



Rocky Mountain Remediation Services, L.L.C.  
... protecting the environment

Revision 3

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# Quality Assurance Program Description (QAPD)

## RMRS-QAPD-001

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This document supersedes revision 2 of the QAPD, and as a complete re-write, revision bars have not been used.

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**APPENDICES**

Appendix 1, Closure Projects and Environmental Restoration QA Program Supplement



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## **RMRS Policy Quality Assurance**

**RMRS is committed to a performance-based quality assurance program to ensure: that the company's mission and business objectives are accomplished in the most cost effective manner possible; that the products and services are safe and reliable and meet or exceed the requirements and expectations of the customer; and that any hazards to the public, workers or the environment are minimized.**

**The RMRS Quality Assurance program is based on the principle that the employees performing the work are responsible for the level of quality achieved. Quality assurance standards shall be applied, as appropriate, based on risks, hazards, uncertainty and consequences associated with specific work.**

## 1. INTRODUCTION

Rocky Mountain Remediation Services, L.L.C. (RMRS) is a subcontractor to Kaiser-Hill Company L.L.C. (K-H) and is responsible for the waste management, environmental restoration, decommissioning, facilities management, and related engineering and construction activities at the Rocky Flats Environmental Technology Site (the Site). The general scope of work is defined and implemented under the provisions of RMRS contract No. KH00003NS1A. The contract requires compliance to the requirements of *10 CFR 830.120*, *Quality assurance requirements*, and *DOE Order 414.1, Quality Assurance* and also requires compliance with all applicable environmental, safety, and health requirements.

**The requirements defined within this QAPD apply to all RMRS work activities performed to meet the requirements of the RMRS contract. Additional requirements apply to work activities involving the following areas:**

- **Transuranic (TRU) waste management**
- **Low Level Waste (LLW) management**
- **Closure Projects**
- **Environmental Restoration (ER)**

Compliance to *ASME-NQA-1-1989, Quality Assurance Requirements for Nuclear Facility Application*, (NQA-1) within the TRU waste management programs and projects is achieved through the application of *1-MAN-008-WM-001, TRU Waste Management Manual, INS-246, Transuranic Waste Characterization Project (TWCP) QAPD Procedures Matrix, and 95-QAPjP-0050, Site Quality Assurance Project Plan (QAPjP)*. Compliance to NQA-1 for LLW management programs and projects is achieved through the application of *94-RWP/EWQA-0014, LLW Management Manual*.

The Rocky Flats Cleanup Agreement (RFCA) is the legally binding agreement between the Department of Energy (DOE), the Environmental Protection Agency (EPA), and the Colorado Department of Public Health and Environment (CDPHE) to accomplish the required cleanup of radioactive and other hazardous substances and contamination at and from the Rocky Flats Environmental Technology Site (RFETS). The RFCA requires that work is performed properly and pursuant to EPA and CDPHE protocols, standards, regulations, and guidance.

The RMRS QAPD has been developed as required by the Kaiser-Hill Team Quality Assurance Program (QAP) and meets the requirements of *10 CFR 830.120*, and *DOE Order 414.1*. DOE Order 5700.6C has been superseded by DOE Order 414.1 and is expected to replace existing references to DOE 5700.6C in the extension of the RMRS contract.

The QAPD will be reviewed annually and revised as necessary by the RMRS QA organization. The QAPD was developed in accordance with *1-C40-QAP-02.01, Preparation of Quality Assurance Program Plans*. The QAPD and associated appendices are controlled documents.

A diagram of the Quality Assurance requirements and implementing documents is shown in Figure 1.

Figure 1, QA Requirements and Implementing Documents

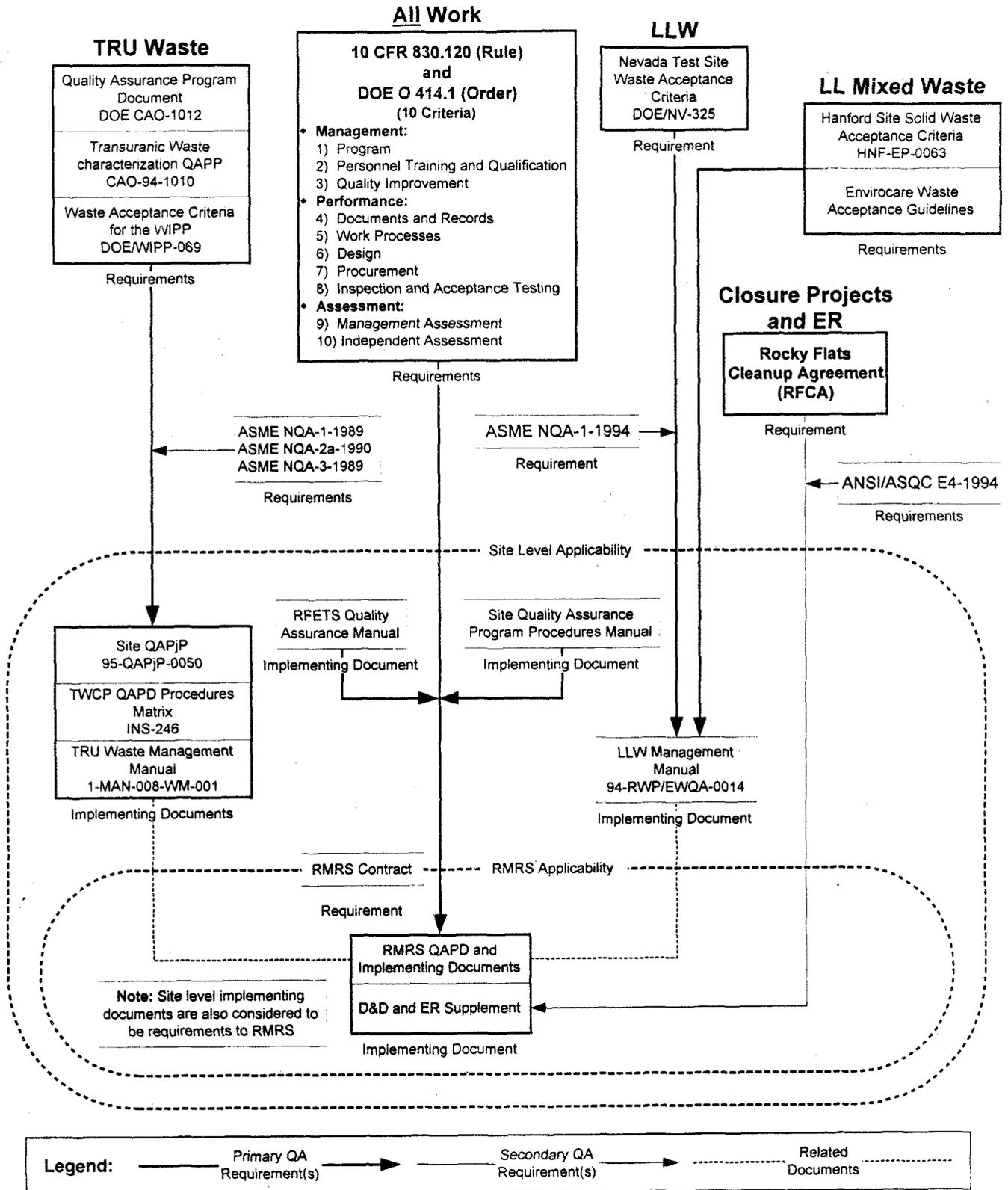


Figure 2, RMRS QA Program Elements Comparison to NQA-1

RMRS QA Program		ANSI/ASME NQA-1																				
Management	Performance	Assess.	Organization	QA Program	Design Control	Procurement Doc. Control	Instc., Proced., and Draw.	Document Control	Control of Purchased Serv.	Ident of Controlled Items	Control of Processes	Inspection	Test Control	Control of M&TE	Handling, Storage, Shipping	Insp., Test & Oper. Status	Contr. of Nonconform. Items	Corrective Action	Records	Audits	Software Quality Assurance	
1. Program			●																			
2. Personnel Training & Qualification			●																			
3. Quality Improvement			●																			
4. Documents and Records			●																			
5. Work Processes			●																			
6. Design			●																			
7. Procurement			●																			
8. Inspection and Acceptance Testing			●																			
9. Management Assessment			●																			
10. Independent Assessment			●																			

Legend: ● Corresponding Requirements, But in Some Cases, Not Specifically The Same



## 2. PURPOSE

The QAPD serves as a map to assist in understanding how the requirements of *10 CFR 830.120, Quality assurance requirements* (for nuclear facilities and activities), and *DOE Order 414.1, Quality Assurance* (for non-nuclear facilities and activities), are implemented by RMRS at the Site. The QAPD describes the roles and responsibilities, and controls employed by RMRS. QA Program implementing documents are in the last section of the QAPD. Site specific and RMRS specific documents are listed separately.

Some portions of work performed are regulated by QA requirements of other regulatory organizations. Common management systems are used as much as possible to satisfy multiple sets of requirements.

The RMRS QA program includes controls for compliance with NQA-1 to meet the waste acceptance criteria and requirements of the Waste Isolation Pilot Project (WIPP) and the Nevada Test Site (NTS).

*Appendix 1, Closure Projects and Environmental Restoration QA Program Supplement*, discusses additional controls employed to specifically meet the Rocky Flats Cleanup Agreement (RFCA) requirements and other state and EPA agreements for environmental and decommissioning programs and projects.

All documents referenced within the QAPD and appendices were active at the issue date of the QAPD. It is the user's responsibility to verify they are using the current revision of the document and has not been superseded or cancelled. Report any inactive, superseded, or cancelled documents to RMRS QA.

## 3. SCOPE

This QAPD applies to the specific operations of RMRS and its subcontractors, and where applicable, to the interface controls between RMRS and K-H, and between RMRS and other K-H subcontractors. Contractual requirements associated with the scope of work are incorporated into the written contracts with subcontractors. The requirements of this QAPD apply to RMRS subcontracted work performed by a lower tier contractor. Lower tier contractors may work to the RMRS QAPD, or they may develop their own QAPD as long as it is consistent with the RMRS QAPD and has been approved by RMRS.

RMRS is responsible for work assigned in the areas of waste management, environmental restoration (ER), engineering, construction, closure projects, facility maintenance/operations, and related activities. RMRS also has the responsibility to administer and coordinate the TRU and low level waste programs for the Site. Responsibilities include development, deployment and implementation of program controls; waste inspection; interface with regulators and the DOE for the Site regarding TRU Waste management; and control of records for the Site related to the WIPP, Nevada Test Site (NTS) and other disposal sites.

RMRS provides direction to the Site for the Radiological Protection Program. In its engineering role, RMRS provides the Site with subject matter experts in the different engineering disciplines including the Welding Program, Fire Protection Program, and Facility Design. RMRS administers the Engineering Document Control Center. RMRS will develop letters of intent, or other agreement based documentation as required to state agreed upon methods for interfacing or for delivery of products and services between K-H and other subcontractor organizations.

The following buildings are managed by RMRS and are considered to be contributors to the risk of the facilities on the Site and are subject to enforcement under *10 CFR 830.120* due to consequences of unmitigated releases of radioactive material or potential radiological harm:

<b>Nuclear Hazard Category 2</b>	Building 440	Waste Storage, Shipping, & LLW Repackaging
	Building 444	Storage of Depleted Uranium and Beryllium
	Building 569	Crate Counter Facility
	Building 664	Waste Storage and Shipping
	750 Pad (Tents 2 & 12)	Waste Storage Facility
	Building 776/777	Manufacturing
	Building 771	Plutonium Recovery Facility
	Building 774	Liquid Waste Treatment
	Building 779	Plutonium Development Building
	Building 886	Criticality Laboratory
<b>Nuclear Hazard Category 3</b>	Building 991	Product Warehouse
	750 Pad (Except Tents 2 & 12)	Waste Storage Facility
	Building 881	Manufacturing and General Support
<b>Radiological Facility</b>	904 Pad	Waste Storage Facility
	Building 906	Waste Storage Facility
	Building 865	Material and Process Development
	Building 883	Manufacturing
	903 Pad	Environmental Restoration Site

The complete list of contributors to the risk of the facilities on the Site and the Facilities Hazard Summaries are identified in the *Site Safety Analysis Report* (SAR). The SAR is required by *DOE Order 5480.23, Nuclear Safety Analysis Reports*. Nuclear hazard category 2 & 3 facilities are also identified in the various building authorization basis documents.

Activities with potential to cause radiological harm are also subject to enforcement under *10 CFR 835, Occupational Radiation Protection*. Activities enforceable under *10 CFR 830.120*, and *10 CFR 835* include environmental restoration, engineering, construction, closure projects; and waste operations activities.

#### 4. RESPONSIBILITIES

Additional responsibilities may be identified in program specific management plans and project specific quality documents (TRU Waste Management Plan, LLW Management Plan, etc.).

##### 4.1 The RMRS President is responsible for:

- Establishing overall policy and management direction for the RMRS QA Program
- Serving as the final decision authority for QA issues that cannot be resolved at lower management levels
- Ensuring that contract modifications are formally reviewed to determine RMRS capabilities and effectiveness in meeting contract changes

##### 4.2 The RMRS Vice Presidents are responsible for:

- Providing funding necessary to implement all the elements of the RMRS QA Program
- Developing, implementing, and assessing controls to meet QA Program requirements applicable to RMRS work
- Implementing the RMRS quality assurance policy, program, and procedures
- Providing leadership for implementing process and quality improvement
- Defining and implementing training and qualification requirements for subordinate employees

**4.3 All RMRS Directors and Management are responsible for:**

- Providing resources necessary to implement the QA Program
- Ensuring timely QA involvement in project/program planning, and budget/document reviews
- Complying with Site infrastructure, including quality, Price Anderson Amendments Act (PAAA), and corrective action systems
- Ensuring that QA and PAAA requirements are incorporated in documents that govern quality affecting activities, and the procurement of items and services
- Ensuring timely corrective action for identified quality problems and improvement opportunities
- Ensuring that applicable QA requirements are passed down to lower tier sub-contractors
- Providing timely response to requests for reviews of documents controlling quality affecting activities
- Ensuring that their employees and subcontractors are trained, qualified, and competent to complete activities assigned, prior to initiating work
- Performing management assessment responsibilities
- Ensuring the effective implementation of business service and finance controls

**4.4 The Vice President of Technical Support is responsible for:**

- Directing the Site Radiological Safety Program and implement the RMRS radiological safety program
- Directing the RMRS Central and Project Engineering organizations and the Site core engineering programs for computer aided design, pressure safety, nuclear filtration and ventilation, engineering document control, fire protection engineering, welding, and site-wide standards and procedures
- Directing the RMRS Nuclear Safety Program
- Directing the RMRS Independent Safety Review Program
- Directing the development and implementation of all RMRS training programs
- Directing the RMRS characterization program
- Serving as the RMRS point-of-contact for various site committees including: Price Anderson Amendment Act (PAAA) compliance, Criticality Safety, and As Low As Reasonably Achievable (ALARA) oversight
- Directing the RMRS Integrated Safety Management (ISM) Program

**4.5 The RMRS General Counsel is responsible for:**

- Advising RMRS management concerning PAAA issues

**4.6 The RMRS Quality Assurance and Environmental Compliance (QAEC) Director is responsible for:**

- Serving as principal advisor to the Operations and Closure Projects organizations on matters of quality and environmental compliance
- Monitoring operations and advising line management on compliance to quality and environmental regulations and requirements
- Advising and assisting the RMRS Executive Management Team in establishing quality improvement goals and environmental compliance performance goals
- Directing quality and environmental compliance inspections, surveillances, and audits
- Compiling and distributing performance indicators and reports on RMRS' quality and environmental compliance performance
- Serving as company representative on all quality and environmental compliance activities, issues, and addressing questions with the customer and Regulatory Agencies

**4.7 The RMRS Quality Assurance Manager is responsible for:**

- Establishing, monitoring implementation, and improving the RMRS QA program
- Providing direction, leadership, and management to the QA organization
- Serving as the RMRS subject matter expert (SME) for interpretation of QA requirements and PAAA QA issues
- Participating in Site wide efforts to establish and improve the Site QA program
- Providing technical direction for the Site waste inspection program
- Providing QA personnel support to RMRS operations
- Establishing and implementing the Independent Assessment program for RMRS
- Establishing and implementing Site QA programs to meet LLW and TRU waste repository QA requirements

**4.8 All RMRS personnel are responsible for:**

- Performing activities in accordance with approved documents
- Identifying and participating in quality improvements
- Knowing their internal customers, their suppliers, and the processes they are responsible for
- Exercising stop work authority due to safety concerns or significant conditions adverse to quality
- Attending training and knowing their qualification status

**5. DEFINITIONS & ACRONYMS**

Definitions are listed in the Site Quality Assurance Program Manual, Glossary of Terms.  
The following acronyms are used in this document:

AB	Authorization Basis
ALARA	As Low As Reasonably Achievable
CAO	Department of Energy Carlsbad Area Office
CBT	Computer Based Training
CDPHE	Colorado Department of Public Health and Environment
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CPB	Closure Projects Baseline
CSM	Computer Software Management
CSO	Customer Service Organization
DDCP	Decontamination and Decommissioning Characterization Protocol
DOE	Department of Energy
DOP	Decommissioning Operations Plans
DPP	Decommissioning Program Plan
DQO	Data Quality Objective
ECATS	Environmental Compliance Action Tracking System
EDP	Engineering Design Package
EPA	Environmental Protection Agency
ER	Environmental Restoration
ESL	Evaluated Subcontractors List
EWP	Enhanced Work Planning
FDPM	Facility Disposition Program Plan
ISM	Integrated Safety Management
IWCP	Integrated Work Control Program
K-H	Kaiser Hill, L.L.C.
LLMW	Low Level Mixed Waste

LLW	Low Level Waste
M&TE	Measuring & Test Equipment
MAL	Master Activity List
MOU	Memorandum of Understanding
NCR	Nonconformance Report
NIST	National Institute of Standards and Technology
NTS	Nevada Test Site
PAAA	Price Anderson Amendments Act
PAD	Project Authorization Directive
PATS	Plant Action Tracking System
PBD	Project Baseline Description
PL-1, PL-2, PI-3	Procurement Level-1, Procurement Level-2, Procurement Level-3
PMP	Project Management Plan
QA	Quality Assurance
QAEC	Quality Assurance and Environmental Compliance
QAP	Quality Assurance Program
QAPD	Quality Assurance Program Document
QAPP	Quality Assurance Program Plan
QAPIDL	Quality Assurance Program Infrastructure Documents List
QAPJP	Quality Assurance Project Plan
RCRA	Resource Conservation and Recovery Act
RFC A	Rocky Flats Cleanup Agreement
RFCSS	Rocky Flats Closure Site Services
RFFO	Rocky Flats Field Office
RMRS	Rocky Mountain Remediation Services, L.L.C.
SAR	Safety Analysis Report
Site	Rocky Flats Environmental Technology Site
SME	Subject Matter Expert
SMP	Software Management Program
TIP	Training Implementation Plans
TRU	Transuranic
TSCA	Toxic Substances Control Act
TUM	Training User Manual
WEMS	Waste and Environmental Management System
WIPP	Waste Isolation Pilot Project
W/RT	Waste Residue Traveler

## 6. QUALITY ASSURANCE CRITERIA/IMPLEMENTATION

This section of the QAPD identifies the QA elements of the RMRS QA Program and defines them in the context of principles, and implementing programs and controls. Principles are used to summarize the approach used by RMRS to provide the reader with a better understanding of the RMRS quality program. RMRS will delete, revise, and develop company specific procedures to eliminate redundancy and develop specific control strategies for implementing the RMRS QA policy and philosophy.

Implementing documents are identified in Section 7 of this QAPD. These documents provide identification of the implementing program and the controls for QA requirements.

## 6.1 Program

### 6.1.1 Requirements

*10 CFR 830.120* (c) (1) (i) for Nuclear Facilities/Activities, and *DOE Order 414.1*, 4. b. (1) (a) for Non-Nuclear Activities

"A written quality assurance program (QAP) shall be developed implemented, and maintained. The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. The QAP shall describe management processes, including planning, scheduling, and resource considerations."

### 6.1.2 Principles

RMRS is contractually obligated to develop and implement a QA program that complies with *DOE Order 414.1* for all activities that are not defined as a nuclear activity. The RMRS QA program complies with *10 CFR 830.120* for all activities that have the potential to cause radiological harm. The RMRS QA program also complies with *NQA-1* for TRU waste management programs and projects, and LLW management programs. In addition to these requirements, RMRS identifies and implements best practices and standards to enhance the overall effectiveness of the QA Program.

The RMRS QA Program places emphasis on QA participation in the work planning process. The primary principle is that quality is embedded within the work processes, and assessment should be used as a tool for monitoring performance and to support continuous improvement activities.

RMRS requires that QA activities be appropriately planned in accordance with the provisions of this document. When activities deviate from planned outcomes and indicate significant conditions adverse to quality or safety, RMRS personnel are required to stop the process until corrections are made. In addition to the provisions of *ANSI/ASQC E4-1994, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, RMRS requires that work activities include measurable elements that are represented in performance measurement documentation.

Integrated Safety Management (ISM) at the Site is the integration of safety into management – the management of projects and activities and the safe performance of work. Safety must be an integral part of the definition, planning, design, analyses, and execution of work from beginning to end. Safety must be the driving factor in the minds of people as they engage in actions that result in work being accomplished. The Integrated Work Control Program (IWCP) manual is to be used for the planning and safe accomplishment of activities at the Site, including hazard reduction efforts, remediation, maintenance, engineering, research & development, experiments, construction, de-activation, decommissioning, and any other activities that pose a potential hazard to the worker, the public, and the environment.

### 6.1.3 Mission

The mission of RMRS at the Site is to provide environmental restoration, waste management and decommissioning services. The highest priority of RMRS is to accomplish our mission in a manner that assures employee safety and provides value to our customers and stakeholders. Safety, quality, and environmental controls and compliance are integral components to accomplishing our mission. A rigorous quality assurance program has been implemented to ensure compliance with applicable laws, regulations, and DOE orders, and the compliance is appropriately documented and maintained.

#### **6.1.4 Management and Organization**

##### **General**

The RMRS organization chart is available through RMRS human resources. The management of each organization, in conjunction with human resources, is responsible for hiring qualified personnel. Acquisition of specific skills or additional training may be required of the employee prior to assigning them to specific project duties. Each RMRS employee and subcontractor working directly under the RMRS QA Program shall be trained to the requirements of this QAPD.

##### **RMRS QA Organization**

The RMRS QA Manager is designated by the RMRS President as the representative for quality assurance activities, and is responsible and authorized to stop work when significant conditions adverse to quality are detected. The QA Manager reports directly to the RMRS QAEC Director and is responsible for assessing the effectiveness and compliance to quality concepts, requirements, and directives identified in this QAPD and associated implementing procedures. QA issues may be reported directly to the RMRS President for resolution at the discretion of the QA Manager. The RMRS QA Manager is also responsible for documenting identified deficiencies, facilitating corrective actions, verifying corrective action effectiveness, and tracking deficiencies to prevent recurrence and promote continuous improvement.

#### **6.1.5 Graded Approach**

RMRS follows the graded approach that is described in the K-H QA Program as a process by which the level of detail in analysis, documentation, and actions necessary to comply with a requirement in this Part are commensurate with:

- The relative importance to safety, environment, safeguards, and security
- The magnitude of any hazard involved
- The life cycle stage of a facility or activity
- The programmatic mission of a facility or activity
- The particular characteristics of a facility or activity
- Any other relevant factors

The following general criteria are guiding principles in the application of the graded approach:

- Graded approach may not be used to avoid compliance with federal, state, and local regulations.
- The higher the risk, the more rigor is required to ensure that requirements are met.
- Site facilities and activities are graded as either nuclear or non-nuclear facilities or activities.
- The program owner organization, because it has detailed knowledge of processes, items, activities, and programs, uses best judgement in determining the rigor of requirement implementation, administrative controls, and business practices to be applied to ensure requirements are met.
- Implementing procedures and work plans reflect the use of the graded approach by setting forth direction for the amount of analysis, documentation, and actions required to ensure requirements are met.

Activities related to TRU waste generation, packaging, certification, and transportation are addressed in specific documents.

## **6.2 Personnel Training and Qualification**

### **6.2.1 Requirements**

*10 CFR 830.120* (c) (1) (ii) for Nuclear Facilities/Activities, and *DOE Order 414.1*, 4. b.(1)(b) for Non-Nuclear Activities

"Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained."

### **6.2.2 Principles**

Competencies of personnel to perform their assigned tasks are based on a combination of experience, education, and training. Key job descriptions are contained in the Training Implementation Plans (TIPs) and are supported with job and task analyses performed by the first-line supervisor. Maintenance of qualifications shall be established through controlled measures and ensure that employees maintain competency for the tasks they are assigned. Education and experience are the primary means of qualification. RMRS will consider the defensible competency or qualification of individuals performing the work as a factor in the mitigation of risk in the graded approach methodology.

Training shall be appropriate for the complexity and hazards of the work involved. Typical training methods include computer based training (CBT), classroom instruction, required reading, and on-the-job training.

Qualification requirements and training records shall be maintained and retrievable through RMRS managers, procurement and contractual agreements. Original records are retained at a centralized training record repository, maintained and operated by Kaiser-Hill Training and Scheduling Records. Evidence of qualification shall be established through documented records such as sign-in sheets, certificates, transcripts, registrations, and specific training records in accordance with the applicable RMRS controlling document.

The K-H Training User's Manual (TUM) establishes the requirements to determine and document employee qualifications including education, training, experience, and certifications required to perform assigned tasks. Various lower tier procedures are used to implement the provisions of the TUM and to define company specific training activities.

The qualification and training process is designed to enable RMRS to determine and document job-specific and general training requirements for each employee, and to ensure that qualifications and training are maintained current for their work assignment. Training methods include formal training conducted by qualified instructors, briefings conducted by management-approved personnel, required readings, workshops, seminars, and awareness training.

### **6.2.3 Quality Professionals**

The RMRS QA Manager establishes requirements for the competency of individuals planning, developing, assessing, and inspecting QA related work activities. Assessors, inspectors, quality engineers, and personnel conducting surveillances shall have training, qualifications, technical knowledge, and experience commensurate with the scope and complexity of the activities being evaluated. Evidence and maintenance of competency is established and recorded under approved processes. The qualification and competency requirements for quality professionals working within the TRU waste program are governed by specific TRU waste specific documents.

## 6.3 Quality Improvement

### 6.3.1 Requirements

*10 CFR 830.120* (c)(1)(iii) for Nuclear Facilities/Activities, and *DOE Order 414.1*, 4.b.(1)(c) for Non-Nuclear Activities.

"Processes to detect and prevent quality problems shall be established and implemented. Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction shall include identifying the causes of problems and working to prevent recurrence. Item characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items, services, and processes needing improvement."

### 6.3.2 Principles

Several approaches are taken to continuously improve the quality of RMRS products and services. These approaches include the following:

Management shall foster a *no-fault* policy where all personnel are encouraged to identify and report problems to the appropriate level of management for the purpose of corrective action. Personnel are authorized to stop work when conditions adverse to quality are identified. Supervision or management must be contacted immediately in the event of work stoppages caused by quality issues.

Management shall empower personnel to eliminate ineffective systems and improve performance by driving decision-making authority to the lowest effective organizational level.

Management shall encourage the appropriate use of established tools, such as statistical methods, to improve and substantiate confidence in program and project decision-making.

Management shall monitor and facilitate the disposition of quality deficiencies. The extent of root cause analysis and corrective action shall be commensurate with the significance of the failure or problem. Lessons learned shall be communicated to staff from management when appropriate.

### 6.3.3 Problem Prevention

RMRS management takes a preventive approach to problems through implementation of the RMRS QAPD, organizational structure, in-depth project planning, independent and management assessments, various self-assessment tools, surveillance, monitoring, corrective action, and recurrence control.

Quality Engineers participate in the work planning process, review work control packages prior to implementation, and conduct surveillances of work as it is being performed. QA and line management monitor performance through assessments, trend analysis and periodic reports, and make corrections to processes to continuously reduce the number of item and process failures. RMRS uses a preventive approach to improve processes and related controls through the development and implementation of self-assessment activities. Self-assessment within RMRS relies on worker involvement and promotes empowerment to facilitate change and enhance overall effectiveness.

The Site Lessons Learned program is used as a means of problem prevention. RMRS fully discloses known deficiencies and problem occurrences as a means of supporting the prevention of similar situations in other organizations at the Site and across the DOE complex.

#### **6.3.4 Surveillance**

RMRS QA conducts surveillance activities as a continuous barometer of quality requirement compliance, implementation, and program effectiveness. Surveillances are planned on an annual basis and are conducted using qualified personnel in accordance with approved instructions.

#### **6.3.5 Control of Nonconforming Items**

Items that do not meet established requirements are identified, segregated, controlled, documented, analyzed, and corrected in accordance with approved processes.

Nonconformances associated with radioactive waste, and waste packages that have been assigned a Waste and Environmental Management System (WEMS) identification number are identified through the waste NCR process and are corrected according to specific waste management approved processes.

#### **6.3.6 Corrective Action**

Conditions adverse to quality are identified and the causes of deficiencies are determined to the degree appropriate for the identified condition using approved processes.

When conditions adverse to quality are identified and require stopping operations to prevent continued deficiencies, the stop work or work pause process is initiated. The process will be restarted only after appropriate analysis and actions are taken to prevent recurrence of the condition, or when controls have been initiated to reduce risks to an acceptable level. Products or services deployed under the adverse condition will be identified and corrected as appropriate in accordance with the provisions for nonconformances.

The RMRS Corrective Action process is consistent with the Site Corrective Action process. The Plant Action Tracking System (PATS) is used to track deficiencies. Exceptions to use of the PATS must be authorized by the RMRS Quality Manager. Issues related to the Site RCRA Permit or environmental management shall be tracked in the Environmental Compliance Action Tracking System (ECATS) as authorized by the QAEC Director.

Operational deficiencies that are determined to be enforceable under PAAA are reported to the Site Noncompliance Tracking System. All PAAA reportable deficiencies are subject to a root cause analysis determination prior to development of the corrective action plan and will be independently verified for completion by RMRS QA prior to closure.

#### **6.3.7 Trend Analysis**

RMRS QA is responsible for the analysis of item and service quality. Information to support trending is gained through audit reports, inspection reports, surveillance reports, corrective actions, management assessments, performance indicators, and lessons learned. Trending of deficiency types includes cause assignment; equipment, management systems, procedures, personnel, work environment, etc.

### **6.4 Documents and Records**

#### **6.4.1 Requirements**

*10 CFR 830.120* (c)(1)(iv) for Nuclear Facilities/Activities, and *DOE Order 414.1*, 4.b.(1)(d) for Non-Nuclear Activities

"Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specifications requirements, or establish design. Records shall be specified, prepared, reviewed, approved, and maintained. "

#### **6.4.2 Principles**

Documents affecting Quality, such as work plans, IWCP documents, design documents, standard operating procedures, health and safety plans, etc., shall be controlled, where control is constituted by the following criteria:

- Documents prepared in accordance with approved processes
- Documents have received the required reviews and approvals
- Documents are uniquely identified and are controlled
- Personnel performing work receive the latest approved versions of the document
- Superseded, obsolete, out-of-date, down level, or voided documents are removed from use

Policies, plans, procedures, decisions, data, and transactions of RMRS will be documented to an appropriate level of detail and will receive the appropriate level of review and approval. The objective of RMRS is to maximize the usability of records and data for performance objectives while minimizing the administrative cost and paperwork for RMRS and lower-tier contractors.

Quality records are defined in approved processes and plans and will be managed to ensure the information is recorded, legible, maintained, and retrievable. Quality records involving measurements or sampling activities shall be authenticated by the originator and receive subsequent approval.

A person other than the data entry person shall review data input from quality records for accuracy. The reviewer must authenticate the hard copy output. Errors on quality records shall be documented and corrected in accordance with approved instructions, and information on the error and correction will be retained for trending purposes. Authentication is required for any corrections. Evidence of authentication shall be retained as a quality record.

#### **6.4.3 Document Control System**

RMRS Document Control is responsible for administration and control of RMRS controlled documents. Site Document Control is responsible for administration and control of Site level controlled documents.

RMRS controls company specific documents in accordance with approved procedures. RMRS project budget documents are controlled in accordance with the existing Management Control System procedures. Site level design documents are controlled in accordance with approved procedures.

To ensure broad access to current infrastructure (controlled documents), RMRS has implemented a "Model Office" process to provide a comprehensive collection of controlled documents. The "Model Offices" are strategically located for access by personnel involved in RMRS operations.

#### **6.4.4 Records Administration**

RMRS records are defined in procedures, compliance agreements, permits, and regulations. RMRS records are captured, indexed, protected, and maintained in accordance with approved processes, unless specifically excluded by Contract No. KH00003NS1A, Section H.4. Records are maintained and protected by RMRS until they are deemed appropriate for archival. Records identified for archival are formally transmitted to Site Records Management for long term storage. The DOE RFFO is responsible

for the CERCLA Administrative Records that are processed by RMRS. Records associated with the characterization and shipment of TRU waste to the Waste Isolation Pilot Plant, and Low Level Waste shipped to the NTS are maintained and protected by Source One Management under a Task Order agreement to RMRS. Specific WIPP records that are identified by the Department of Energy, Carlsbad Area Office (CAO), will be transferred to CAO for permanent storage as required.

#### 6.4.5 Computer Software

The Computer Software Management manual (CSM) implements a Site QA program requirement contained in the Site quality assurance manual to establish software quality assurance for nuclear computer software and any other application software at the Site. The CSM and specific program plans meet NTS and WIPP requirements for software quality assurance controls. Application of software quality assurance controls is dependent on the importance of use and takes into account the costs (purchase, development, replacement, and lifetime maintenance), consequences of failure, impact to safety, and potential liabilities. Additional information regarding software requirements of computer software for nuclear applications can be found in NQA-1-1989, Part II, Subpart 2.7, Quality Assurance Requirements of Computer Software for Nuclear Facility Applications.

### 6.5 Work Processes

#### 6.5.1 Requirements

*10 CFR 830.120* (c)(2)(i) for Nuclear Facilities/Activities, and *DOE Order 414.1*, 4.b.(2)(a) for Non-Nuclear Activities

"Work shall be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained."

#### 6.5.2 Principles

RMRS processes and activities shall be controlled to a degree commensurate with the associated risks. Controlled conditions shall include the following as appropriate:

- The use of documented and approved procedures, instructions, or other appropriate means to control processes and activities
- Identification of items to ensure their proper use
- Maintenance of items to prevent their damage, loss, or deterioration
- The use of suitable, approved equipment in a suitable, approved working environment
- The use of and compliance with technical standards, workmanship criteria, quality plans or other requirements
- Monitoring and control of process characteristics
- Maintenance and calibration of equipment used for process monitoring or data collection
- Qualified workers with documented qualifications

Process qualification and product acceptance criteria are defined and documented, and are utilized for determining effectiveness of processes. As processes consistently reflect stability or improvement, surveillances are reduced. When processes exhibit excessive variation or variation beyond specified tolerances, surveillances should increase.

### 6.5.3 Planning

Work is planned and authorized as described in the Site Management Control System procedures and in accordance with the provisions of the RMRS contract. During the budget call, RMRS identifies specific activities to be accomplished in order to meet contract provisions. Work activities are planned, scheduled, resource loaded, and documented in work packages that are approved and tracked, and implemented through Project Authorization Directives (PADs).

On June 30, 1999, an Authorization Agreement (AA) invoking the Site SAR became effective. This AA supersedes and cancels a previous AA, which had invoked the Master Activity List (MAL) as a means of authorizing activities not covered by another AA. The MAL has been eliminated. The new AA authorizes activities through the Site SAR, which describes how Site infrastructure programs (such as IWCP) are used to assure activities are performed in accordance with appropriate orders and standards.

Work is planned and performed in accordance with approved processes, including the IWCP process. The IWCP process provides a single process through which work on the site is performed and is the method by which ISM is implemented on the job. Documentation related to the conduct of work includes acceptance criteria and describes inspection/testing requirements for the acceptance of work. Work planning and performance documents, with the exception of minor maintenance, are reviewed by QA prior to implementing the work. The purpose of the review is to ensure that customer's QA requirements are adequately addressed and appropriate QA resources are allocated to support the requirements. In addition to the applicability of QA requirements, facility operations comply with the defined Authorization Basis (AB) for the operation.

Each RMRS project-controlling document references the specific instructions applicable to the activities addressed in this document. Tasks and resources should be included within work packages to achieve compliance with the customer's QA requirements. Work process documents should address process elements to prevent the use of incorrect or nonconforming items and to ensure items requiring traceability are identified and controlled. Documents should describe methods to control packaging, shipping, handling, storage, and preservation of items to prevent damage, loss, or deterioration.

If an existing instruction does not adequately address an activity in a controlling document: a new instruction should be developed; an existing instruction should be changed (temporary or permanent); or actions and controls should be added to the project-controlling document.

### 6.5.4 Procedures, Instructions, and Drawings

Activities affecting quality are prescribed by and performed according to documented instructions, procedures, and drawings. RMRS subscribes to the design control process for the development of instructions and procedures. Specific inputs and outputs are considered during the development of instructions and procedures. RMRS maintains procedures to guide the development, preparation, and control of RMRS specific documents. RMRS adheres to Site document requirements for Site level documents.

The extent of detail is dependent on the complexity and risk of the activity, the experience of the users, and the frequency of performance. Creation and control of drawings is described in the Conduct of Engineering Manual and the Site Engineering Requirements Manual. Maintenance tasks are controlled under the procedures in the Integrated Work Control Program Manual. Work planning and control tasks are controlled under the Management Control System procedures.

### 6.5.5 Collection and Evaluation of Environmental Data

Activities related to measurement and data acquisition include collecting environmental and decommissioning samples and data, and generating analytical and measurement data. Controls are incorporated through the use of sampling plans, analysis plans, and field sampling in order to ensure the accuracy and integrity of data being generated. Data used to base environmental response, decommissioning, and area/facility/equipment release decisions shall be collected, controlled, validated, analyzed, and reported in a manner that leaves the data defensible.

Calculations, models, and methods used to analyze data in support of making conclusions shall be documented, reviewed, and approved. Personnel performing calculations should be qualified and should document the calculation method in such a manner that a qualified individual could repeat the calculation, and achieve identical results, without consulting the author.

Each project-controlling document shall include a description of the implementation process and the appropriate Data Quality Objectives (DQOs). The document shall ensure that the activity is conducted in a manner that achieves the project goals while minimizing the cost and impacts on the worker, public health, safety, and the environment, to the extent practicable. DQOs should reflect the current guidance established by the EPA (EPA QA/G4), and shall be developed in the planning stage of all environmental data collection efforts. The DQO process is integrated with the development of sampling and analysis plans included in the specific work controlling process.

Data not generated under the direct control of RMRS shall undergo subsequent verification to assure the data is defensible and appropriate for the application, if the data is used to support environmental remediation, and waste management operations decisions.

### 6.5.6 Waste Operations

The generation, characterization, treatment, packaging, storage, and disposal of wastes are governed by requirements that depend upon the type of waste being generated. These requirements have been established in regulations, DOE orders, the Resource Conservation and Recovery Act (RCRA) permit, and the respective disposal site waste acceptance criteria. Procedures and controls have been established to ensure that the generation and handling of wastes, including sanitary waste, meets governing requirements. The Waste and Environmental Management System (WEMS) tracks and controls the inventory, movement, and various waste management activities for radioactive, nonradioactive, hazardous, nonhazardous, Toxic Substances Control Act (TSCA)-regulated, and mixed waste packages onsite and shipments to offsite facilities.

The Waste Isolation Pilot Plant (WIPP) in Carlsbad, New Mexico, is the designated disposal site for TRU/TRU Mixed Waste generated at the Site. The WIPP requires specific program documents to address their QA program requirements. The Site TRU Waste Management Plan addresses the requirements of the WIPP QA Program Document. The Site WIPP TRU Waste Characterization QA Project Plan addresses the WIPP Characterization QA Program Plan.

The Nevada Test Site (NTS) is a disposal site for Site LLW. Envirocare of Utah and Hanford are disposal sites for Site Low Level Mixed Waste (LLMW). The LLW Management Manual describes the systems and controls implemented for waste stream characterization, waste certification, quality assurance, and waste package transfer to meet the requirements of the waste acceptance criteria defined in the treatment disposal and storage facility documents for each waste disposal site.

### 6.5.7 Transportation and Shipment of Waste

The K-H Traffic Department has the program responsibility for the quality and regulatory compliance for the transfer, shipping, and transportation of LLW and TRU/TRU mixed waste materials. The Rocky Flats Transportation Safety Manual provides shipping and transfer requirements, and instructions and includes the On-Site Transportation Manual, and the Off-Site Transportation Manual. RMRS is responsible for packaging waste for on-site and off-site shipments of LLW and TRU/TRU mixed waste materials. RMRS is responsible for providing accurate information for the hazardous waste manifest.

### 6.5.8 Closure Projects

Closure project control documents will ensure that the activity is conducted in a manner that meets the project goals while minimizing the cost and impact on the worker and public health and safety, the work, and the environment. For decommissioning activities, the project control documents normally include a decommissioning plan and subordinate implementing plans that cover specific subject areas.

Decommissioning plans shall be consistent with *DOE Order 5400.5, Radiation Protection of the Public and the Environment*, and *DOE Order 5820.2A, Radioactive Waste Management* (to be superceded by DOE O 435.1, Radioactive Waste Management), and the *DOE Decommissioning Handbook*.

Decommissioning plans shall consider the guidance in *NUREG/CR-2082, Monitoring for Compliance with Decommissioning Termination Survey Criteria*; *NUREG/CR-5512, Residual Radioactive Contamination from Decommissioning: Technical Basis for Translating Contamination Levels to Annual TEDE*; and *NUREG/CR-5849, Guidance Manual for Conducting Radiological Surveys in Support of License Termination*. Decommissioning plans include a description of the checks and balances that are used during execution of work to ensure compliance with work control documentation and acceptance criteria.

### 6.5.9 Welding

RMRS maintains the RMRS Welding Manual that includes design control, material control, welder qualification and records, fabrications or repairs, inspection and testing, nonconforming items, subcontractors, safety requirements, and specifications.

## 6.6 Design

### 6.6.1 Requirements

*10 CFR 830.120* (c)(2)(ii) for Nuclear Facilities/Activities, and *DOE Order 414.1*, 4.b.(2)(b) for Non-Nuclear Activities

"Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled. The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work. Verification and validation work shall be completed before approval and implementation of the design."

### 6.6.2 Principles

Sound engineering/scientific principles, and appropriate technical standards are to be incorporated into designs to assure intended performance. The Site infrastructure programs provide controls for the design of items and processes. Design work includes incorporation of applicable requirements and design bases, identification and control of design interfaces, and verification or validation of the adequacy of design

products by individuals or groups other than those who performed the work. The verification and validation shall be completed before approval and implementation of the design.

### 6.6.3 Control of Design Processes

Design control processes have been established for the control of design inputs, outputs, verifications, reviews, changes, modifications, and configuration change control. Design control requirements for procured design and engineering services are incorporated into procurement specifications. Requirements for engineering and engineering design activities including design, change control, interfaces, and oversight control have been established. Engineering Design Package (EDP) requirements for developing a design package, including technical content and format have been established.

Design control of computerized systems shall be commensurate with the risks associated with the process that the computer system controls. Systems that control critical health and safety processes shall be verified and validated under simulated working conditions, prior to actual usage and shall be tested periodically to ensure functionality.

Special processes such as welding, heat treating, nondestructive testing, chemical decontamination, etc., cannot be verified without destruction or degradation of the item. Special processes are controlled by the Site work control process and must be identified by the organization originating the project. Special processes require additional process controls such as observation of equipment settings, process parameters, or operator training, qualification, and certification.

## 6.7 Procurement

### 6.7.1 Requirements

*10 CFR 830.120* (c)(2)(iii) for Nuclear Facilities/Activities, and *DOE Order 414.1*, 4.b.(2)(c) for Non-Nuclear Activities

"Procured items and services shall meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria. Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented."

### 6.7.2 Principles

RMRS uses the procurement and subcontracts system developed by K-H. Procurement levels defined in the Site controls are used by RMRS for purchased services. Procurement of items (commodities) is controlled and facilitated through Rocky Flats Closure Sites Services (RFCSS).

RMRS personnel requisitioning items and services are responsible for identifying and defining the QA requirements in the associated procurement documentation. The process for the determination and application of QA requirements to be included in procurement documents for items and services (including construction) has been defined.

RMRS employs the use of credit cards for acquisition of services and for certain commodities. The conditions for use of credit cards for purchases are addressed in the Site Credit Card Procedure.

Memorandums of Understanding (MOUs) are used to define operational agreements between the Customer Service Organization (CSO) and other K-H Team organizations for procurement of waste commodities.

### **6.7.3 Procurement Documents**

Procurement documents, except those for office supplies and equipment, receive an independent quality review by RMRS QA to assure incorporation of appropriate quality assurance requirements, and health and safety requirements. The RMRS QA organization reviews procurement documents to ensure that the requirements for items and services are clearly depicted, including specific performance requirements.

Procurement documents for items purchased by RFCSS are retained and administered by RFCSS. Procurement documents for services other than normal maintenance agreements for services and credit card purchases, are retained and administered by RMRS in accordance with approved procedures.

### **6.7.4 Supplier Selection and Procurement Levels**

Procurement Level 1 (PL-1) – Procurement of items or services that could: (1) affect the safety of the public, worker or environment or, for Site waste certification programs, could (2) affect the quality of characterization data, or (3) affect the quality of certification of the waste to be transferred. PL- I procurement shall be from a subcontractor that has an evaluated/approved QA program or has had the required QA program elements evaluated/approved and is listed on the Evaluated Subcontractors List (ESL). K-H or RMRS performs on-site evaluation of suppliers as part of the process of qualifying a supplier for listing on the ESL. The requisitioning RMRS organization may also provide input or participate in the evaluation process. The ESL is available on the Site intranet.

Procurement Level 2 (PL-2) – Procurement of items or services that could: (1) affect the safety of the public, worker or environment, or, for Site waste certification programs, could (2) affect the quality of characterization data, or (3) affect the quality of certification of the waste to be transferred. PL-2 is used for procurement is from suppliers that do not have an approved QA program. Conformance to requirements for PL-2 items can be verified by mandating the use of existing Site/RMRS infrastructure that can include source inspection or alternate testing or verification.

Procurement Level 3 (PL-3) – Procurement of non-quality related items or services from a subcontractor that may or may not have had QA program or program elements evaluated.

RMRS provides specification input for items and develops acceptance criteria. Engineering Design Package (EDP) requirements for developing a design package, including technical content and format have been established. RMRS takes full advantage of third party certifications and other supplier audits through the use of the Supplier Quality Information Group.

### **6.7.5 Acceptance of Items and Services**

RMRS employs methods for the acceptance of items and services that include observation of selected operations at vendor facilities, post-installation testing, certificate of conformance, receiving inspection by RFCSS, surveillance or audit, and verification of data. RMRS selects the acceptance criteria based on the Site procurement levels in accordance with approved processes and guidance. Items and services not meeting specifications and requirements are identified, controlled, and dispositioned in accordance with Site requirements and controls.

### **6.7.6 Fraudulent Material and Suspect or Counterfeit Items)**

Any fraudulent material and suspect or counterfeit items found at the Site shall be identified, controlled, and dispositioned in accordance with the Site NCR Process Instances of fraudulent and suspect or

counterfeit items are to be reported through the Occurrence Reporting Process and to the Inspector General.

### **6.7.7 Identification and Control of Items**

RMRS employs Site control systems for identification, maintenance, and control of items, including consumables. The controls ensure that items are properly labeled, tagged, or marked, and that only appropriate items are used for the application. When physical marking is not possible, item identification is facilitated through serial number or other traceable means. Site controls ensure that items are identified, handled, stored, transferred, and shipped in a manner that prevents loss, damage, or deterioration.

## **6.8 Inspection and Acceptance Testing**

### **6.8.1 Requirements**

*10 CFR 830.120* (c)(2)(iv) for Nuclear Facilities/Activities, and *DOE Order 414.1*, 4.b.(2)(d) for Non-Nuclear Activities

"Inspection and testing of specified items, services, and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspections and tests shall be calibrated and maintained."

### **6.8.2 Principles**

Items or activities that require inspections and/or acceptance testing will be specified in work-controlling documentation, such as work plans, standard operating procedures, data management plans, etc. Acceptance criteria and any hold points shall be clearly defined.

Equipment used for inspection and testing will be calibrated and maintained. Inspections, tests, and calibrations used to verify the conformance of an item to specifications or requirements, or satisfactory performance for service will be performed using a graded approach according to the level of risk.

Inspection and acceptance test criteria are included in procurement documents as required. Inspections performed by RMRS are performed in accordance with approved processes. Source inspection for items may be performed at the supplier's site and is the responsibility of the requisitioning organization. Qualified personnel must perform source inspections. Source inspection results and reports should be forwarded to RFCSS for record keeping purposes.

Oversight and acceptance of services is the responsibility of the requisitioning organization, and shall be performed in accordance with approved Site procedures by qualified personnel.

### **6.8.3 Receiving Inspection**

Items received in the warehouse are inspected by RFCSS in accordance with the applicable procurement specifications and approved operating procedures. Inspection methods include visual inspection, dimensional measurement, examination of labeling and markings, and procurement document review. Acceptance status is indicated and forwarded with the item prior to release for use. Items failing inspection are identified as nonconforming and handled in accordance with Site requirements and controls.

#### 6.8.4 Testing

Testing of items and processes is conducted by RMRS to ensure conformance to requirements. Testing is planned and performed in accordance with procedures that identify necessary test requirements, personnel qualifications, acceptance criteria, and test data documentation requirements.

#### 6.8.5 Status Indicators

Methods have been established to provide for the identification and control of nonconforming items to prevent their inadvertent use. The PATS and the RMRS Corrective Action Process (CAP) provides status indicators. The calibration program administered by RFCSS provides for clear identification of M&TE calibration status. Respective programs contain provisions for tagging, logging, and other visual displays as required.

#### 6.8.6 Measuring and Test Equipment

Measurement and test equipment (M&TE) and radiological measurement equipment used for inspection and testing shall be controlled. The M&TE calibration program is administered by RFCSS. Calibrations shall be traceable to National Institute of Standards and Technology (NIST), or recognized Site or industry standard.

M&TE found to be out of tolerance shall be tagged 'out of service' and segregated to prevent inadvertent use of the equipment. Evaluation of the equipment and data should be performed to determine the validity of the previous inspections or tests, and the acceptability of those results.

M&TE used for ER and closure projects is addressed in the Measuring and Test Equipment section in Appendix 1 for specific calibration requirements. Instrument calibration information will be provided to the metrology laboratory for tracking purposes.

#### 6.8.7 Waste Inspection

LLW, TRU, and mixed radioactive waste generated at the Site is inspected at defined hold-points by qualified waste inspectors. Inspections consist of observing and verifying waste packaging activities to Site and waste repository requirements and acceptance criteria. The results of these inspections are recorded on the Waste Residue Traveler (W/RT). Inspections also include a review of the waste package documentation for completeness and accuracy. Nonconformances are documented, tracked, and resolved in accordance with approved processes.

Technical direction, training, qualification of waste inspectors, and verification of corrective actions for waste NCRs is provided by the RMRS QA organization.

Custodians of RMRS RCRA units conduct inspections of hazardous wastes in accordance with the RCRA Part B permit.

#### 6.9 Management Assessment

##### 6.9.1 Requirements

10 CFR 830.120 (c)(3)(i) for Nuclear Facilities/Activities, and DOE Order 414.1, 4.b.(3)(a) for Non-Nuclear Activities

"Managers shall assess their management processes. Problems that hinder the organization from achieving its objectives shall be identified and corrected."

### 6.9.2 Principles

RMRS has an established assessment program for planning and implementing assessments. Assessments include audits, surveillances, inspections, reviews, evaluations, appraisals, and process monitoring.

Assessments are scheduled based on the risk of the activity and results of performance indicators. The results of assessments are documented and communicated to the appropriate RMRS management. Assessments are tracked to verify the effective development and implementation of corrective actions.

### 6.9.3 Planning

RMRS plans, develops, and maintains management assessment schedules for the various management levels within the organization. The schedules are controlled by executive management, typically Director level and above.

### 6.9.4 Management Assessments

RMRS executive management periodically evaluates the effectiveness of the QA Program and overall organization performance. These assessments are to be conducted by management and should not be delegated. Management assessments are documented through reports, periodic status reports, or other suitable reporting mechanisms.

Line and senior management periodically assess their operations to determine compliance to the Quality Assurance Program. Improvements or corrections to operations and performance are documented and implemented. The methodology for documenting findings and implementing corrective actions is provided in approved procedures.

## 6.10 Independent Assessment

### 6.10.1 Requirements

*10 CFR 830.120 (c)(3)(ii)* for Nuclear Facilities/Activities, and *DOE Order 414.1, 4.b.(3)(b)* for Non-Nuclear Activities

"Independent assessments shall be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. The group performing independent assessments shall have sufficient authority and freedom from the line to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed."

### 6.10.2 Principles

The QA organization within RMRS is afforded autonomy and authority by the President of RMRS to perform planned periodic assessments assessing the adequacy and effectiveness of the performance of work, and quality of items and services delivered by RMRS. Assessments are intended to provide useful feedback to promote improvement activities regarding mission and performance objectives. Assessments are conducted in a manner that the organization being assessed is the *customer* of the assessment results. Assessments are coordinated and scheduled at a Site level to avoid duplication of external assessments.

RMRS assessments may be scheduled by management to determine the adequacy of performance in particular areas of operations prior to evaluations by other organizations. Findings are addressed through

approved processes and are evaluated in accordance with cause analysis and lessons learned programs as required.

### **6.10.3 Integration**

RMRS integrates the full scope of independent assessments through the Site Integrated Oversight Plan and takes into account the assessments being performed by various stakeholders. Independent assessments are conducted by independent RMRS personnel qualified to assess the area being considered. The assessments are tracked to verify the effective development and implementation of corrective actions. The RMRS QA system will be fully assessed on an annual basis in accordance with *DOE Order 414.1*.

### **6.11 Radiological Protection**

The Site Radiological Control Manual is used to implement the requirements of 10 CFR 835, and applies to activities covered by 10 CFR 835, Occupational Radiation Protection.

### **6.12 Fire Protection**

Requirements for fire protection systems sufficient to minimize losses from fire and related hazards have been established in Site level documents.

### **6.13 Nuclear Safety**

The Site Nuclear Safety manual is used to implement the requirements of 10 CFR 835, and applies to activities covered by 10 CFR 835. RMRS subscribes to the existing Site infrastructure for Nuclear safety.

### **6.14 Closure Project Planning**

The Kaiser-Hill Team in cooperation with DOE, RFFO has developed a Closure Project Baseline (CPB) showing achievement of the RFCA and interim end-state (interim closure) by the year 2006. Each year, a two-year window of the CPB is expanded to greater detail to form the annual work plan, which becomes the basis of authorization by DOE, RFFO for execution year funding. All changes to the baseline are governed by rigorous change control procedures.

Overall scoping and planning for work supporting the closure mission of RFETS is described in the Rocky Flats Closure Project (RFCP) Project Management Plan (PMP), a part of the CPB. The PMP is the 'top-level' document for the Project identifying or referencing all aspects of the closure project. The PMP is a work-activity-based plan that delineates the project's work scope, establishes a schedule for those work activities, and estimates associated costs. The plan also defines the required processes to plan and execute the project. The PMP addresses the project Scope, Schedule, Cost Estimates, and Management Systems necessary to control the closure project.

The work scope flow down from the PMP is documented in Project Baseline Descriptions (PBD). Each PBD is a K-H sub-project summary that contains the entire work scope for a particular sub-project within the RFCP. The PBD is the only document detailing the complete sub-project work scope and is tied to the closure project schedule through the Work Breakdown Structure (WBS). Collectively, all the PBDs define the entire RFCP work scope.

Collectively the PMP and the PBDs delineate the Site requirements and programs used to accomplish the closure activities. These include the RFCA, the Site Quality Assurance Program, the Site Conduct of Operations Program, and the Integrated Safety Management program as implemented through the IWCP.

## 6.15 Closure Projects

The Site is in the post-production, cleanup, and closure phase of its life cycle. Major planning activities are currently underway to support accelerated Site closure. The current Site vision, which was developed in conjunction with the RFCA, is to accelerate cleanup and closure; minimize risk to the worker, public and environment; and dispose of contamination, wastes, buildings, facilities and infrastructure in compliance with applicable state and federal environmental laws.

As required by RFCA, the Decommissioning Program Plan (DPP) establishes the regulatory steps for decommissioning buildings. The DPP is the level one document for the Kaiser-Hill Closure Projects Group.

The Closure Projects Group has developed several documents to guide and control closure project execution. The primary documents implementing the DPP, the *Facility Disposition Program Manual (FDPM)*, and the *RFETS Decontamination and Decommissioning Characterization Protocol (DDCP)*. The FDPM establishes the processes and requirements for facility disposition, and outlines the project-specific documentation requirements and the relationship between closure project activities and Site programs. The DDCP establishes the processes and requirements for characterizing a facility during disposition activities. The FDPM and DDCP contain QA sections, which clarify the quality approach with respect to facility disposition and facility characterization.

Facility disposition involves several phases of planning, execution, and closeout. The planning phases involve assessing the status of the facility and determining the best method and process of disposition. Planning activities will be documented in project-specific Project Execution Plans (PEP), which will be updated throughout the planning phases. All work activities at the Site, during planning and execution, will be controlled through the Integrated Work Control Program. Waste resulting from the facility disposition will be controlled through the individual Site programs for TRU, TRU mixed, low-level, low-level mixed, hazardous, and sanitary wastes.

Overall administration of closure projects is performed by the Closure Projects Group, which includes four organizations: Construction Services, Closure Projects Advanced Planning, Project Controls, and Closure Projects Project Execution.

## 7. IMPLEMENTING DOCUMENTS (10 CFR 830.120 AND DOE ORDER 414.1)

### Section 6.1, Program - Management, Criterion 1

#### *Site Specific:*

- 1-C40-QAP-02.01, Preparation Of Quality Assurance Program Plans
- 1-D41-HWRM-22, Interaction with Environmental Regulatory Agencies and Enforcement Inspectors
- 1-MAN-008-WM-001, TRU Waste Management Manual
- 1-MAN-036-EWQA-Section 1.6.1, Waste Characterization Manual
- 94-RWP/EWQA-0014, Low Level Waste Management Plan
- 95-QAPjP-0050, RFETS TRU Waste Characterization Program Quality Assurance Project Plan (QAPjP)
- CAO-94-1012 (QAPD), Quality Assurance Program Document
- INS-246, Transuranic Waste Characterization Project (TWCP) QAPD Procedures Matrix
- Rocky Flats Cleanup Agreement
- Site Quality Assurance Manual

- Site Quality Assurance Program Procedures Manual
- Specific program manuals, plans and controls for transportation, laboratory services, radiological engineering, health and safety, radiological control, etc.
- PRO-486-WIPP-006, TRU Waste Characteristic Project QA Grading

***RMRS Specific:***

- RMRS Contract KH00003NS1A
- RMRS-QAPD-001, Quality Assurance Program Description (QAPD)
- RMRS Quality Assurance Documents Binder

**Section 6.2, Personnel Training and Qualification - Management, Criterion 2**

***Site Specific:***

- 3-MAN-002-T&Q-01, Kaiser-Hill Training and Qualification Program
- Training Users Manual

***RMRS Specific:***

- 3-21000-ADM-02.02, Personnel Position Description
- PLN-97-007, TRU Waste Characterization Program Training Implementation Plan
- RF/RMRS-97-040, RMRS Training Manual
- RMRS-QA-02.01, RMRS Qualification and Certification of Quality Assurance Personnel
- Various building specific Training Implementation Matrices

***Specific Implementation details for building programs and projects are found in:***

- INSTR.003, Instruction for Tracking/Scheduling Training, and Qualifications and Retention of Records for Training
- OPS-DIR-007, List of Qualified Individuals
- OPS-DIR-009, Building Indoctrination
- RMRS-TR-02.01, Development and Use of Training Implementation Plans (TIPs)
- RMRS-TR-02.02, Qualification and Evaluation of Training Personnel
- RMRS-TR-02.04, Identifying Training and Qualification Requirements
- RMRS-TR-02.05, Development and Use of Qualification Documents (QDs)
- RMRS-TR-02.06, Development, Use and Control of List of Qualified Individuals (LOQI)
- RMRS-TR-02.07, Design/Development of Training Materials
- RMRS-TR-02.08, Operating Organization Requirements for Continuing Training Programs
- Training Implementation Plans

**Section 6.3, Quality Improvement - Management, Criterion 3**

***Site Specific:***

- 1-A65-ADM-15.01, Control of Nonconforming Items
- 1-D97-ADM-16.01, Occurrence Reporting Process
- 1-E93-ADM-16.18, Data Analysis and Trending for Performance Improvement
- 1-MAN-012-SCARM, Site Corrective Action Requirements Manual
- 1-MAN-013-SIOM, Site Integrated Oversight Manual
- 1-MAN-017-LLGI-RM, Site Lessons Learned/Generic Implementations Requirements Manual
- 1-MAN-022-PAAAPROG, Price Anderson Amendments Act Program Manual
- 1-MAN-075-SMM, Standards Management Manual
- 1-P04-PATS-16.00, Plant Action Tracking System
- 1-PRO-072-001, Inspection and Acceptance Test Process
- 1-Q05-ADM-02.06, Standards Identification, Assessment, and Noncompliance Process

- 1-V10-ADM-15.02, Stop Work Action
- 3-X31-CAP-001, Corrective Action Process
- MAN-062-CAUSE ANALYSIS, Cause Analysis Requirements Manual
- PRO-U76-WC-4030, Control of Waste Nonconformances

***RMRS Specific:***

- INSTR.012, Radiological Deficiency Report Administration
- OPS-INSTR.015, Management Self-Assessments
- Quality Assurance Improvement Plan-FY99
- RMRS-QA-03.01, Corrective Action
- RMRS-QA-10.03, RMRS Price-Anderson Amendments Act Implementation Program
- WIPP-007, TRU Waste Characterization Project Conditions Adverse to Quality Trending and Analysis

**Section 6.4, Documents and Records - Management, Criterion 4**

***Site Specific:***

- 1-11000-ADM-003, Correspondence Control Program (To be superseded by 1-L43-IMS-001)
- 1-MAN-004-CSMM, Computer Software Management Manual
- 1-PRO-077-WIPP-005, Management of WIPP Information Prior to Transmittal to the WIPP Project File
- 1-V41-RM-001, Records Management Guidance for Records Sources
- 1-W56-COEM-AMN-001, Site Design Document Control
- MAN-001-SDRM, Site Documents Requirements Manual
- MAN-063-DC, Document Control Program.

***RMRS Specific:***

- OPS-DIR-004, Procedures and Document Control
- RM-06.02, Records Identification, Generation, and Transmittal
- RM-06.04, Administrative Record Document Identification and Transmittal
- RM-06.03, Records Receipt, Processing, Retrieval, and Disposition
- RMRS-DC-06.01, Document Control Program
- RMRS-QA-05.01, Preparation and Control of RMRS Documents
- RMRS-QA-05.02, QA Review of RMRS Documents

**Section 6.5, Work Processes - Performance, Criterion 5**

***Site Specific:***

- 1-40 ADM-MCS-1002, Work Package Development and Documentation
- 1-40 ADM-MCS-1003, Work Breakdown Structure Baseline Change Control
- 1-40 ADM-MCS-1004, Work Authorization and Suspension
- 1-86-WELD-001, Welding Program Plan
- 1-C78-WP1027-NONRAD, Nonradioactive Waste Packaging
- 1-I15-SAN-001, Sanitary Waste Management
- 1-M12-WO-4034, Solid Radioactive Waste Packaging Requirements
- 1-MAN-016-ISM, Integrated Safety Management System Manual
- 1-MAN-018-NSM, Nuclear Safety Manual
- 1-MAN-039-WEM-WP-1200, Waste and Environmental Management System (WEMS) Program Requirements Manual
- 1-R97-F&A-MCS-001, Management Control System (MCS)
- 1-V51-COEM-DES-210, Design Process Requirements

- 1-W56-COEM-AMN-101, Site Design Document Control
- 1-W86-WELD-001, Welding Program
- 4-N06-WO-1220, Waste and Environmental Management System (WEMS) Liquid Waste Tracking
- MAN-001-SDRM, Site Documents Requirements Manual
- MAN-027-SERM, Site Engineering Requirements Manual
- MAN-040-RDM, Readiness Determination Manual
- MAN-066-COOP, Site Conduct of Operations Manual
- MAN-071-IWCP, Integrated Work Control Program Manual
- MAN-095-CMPM, Configuration Management Program Manual
- Master Activity List
- Rocky Flats Environmental Technology Site Radiological Control Manual

***RMRS Specific:***

- RMRS-MAN-98-001, RMRS Welding Manual
- RMRS Operations Instructions Manual
- RMRS Operations Procedures Manual
- OPS-INSTR.002, EWP Implementation Instruction
- OPS-DIR-008, ALARA Action Committee Charter
- WIPP-009, RCRA Characterization of TRU Waste to be Disposed of at WIPP

**Section 6.6, Design Control - Performance, Criterion 6**

***Site Specific:***

- 1-52000-ADM-02.01, Operations Review Requirements
- 1-C10-NSM-04.03, Safety Evaluation Screen
- 1-C11-NSM-04.05, Unreviewed Safety Question Determination
- 1-MAN-004-CSMM, Computer Software Management Manual
- 1-MAN-010-S&A, Safeguards and Accountability Manual
- 1-MAN-018-NSM, Nuclear Safety Manual
- 1-V51-COEM-DES-210, Design Process Requirements
- 2-C93-COEM-DES-273, Engineering Standards for Procurement
- Configuration Change Control Program Manual
- Engineering Drafting Manual
- MAN-027-SERM, Site Engineering Requirements Manual
- MAN-066-COOP, Site Conduct of Operations Manual
- MAN-071-IWCP, Integrated Work Control Program Manual

***RMRS Specific:***

- RMRS subscribes to the existing Site infrastructure for controlling design activities

### **Section 6.7, Procurement - Performance, Criterion 7**

***Site Specific:***

- 1-J55-ADM-08.10, Supplier Quality Evaluations
- 1-W36-APR-111, Acquisition Procedure for Requisitioning Commodities and Services
- 2-C93-COEM-DES-273, Engineering Standards for Procurement
- 3-PRO-T21-CCP, Credit Card Procedure
- K-H Procurement System, Volume I and Volume II
- PRO-572-PQR-001, Procurement Quality Assurance Requirements

***RMRS Specific:***

- RMRS-QA-07.01, Evaluation of Suppliers
- RMRS subscribes to the existing Site infrastructure for the procurement of items and services

### **Section 6.8, Inspection and Acceptance Testing - Performance, Criterion 8**

***Site Specific:***

- 1-A65-ADM-15.01, Control of Nonconforming Items
- 1-D97-ADM-16.01, Occurrence Reporting Process
- 1-PRO-072-001, Inspection and Acceptance Test Process
- 1-V51-COEM-DES-210, Design Process Requirements
- MAN-066-COOP, Site Conduct of Operations Manual
- MAN-071-IWCP, Integrated Work Control Program Manual
- MAN-092-M&TEM, Measuring and Test Equipment Management Manual
- PRO-U76-WC-4030, Control of Waste Nonconformances

***RMRS Specific:***

- RMRS subscribes to the existing Site infrastructure for Inspection and Acceptance Testing and for Instrument Calibration (Exceptions are noted in section 6.8)

### **Section 6.9, Management Assessment - Assessment, Criterion 9**

***Site Specific:***

- 1-MAN-013-SIOM, Site Integrated Oversight Manual
- 1-W37-IA-002, Integrated Planning and Scheduling of Independent Assessment Activities

***RMRS Specific:***

- RMRS-QA-09.01, Management Assessments
- RMRS-QA-10.02, Conduct of Surveillances

### **Section 6.10, Independent Assessments - Assessment, Criterion 10**

***Site Specific:***

- 1-MAN-013-SIOM, Site Integrated Oversight Manual
- 1-N92-ADM-02.03, Training, Qualification and Certification of Independent Auditors and Assessors
- 1-W37-IA-002, Integrated Planning and Scheduling of Independent Assessment Activities
- 3-B52-IA-003, Conduct of Independent Assessment Activities
- MAN-040-RDM, Readiness Determination Manual
- OPS-INSTR.015, Management Self-Assessments

***RMRS Specific:***

- RMRS-QA-03.01, Corrective Action
- RMRS-QA-10.01, Independent Assessments
- RMRS-QA-10.02, Conduct of Surveillances

**Section 6.11, Radiological Protection**

***Site Specific:***

- Rocky Flats Environmental Technology Site Radiological Control Manual (Site RCM)

***RMRS Specific:***

- RMRS subscribes to the existing Site infrastructure for Radiological Protection

**Section 6.12, Fire Protection**

***Site Specific:***

- SF-100, Fire Protection

***RMRS Specific:***

- RMRS subscribes to the existing Site infrastructure for Fire Protection

**Section 6.13, Nuclear Safety**

***Site Specific:***

- 1-MAN-018-NSM, Nuclear Safety Manual

***RMRS Specific:***

- RMRS subscribes to the existing Site infrastructure for Nuclear Safety

**Section 6.14, Closure Project Planning**

***Site Specific:***

- 1-MAN-036-EWQA, Section 1.6.1, Waste Characterization Manual
- Decommissioning Operations Plans
- Waste Management Plans
- MAN-071-IWCP, Integrated Work Control Program Manual
- MAN-076-FDPM, Facility Disposition Program Manual (FDPM)

***RMRS Specific:***

- RMRS subscribes to the existing Site infrastructure for Closure Project Planning

**Section 6.15, Closure Projects**

***Site Specific:***

- Decommissioning Operations Plans
- Waste Management Plans
- MAN-077-DDCP, RFETS Decontamination and Decommissioning Characterization Protocol (DDCP)
- MAN-071-IWCP, Integrated Work Control Program Manual
- MAN-076-FDPM, Facility Disposition Program Plan (FDPM)

***RMRS Specific:***

- RMRS subscribes to the existing Site infrastructure for Decontamination and Decommissioning

**Appendix 1**

**Closure Projects**  
**and**  
**Environmental Restoration (ER)**  
**QA Program Supplement**

The Closure Projects and Environmental Restoration (ER) Quality Assurance Program Supplement consists of three separate sections:

- I** Control of Investigations Supporting Closure Projects and ER Operations
- II** Software Quality Assurance
- III** Measuring and Test Equipment.

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## **I CONTROL OF INVESTIGATIONS SUPPORTING CLOSURE PROJECTS AND ER OPERATIONS**

### **1 PURPOSE**

This section describes the requirements and methods used for investigations, analyses, and report preparation controlled and verified by the applicable Rocky Mountain Remediation Services (RMRS) Departments for environmental restoration, and decontamination and decommissioning projects.

These controls include requirements for the establishment of data quality objectives; sampling procedures; data reduction, validation, and reporting; internal quality control checks; data assessment; data validation criteria; peer review; and design records.

### **2 APPLICABILITY**

These requirements apply primarily to scientific investigations, which include field sampling, sample and data handling, and analysis and interpretation as required under the Rocky Flats Cleanup Agreement and referenced guidance documents. This section is applicable to personnel performing work activities affecting the data quality required for those activities.

Designed, engineered, or constructed plant facilities are addressed in the requirements of the RMRS QAPD, Rocky Flats Cleanup Agreement (RFCA) and the Site Facilities Engineering and Project Management Manual, used to satisfy DOE Order 6430. 1A.

### **3 REQUIREMENTS**

#### **3.1 Data Quality Objectives**

Data quality objectives (DQOs) quantitatively and qualitatively describe the uncertainty that a decision-maker is willing to accept in results derived from analytical data. This uncertainty is used to specify the quality of the measurement data required, usually in terms of precision, accuracy, representativeness, comparability, and completeness (PARCC) parameters. The establishment of DQOs assists all aspects of investigations, including determining methods for sampling, sample preparation, and selection of appropriate analytical methods.

The process for establishing project/site specific DQOs is described in the Environmental Protection Agency (EPA) QA/G-4, Guidance for the Data Quality Objectives Process and NUREG 1575, Multi-Agency Radiation Survey and Site Investigation Manual

DQOs must be established prior to the initiation of investigative activities. The project/site specific data users, use(s) of data, data objectives, sampling methods, and appropriate analytical levels will be established in individual sampling and analysis plans. The project/site specific analytical methods and PARCC parameters will be summarized in work planning documents such as workplans, field implementation, survey and sampling plans that are developed for each project. These DQOs include field instrument precision and accuracy as well as objectives for field Quality Control (QC) measures such as acceptable variance in field duplicate, trip and rinsate samples, and other specific field tests.

#### **3.2 Sampling Procedures**

The Standard Operating Procedures (SOPS), which together with this QAPD comprise the Site-wide

Sampling and Analysis Plan (SAP) for the RMRS Closure Projects and Environmental Restoration (ER) Programs, outline specific procedures for Closure Projects and ER activities.

The work planning documents for each Closure Projects and ER project will be reviewed and approved by the RMRS Quality Assurance organization and DOE/Regulators as specified by RFCA. As part of this review and concurrence process, the Sampling Plan portion of the work controlling documents will be reviewed to ensure that the proposed sampling activities are planned to be conducted according to approved SOPs and instructions. Where site or activity specific variations to SOPs are needed to effectively conduct sampling, formal document modifications will be prepared. For unique or one-time sampling activities, the SOPs will be modified and controlled or the SAP will include the additional requirements and steps to accurately reflect the methodology to be used.

New procedures that are needed may be submitted and/or recommended in the work planing documents on an individual basis. All requests for new or revised SOPs must be submitted to the RMRS Quality Assurance Organization. The RMRS Project Manager or his designee shall obtain the required approvals, including EPA/CDPHE as required by RFCA.

In order to assure that approved sampling procedures are being adhered to during field sampling activities, quality verification field surveillances will be conducted. The RMRS Quality Assurance (QA) organization will develop a surveillance schedule based on the field activity schedule presented in the workplanning documents. The specific tasks and frequency of field surveillances shall be documented in accordance with the requirements of the RMRS QAPD. An example of tasks and frequency of surveillances to be addressed would be; "Approximately 10 percent of the boreholes and well installations on a project; and approximately 5 percent of the samples for each type of sample collected will be reviewed".

### ***3.3 Analytical Procedures***

The K-H Analytical Services Division defines laboratory analytical requirements for the Site. These requirements are generally consistent with those specified in Statements of Work (SOWs) used in the U.S. EPA's Contract Laboratory Program (CLP). The SOWs are used for analysis of parameters where CLP methods are available. K-H Analytical Services Division (ASD) is responsible for developing and implementing the requirements for subcontracted services as identified in the ASD General Requirements (GRs) procedures. The method for particular analysis must be used such that the required detection limits (or minimum detectable activity) that are specified in the K-H GRs are achieved.

### ***3.4 Data Reduction, Validation, and Reporting***

KH ASD will submit analytical data results to the RMRS Project Manager. The data will include results from field surveys and laboratories. KH ASD shall independently validate analytical results and the results will be submitted to the RMRS project manager. The responsible project manager will review DQOs specified in the SAPs to determine if existing analytical and validation guidelines address validation needs.

If validation guidelines do not address DQO needs, the existing guidelines will be revised or new guidelines will be developed. The percentage of sample delivery groups to be validated will be determined by the responsible project manager with a minimum of 25% being validated. Special needs may require 100% validation and will be specified in the SAPs. All validation will be conducted through the K-H ASD.

### **3.5 Data Reduction**

Data reduction functions are divided into field and laboratory reduction activities. Each of these activities is summarized below.

#### **3.5.1 Field Data Reduction**

Field measurements, data, and observations shall be recorded in project logbooks, on field data forms, or on similar permanent records. Entries shall be legibly recorded in field logbooks or field forms using indelible ink. All entries signed and dated, or as specified in SOPs (Note: for some field measurements, this may not be appropriate, [i.e., seismic logs, strip charts]; accepted standard methods specific to these activities will be used). If entries must be changed, the change shall not obscure the original entry. The reason for the change shall be stated and the correction and explanation shall be signed and dated or otherwise appropriately identified at the time the correction is made. Field data records will be organized into standard formats whenever possible and retained in the QA records system. All RMRS SOPs shall specify the field data and sampling records that will be generated as a result of implementing the procedure. Generic examples of the types of field operations and sampling records specified in the RMRS SOPs include but are not limited to:

- Field data sheets and field logs
- Data processing and storage records
- Sample identification and chain-of-custody (COC) records
- Document control, inventory, and filing records
- QA/QC records
- Health and safety records

The combined data records should be sufficiently detailed to provide a complete and accurate history of data gathering and results.

#### **3.5.2 Laboratory Data Reduction**

Laboratory data shall be recorded or acquired during analysis and then prepared for review through computerized or manual algorithms to produce a raw data set (Note: the GRs specify the use of ASCII format). Raw data shall be verified in accordance with ASD requirements.

### **3.6 Validation**

Validation activities consist of reviewing and verifying field and laboratory data and evaluating data quality. Data validation will be performed in accordance with the ASD SOW for validation. The field and laboratory validation activities are described below.

#### **3.6.1 Field Data Validation**

Validation of field technical data will be performed on two different levels. The data shall be validated by periodic surveillances at the time of field collection by following RMRS SOPs for data collection, and the K-H ASD or subcontractors shall validate data.

Replicates of field measurements will be taken periodically by the field sampling crews to ensure the

validity and reproducibility of technical data from field instruments. Replicate measurements shall be performed under field conditions that are as similar as practical to the field conditions of the original measurements (e.g., weather, wind, temperature, etc.).

Whenever possible, in-house peer review will also be incorporated into the data validation process in order to maximize consistency among field personnel. K-H ASD subcontractors will validate data prior to inclusion into the RMRS soil and water database.

### 3.6.2 Laboratory Data Validation

Laboratory data shall be reviewed and validated by the K-H ASD laboratory validation subcontractor. Results of data review and validation activities are compiled electronically, delivered to K-H ASD to be uploaded to the K-H analytical database where it is captured by the RMRS soil and water database for retrieval and use.

Analytical data generated for RMRS Closure Projects and ER activities are assigned data usability qualifiers. Data usability qualifiers are assigned as a result of the data validation process and are consistent with EPA data usability qualifiers.

- V Valid (usable for all purposes)
- A Acceptable with qualifications (usable for most purposes)
- R Rejected (unusable for most purposes)

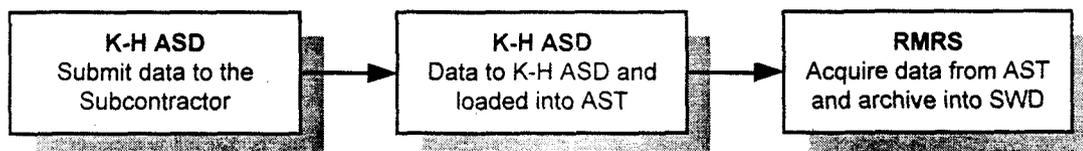
All data generated in conjunction with RFCA specified activities are subject to verification and validation or as agreed to between DOE/CDPHE/EPA. Data review and validation criteria (e.g., holding times, instrument calibration requirements, detection limits, and QC sample analysis) are referenced in the K-H General Requirements (GRs). Other data review and validation criteria are to be specified in the SAPs/QAPs and supporting SOPS.

### 3.7 Reporting

Sample analysis reporting turnaround times are presented in the K-H ASD GRs. The reporting frequencies have been established for Closure Projects and ER routine analyses. Reporting times for some analyses may be accelerated.

K-H ASD and the validation subcontractor receive analytical data packages that are prepared by the laboratories as soon as they are available. The validation subcontractor validates the data and submits the validated data to K-H ASD per the GRs.

Figure 1



### 3.8 Field Sampling Quality Control Procedures

The field duplicate, the trip blanks, and the equipment rinsate blanks, where appropriate, will be sent

with the samples from the field to the analytical laboratories. Other QC techniques may be employed with geotechnical or geophysical data where replicates or blanks are not practical. Table 1 shows general guidelines used for the collection frequency of QC samples.

**Table 1**  
**QC Sample Collection Frequency**

<b>Activity</b>	<b>Frequency</b>
Field Duplicate	1 in 20
Field Blanks	As specified in the SAP
Trip Blank	As specified in the SAP
Equipment Rinsate Blank	As specified in the SAP
Other QC Activities	As specified in the SAP

### *3.8.1 Field Duplicate Samples*

Field duplicate samples are collected and analyzed to provide an indication of overall sampling and analytical precision. Field duplicates are collected following the same sampling procedures used to obtain the regular sample.

A field duplicate sample is typically obtained when a sample from one location is split into two equal portions, with each portion going to the laboratory in a separate container. Exceptions to splitting samples to obtain a duplicate apply to duplicates for volatiles and for atmospheric and air quality (e.g., particulate) samples. Duplicate samples of volatiles will be collected independently to reduce the possibility of volatilization in the sample. For atmospheric and air quality samples, a field duplicate is obtained by a complete separate sample taken from a separate, co-located sampler and collected at the same time and/or over the same time period.

### *3.8.2 Equipment Rinsate Blank*

Equipment blanks shall be prepared for manual and small-automated sampling equipment used to collect samples. Equipment rinsate blanks shall be collected once per every 20 samples or once per day, whichever is more frequent. If disposable or dedicated equipment is used, then equipment blanks will not be collected. The procedure for collecting rinsate blanks consists of pouring volatile-free ASTM Type 11 reagent water into/through/over a decontaminated piece of sampling equipment (such as a bailer) and then dispensing it into prepared sample bottles.

Sample bottles will be randomly selected from the supply of prepared sample bottles, selecting a sample container appropriate for each type of analysis for which environmental samples are being collected. Analyses of equipment rinsates are used to assess the efficiency of implementation of equipment decontamination SOPs. Unless specified otherwise in the SAP, equipment rinsate blanks shall be obtained where sample collection requires the use of sampling equipment.

### *3.8.3 Field Blanks*

Field blanks consist of volatile-free ASTM Type II reagent water that are prepared in the field in the

same manner as regular samples. The blanks serve to identify contamination that is potentially associated with sample collection, preparation, and transportation. Field blanks for groundwater and surface water sampling are prepared with an unused, sealed bottle of volatile-free ASTM Type II reagent water and preparing a sample bottle for the reagent water following the same preparation procedures that are applicable to a regular sample, including filtering and adding preservatives, as appropriate.

The field blank sample is then transported to the lab for analysis with the regular samples. The field blanks are then analyzed in the laboratory as if they were regular samples. The typical frequency for preparation of field blanks is once per every 20 samples. The need for field blanks and their frequency will be determined on a site or activity specific basis. The use and frequency of field blanks will be specified in the SAPs/QAPs.

Field blanks for atmospheric data (e.g., new particulate filters) are taken to the field and handled, prepared, and transported for analysis (e.g., drying and weighing of filters) in the same manner as regular sample media. The blanks are not exposed to atmospheric conditions.

The use of field blanks for soil and sediment sampling at the Site is not appropriate because of the lack of commercially available blank soils and solid materials that adequately reflect the various soil types encountered. Developing blank soil types within the Site region is not practical due to the subjectivity of characterizing background soil conditions and the variability of soil types.

#### *3.8.4 Trip Blanks*

Trip blanks consist of volatile-free ASTM Type R reagent water samples that are prepared in the laboratory. Trip blanks serve to assess contamination of sample containers during storage and transport, and to assess contamination of samples during preparation for analysis at the laboratory. Trip blanks for groundwater and surface water samples are prepared at the laboratory prior to the sampling trip by pouring volatile-free ASTM Type II reagent water into prepared (i.e., preservative added where appropriate) bottles. These sample bottles will be randomly selected from the supply of prepared sample bottles. The sample bottles will be filled with an appropriate amount of water for the analysis required. These trip blanks will be shipped to the sampling site with the regular sample bottles, and transported back for analysis with the samples collected during the sampling event. The trip blanks will remain unopened throughout the sampling event. The trip blanks will be prepared and analyzed at the laboratory as if they were regular samples. Trip blanks will be utilized in place of field blanks for volatile samples only, unless rinsate and/or field blanks indicate possible contamination; then trip blanks will be prepared for other analytes. The frequency of trip blank use is typically once per every 20 samples. The need for and frequency of trip blanks will be determined on a site or activity specific basis. The use of trip blanks and the frequency will be specified in the SAPs/QAPs.

#### *3.8.5 Laboratory Quality Control Procedures*

Laboratory QC procedures are used to provide measures of internal consistency of analytical and storage procedures. Specific QC procedures and QC criteria are in place for organic, inorganic, water quality parameter, and radiochemical analyses. The laboratory QC procedures and samples used are described in detail in the analytical methods cited and in the K-H ASD GRs.

### **3.9 Data Assessment**

RMRS project personnel are responsible for evaluating analytical data from K-H subcontract

laboratories. In addition, the RMRS QA personnel may assist the project personnel in determining data usability and acceptance.

### 3.9.1 Calculations

Calculations shall be performed according to approved procedures. To ensure defensibility of the records, calculations shall be legible and in logical progression so that the steps and the reasoning behind the calculations can be understood. For calculations performed using a programmable calculator or computer, a sample calculation will be included in the permanent files together with a program listing and printout of input data. The calculated results also shall be placed in the QA records system files. A calculation or series of calculations shall contain the following, as a minimum:

- Task number, date performed, and signature of person who performed the calculation
- Purpose for calculation
- Assumptions made or inherent in calculation
- Reference (including page, where applicable) for each piece of input data (e.g., standard notebook, telephone memorandum, technical paper)
- Method used for calculations
- Results (underlined)

Calculations shall be reviewed by an independent engineer or scientist of professional level equal to or higher than that of the originator. After completing the check, the reviewer shall sign his or her name and the date immediately below that of the originator on the calculations. Both the originator and reviewer are responsible for the completeness and accuracy of the calculations and must initial any corrections or changes. This process certifies that the methodology or computer program is as expected.

### 3.9.2 Data Assessments

Field and laboratory data are assessed by reviewing field and laboratory data reports and identifying anomalous data. Any anomalous data will be flagged by K-H ASD as invalid. Analytical data will be assessed in two ways: (1) validity and (2) usability. Data validity and usability are closely related and may be assessed as:

- V** Valid; usable for all purposes
- A** Acceptable with qualifications; usable for most purposes
- R** Rejected; unusable for most purposes

The quality, validity, and appropriate use of environmental measurement data collected for this project will be determined prior to use by the Data Users.

### 3.9.3 Data Validation and Usability Classification

The acceptance and review criteria for validation standards are specified by K-H ASD and in the applicable GRs.

The following three levels of data usability are utilized for the Closure Projects and ER Programs at the Site.

- a. Data is usable for all purposes if all of the following criteria are met:
  - Data quality is classified as valid
  - All data quality objectives are achieved
  - All specific agreements and/or regulatory requirements are met
- b. Data is considered usable for some purposes if any of the following conditions occur:
  - Data quality is classified as valid or acceptable with qualifications (rejected data may be usable for some very limited purposes such as screening)
  - Not all data quality objectives are achieved
  - Not all specific program requirements are not met
- c. Data may be unusable if any or all of the following conditions are met:
  - Data quality is classified as rejected
  - Data quality objectives are not achieved
  - Specific program requirements not met

### **3.10 Peer Reviews**

When ER activities involve state-of-the art or untried technologies, peer reviews of data, reports, conceptual designs, etc. shall be performed. A peer review team will be appointed by the appropriate project manager(s). The peer review team shall consist of independent qualified experts. The appropriate project manager shall document the review and approval of the team members' credentials, including verification of education and experience. Peer reviews shall be documented and prepared by the project manager. During the peer review, all review comments shall be documented, as well as the resolution of all comments. Dissenting opinions that cannot be resolved shall also be clearly indicated.

The original document submitted for peer review comments and resulting changes to the documents shall be included in the document package and forwarded to the QA records management system.

### **3.11 Design Records**

Design documentation for scientific investigations, analyses, and preparation of reports, including the design bases, input documents, references, design decision documentation shall be considered QA Records and controlled in accordance with the RMRS QAPD. The design documentation includes, but is not limited to, memoranda, analyses, drawings, specifications, as-built drawings and records, other design output documents, evidence of design verification/evaluation, qualification records of reviewers, and documents confirming interface control, and all approved changes.

## **II SOFTWARE QUALITY ASSURANCE**

### **1 PURPOSE**

This section defines the requirements and methods for the control and documentation of computer software utilized for Closure Projects and ER Program activities.

### **2 APPLICABILITY**

This section applies to computer software used for Closure Projects and ER Program activities to produce or manipulate data that is reported to state or federal regulatory agencies. Specific details for the implementation of the requirements contained in this section are contained in Closure Projects and ER Department software control procedures. The extent that these requirements apply is related to the nature, complexity, and importance of the software application.

### **3 REQUIREMENTS**

Computer software will be developed, controlled, and maintained to reduce the likelihood of mistakes entering executable codes during development, modification, and operation, and to ensure that the end product satisfies the requirements of its intended application. Software shall be verified, validated, and documented consistent with the nature, complexity, and its' intended application.

#### **3.1 Software Development**

Software development shall be accomplished in a traceable, planned, and orderly manner. The number of phases and the relative emphasis placed on each phase of software development will depend on the nature and complexity of the software. Software development may be performed in a sequential or non-sequential manner.

##### **3.1.1 Requirements**

The requirements of the software regarding functionality, performance, design constraints, attributes, and external interfaces shall be specified, documented, and reviewed. These requirements shall define the response of the software to input data, and shall provide the detail and information necessary to design the software. The appropriate level of management as described in written procedures shall approve the requirements.

##### **3.1.2 Design**

During the design phase, the design will be developed, documented, reviewed, and approved. The design shall specify the overall structure (control and data flow), and the reduction of the overall structure into physical solutions (algorithms, equations, control logic, and data structures).

##### **3.1.3 Implementation**

During the implementation phase, the design shall be translated into a programming language, and the implemented software shall be analyzed to identify and correct errors. Implementation phase software verification activities shall consist of the examination of source code listings to assure adherence to internal coding standards and conventions.

### *3.1.4 Testing*

During the testing phase, the software code shall be evaluated by executing test cases. Failure to successfully execute the test cases shall be reviewed to determine if modifications of the requirements, design, implementation, or test plans and test cases are required. The code shall not be used until the cause is found and resolved.

Testing phase activities shall consist of the validation of the code to assure adherence to the requirements, and to assure that the software produces correct results for the test cases. To evaluate technical adequacy, the software test case results can be compared to results from alternative methods, such as:

- Analysis without computer assistance
- Other validated computer programs
- Experiments and tests
- Standard problems with known solutions
- Confirmed published data and correlations

### *3.1.5 Installation and Checkout*

During the installation and checkout phase, the software becomes part of a system incorporating applicable software components, hardware and data. The process of integrating the software with applicable components may consist of installing hardware, installing the program, and verifying that all components have been included. Installation and checkout phase software verification and validation activities shall consist of execution of tests for installation and integration, and documentation of the approval of the software for operational use.

## **3.2 Commercial Software**

Where commercial "off-the-shelf" software is used (including computer code available in the public domain) it shall be placed under the configuration controls required by this section prior to use. Available documentation from the software supplier shall be obtained in order to evaluate the adequacy of the software. Examples of this type of software include mathematical/numerical data reduction software, models, data management software, computer language compilers, etc. Source code is generally not available and controls are limited to unique version identification and user-related manuals for such software. Documented validation is required to demonstrate that the software performs its stated and intended capabilities and functions.

## **3.3 Acquired Software**

"Acquired Software" is non-commercial software acquired from organizations outside the ER and Closure Projects Departments. Software that has not been developed or originated by the RMRS and is not commercially available requires documented validation to demonstrate that the software performs its stated and intended capabilities and functions. Closure Projects and ER Departments or subcontractor personnel shall test the software in accordance with written test plans to validate the software. The specific form of the test plan is selected by the tester and must identify the software options to be tested; the data to be used as input, the expected results, and the acceptance criteria.

### ***3.4 Software Verification and Model Validation***

The results of software verification and model validation activities shall be documented. Personnel other than those who designed the software shall perform software verification and model validation.

Software verification activities shall ensure that the software adequately and correctly performs all intended functions, and that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system.

Software verification and validation activities shall be planned and performed for each system configuration, which may impact the software.

Software verification shall be performed during the software development to ensure that the products of a given cycle phase fulfill the requirements of the previous phase or phases.

#### ***3.4.1 Software Validation***

Computer models shall be validated. Model validation activities shall be performed to demonstrate that models, as embodied in computer software, are correct representations of the process or system for which they are intended. Model validation demonstrations are commonly achieved by comparing data produced by the model with data taken from the real world process or system. The latter data might be laboratory experimental data, field experimental data, raw field observations, or in-situ testing data. Specific sets of data used in the validation process shall be identified and justification shall be made for their use.

When data are not available from the sources mentioned above, alternative approaches that are used shall be documented. Alternative approaches may include peer review and comparisons with the results of similar analysis performed with other validated models and verified software.

The results of model validation shall be documented as QA Records.

### ***3.5 Software Configuration Control***

#### ***3.5.1 Configuration Identification***

A configuration baseline shall be defined at the completion of the software development. Approved changes created at a later date shall be added to the baseline. A baseline shall define the most recent approved software configuration.

#### ***3.5.2 Configuration Change Control***

Changes to software shall be formally documented. This documentation shall contain a description of the change, the rationale for the change, and the identification of affected baselines. The change shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes. Only authorized changes shall be made to software baselines.

### ***3.6 Software Documentation***

Software documentation shall be maintained as a QA record per the RMRS QAPD. Documentation shall include:

- Software requirements
- Software design documentation
- Software change documentation
- Description of mathematical models and numerical methods
- Software verification documents
- Model validation documentation
- Software configuration management documentation
- User's instructions or manual

### **3.7 *Software Application Control***

Application control (the control of how an application is run) shall be implemented for software runs performed to generate or process data to develop conclusions that are to be reported to regulatory agencies. The requirements for software application control will be contained in written procedures, which will be developed by the end function responsible for performing the analysis prior to the application's use. The intent is to assure that configuration-managed software is applied under the conditions specified in verification and validation documents.

### **3.8 *Software Security***

Access to computer software and computer-based data shall be controlled to prevent possible inadvertent or malicious misuse, modification, or disclosure.

### **3.9 *Software Deficiencies***

Deficiencies in software shall be documented on the NCR and dispositioned in accordance with the RMRS QAPD. Software users will be notified of deficiencies found in software so they may determine any impact on previously reported results or conclusions.

### **3.10 *Quality Assurance Records***

The documentation requirements identified in this section and any referenced software control procedures constitute QA Records and shall be maintained in accordance with the requirements identified in the RMRS QAPD.

The project specific QAPs shall specify the applicable QA Records to be maintained in accordance with the requirements identified in the RMRS QAPD.

### III MEASURING AND TEST EQUIPMENT (M&TE)

#### 1 PURPOSE

This section implements the operational practices to comply with the requirements and policies of *MAN-092-M&TEM, Measuring and Test Equipment Manual*, for the control of Measuring and Test Equipment used in Closure Projects and ER activities. The controls for analytical laboratory equipment are determined by K-H ASD.

#### 2 APPLICABILITY

The requirements are applicable to the RMRS Closure Projects and ER programs and subcontractors who perform work at the Site and whose activities involve the use of measuring and test equipment.

#### 3 REQUIREMENTS

##### 3.1 Selection

An all-inclusive system is used for the calibration and maintenance of M&TE and measurement standards. The system provides for such items to be of proper type, range, accuracy, and tolerances to accomplish the function of determining conformance to specified requirements. M&TE and measurement standards are calibrated and utilized in an environment controlled to the extent necessary to assure continued measurements of required accuracy, giving due consideration to temperature, humidity, vibration, cleanliness, and other controlled factors.

The application requirements of the M&TE and measurement standards determine the selection of the type of M&TE to be used. M&TE to be used for the determination of each major measurement parameter shall be selected such that the accuracy and precision of the M&TE meets or exceeds the accuracy and precision requirements for the parameter being measured.

##### 3.2 Identification

M&TE are uniquely identified both on the specific item and in accompanying records. This is accomplished by physically marking the equipment with the unique identifier status tag, color code, and/or calibration sticker that includes the M&TE unique identifier, calibration, and calibration due date. The identifier is recorded on the data sheet, log book page, etc., along with the data recorded when using the item. This will be supplied by the Site Metrology services for traceability.

##### 3.3 Calibration

M&TE is calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid and traceable relationships to nationally recognized standards such as National Institute of Standards and Technology (NIST). When nationally recognized standards do not exist, the basis for calibration is documented.

Measurements standards used in the calibration system are supported by certificates, reports, or data sheets attesting to the description or identification of the item; the calibration source; date calibration; calibration assigned value; statement of uncertainty; and environmental or other conditions under which the calibration results were obtained.

The standardization/calibration of in-situ monitoring equipment and field test probes and kits will be completed according to manufacturers specifications, and at frequencies specified in SAPs or for field M&TE. Photoionization detectors (PIDs), flame ionization detectors (FIDs), and gas chromatographs (GCs), will be used for field gas sampling. The calibration, use, and maintenance of the PIDs, FIDs, and GCs is dependent on the specific type of instrument being used and is performed according to the manufacturers instructions.

A calibration log shall be maintained for field instruments and all calibrations shall be documented in the log sheet. Calibration stickers may also be used to indicate calibration status. M&TE calibration documentation includes the following information as a minimum:

- Unique identification of the M&TE (e.g., serial # 12345)
- Description of the item (e.g., Digital Multimeter, model #xyz)
- Frequency of Calibration (e.g., every year)
- Date of last calibration
- Date of next calibration
- Traceability information (e.g., Traceability to NIST voltage standard ser.# 295123, traceable to ASTM standard methodology for Sulfur Dioxide spike samples ASTM-6543-1976)
- Calibration procedure (e.g., SOP#CP-999Z-Rev.1, Fluke Multimeter calibration procedure for model 999X, dated 7/4/90)
- Preventative Maintenance Schedule (e.g., and major preventative maintenance may be concurrent with calibration schedule)

### **3.4 Calibration Procedures**

Written procedures are utilized for the calibration of all M&TE and measurement standards. The calibration procedures for M&TE required for the implementation of a SOP are described in the procedure section of the particular procedure. Calibration procedures described in the SOPs specify the measurement standards and equipment to be used; the required parameter, range, and accuracy of the measurement standard; and the acceptable tolerance of each instrument characteristics being calibrated. At a minimum each calibration procedure includes the following:

- Reference EPA-approved or other validated, standard method
- Specific acceptance criteria for all calibration measurements
- description of non-standard or modified methods and references to support these methods
- Description of calibration frequency
- List of any critical spare parts that may be required for calibration purposes

### **3.5 Preventative Maintenance Procedures and Schedules**

Preventative maintenance for M&TE is implemented according to manufacturer's instructions, or according to specific requirements stated within the Procedures section of a particular SOP.



A tracking system is utilized to provide a maintenance schedule of M&TE and measurement standards to assure timely maintenance, thereby precluding use of an instrument beyond its maintenance due date. Prior to use of M&TE, personnel verify that the maintenance due date has not expired. If the maintenance due date has expired, the item shall be tagged and segregated if possible, and a Non-conformance report prepared.

### **3.6 Nonconformances**

If any M&TE or measurement standard is found to be significantly out-of-tolerance during the calibration process, the calibration system shall provide for the notification to the respective user and the QA organization of the out-of-tolerance condition with associated measurement data so that the appropriate action can be taken.

### **3.7 Handling and Storage**

Proper protection, handling, storage, and environmental conditions are maintained for M&TE. The effects of environmental or other factors of an item's uncertainty are considered when calibration specifications are established and appropriate protection measures taken. Limitations on the handling, use, and storage of items are defined in the applicable calibration test, and item-specified M&TE implementing procedures.

### **3.8 Commercial Devices**

Calibration and control measures are not required, for example, with rulers, tape measures, levels, and other such devices, when normal commercial equipment provides adequate accuracy.

### **3.9 Quality Assurance Records**

Documents generated as a result of control, use, or calibration of M&TE are considered to be QA Records, and are maintained in accordance with the RMRS QAPD. Records documenting the schedules and procedures to maintain accuracy of M&TE and measurement standards include individual calibration records or other means of control for each item. Such records shall provide a description or identification of the item, calibration interval, date calibrated, identification of the calibration source, calibration procedure used, calibration results, and calibration actions taken. In addition, the individual record of any item whose accuracy must be reported via a calibration certificate or report shall state the certificate or report number.

