval process, as well as the person(s) authorized to make such decisions.

b. Major changes

1. Changes to documents other than those classified as minor changes are considered major changes and require the same review and approval process as the original document. These documents should be reviewed and approved by the organization that originally reviewed and approved the documents. An alternative organization may be designated, based on technical competence and capability. Timeliness guidelines should be implemented for distribution of new or revised controlled documents. The organization performing the review and approval process shall have access to pertinent background data or information on which to base its approval.

4.2 RECORDS

4.2.1 General

a. Records that furnish documentary evidence of quality shall be specified, prepared, and maintained. Records shall be legible, identifiable, written in blue or black indelible ink, and retrievable. Corrections to records shall be marked through with a single line and initialed and dated by the individual making the corrections. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.

b. The UMTRA Project record requirements are contained in the latest version of the UMTRA *Project Document Control System Manual* (DOE, 1994). The UMTRA Project has also delegated responsibility to the Project contractors to develop a system for establishing and maintaining their UMTRA related-records.

c. Each UMTRA Project contractor shall establish and maintain a records management system in accordance with the procedures, including methods and responsibilities, as specified in their individual QAPPs. These systems shall be developed so the records can be integrated into the format of the Project Document Control System (PDCS) manual (DOE 1994).

4.2.2 Requirements

a. The records program activities for the UMTRA Project shall be defined, implemented, and enforced in accordance with written procedures. These procedures shall adequately describe the methods used to create, identify, control, process, organize, and distribute records.

b. The record program shall ensure that sufficient records (for example, records of design, environmental conditions, applied research and development, procurement, construction, data acquisition, assessments, inspection, testing, maintenance, and modification) are specified, prepared, reviewed, approved, and maintained to accurately reflect completed work. Maintaining records shall include provisions for retention, protection, preservation, traceability, accountability, retrievability, and disposition of UMTRA Project records.

4.2.3 ERD UMTRA Project Document Control System

a. UMTRA Project

1. Records control for the UMTRA Project shall be specified in the PDCS manual (DOE, 1994). The ERD director shall approve the PDCS manual and ensure that the necessary document control interface among Project participants is established and maintained. The ERD has delegated the authority for administering the UMTRA PDCS and the responsibility for providing guidance to the UPDCCs to the TAC.

2. The ERD UMTRA Project has specified record types that shall be developed, maintained, and submitted to the UPDCC by UMTRA contractors and other participants through record listing. The UPDCC shall use this listing to develop and maintain the overall records index. The ERD UMTRA Project shall approve UMTRA contractor and other participating organizations' record listings to ensure that adequate records are maintained.

b. Technical Assistance Contractor

1. The TAC shall provide support and guidance to the ERD UMTRA Project to ensure efficient operation of the UMTRA PDCS by recommending changes, improvements, policies, and procedures.

2. Also, the TAC shall be responsible for the following activities:

a. Developing and implementing SOPs for the UPDCC operations.

b. Reporting on the operation of the UPDCC.

c. Recommending improvements or changes to the UPDCC.

d. Reviewing and updating the PDCS manual annually, or as significant changes warrant.

c. Project participants

1. Project participants shall be responsible for routinely transferring UMTRA Project documents to the UPDCC according to the provisions described in

the UMTRA PDCS manual. UMTRA Project participants involved in the administration of documents shall meet before the annual issuance of the UMTRA PDCS manual to resolve problems and recommend changes or enhancements to the UMTRA PDCS.

2. UMTRA Project contractors and other participating organizations may forward all pertinent records to the UPDCC at the completion of each major work package, but shall forward records no later than the conclusion of their involvement in the UMTRA Project. Records transfer shall be made as mutually agreed upon between the ERD and the sender, including the transfer of records that are in addition to records initially planned for transfer.

4.2.4 Records system

a. The ERD UMTRA Project shall maintain sufficient records to support conclusions reached from investigations, tests, or other bases for remedial action accomplished under the auspices of the UMTRA Project. The UPDCC shall be established and controlled at a location specified by the ERD. While the record keeping tasks shall be assigned to the TAC, the ERD UMTRA Project shall retain the responsibility for all record keeping requirements.

b. For records that require special processing and control, such as computer codes or information on high density media or optical disks, hardware and software required to maintain and access records shall be controlled to ensure that records are usable.

c. Documented procedures shall define requirements for submitting records to the UPDCC, reviewing incoming records, filing methods, accessing control, and reproducing records upon request. Once accepted into UPDCC storage, a system shall be established and implemented to control document removal, tracking, and retrieval.

d. The UPDCC facilities shall provide necessary precautions against destruction of records by fire or natural causes. The ERD UMTRA Project has assigned the TAC with fire and security protection responsibility and the responsibility to provide access control measures for records storage areas.

e. A record index shall be developed and implemented to include a record index numbering system, storage location, and retention time. Index requirements shall be defined in the PDCS manual.

f. Temporary record-holding facilities are reserved for storing inactive records and may not meet the physical requirements or have appropriate staff to maintain active records. Active records requiring special handling, storage, and processing should not be sent to records-holding facilities. Users should refer to the General Records Schedule (GRS) or DOE Order 1324.2A for retention and disposition of records.

g. The National Archives and Records Administration (NARA) exercises final authority for approving the disposition of Government records. Use of the GRS, which is published by the NARA, and the DOE unique schedules approved by the NARA is mandatory.

h. Some standards that provide interpretive QA guidance may differ in records management terminology from the NARA requirements. In those instances, care should be taken to ensure that the requirements of both the NARA and the standards are followed.

4.3 ERD UMTRA PROJECT EVALUATION

4.3.1 The ERD UMTRA Project shall evaluate the adequacy of the UMTRA Project contractors' document control and record system specified in Sections 4.1 and 4.2 of this QAPP through verification techniques such as reviews, audits, and surveillances that will be conducted in compliance with Section 1.0, paragraph 1.10.1(f).

5.0 WORK PROCESSES

5.1 WORK

5.1.1 General

a. Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

b. The ERD UMTRA Project has delegated the responsibility of work activities to the Project contractors.

c. Work activities of each UMTRA Project contractor shall be accomplished in accordance with procedures specified in their individual QAPPs.

5.1.2 Requirements

a. Activities on the UMTRA Project are prescribed by and controlled in accordance with DOE Orders. The DOE Orders are established by DOE-HQ, passed down to DOE-AL, and implemented by the ERD UMTRA Project. Work controls, which include instructions, procedures, and drawings, shall be applied to processes and activities that are performed by the ERD UMTRA Project and its Project contractors. The work controls shall be implemented by UMTRA Project contractors.

5.1.3 Work processes, instructions, procedures, and drawings

a. All activities affecting quality on the UMTRA Project shall be defined by instructions, procedures, and drawings that are prepared, reviewed, and approved in accordance with the QAPP of the originating organization. These documents shall include appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities are satisfactorily accomplished. The work-related instructions, procedures, drawings, and other forms of direction shall be developed, verified, validated, and approved by authorized, technically competent personnel.

b. All work should be planned, authorized, and accomplished under controlled conditions following technical standards, instructions, written procedures, drawings, or other appropriate means of a detail commensurate with the complexity and risk of the work.

c. Organizational personnel are responsible for the quality of their work. Performance objectives shall be established to ensure that quality work is achieved. Supervisors shall ensure that personnel under their supervision are

provided the necessary training, resources, and administrative controls to accomplish their assigned tasks. Criteria describing acceptable work performance shall be defined. Supervisors shall review work and related information to ensure that the desired quality is achieved and to identify areas that need improvement.

d. Personnel assigned to perform activities that affect the quality of an item or activity shall receive appropriate training before performing their work activities. Personnel shall be knowledgeable about the requirements for the work they perform and the capability of the tools and processes they use.

5.2 IDENTIFICATION AND CONTROL OF ITEMS

5.2.1 General

a. Controls shall be established to ensure that only correct and accepted items are used or installed. Identification shall be maintained on the items or in documents traceable to the items, or in a manner that ensures identification is established.

b. The ERD UMTRA Project has delegated the work associated with the identification and control of materials, parts, and components to UMTRA Project contractors.

c. Identification and control of items by each UMTRA Project contractor shall be accomplished in accordance with procedures, including methods and responsibilities, specified in the UMTRA Project contractors' individual QAPPs.

5.2.2 Requirements

a. Processes shall be established and implemented to identify, control, and maintain items purchased for use on the UMTRA Project. Materials, parts, and components shall be identified and controlled by the contractor that will use such items.

b. Procedures shall describe the methods for ensuring that only correct and accepted materials, parts, and components are used. Identification and methods of control shall be maintained on, or in documents traceable to, the materials, parts, and components.

c. Identification of the materials, parts, and components shall be maintained to ensure appropriate traceability. Physical identification shall be used to the maximum extent possible. Where physical identification on the items is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed. Procedures shall be established and implemented to control consumables and items with limited shelf or operating life, prevent the use of incorrect or defective items, and control

samples (including chain-of-custody). Identification markings shall provide a clear and legible identification and not detrimentally affect the function or life of the items.

5.3 HANDLING, STORAGE, AND SHIPPING

5.3.1 General

a. Handling, storage, cleaning, packaging, shipping and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration.

b. The ERD UMTRA Project has delegated the responsibility for handling, storage, and shipping activities to the UMTRA Project contractors.

c. These activities shall be accomplished by UMTRA Project contractors in accordance with procedures, including methods and responsibilities, specified in their individual QAPPs.

5.3.2 Requirements

a. Procedures shall be established that delineate identifying, packaging, handling, shipping, storage, cleaning, and preserving items to prevent damage, loss, or contamination; minimize deterioration; and protect personnel. Handling, storing, cleaning, packaging, shipping, and preserving field and laboratory environmental samples must meet chain of custody requirements and shall be performed in accordance with written procedures prescribed in the UMTRA Project contractors' individual QAPPs.

b. Furthermore, these procedures shall address maintenance of marking and labeling throughout packaging, shipping, handling, and storage activities. The information provided by marking and labeling shall identify items and provide instructions or special controls to preserve the items' integrity. Off-site transportation requirements shall be established and implemented through written procedures. Special protective measures (such as containers, shock absorbers, accelerometers, inert gas atmospheres, and specific temperature and moisture levels) should be specified and provided when required to maintain acceptable quality.

5.4 CALIBRATION AND MAINTENANCE OF MONITORING AND DATA COLLECTION EQUIPMENT

5.4.1 General

a. A system shall be established and implemented to control the calibration, maintenance, and use of measuring and test equipment used for monitoring and data collection.

b. No calibration or maintenance of monitoring and data collection equipment is directly performed by the ERD UMTRA Project. The activities requiring the use of this equipment have been delegated by the ERD UMTRA Project to the UMTRA Project contractors.

c. These activities shall be accomplished by the UMTRA Project contractors in accordance with procedures, including methods and responsibilities, specified in their individual QAPPs.

5.4.2 Requirements

a. Monitoring and data collection equipment shall be of the accuracy and type suitable for their intended use. The types of equipment included shall be specified. Equipment calibration certification shall be traceable to national standards. Equipment requiring calibration shall be identified by a serial number or a control identification number. The equipment shall have a calibration tag or sticker affixed in a conspicuous location to readily identify its calibration status. Typically the calibration tag or sticker will list the calibration date, instrument serial number, next calibration date, and name of the person who last calibrated the instrument.

b. Monitoring and data collection equipment that is of special design for a particular activity shall be designed, developed, and manufactured or procured under the control of the Project contractor involved. Before any equipment is used, a complete functional check shall be conducted according to written procedures to ensure conformance to specifications and to ensure that the equipment is properly calibrated.

c. Written procedures for calibrating specific monitoring and data collection equipment shall be provided to ensure that calibration requirements are identified and followed. Monitoring and data collection equipment shall be calibrated at specified intervals on the basis of each item's required accuracy, intended use, frequency of use, stability characteristics, and other conditions affecting its performance. The equipment shall be calibrated against standards having an accuracy that will ensure calibration within required tolerances. Monitoring and data collection equipment shall be labeled, tagged, or otherwise controlled to indicate its calibration status and ensure traceability to calibration test data.

d. Monitoring and data collection equipment found out of calibration or out of tolerance shall be tagged and/or segregated and not used until it is successfully recalibrated. The acceptability of items or processes measured, inspected, or tested with an out-of-tolerance device shall be evaluated. Records of monitoring and data collection equipment shall include scheduled calibrations, if applicable. Calibration records of equipment requiring calibration shall be maintained. References or standards used to perform calibrations shall have calibration certificates traceable to National Institute

of Standards and Technology (NIST) standards or documentation from other nationally recognized standards.

e. Maintenance shall be accomplished at specified intervals and in accordance with approved procedures.

5.5 ERD UMTRA PROJECT EVALUATION

5.5.1 The ERD UMTRA Project will evaluate the work activities, identification and control of items, and handling, storage, shipping, calibration, and maintenance of UMTRA Project monitoring and data collection equipment contractors to verify their implementation and effectiveness. These evaluations will include audits, in-process surveillances, and reviews that will be conducted in compliance with Section 1.0, paragraph 1.10.1(f).

6.0 DESIGN

6.1 GENERAL

6.1.1 The designs used on the UMTRA Project shall be defined, controlled, and verified. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents. Design interfaces shall be identified and controlled.

6.1.2 Design control is the responsibility of the ERD UMTRA Project, which has delegated the responsibility of design to the TAC and the RAC.

6.1.3 Design activities of each UMTRA Project contractor shall be accomplished in accordance with procedures specified in their individual QAPPs. These procedures shall:

a. Describe the process by which design activities from conceptual design through final design are planned, controlled, and implemented.

b. Describe the control of design inputs, organizational interfaces, processes, outputs, records review, changes, and deficiencies.

c. Address the control of scientific investigation.

6.2 ERD UMTRA PROJECT CONTROL OF DESIGN ACTIVITIES

6.2.1 UMTRA design activities by UMTRA Project contractors shall be accomplished using sound engineering/scientific principles and appropriate standards, in accordance with procedures described in their individual QAPPs.

6.2.2 The ERD director is responsible for approval of the design criteria, conceptual design, and final design for each remedial action disposal site. The ERD UMTRA Project, with assistance from the TAC, shall review documentation generated by Project contractors for programmatic, policy, design, and quality content. The TAC is responsible for developing the conceptual design for each remedial action site. The conceptual designs are approved by the ERD UMTRA Project director and submitted to the RAC for final design. The final design for each remedial action site is subject to review by the TAC and subsequent approval by the ERD director.

6.3 SCIENTIFIC INVESTIGATION

6.3.1 The adequacy of a disposal cell depends heavily upon the results of the scientific investigations conducted to characterize the disposal site. Therefore, the performance of these scientific investigations shall be controlled in accordance with written procedures.

6.3.2 The TAC's scientific investigations shall be conducted by the TAC at the direction of the ERD UMTRA Project. The TAC shall perform special technical studies to investigate general areas of programmatic impact that result in establishing criteria or Project direction or confirming results or conclusions of participating organizations. Scopes of work prepared by the TAC for subcontract applications shall define these special study activities. Approved procedures contained in the TAC QAPP shall specify the controls for the review, approval, and changes to these scopes of work.

6.4 PROCESSING DATA

6.4.1 Data collection, qualification, analysis, identification, and recording activities related to the design of the disposal sites shall be controlled. The TAC and the RAC shall conduct data collection and processing at the direction of the ERD UMTRA Project in accordance with written procedures.

6.5 DESIGN PROCESS

6.5.1 Design activities shall be conducted primarily by UMTRA Project contractors. Design reviews will be approved by all technical fields that are affected by or with construction activities and shall include a QA review. The ERD UMTRA Project shall be responsible for the preparation and control of requirement documents for the system elements.

6.5.2 Applicable design input, such as design bases, performance and reliability requirements, codes, and standards, shall be correctly translated into design output, such as specifications, drawings, procedures, and instructions. The design input for the requirement documents shall be controlled by the ERD UMTRA Project. Design interfaces should be identified and controlled, and design efforts should be coordinated among and within participating organizations. Interface controls should include the assignment of responsibility and establishment of procedures among participating design organizations.

6.5.3 The ERD UMTRA Project shall ensure that design interface responsibilities between Project contractors are properly specified and documented. UMTRA Project contractors shall address the control of design interfaces by 1) identifying who is responsible for each element of the design, 2) establishing interface controls among participating design organizations, 3) describing the process for developing an integrated design, and 4) establishing requirements for documenting, maintaining, and controlling a technical baseline. Calculations developed as part of the design process shall be reviewed and approved.

6.6 COMPUTER SOFTWARE

6.6.1 The ERD UMTRA Project is not directly involved in performing design activities that require the use of computer software. Design activities necessitating the use of computer software shall be conducted by UMTRA Project contractors. Computer programs shall be proven through previous use, or validated through

testing or simulation prior to use. Provisions for controlling computer software shall be reflected in UMTRA Project contractors' QAPPs.

6.7 READINESS/ON-BOARD REVIEWS FOR DESIGN ACTIVITIES

6.7.1 Readiness/on-board reviews shall be conducted prior to the start of a design activity or various design phases for each site, such as collection of site characterization data or model development. The RAC shall host the readiness/on-board review. Representatives attending the review shall be the TAC site manager, TAC site engineer, and the DOE site engineer. The DOE site engineer shall provide input and recommend approval. Readiness/on-board reviews shall ensure conformance to the following minimum elements:

a. The required engineering approach to design development is factored into design schedules and related planning documents.

b. Applicable regulatory requirements, codes, standards, and quality levels are identified, and SOPs reflect these required design inputs.

c. Design responsibilities and interface are defined in written procedures.

d. Procedures discuss requirements for in-process and design reviews. Design schedules identify milestone design reviews.

e. Procedures exist for baselining design documents and controlling subsequent changes.

6.7.2 The results of the readiness/on-board reviews shall be documented and approved by the DOE site engineer.

6.8 DESIGN VERIFICATION

6.8.1 The adequacy of technical documents shall be verified prior to approval and issuance for use in accordance with written procedures described in the UMTRA Project contractors' individual QAPPs. The acceptability of design work and documents, including design input, processes, outputs, and changes, shall be verified. Design verification shall be performed by qualified individual(s) or groups other than those who performed the original design, although they may be from the same organization. The extent of verification should be based on the complexity, risk, and uniqueness of the design. Verification methods include, but are not limited to, design reviews, alternate calculations, and qualification testing. Separate verification may not be needed for multiple uses of identical or previously proven designs, unless they are intended for different applications or different performance criteria.

6.8.2 The RAC shall host the design verification. The TAC site manager, TAC site engineer, and the DOE site engineer shall attend. The DOE site engineer shall provide input and recommend approval. Reviews shall be conducted in

accordance with written procedures as described in the UMTRA Project contractors' approved procedures.

6.8.3 Testing to verify or validate acceptability of a specific design feature should demonstrate acceptable performance under conditions that simulate the most adverse design conditions.

6.8.4 For the remedial action disposal sites, it may be necessary to conduct the design verification through a design review. Design reviews shall be conducted when the adequacy of information or the suitability of procedures and methods cannot be established through tests, alternate calculations, or reference to established standards. Design reviews shall be conducted at appropriate times and as necessary by all applicable design groups involved in the UMTRA Project. These reviews shall be conducted to verify the design, to ensure that quality requirements are specified, and to verify documentation.

6.8.5 Design verification shall be completed before design output is used by other organizations or to support other work, such as procurement, manufacture, construction, or experiment. When this timing cannot be achieved, the unverified portion of the design should be identified and controlled. In all cases, design verification shall be complete before an item is functional and before installation becomes irreversible (requiring extensive demolition or rework).

6.9 DESIGN CHANGE CONTROL

6.9.1 Changes to design documents shall be justified and processed using the same methods that were applied to the preparation of the original document. Changes shall be controlled, reviewed, and approved by the organizations that reviewed and approved the original design documents. Changes shall incorporate all applicable regulations and standards. The impact of design changes on procedures and training shall be evaluated. The changes shall be communicated to all affected groups or individuals. The RAC is responsible for design change control.

6.10 DESIGN ERROR AND DESIGN DEFICIENCY CONTROL

6.10.1 Errors and deficiencies identified in approved design documents and design information used by the ERD UMTRA Project will be controlled and resolved in accordance with Section 3.4 of this QAPP. The impact of such deficiencies on previous work shall be evaluated, and the necessary corrective measures shall be applied.

6.10.2 Design deficiency reports shall be sent to the ERD UMTRA Project management for information or action in accordance with the design deficiency system of the UMTRA Project organizations. Design deficiencies shall be tracked by the organizations until disposition has been assigned, approved, and implemented. Deficiencies that represent conditions adverse to quality shall be documented and controlled in accordance with Section 3.4 of this QAPP.

6.11 RECORDS

6.11.1 Design records shall be maintained to document that the design was properly accomplished. Design records shall include not only the final design output and its revision, but also important design steps (calculations, analyses, and computer programs), and sources of input that support final output.

6.12 ERD UMTRA PROJECT EVALUATION

6.12.1 The ERD UMTRA Project shall evaluate the design control measures of the UMTRA Project contractors through the use of audits, in-process surveillances, and reviews which will be conducted in compliance with Section 1.0, paragraph 1.10.1(f).

7.0 PROCUREMENT

7.1 GENERAL

7.1.1 The procurement of items and services shall be controlled to ensure conformance with specified requirements. Such control shall provide for the following, as appropriate:

a. Incorporation of applicable requirements in procurement documents.

b. Source evaluation and selection.

c. Evaluation of objective evidence of quality furnished by the supplier.

d. Source inspection, audit, and examination of items or services upon delivery or completion.

7.1.2 All materials, equipment, and services purchased on behalf of the UMTRA Project become the property of DOE-AL. However, the ERD UMTRA Project has delegated the procurement of these items and services to the Project contractors as needed to properly conduct their activities.

7.1.3 The Project contractors' procurement requirements, including methods and responsibilities, shall be contained in their respective QAPPs.

7.2 REQUIREMENTS

7.2.1 The QAPPs shall contain procedures describing the UMTRA Project contractors' purchasing process, including procurement planning, documentation review and approval, and change control. Additionally, the QAPPs shall include the requirements necessary to ensure that purchased materials, equipment, and services are controlled; meet established requirements; and perform as expected. The QAPPs shall also define or reference methods of supplier evaluation, verification of supplier conformance to specifications, and periodic surveillance of contractors.

7.3 PROCUREMENT DOCUMENTS

7.3.1 Procurement documents issued shall include provisions for the following, as deemed necessary by the purchaser:

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

b. Either reference to or incorporation of applicable technical and administrative requirements, such as specifications, codes, standards, tests, inspections, and include acceptance criteria.

c. Requirements that the supplier have a documented QA program implementing applicable requirements of the UMTRA Project contractors' QAPPs.

d. Access to the supplier's plant facilities and records for inspection or audit by the purchaser or other parties authorized by the purchaser.

e. Identification in procurement documents of the documentation required for information, review, time of submittal, evaluation against acceptance criteria, or approval by the purchaser.

7.3.2 Procurement documents and changes thereto shall be prepared, reviewed, approved, issued, and controlled by the purchasing and/or contracting departments of the UMTRA Project contractors on behalf of the ERD UMTRA Project. Personnel responsible for initiating the procurement requirement shall participate in the review and approval process to ensure that the applicable requirements are incorporated in the procurement documents. Procurement documentation procedures shall include methods for review of original documents, document revisions, and changes to ensure that documents transmitted to prospective suppliers include appropriate provisions ensuring that items or services meet specified UMTRA Project requirements.

7.3.3 Reviews shall verify that procurement documents:

a. Are prepared in accordance with applicable procedural requirements.

b. Reflect adequate and appropriate quality requirements.

c. Include applicable regulatory design basis and related technical information, and that requirements are properly stated.

7.4 PROCUREMENT CONTROL

7.4.1 Activities to control purchased materials, equipment, and services shall be established and implemented by written procedures. These procedures shall also describe the methods used to evaluate the contractors' performance in meeting the UMTRA Project objectives. The system for controlling purchased materials, equipment, and services includes 1) procurement planning, 2) supplier selection, 3) supplier performance evaluation, 4) supplier-generated document control, 5) acceptance of materials, equipment, and services, and 6) nonconformances.

7.5 PROCUREMENT PLANNING

7.5.1 Procurement planning shall determine what is to be accomplished, who is to accomplish it, and how and when it is to be accomplished. Planning shall include appropriate controls for the selection, determination of suitability, source evaluation and selection where determined necessary, and receipt of all

purchased items. Planning shall be accomplished and documented as early as practical to provide appropriate interface compatibility and to ensure a systematic approach to the procurement process.

7.5.2 Planning shall provide for coordination of the following:

a. Procurement document preparation, review, and change control.

b. Selection of procurement sources.

c. Bid evaluation and award.

d. Purchaser evaluation of supplier performance.

e. Verification (surveillance, inspection, or audit) activities by purchaser, including notification for hold and witness points.

f. Control of nonconformances.

g. Corrective action.

h. Acceptance of materials, equipment, or services.

i. QA records.

7.6 SUPPLIER SELECTION

7.6.1 The UMTRA Project contractors shall be responsible for soliciting bid offers or proposals, and evaluating prospective suppliers to ensure that only qualified suppliers are selected. Methods for evaluating and selecting supplier sources, and the results obtained from these evaluations and selections, shall be documented, and signed by the individuals performing the review. These methods include one or more of the following:

a. Evaluation of the supplier's history of providing an identical or similar product or service that performs satisfactorily in actual use. The supplier's history shall reflect their current capabilities.

b. Evaluation of the supplier's current quality records, supported by documented qualitative or quantitative information.

c. Supplier's technical and quality capabilities as determined by a direct evaluation of the facilities and personnel and the implementation of the supplier's QA program.

7.7 SUPPLIER PERFORMANCE EVALUATION

7.7.1 Qualified suppliers and necessary subtier suppliers shall be monitored periodically to ensure that acceptable items or services continue to be supplied. The methods used shall include one or more of the following: 1) establishment and evaluation of performance objectives, 2) review of suppliers records and nonconformance controls, or 3) performance of management reviews, audits, inspections, and surveillances.

7.7.2 Furthermore, all contract laboratories performing radiochemical environmental analyses shall participate in the DOE-Environmental Measurement Laboratory (EML) Interlaboratory Performance Evaluation Study. Additionally, contractors shall establish a process to periodically examine the results of the DOE-EML studies. If significant deviations are noted, the contractors shall interface with the laboratory to determine the cause of the problem and actions to be taken.

7.8 SUPPLIER-GENERATED DOCUMENT CONTROL

7.8.1 The requirements for submitting supplier-generated documents for use, review, approval, or concurrence shall be controlled, handled, approved, and submitted in accordance with written procedures and referenced or included in the procurement documentation.

7.9 ACCEPTANCE OF MATERIALS, EQUIPMENT, AND SERVICES

7.9.1 Acceptance of purchased materials, equipment, and services includes one or more of the following:

a. Technical evaluation of the purchased item, data, or report.

b. Surveillance and/or audit of the supplier.

c. Review of objective evidence of conformance with procurement requirements.

d. Periodic evaluations of each supplier's certifications of conformance by audits, independent tests, peer reviews, or other appropriate verification methods to ensure that the certifications are valid and that the proper results are documented.

e. Source and/or receiving instructions.

f. Preinstallation and/or postinstallation testing.

7.9.2 Before a procured item is placed in service, procurement specifications and inspection and test requirements shall be satisfied and nonconformances properly dispositioned.

7.9.3 The quality of purchased items and services should be verified to a degree consistent with their complexity, risk, quantity, and frequency of procurement.

7.10 NONCONFORMANCES

7.10.1 Procurement documents shall include the purchaser's requirement for reporting and approving disposition of nonconformances. Through written procedures, the UMTRA Project contractors shall establish methods for disposition of items and services that do not meet procurement documentation requirements. These written procedures shall contain provisions for the evaluation of nonconforming items and submittal of nonconformance notice to purchaser by the supplier. These submittals shall include supplier-recommended disposition (e.g., use-as-is or repair) and technical justification, purchaser disposition of supplier recommendation, verification of the implementation of the disposition, and maintenance of records of supplier-submitted nonconformances.

7.11 FRAUDULENT ACTIVITIES

7.11.1 When there are indications that suppliers knowingly supplied items and services of substandard quality, this information should be forwarded to the ERD.

7.12 ERD UMTRA PROJECT EVALUATION

7.12.1 The ERD UMTRA Project shall evaluate the adequacy of the UMTRA Project contractors' procurement control systems through verification techniques such as audits, in-process surveillances, and reviews that will be conducted in compliance with Section 1.0, paragraph 1.10.1(f).

8.0 INSPECTION AND ACCEPTANCE TESTING

8.1 INSPECTION

8.1.1 General

a. Inspections required to verify conformance of an item or activity to specified requirements shall be planned and executed. Characteristics to be inspected and inspection methods to be employed shall be specified.

b. The ERD UMTRA Project has delegated the responsibility for inspection to the Project contractors.

c. The UMTRA Project contractors' systems for controlling and conducting inspection activities, including methods and responsibilities, shall be specified in their respective QAPPs.

8.1.2 Requirements

a. The contractor's written procedures shall address the requirements for 1) inspection planning, 2) acceptance of data, 3) identification of item characteristics and processes to be inspected, 4) inspection techniques to be used, 5) establishment of inspection hold points, 6) acceptance criteria, 7) responsibilities for performing inspections, 8) acceptance, and 9) documentation of inspection results. The procedures shall require that inspections be performed by qualified personnel. Qualification requirements for inspection personnel shall be defined in the UMTRA Project contractors' QAPPs. Inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected.

8.1.3 Inspection

a. The work associated with inspections of the remedial action sites shall be accomplished in accordance with site-specific RAIPs and site specifications which are the responsibility of the RAC to prepare. The TAC shall review the site-specific RAIPs at the request of the ERD.

b. Both "one-of-a-kind" and commercial items of hardware and equipment purchased to support the Project shall be subject to the inspection controls previously described. The inspection procedures shall specify when and what type of inspections, the extent of the inspections (source, in-process, receiving, final, in-service, and the like), acceptance and rejection criteria, the designation of inspection personnel or organizations, and the requirement for recording the inspection results and acceptance action. Indirect monitoring shall be conducted as necessary to establish the adequacy of the item; personnel may not inspect their own work for

acceptance. The level of inspection and degree of independence of inspection personnel should be based on risk and complexity.

c. Administrative controls and status indicators shall preclude inadvertently bypassing required inspections and preventing inadvertent operations of the item or process. The acceptance of items, materials, and processes shall be documented and approved by authorized personnel. When acceptance criteria are not met, deficiencies should be resolved and reinspection shall occur as required.

8.2 ACCEPTANCE TESTING

8.2.1 General

a. Tests required to verify conformance of an item to specified requirements and to demonstrate satisfactory performance shall be planned and executed. Characteristics to be tested, environmental sampling criteria, and test methods to be employed shall be specified.

b. Testing activities are not performed by the ERD. The work associated with test control has been delegated by the ERD to its UMTRA Project contractors.

c. The UMTRA Project contractors' systems for controlling and conducting acceptance testing activities, including methods and responsibilities, shall be described in their respective QAPPs.

8.2.2 Requirements

a. Acceptance testing procedures, including those for field and laboratory environmental sampling, shall describe the methods for ensuring that tests are properly planned, executed, documented, and evaluated. Required tests shall be performed to verify conformance of an item to specified requirements, to demonstrate that items will perform satisfactorily in service, and to collect data (such as siting or design input). Testing shall include appropriate field and laboratory environmental sampling, bench tests and proof tests before installation, preoperational tests, postmaintenance tests, postmodification tests, and operational tests.

8.2.3 Acceptance testing

a. The work associated with acceptance testing of the remedial action sites shall be accomplished in accordance with site-specific RAIPs and site specifications that are the responsibility of the RAC to prepare. The TAC will review the site-specific RAIPs at the request of the ERD.

b. Testing may be implemented by or for the organization performing the work to be tested; however, personnel within the organization shall not test their

own work for acceptance. Qualification requirements for testing personnel shall be defined.

c. Test procedures shall define the administrative controls and status indicators which shall be used to preclude inadvertent bypassing of required tests or operation of the item or process. Test procedures shall include sampling; test article configuration; instructions and prerequisites to perform the test; completeness and accuracy of data; acceptance criteria; specific test equipment, including calibration requirements; suitable environmental conditions; testing hold points as required; and documentation of test results. Acceptance of items, materials, processes, and environmental sampling results shall be documented and approved by authorized personnel.

d. All activities involving the generation, acquisition, and use of environmental data shall be planned and documented. Procedures shall be established and implemented to perform inspections and acceptance testing (including the use of QC samples) of environmental sampling and measurement systems and their components according to the intended use of the items as specified by the design. The type and quality of environmental data needed for their intended use shall be defined and documented using the DQO process and shall involve key users of the data as well as those responsible for activities affecting data quality.

e. The data collection process for characterizing environmental processes and conditions shall be defined, controlled, verified, and documented. The data collection design process includes the design of field sampling events, sample handling and custody, analytical operations, data validation and verification methods, techniques for assessing limitations on data use, and data reporting requirements. The design process also applies to data compilation for modeling or additional studies.

f. Retesting items or processes to determine if they meet acceptance criteria is required after deficiencies have been corrected.

8.3 MEASURING AND TEST EQUIPMENT

8.3.1 General

a. A process shall be established and implemented to control calibration, maintenance, and accountability of tools, gages, instruments, and other measuring and test equipment used for activities affecting quality. To maintain accuracy within necessary limits the measuring and test equipment shall be controlled and at specified periods calibrated and adjusted.

b. No activities requiring measuring and test equipment are directly performed by the ERD. The ERD will maintain control of measuring and test

equipment, but the activities requiring the use of equipment have been delegated by the ERD to the UMTRA Project contractors.

c. The UMTRA Project contractors shall establish a system to ensure that all measuring and test equipment is of the proper type, properly calibrated within a recall system, identified, and traceable to their calibration test data. The requirements for this system shall be contained in their respective QAPPs.

8.3.2 Requirements

a. The types of equipment to be used shall be defined. Measuring and test equipment that is of special design for a particular activity shall be designed, developed, and manufactured or procured under the control of the UMTRA Project contractor involved. Before such equipment is used, a complete functional check shall be conducted according to written procedures to ensure conformance to specifications and to ensure that the equipment is properly calibrated.

b. Written procedures for calibrating specific measuring and test equipment shall be provided to ensure that calibration requirements are identified and followed. Calibration records and schedules shall be maintained for each item of equipment requiring calibration.

c. Measuring and test equipment should be calibrated at specified intervals on the basis of the item's required accuracy, intended use, frequency of use, stability characteristics, and other conditions affecting its performance. The equipment shall be calibrated against standards having an accuracy that will ensure that equipment being calibrated will be within required tolerances. The calibration standards should be traceable to nationally recognized calibration standards. Calibration shall be performed only by laboratories or personnel who are properly qualified.

d. Measuring and test equipment shall be labeled, tagged, or otherwise controlled to indicate its calibration status and ensure traceability to calibration test data.

e. Measuring and test equipment found out of calibration or out of tolerance shall be tagged and/or segregated and not used until it is successfully recalibrated. The acceptability of items or processes measured, inspected, or tested with an out-of-tolerance device shall be evaluated.

f. Maintenance shall be accomplished at specified intervals and in accordance with approved procedures.

8.4 ERD UMTRA PROJECT EVALUATION

8.4.1 The ERD will evaluate the Project contractors' systems for inspection, acceptance testing, and control of measuring and test equipment through verification techniques such as audits, in-process surveillances, and reviews which will be conducted in compliance with Section 1.0, paragraph 1.10.1(f).

9.0 MANAGEMENT ASSESSMENTS

9.1 GENERAL

9.1.1 Management assessments shall focus on how well the integrated QA program is working and shall identify management problems that hinder the organization from achieving its objectives in accordance with quality, safety, and environmental requirements. Conducted on an annual basis, these assessments shall be established and implemented to improve quality.

9.1.2 The ERD shall implement a system for management assessments of its integrated QA program. Furthermore, the ERD has assigned UMTRA Project contractors the responsibility for conducting management assessments of their respective integrated QA programs.

9.1.3 The UMTRA Project contractors' requirements for management assessments, including methods and responsibilities, shall be specified in their respective QAPPs.

9.2 REQUIREMENTS

9.2.1 Annual management assessments shall provide a means for determining and taking necessary response actions regarding the following:

a. Effectiveness of the system of management controls that are established to achieve and ensure quality.

b. Adequacy of resources and personnel provided to achieve and ensure quality in all activities.

9.2.2 Senior management shall retain overall responsibility for these management assessments. Direct participation by senior management (the manager or managers responsible for mission accomplishment and overall operations) is essential. This process shall include the direct participation of all appropriate levels of management. As deemed appropriate, assessments of designated organizations and programs may include the participation of qualified internal staff or independent reviewers.

9.3 ASSESSMENT PURPOSE/RESULTS

9.3.1 The results of the assessment shall be documented. Senior management shall take prompt action and document decisions in response to recommendations resulting from the management assessment process. Follow-up reviews for recommendations shall include an evaluation of the effectiveness of management's actions.

9.4 ERD UMTRA PROJECT EVALUATION

9.4.1 The ERD shall evaluate the UMTRA Project contractors' management assessment programs through verification techniques such as audits, in-process surveillance, and reviews which will be conducted in compliance with Section 1.0, paragraph 1.10.1(f).

10.0 INDEPENDENT ASSESSMENT

10.1 GENERAL

10.1.1 A process of planned independent assessments shall be established and implemented by the ERD and its UMTRA Project contractors. Independent assessments shall evaluate all quality, ES&H, and radiological operations to ensure compliance to UMTRA Project requirements, which include Federal, state, tribal, and local laws, and improve UMTRA Project activities and processes. Independent assessments shall consist of reviewing, inspecting, testing, checking, conducting surveillances, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements.

10.1.2 The ERD shall establish and implement a system for conducting and documenting independent assessments to determine the degree of compliance to the specified requirements. The ERD has delegated to the UMTRA Project contractors the responsibility of establishing, implementing, and documenting independent assessments of their QA, ES&H, and radiological programs.

10.1.3 The UMTRA Project contractors shall establish and implement a system to ensure that independent assessments are conducted. The independent assessment requirements, including methods and responsibilities, shall be specified in their individual QAPPs.

10.2 REQUIREMENTS

10.2.1 The independent assessments shall be conducted to determine the degree of compliance to UMTRA Project requirements and approved procedures. Independent assessments shall be conducted on all remediation activities conducted at processing sites, disposal cells, or vicinity properties. Vicinity property independent assessments shall be dependent upon remediation activities in progress during site visits. With concurrence from the ERD, all independent assessments may include disciplines such as health and safety, radiology, and environmental specialists to assist during these activities. Documented assessment results shall provide the respective managers an independent technical and/or programmatic evaluation of their activities.

10.2.2 The ERD and UMTRA Project contractors shall establish and implement a schedule for independent assessments.

10.2.3 Independent assessments, audits, or in-process surveillances of QA, ES&H, or radiological activities shall be conducted by personnel who meet the qualifications outlined in Section 10.4, Audit Personnel. Independent assessments that address various disciplines (i.e., administration, planning, scheduling, procurement contracts, cost/scheduling, accounting, and the like),

shall be conducted by personnel whose qualifications shall be specified in the UMTRA Project contractors' individual QAPPs.

10.2.4 Personnel performing these independent assessments shall act in a management advisory function. Their responsibilities are to 1) monitor work performance using criteria that describe acceptable performance, 2) identify satisfactory, exceptional, and abnormal performance and precursors of potential problems, 3) identify opportunities for improvement, 4) report results to a level of management having the authority to effect corrective action, and 5) verify satisfactory resolution of the corrective action. The personnel performing these independent assessments shall be qualified and knowledgeable about the activity being assessed, shall focus on improving the quality of the activity, and shall not have direct responsibilities in the area they are assessing.

10.3 SCHEDULING

10.3.1 Scheduling these assessments and allocating on resources shall be based on the status, risk, and complexity of the activity or process being assessed. Scheduling shall be flexible. Areas of questionable performance shall be addressed. Organizational activities may be assessed several times a year or at longer intervals, depending on the activity or the quality, ES&H, and radiological aspects of the activity.

10.3.2 The ERD shall perform independent audits/surveillances of the Project activities. The ERD shall develop a schedule that covers audit and surveillance activities for the RAC and active remedial action sites. This schedule is developed as a result of monthly scheduling meetings with representatives of DOE, RAC, and TAC QA, ES&H, and radiological services. The TAC QA Department is responsible for preparing and tracking the audit/surveillance schedules for the RAC and active remedial action sites planned for each fiscal year. The audit/surveillance schedules shall be submitted to the respective ERD, RAC, and TAC organizations. The audit/surveillance schedule shall be reviewed monthly or at the discretion of the ERD, depending on ERD activity, and revised accordingly to ensure that schedules are kept current.

10.3.3 Additional audits/surveillances shall be scheduled on an unannounced basis as directed by the ERD.

10.3.4 UMTRA Project contractors shall schedule and perform their internal organizational assessments, including audits and surveillances, as determined necessary by the UMTRA Project contractors' QA managers or at the request of the ERD.

10.4 AUDIT PERSONNEL

10.4.1 UMTRA Project contractor QAPPs shall specify qualification and maintenance requirements for lead auditors for quality-related, ES&H, and radiological audits.

10.4.2 TAC lead auditors for quality-related, ES&H, and radiological audits shall be selected and assigned for each activity. Prior approval of lead auditors shall be obtained from the ERD QA manager.

10.4.3 Maintenance of qualification and proficiency of lead auditors shall be accomplished through one or more of the following: regular and active participation in the audit process; review and study of codes, DOE orders, standards, procedures, instructions, and other documents related to QA program auditing; or participation in training program(s). Requalification of lead auditors who fail to maintain their proficiency for a period of 2 years or more shall require requalification as outlined in paragraph 10.4.4.

10.4.4 Lead auditor initial qualification shall be approved in writing by the ERD QA manager. The TAC QA Department shall submit documentation of education and experience of proposed candidates for lead auditor status. Before individuals can be considered as candidates, each shall have participated in a minimum of five hands-on audits under the supervision of a qualified lead auditor. Two of the five audits shall be UMTRA site-related.

10.4.5 The ERD QA manager may grant an exception to the above requirements based on an individual's education, special training, and experience, including audit experience. Such information shall be documented and provided for ERD approval.

10.4.6 The lead auditor may select, as appropriate, additional team members to participate in the audit. When required, UMTRA Project contractors may use specialists in specific areas for their expertise to assist in performing audits. Formal approval shall be obtained from the ERD QA manager prior to the specialist assisting in any audit.

10.5 AUDIT PREPARATIONS

10.5.1 An audit notification letter for announced audits shall be provided by the ERD QA manager to the organization being audited 2 weeks before the audit starts.

10.6 AUDIT PERFORMANCE

10.6.1 For the ERD audits, a DOE representative shall be in attendance at the audit opening meeting and the audit exit meeting. However, DOE attendance at the audit opening meeting may be waived by the ERD QA manager.

10.6.2 Audits shall follow checklists. Audits shall consist of a preaudit meeting, audit activity, and a postaudit meeting. This meeting shall be followed by a report documenting evaluation of the activity compliance, including recommended corrective action. For ERD audits, the DOE representative and the audit team shall, at the conclusion of each day's audit activities, meet and brief the UMTRA Project contractor's staff of the audit team's findings and observations for that

day. All findings and observations, regardless of their magnitude, shall be presented during these debriefings.

10.6.3 Elements that have been selected for the audit shall be evaluated against specified approved requirements. Documented and physical objective evidence shall be examined as necessary to determine if activities are being conducted in accordance with prescribed and approved requirements and procedures. Auditors shall inspect findings and observations from previous audits to ensure that all corrective actions have been implemented. If corrective actions have not been implemented for all findings and observations, the audit team shall promptly notify the appropriate field management personnel and ERD. These findings shall be documented in the audit report, as will any new findings.

10.6.4 Any condition found during the audit that requires immediate corrective action shall be documented and reported promptly to the management of the organization being audited. Observations/findings identified during independent assessments that require a response or a corrective action shall be reviewed during the next independent assessment.

10.7 AUDIT REPORTING

10.7.1 An audit report shall be prepared and signed by the lead auditor and audit team members. The audit report shall contain all findings and observations, regardless of magnitude or whether or not they were corrected immediately. The report shall then be transmitted to the manager of the audited organization. The report shall include, but not be limited to, the following information:

a. Audited organization.
b. Audit date.
c. Team members.
d. Organization's personnel contacted.
e. Summary of results.
f. Criteria references.
g. Observations.
h. Recommendations (if applicable).

10.7.2 Audit reports shall be issued within 10 working days from conclusion of audit. Audit transmittal memos shall require that the audited organization perform a root-cause analysis for each observation or finding that requires a response.

10.8 AUDIT RESULTS/RESPONSE

10.8.1 The audit results shall be tracked and resolved by management having responsibility in the area audited. Follow-up reviews of deficient areas shall be initiated as deemed necessary. The responses to the results of the audits shall include, as applicable, action to correct the deficiency, cause identification, and action to prevent recurrence.

10.8.2 For ERD audits conducted on remedial action sites, the UMTRA Project contractor shall furnish a schedule and the recommended corrective action for all findings and observations to the ERD within 15 working days from the date of the letter that transmitted the audit report. All corrective action shall be completed within 40 days of the date of transmittal. An extension may be granted by the ERD QA manager if circumstances dictate the need.

10.8.3 For QA, ES&H, and radiological audits performed for the ERD, the appropriate TAC department shall, at the request of the ERD, review proposed corrective action to ensure that unacceptable conditions have been adequately addressed and corrected. A follow-up audit also may be required by the ERD if significant corrective action is necessary or to verify implementation of proposed corrective action.

10.8.4 Project contractors shall initiate follow-up audits as necessary to verify whether corrective action is accomplished and effectively precludes recurrence of adverse conditions.

10.9 AUDIT SCHEDULES

10.9.1 ERD audit activities shall be accomplished in accordance with the schedule shown in Figure 10.1. All UMTRA Project contractors shall specify in written procedures the schedules associated for their respective audit activities.

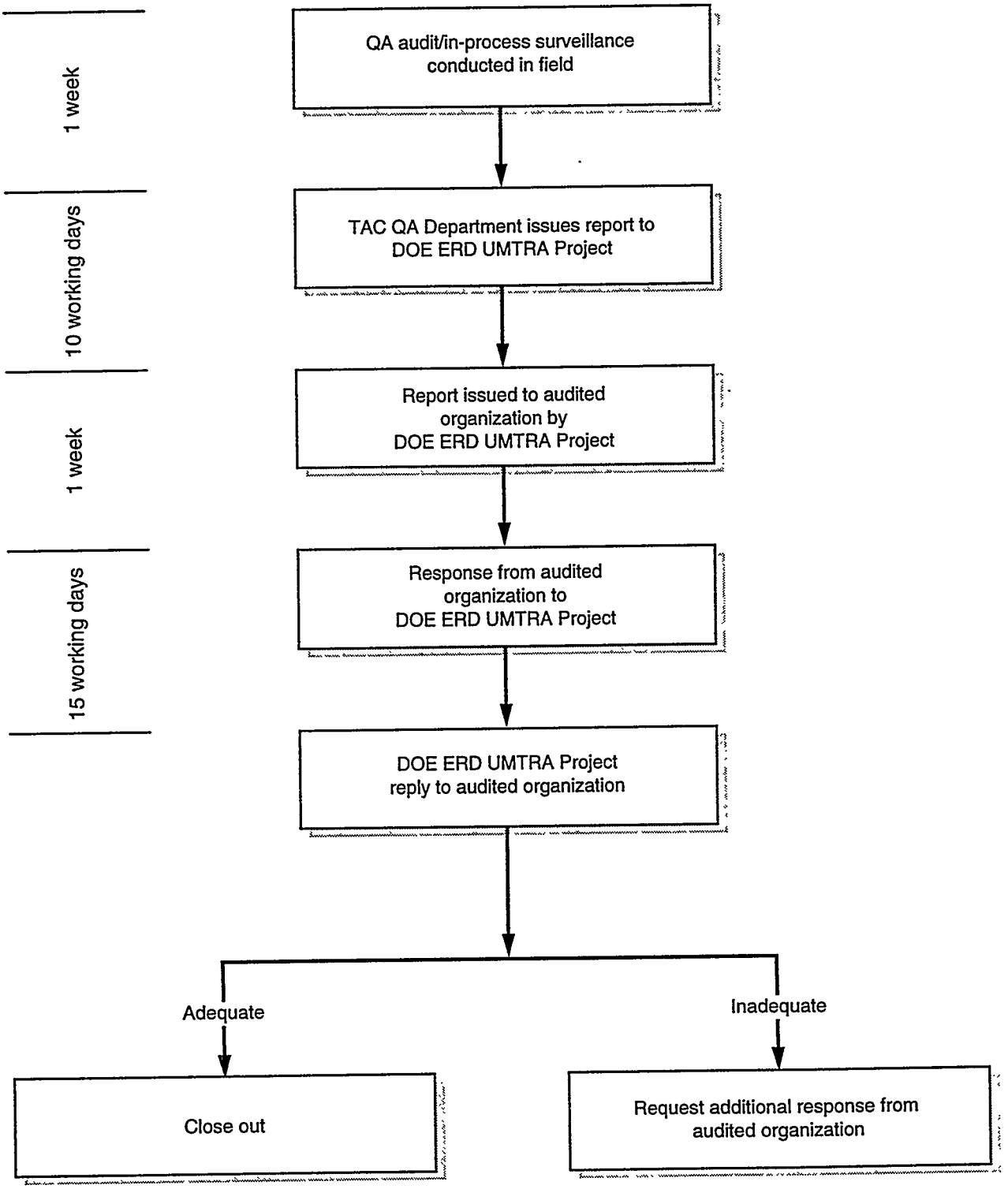
10.10 FOLLOW-UP AUDITS

10.10.1 Follow-up audits may be performed to verify whether corrective action is accomplished and precludes recurrence of unacceptable conditions.

10.11 ERD UMTRA PROJECT EVALUATION

10.11.1 The ERD shall evaluate the UMTRA Project contractors' independent assessment systems through verification techniques such as audits, in-process surveillances, and reviews which shall be conducted in compliance with Section 1.0, paragraph 1.10.1(f).

Figure 10.1
Quality Assurance Audit Report Time Schedule



11.0 REFERENCES

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DOE ORDERS

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CODE OF FEDERAL REGULATIONS

10 CFR Part 830, *Quality Assurance Requirements* (1994).

PUBLIC LAWS

PL 95-604 (Public Law 95-604), 1978. *Uranium Mill Tailings Radiation Control Act of 1978*, 42 USC 7901, November 8, 1978, 95th Congress of the United States of America, Washington, D.C.

ATTACHMENT A

DOE ORDER 5700.6C, *QUALITY ASSURANCE*, CRITERIA VERSUS ASME NQA-1 QUALITY ASSURANCE PROGRAM FOR NUCLEAR FACILITIES

ERD UMTRA PROJECT QUALITY ASSURANCE PROGRAM PLAN

DOE ORDER 5700.6C, *QUALITY ASSURANCE*, CRITERIA VERSUS ASME NQA-1[a] QUALITY ASSURANCE PROGRAM FOR NUCLEAR FACILITIES ERD UMTRA PROJECT QUALITY ASSURANCE PROGRAM PLAN

DOE ORDER 5700.6C CRITERIA	NQA-1 BASIC REQUIREMENTS
Management	
1.0 Program[b]	1. Organization
	2. QA Program
2.0 Personnel Training and Qualifications[b]	2. QA Program
3.0 Quality Improvement[b]	15. Control of Nonconforming Items
	16. Corrective Action
4.0 Documents and Records	6. Document Control
	17. QA Records
Performance	
5.0 Work Processes	
a. Work	2. QA Program
	5. Instructions, Procedures, and Drawings
	9. Control of Processes
	14. Inspection, Test, and Operating Status
b. Identification and Control of Items	8. Identification and Control of Items
c. Handling, Storing, and Shipping	13. Handling, Storage, and Shipping
d. Calibration and Maintenance Monitoring and Data Collection Equipment[b]	12. Control of Measuring and Test Equipment
6.0 Design	3. Design Control
7.0 Procurement	4. Procurement Document Control
	7. Control of Purchased Items and Services
8.0 Inspection and Acceptance Testing	
a. Inspection	10. Inspection
b. Acceptance Testing	11. Test Control
c. Measuring and Test Equipment	12. Control of Measuring and Test Equipment
Assessment	
9.0 Management Assessment[b]	2. QA Program
10.0 Independent Assessment[b]	18. Audit

[a]ANSI/ASME (1989).
[b]5700.6C criteria contain requirements that are either new or more specific than shown in the corresponding NQA-1 Basic Requirement.