

Rocky Flats Environmental Technology Site

MAN-131-QAPM

REVISION 2

QUALITY ASSURANCE PROGRAM MANUAL

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1. PURPOSE

This Manual delineates the requirements for the Rocky Flats Environmental Technology Site (Site) Quality Assurance Program (QAP) This Manual is the implementing document for Kaiser-Hill (K-H) Quality Assurance Policy at the Site

2. SCOPE

This Manual provides a road map for organizations, management, and stakeholders to help them understand how Quality Assurance (QA) requirements are implemented This is a complete revision to and supersedes previous QAP Manual revisions

This Manual describes the responsibilities for implementing the requirements of 10 CFR 830 122 for nuclear facilities and activities, and Department of Energy (DOE) Order 414 1A for non-nuclear facilities, activities, and services It is applicable to all work on Site

The requirements associated with QAP criteria are applicable to Site areas, structures, systems, components, services, projects, programs and activities These activities include design, construction, operation, maintenance, deactivation, decontamination and decommissioning, waste packaging and oversight, and environmental restoration of nuclear and non-nuclear facilities

QAP criteria provide the standards to balance the performance based and prescriptive processes, and meet all Closure Contract commitments, and customer requirements and expectations This includes fundamental processes for the systematic identification of quality problems and the implementation of corrective actions in a safe, effective, and efficient manner while providing prudent corporate management of the liabilities inherent in hazard reduction associated with Site stabilization and cleanup

3. REQUIREMENTS DOCUMENTS

This Manual has been developed as required by 10 CFR 830 122 and DOE Order 414 1A DOE Order 414 1A and 10 CFR 830 122 specify basic requirements that apply to the QAP For Site activities where Transuranic (TRU) waste will be characterized, packaged or shipped, the DOE Carlsbad Area Office (CAO) QAP Document and the Waste Isolation Pilot Plant (WIPP) RCRA Part B Permit **SHALL**¹ apply The Nevada Test Site (NTS) Waste Acceptance Criteria (WAC) **SHALL**² apply for those activities where Low Level Waste (LLW) is characterized, certified, packaged, or shipped

Since 10 CFR 830 122 and DOE Order 414 1A include similar criteria, K-H has incorporated the requirements into a single program document The primary distinction between the two requirements is enforceability and applicability From the perspective of applicability and enforceability, 10 CFR 830 122 applies to nuclear facilities and nuclear activities (activities with the potential to cause radiological harm), and DOE Order 414 1A applies to non-nuclear facilities, activities, and services The single substantive difference in wording (Work Processes, Criterion 5 of 10 CFR 830 122 concerning hazard controls) was specifically noted in the Response to Comments discussion promulgated as part of the issuance of 10 CFR 830 122 not to apply to nonnuclear facilities and activities

The Closure Contract contains a list of these and other DOE Directives applicable to QA QA requirements are identified in Section 6

A hierarchy of documents was selected to determine applicable requirements, place a relative level of importance on selected documents, and resolve conflicts between documents QA criteria from 10 CFR 830 122 and DOE Order 414 1A were

incorporated. The remaining applicable documents were reviewed and appropriate sections selected that included the requirements and criteria of 10 CFR 830.122 and DOE Order 414.1A. Several documents that were applicable but not used contain information that is redundant, or not as clear as, other sources. Selected documents/sections are listed in Section 9, Shall Statement Index.

In addition, DOE CAO Quality Program requirements that are applicable to Site activities, where the TRU waste will be characterized, packaged or shipped, are specified in DOE CAO QAP Document, CAO-94-1012, and the WIPP RCRA Part B Permit (Permit) issued by the State of New Mexico. Site implementation of these requirements is specified in the TRU Waste Management Manual, and the RFETS TRU Waste Characterization Program Quality Assurance Project Plan.

Appropriate requirements from these documents **SHALL**³ be incorporated into subcontractor Quality Assurance Program Plans (QAPPs). K-H is responsible for communicating to its subcontractors the performance requirements of, and the need to comply with, the Permit and CAO-94-1012. In addition K-H is responsible for the verification of compliance with these requirements.

NTS Quality Program requirements that apply to Site activities where LLW is characterized, certified, and packaged or shipped are specified in the NTS-WAC. The Site implements the NTS-WAC, including NTS QA requirements, in the Low Level/Low Level Mixed Waste Management Plan (LLWMP). Operations that process LLW must comply with the requirements and procedures identified in this QAP and the LLWMP.

Environmental Remediation activities must consider environmental quality and data quality requirements in planning and execution. Several provided references contain necessary information for this process.

4. OVERVIEW

The Site Quality Management System is most effectively accomplished by achieving the proper balance between the functions of management, performance and assessment. The importance of these three functions is recognized in the 10 criteria from both 10 CFR 830.122 and DOE Order 414.1A. Management includes those things done to plan and prepare to accomplish work. Management is governed by Quality Criteria 1, 2, 3 and 4. Performance includes those things done to control the quality of work being accomplished. Performance is governed by Criteria 5, 6, 7 and 8. Assessment includes those things done to assess how well the work is being accomplished. Assessment is governed by Criteria 9 and 10.

4.1 SITE QUALITY MANAGEMENT SYSTEM

The Site Quality Management System is applied to the Site through the use of a "graded approach." The "graded approach", ensures that the level of analysis, documentation, verification and other controls necessary to comply with requirements are sufficient to provide safety and quality commensurate with the

- Relative importance/risk to safety, safeguards, and security,
- Magnitude of any hazard involved,
- Life-cycle stage of the facility,
- Programmatic mission of the facility,
- Particular characteristics of the facility,
- The relative importance of radiological and nonradiological hazards, and
- Any other relevant factor

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

- The graded approach **cannot** be used to avoid compliance with Federal, State, and local regulations,
- Site facilities and activities are graded as either nuclear or non-nuclear facilities or activities (such grading may be revised for any given facility based on its place in the lifecycle transition from nuclear facility to an industrial classification),
- The Program Owner organization, because it has detailed knowledge of processes, items, activities, and programs, uses best judgment in determining the level of requirement implementation, administrative controls, and business and safety 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

This approach provides the flexibility to implement the programs in a way that best suits the facility or activity, while maintaining full compliance with the 10 CFR 830 122 and DOE Order 414 1A. This is important because the facilities at the Site are identified as Hazard Category 2 or 3 nuclear facilities, radiological facilities, or other facilities (There are no Hazard Category 1 nuclear facilities at the Site)

Consistent with DOE-STD-1082-94, the K-H organization responsible for a nuclear safety requirement has been empowered to use best judgement in the determination of the appropriate graded approach to be used to achieve full implementation of the requirement. This judgment is based on detailed knowledge of the specific requirements, features, resources, needs, goals, and interface with other organizations and facilities

Additionally, procedures and other documents that implement Site infrastructure programs with direct impact on work and work processes receive technical and (if required by Site criteria) independent review under the existing Site infrastructure. This review utilizes an interdisciplinary technical evaluation process to evaluate technical, compliance, and safety issues. This process as a whole validates the grading and application of QA requirements

The quality program as described and executed in Site infrastructure documents integrates the Safety Management System for the. Most significant among these for this purpose are the Integrated Safety Management Manual (MAN-016-ISM) and the Integrated Work Control Process Manual (MAN-071-IWCP). This integration fulfills the expectation of 10 CFR 830 121 c (2)

4.2 EXEMPTIONS

Directives that are required by law or contract are mandatory unless an agency having proper regulatory authority has granted a temporary or permanent exemption from that requirement. Criteria for granting an exemption to a DOE nuclear safety requirement are specified in 10 CFR 820 62 and are incorporated here by reference

5. RESPONSIBILITIES

Quality Assurance is a shared interdisciplinary function. It involves management and individual contributors of all organizations responsible for producing items, performing activities and services, and independently verifying that items, activities, and services comply with specified standards and requirements

Each individual is responsible for the quality of their work, for reducing costs, for identifying nonconforming items, and for complying with requirements and procedures

Individuals, who are responsible for producing an item or performing an activity, and their immediate management, have direct and final responsibility for the quality of the item, activity, or service. They are responsible for reviewing item reliability, process implementation, and other quality-related information and analyzing data to identify items and processes needing improvement.

Individuals or organizations assigned responsibility for the quality function and for verifying that activities affecting quality have been correctly performed have sufficient authority, access to work areas, and organizational freedom to

- Identify quality problems and initiate, recommend, or provide solutions to resolve identified problems,
- Verify implementation of solutions,
- Verify that nonconforming conditions are dispositioned in accordance with approved procedures,
- Have direct access to the levels of management required to resolve identified problems

5.1 PRESIDENT, KAISER-HILL COMPANY, LLC

- Approves overall policy and management direction for the QAP
- Approves allocation of resources to implement QA requirements

5.2 K-H VICE PRESIDENTS AND PROJECT MANAGERS

- Provide necessary resources for their organizations to implement the QA requirements, as applicable
- Incorporate applicable QA requirements into documents that govern work, activities, and the procurement of items and services
- Communicate applicable QA requirements to subcontractors
- Provide integration, coordination, and oversight (self assessments and performance oversight) of activities under their purview
- Stop work when appropriate
- Ensure effective implementation of the QAP for assigned activities, including continuous improvement
- Assess the implementation of the Site QAP for assigned activities through effective self assessment
- Correct identified quality problems in a timely manner
- Provide the direction and assume the responsibility for the QA Program implementation, assessment, and improvement for assigned areas
- Establish and cultivate principles that integrate Quality requirements into daily work and demonstrate commitment and leadership to achieve Quality through active involvement in implementation of the QAP

5.3 VICE PRESIDENT & DIRECTOR, K-H, SAFETY, ENGINEERING, & QUALITY PROGRAMS

- Same responsibilities as in 5.2
- Establishes direction and guidance for defining, implementing, and maintaining the Site Design and Quality Assurance infrastructures
- Resolves QA-related problems not resolved at lower or peer organization level
- Establishes direction and guidance for defining, implementing, and maintaining the Site Corrective Action Process, the Management Assessment Program, the Independent Assessment Program, and the Readiness Determination Process

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5.4 DELETED

5.5 MANAGER, K-H QUALITY PROGRAM

- Identifies, documents, and maintains the QA requirements
- Develops, coordinates, approves, and maintains the QAPM and assigned implementing documents
- Serves as the Site interface with the DOE, RFFO Quality organization on quality-related matters
- Reviews Site performance indicators, trend reports, assessment and audit reports, deficiency reports, quality problems and issues, and corrective actions, as appropriate
- Advises senior management regarding actual and potential issues related to Quality that **may** affect the Site's ability to accomplish its mission or that **may** impact workers, the public or the environment
- Establishes, in coordination with the responsible implementing organizations, controls to ensure that conditions not in compliance with QA requirements are identified and promptly corrected
- Provides assistance, indoctrination, and training in QA practices, procedures, and regulations
- Evaluates the implementation of the Site QAP
- Stops work when appropriate
- Manages the Site Corrective Action Program
- Facilitates/leads the evaluation and resolution of sitewide quality issues or quality issues that cross project boundaries
- Provides an interface/avenue for project QA functions to communicate with senior management for issues that cannot be resolved within project boundaries

5.6 MANAGER, K-H ASSESSMENT

- Maintains readiness determination manuals and documents
- Sponsors an annual QA program implementation audit of the TRU and LLW programs
- Performs independent assessments of Site projects and infrastructure programs, including 10 CFR 835 triennial and annual Material Control and Accountability assessments
- Develops and maintains the integrated independent assessment schedule
- Performs independent readiness determinations of new starts and restarts of nuclear activities
- Performs independent oversight for each of the Projects

5.7 INDIVIDUAL MANAGERS AND SUBCONTRACTORS

- Provide resources to implement applicable Site QA requirements
- Implement Site infrastructure programs and procedures

- Communicate QA requirements to subcontractors
- Assure that appropriate quality assurance requirements are included in procurements under their purview
- Provide oversight of work performed by subcontractors in their area of responsibility
- Perform management assessments of their respective quality-related activities and reports results to management
- Track and provide timely corrective action for identified quality problems
- Stop work when appropriate
- Review quality data to determine measures to strengthen performance
- Facilitate the resolution of quality-related problems
- Correct identified quality problems in a timely manner

5.8 TRU WASTE CHARACTERIZATION PROGRAM SITE PROJECT QUALITY ASSURANCE OFFICER

- Develops, reviews, approves, issues, and maintains the Site QAP/P
- Provides day-to-day guidance on quality-related matters, as necessary, to Project staff
- Identifies and reports quality problems to the TRU Waste Project Manager, and initiates, recommends, and tracks corrective actions to closure, verifies completion of corrective actions
- Reviews and verifies that data packages are complete, including data QA documentation
- Ensures review and approval of disposition of project non-conformances
- Stops WIPP-related work if required
- Tracks and trends WIPP-related Non-Conformance Reports
- Performs surveillances for compliance with the TRU Waste Program
- Reviews the QAP and the subcontractor company-specific QAPPs to assure that these documents are consistent with the TRU Waste Program

5.9 LLW WASTE QUALITY OFFICER

- Reviews, approves, and maintains the QA requirements in the Site LLW Management Manual
- Coordinates quality activities with the Waste Certification Official
- Provides day-to-day guidance on Quality-related matters
- Identifies and reports quality problems to the LLW/LLMW Project Manager, and initiates, recommends, and tracks corrective actions to closure
- Reviews and verifies that data packages are complete
- Reviews the disposition of project non-conformances
- Tracks and trends Non-Conformance Reports

5.10 PROJECT QUALITY ASSURANCE LEADS

- Identify and monitor the implementation of Site QA requirements within assigned projects, document implementation via surveillances, assessments, or other methods
- Provide quality assurance and quality engineering support to the Project Manager

- Serve as the project interface with the K-H Quality Program
- Coordinate with the Manager, K-H Quality Program, resolution of quality issues that cannot be resolved within assigned projects
- Provide assistance, indoctrination, and training in QA practices and procedures at the project level
- Conduct assessments and surveillances of quality-affecting activities at the project level

5.11 PROCUREMENT ENGINEERING AND QUALITY ASSURANCE

- Support implementing quality program requirements in the Site procurement process
- Manage the execution of Procurement Quality Assurance responsibilities as defined in following bullets
- Evaluate suppliers for appropriate development and execution of quality assurance programmatic elements
- Maintain the Site Evaluated Subcontractors List
- Investigate supplier issues, track and trend supplier performance
- Maintain the Site implementation of DOE required procurement programs (Suspect/Counterfeit Items)
- Represent the Site to the DOE contractors' Supplier Quality Information Group

5 12 CERTIFICATION AND INSPECTION

- Conduct required source and receipt inspections on items to verify that items meet applicable requirements and specifications
- Certify that waste packagings meet applicable requirements and specifications
- Maintain inspection records for required items

6. SITE QUALITY ASSURANCE PROGRAM REQUIREMENTS

This Section establishes the QAP requirements for the Site. The Program incorporates requirements from several sources, including 10 CFR 830 122 (See Section 3). Activities with the potential to cause radiological harm are subject to 10 CFR 830 122 and are subject to compliance enforcement under 10 CFR 820. Environmental activities follow the requirements of ANSI/ASQC E4-1994. Analytical Laboratory activities will follow 10 CFR 830 122, DOE Order 414 1A, and consensus standards as stipulated in the Laboratory QAP. Special Nuclear Material (SNM) Packaging and Site Transportation will follow the requirements of 10 CFR 830 122 and 10 CFR 71 Subpart H.

The Waste Analysis Plan (WAP) in the WIPP Hazardous Waste Permit and the CAO Quality Assurance Program Document (QAPD) establish QA program requirements for all programs, projects, and activities sponsored by the CAO. The CAO, and organizations supporting the CAO, **SHALL**⁴ implement the applicable requirements of the WAP and CAO QAPD (CAO-94-1012). They apply to all Site contractors performing activities supporting characterization, certification and transportation of radioactive waste to WIPP. The WAP and CAO QAPD supplement QA criteria in the definition of QAP requirements.

The NTS WAC Document provides the requirements, terms and conditions under which the NTS will accept low-level radioactive waste for disposal. QA requirements for these wastes will follow the NTS WAC Document. Specific NTS requirements are reflected in the LLW Management Plan.

It is the responsibility of K-H and each subcontractor to consider the subset of all requirements that are applicable to their specific mission and to invoke such requirements through project-specific implementing procedures.

K-H and each subcontractor **SHALL**⁵ implement both "General Requirements," and "Specific Additional Requirements" from each of the 10 criteria of Section 6 as they apply to their activities. K-H and subcontractors **SHALL**⁶ comply with all applicable requirements from 10 CFR 820 and 10 CFR 830 122. All requirements applicable to a specific activity **SHALL**⁷ be applied in a graded approach commensurate with

- Relative importance/risk to safety, safeguards, and security,
- Magnitude of any hazard involved,
- Life-cycle stage of the facility,
- Programmatic mission of the facility,
- Particular characteristics of the facility,
- The relative importance of radiological and nonradiological hazards, and
- Any other relevant factor

The basis for the graded approach used **SHALL** be documented, generally in the documents that define the program.

QAP Criteria are subdivided into elements based on the 10 QA criteria of 10 CFR 830 122 and DOE Order 414 1A. Within each of the 10 QA Criteria the following information is provided:

- **Requirements**, which are further subdivided into general requirements and specific additional requirements
- **Program Description**, which provides a summary level description of the actions taken to implement those requirements

- **Implementing Documents**, which lists the major program documents through which these requirements are implemented. A more detailed listing of documents is included in Appendix 2

6.1 MANAGEMENT

6.1.1 Criterion 1 – Program

6.1.1.1 Criterion 1 (Program) - General Requirements

REQUIREMENT SOURCE 10 CFR 830.122 (a)

"(1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work

(2) Establish management processes, including planning, scheduling, and providing resources for the work "

REQUIREMENT SOURCE DOE O 414.1A, Section 2.a.(1)

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

6.1.1.2 Criterion 1 (Program) - Specific Additional Requirements

RADIOACTIVE WASTE

REQUIREMENT SOURCE CAO-94-1012, Section 1.1.2.1

"Program participants **SHALL** develop and follow plans and procedures that effectively implement the requirements described within this QAPD along with those requirements contained within the RCRA Permit Waste Analysis Plan (WAP), Quality Assurance Project Plans, Certification QA Plans, Waste Acceptance Criteria (WAC), and TRUPACT-II Certification of Compliance, including TRUPACT-II Authorized Methods for Payload Control (TRAMPAC), as applicable "

6.1.1.3 Criterion 1 (Program) – Program Description

Actions to meet General Requirements

K-H Quality Program maintains the Site QA program and policy. The Site QA Manual and QAP are developed, implemented, maintained, and approved by K-H. The QAP is consistent with DOE Guide 830.120. It describes the responsibilities and principal documents implementing the QA requirements. These implementing documents or procedures have been developed to utilize a graded approach for implementing QA requirements and procedural instructions. Strategic planning has focused on reducing the risks and hazards in the various Site facilities in order to accomplish the most work possible within a reasonable time and within budget. Documents that govern the graded approach process are the QAPM, Site Document Requirements Manual (SDRM), and the IWCP Manual. The QAPM provides graded approach criteria, while the SDRM describes the controls to assure the criteria are considered when developing implementing procedures. The IWCP Manual integrates these procedures and identifies the controls to be applied when determining the prevention or mitigation of the consequences of hazards.

Line management implements the QAP. The quality organization shown in Appendix 3 reflects this implementation strategy. For each project a QA Lead provides QA support and functional expertise to the Project Manager.

Each subcontractor is required to work to these QA requirements. Individual subcontractors are required to implement the requirements of the K-H QAP. Where necessary, project or company-specific QAPPs may be generated. These QAPPs and changes thereto, **SHALL**⁸ be approved by the K-H Project responsible for the work, with concurrence from the KH Quality Program. Subcontractor QAPPs apply QAP requirements to their work. Alternative implementations of Site infrastructure requirements **SHALL**⁹ be identified in the QAPP.

Actions to meet Specific Additional Requirements

The Site **SHALL**¹⁰ adhere to a CAO QAPD that implements the requirements of regulatorily-mandated standards for

- Waste characterization activities and assumptions,
- Environmental monitoring, monitoring of the performance of the disposal system, and sampling and analysis activities,
- Computations, computer codes, models and methods used to demonstrate compliance with the disposal regulations in accordance with the provisions of this part,
- Design of the disposal system and actions taken to ensure compliance with design specifications,
- Collection of data and information used to support compliance application(s), and
- Other systems, structures, components, and activities important to the containment of waste in the disposal system

6.1.1.4 Criterion 1 (Program) - Implementing Documents

- Quality Assurance (QA) Policy
- Quality Assurance Program Manual
- Kaiser-Hill QA Program Procedures Binder
- 1-MAN-008-WM-001, TRU Waste Management Manual
- 95-QAPP-0050, Site Quality Assurance Program Project Plan

6.1.2 Criterion 2 – Personnel Training and Qualification

6.1.2.1 Criterion 2 (Personnel Training & Qualification) - General Requirements

REQUIREMENT SOURCE 10 CFR 830.122 (b)

- “(1) Train and qualify personnel to be capable of performing their assigned work
- (2) Provide continuing training to personnel to maintain their job proficiency”

REQUIREMENT SOURCE DOE O 414.1A Section 2.a.(2)

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

6.1.2.2 Criterion 2 (Personnel Training & Qualification) - Specific Additional Requirements

None

6.1.2.3 Criterion 2 (Personnel Training & Qualification) – Program Description

Actions to meet General Requirements

The K-H Training program provides the assurance that personnel are trained and qualified, including initial training designed to qualify and train personnel responsible for managing, developing, performing, and assessing work activities. Continuing training is

provided to ensure job proficiency is maintained

The qualification and training process is designed to enable management to determine and document job-specific and general training requirements for their employees. Training methods include formal training conducted by qualified instructors, briefings conducted by management-approved personnel, required readings, workshops, seminars, and awareness training. Implementation requirements and responsibilities for personnel training and qualification **SHALL**¹¹ be documented.

The training and qualification process is applied using a graded approach. Grading is determined using specific program requirements and executed by means that include Lists of Qualified Individuals and work package-required training verifications. Requirements for the indoctrination, training, and continuing training are commensurate with the scope, complexity, and nature of the assigned duties, or the activity, to be performed. The Site Training Implementation Matrix identifies the qualification and certification requirements by job designation for Site nuclear facilities. The TRU Waste Characterization Project Training Implementation Plan identifies the qualification and certification requirements by job designation for TRU waste related activities. Additionally, the Low-Level/Low-Level Mixed Waste Training Implementation Plan contains the project training requirements for LL/LLM Waste related activities.

Actions to meet Specific Additional Requirements

None

6.1.2.4 Criterion 2 (Personnel Training & Qualification)– Implementing Documents

- MAN-094-TPM, Training Program Manual
- Training Implementation Matrix
- PLN-97-007, TRU Waste Characterization Program Training Implementation Plan
- 94-RWP/EWQA-0014, Low Level/Low Level Mixed Waste Management Plan

6.1.3 Criterion 3 – Quality Improvement

6.1.3.1 Criterion 3 (Quality Improvement) - General Requirements

REQUIREMENT SOURCE 10 CFR 830.122 (c)

- "(1) Establish and implement processes to detect and prevent quality problems
- (2) Identify, control, and correct items, services, and processes that do not meet established requirements
- (3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem
- (4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement "

REQUIREMENT SOURCE DOE O 414.1A, Section 2.a.(3)

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

6.1.3.2 Criterion 3 (Quality Improvement) - Specific Additional Requirements

REQUIREMENT SOURCE Kaiser-Hill Quality Assurance Policy

6.1 3 3 Criterion 3 (Quality Improvement) - Program Description

Actions to meet General Requirements

Infrastructure programs have been established and implemented to detect, prevent, and correct quality-related problems

The Corrective Action Program at the Site includes various identification and reporting processes, each developed and implemented in order to satisfy specific laws, requirements, or regulations. Collectively, these processes implement the programmatic requirements for Quality Improvement. These processes are identified in Appendix 4. The Plant Action Tracking System is the default process for deficiencies that do not obviously belong within the scope of other processes.

Those items and activities that do not meet established criteria and/or predetermined quality requirements are identified, documented, analyzed, dispositioned, corrected, and selectively verified in accordance with the Site nonconforming items and/or corrective action process. Nonconforming items are controlled to prevent inadvertent installation, testing, or use. Based upon the importance to safety and the significance of the identified problem, causal factors are evaluated to establish the cause.

Significance determination is based on potential impact to operations, safety, security, reliability, performance, regulatory compliance, and the environment.

Self assessments provide a consistent approach for management to evaluate compliance with requirements and commitments, review effectiveness of established processes and previous corrective actions, identify and correct deficient conditions and work practices, and to implement needed improvements. Item characteristics, process implementation, and other quality-related information and data will be reviewed and the data analyzed to identify items, services, and processes needing improvement based upon a graded approach.

The Cause Analysis process is established to determine the root and contributing causes of events and conditions, and the associated corrective actions, that if implemented, will prevent or minimize the possibility of recurrence. The methodology for cause analysis is based on the significance of the issue.

The Site Lessons Learned Program, while not part of the corrective action process, is established to collect, evaluate, and distribute lessons learned from operating experience.

Potential generic implications for deficiencies are evaluated as a part of the overall corrective action process to prevent quality problems.

It is important that all deficient conditions and nonconforming items be identified, therefore deficiencies and nonconforming items must be identified and put into one (or more) of the processes making up the Site corrective action program. Items that do not conform to requirements are controlled to prevent inadvertent installation or use. Graded approach is built into the corrective action process by evaluating the significance of the item, based on safety and regulatory risk. The significance determines the tracking and cause analysis methodology. Based on significance and risk, item characteristics, process implementation and other quality related information for specific buildings or processes will be reviewed and data analyzed to identify items, services, and processes needing improvement.

Actions to meet Specific Additional Requirements

To ensure that WIPP-related deficiencies are appropriately identified and processed to meet CAO QAPD requirements, the following actions are required:

- All WIPP-related deficiencies, other than Waste Nonconformance Reports generated in accordance with PRO-U76-WC-4030, *Control of Waste Nonconformances*, must be identified and tracked in PATS

The TWCP PQAO will periodically review the PATS database to ensure that WIPP-related items are not inadvertently misidentified. The TWCP PQAO's qualifications and training are sufficient to make this determination.

6.1.3.4 Criterion 3 (Quality Improvement) - Implementing Documents

- 3-X31-CAP-001, Kaiser-Hill Corrective Action Process
- MAN-062-CAUSE ANALYSIS, Cause Analysis Requirements Manual

6.1.4 Criterion 4 – Documents and Records

6.1.4.1 Criterion 4 (Documents and Records) - General Requirements

REQUIREMENT SOURCE 10 CFR 830.122 (d)

"(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design

(2) Specify, prepare, review, approve, and maintain records "

REQUIREMENT SOURCE DOE O 414 1A, Section 2.a (4)

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

6.1.4.2 Criterion 4 (Documents and Records) - Specific Additional Requirements

None

6.1.4.3 Criterion 4 (Documents and Records) – Program Description

Actions to meet General Requirements

The SDRM provides the methodology and requirements for controlling and developing Site documents except for engineering documents controlled by 1-V51-COEM-DES-210 (Site Engineering Process Procedure). The SDRM documents include policies, management directives, manuals, procedures, instructions, and job aids. The SDRM and 1-V51-COEM-DES-210 identify the type, purpose, applicability, and approval requirements for the Site-applicable document types.

When a procedure is identified as the correct document type, then a graded approach is applied to specify the criteria and level of activity by which the applicable set of standards and requirements are met.

Subcontractors are responsible for assuring adherence to the Site Document Control and Records Management Program requirements through their company-specific QAPPs.

The Site Document Control Program is designed such that Site documents to prescribe processes, specify requirements, or establish design are prepared, reviewed, approved, issued, and controlled for use by personnel managing or performing work. Controlled documents are distributed to the user in a manner that ensures the use of the latest revision, ensure that obsolete and superseded documents are stamped, destroyed, or recalled to prevent their inadvertent use, ensure routine verification of controlled status, and the documents are maintained by indices.

The Records Management Program has been established to ensure that Site records providing evidence of quality are specified, prepared, reviewed, approved, authenticated, legible, transferred, collected, maintained, stored, retained to identified retention periods, and indexed for accountability and retrievability. Line Managers normally identify the scope of records to be retained within the procedure that generates the record. The Records Management organization provides assistance to Site organizations in the determination of records and appropriate retention schedules.

Computer hardware and software that are used to store, maintain, index, and access records are controlled to ensure records protection from loss or damage, and to ensure accountability and retrievability.

Actions to meet Specific Additional Requirements

None

6.1.4.4 Criterion 4 (Documents and Records) - Implementing Documents

- Document Control Program
PRO-1329-DM-03, Site Document Control
- Site Procedures Program
MAN-001-SDRM, Site Documents Requirements Manual
PRO-815-DM-01, Developing and Maintaining Documents
1-V51-COEM-DES-210, Site Engineering Process Procedure
Records Management Program
1-V41-RM-001, Records Management Manual
1-PRO-077-WIPP-005, Management of WIPP Information Prior to Transmittal to the Waste Records Center

6.2 PERFORMANCE

6.2.1 Criterion 5 – Work Processes

6.2.1.1 Criterion 5 (Work Processes) - General Requirements

REQUIREMENT SOURCE 10 CFR 830.122 (e)

"(1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means

(2) Identify and control items to ensure their proper use

(3) Maintain items to prevent their damage, loss, or deterioration

(4) Calibrate and maintain equipment used for process monitoring or data collection "

REQUIREMENT SOURCE DOE O 414.1A, Section 2.b.(1)

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

REQUIREMENT SOURCE DOE 440.1, Attachment II, Section 22

"Implement Suspect and Counterfeit Item (S/CI) controls as part of the contractor's Quality Assurance Program to the extent commensurate with the risks posed by the facility and ensure that the controls contribute to a hazard-free workplace "

6.2 1 2 Criterion 5 (Work Processes) - Specific Additional Requirements

None

6.2.1.3 Criterion 5 (Work Processes) - Program Description

Actions to meet General Requirements

Work processes and activities, including special processes, are performed in accordance with Site program documents and implementing procedures such as the IWCP manual, the SDRM and the SERM

Controls for work processes affecting quality are identified through the IWCP. The documents which implement the controls to do the work are defined through the SDRM, IWCP and COOP processes, which result in the establishment of instructions, procedures, drawings, training requirements, and other approved methods. Proceduralized infrastructure programs and process control systems have been established to assure standardized and consistent achievement of requirements, goals, and objectives.

Individual employees and line management are responsible for the achievement of quality. Line managers ensure that activities affecting quality are controlled by approved procedures or other appropriate means.

The extent of the controls applied to the work is commensurate with the scope, complexity, and risk associated with the assigned task. Corrective, preventive, and predictive maintenance will be accomplished for specific equipment based upon a graded approach. Not all items will be maintained to prevent damage and deterioration. Equipment used for monitoring or data collection is calibrated and maintained. Line management observes work performed, reviews work documentation, conducts management assessments, and ensures documentation and correction of deficiencies and nonconformances. Activities affecting quality are controlled through approved documents (e.g., procedures, work packages, subcontracts and task orders, activity control envelopes, design packages).

The Site M&TE Program provides controls to calibrate and maintain M&TE. The Metrology subcontractor provides administrative and technical expertise for Site calibration organizations. Metrology also develops requirements for the control of M&TE. Organizations that are responsible for the M&TE implement requirements for control. M&TE includes measuring and testing instruments, standards, reference materials, and auxiliary apparatus that are necessary to perform a measurement in the course of testing, inspection, or calibration.

Actions to meet Specific Additional Requirements

None

6 2 1.4 Criterion 5 (Work Processes) - Implementing Documents

A list of Site infrastructure documents implementing Site QA requirements is provided in Appendix 2. The following list represents the functional programs represented in Criterion 5.

NOTE. The Site TRU Waste Characterization Program, Quality Assurance Program Description Matrix (INS-246) is a separate document that provides a cross-walk of DOE CAO-94-1012 quality requirements to applicable Site documents. The

Low Level Waste Management Plan provides a delineation of Nevada Test Site QA requirements for waste acceptance with applicable Site documents

- Engineering Program
- Configuration Management Program
- Integrated Work Control Program
- Site Procedures Program
- Conduct of Operations Program
- Environmental Management Program
- Waste Management Program
- Testing, Surveillance, and Maintenance Management Program
- Radiological Protection Program
- Nuclear Safety Program
- Nuclear Material Control and Accountability Program
- Emergency Preparedness Program
- Nuclear Material Control and Accountability Program
- Emergency Preparedness Program
- Procurement Program
- Measuring and Test Equipment Program

6.2.2 Criterion 6 – Design

6.2.2.1 Criterion 6 (Design) - General Requirements

REQUIREMENT SOURCE 10 CFR 830.122 (f)

"(1) Design items and processes using sound engineering/scientific principles and appropriate standards

(2) Incorporate applicable requirements and design bases in design work and design changes

(3) Identify and control design interfaces

(4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work

(5) Verify or validate work before approval and implementation of the design "

REQUIREMENT SOURCE DOE O 414.1A, Section 2.b.(2)

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

6.2.2.2 Criterion 6 (Design) - Specific Additional Requirements

None

6.2.2.3 Criterion 6 (Design) – Program Description

Actions to meet General Requirements

K-H provides an engineering program and engineering oversight for the Site. Subcontractors perform design in accordance with their subcontracts and task orders that establish the QAP requirements. Design requirements upon which final design work is based include inputs such as existing design bases, performance requirements, regulatory requirements, codes, standards, environmental considerations, risk, and interfaces with new or existing structures and equipment.

The design program provides controls for design of items and processes using engineering/scientific principles and appropriate standards. Design work includes the identification of the AB and consideration of nuclear materials safety. Design work includes incorporation of applicable requirements and design bases, identification and control of design interfaces, and verification and validation of the adequacy of design products by individuals or groups other than those who performed the work. The verification and validation is completed before approval and implementation of the design. In this context, 'verification and validation' is taken as a single activity when executed within the Site design process.

Design control applies to items, facilities, and processes and is documented and implemented through procedures, design packages, and work packages. Computer hardware and software elements are treated as a unit for the purpose of configuration control.

Software management is controlled in accordance with the Computer Software Management Manual. Activities covered **SHALL**¹² include the entire period of time known as the hardware and software life cycle. Activities **SHALL**¹³ include conception, requirements document, acquisition, development, design, verification and validation, configuration management, testing, documentation, use or operation, maintenance and/or modification, and sometimes a retirement phase. Configuration accounting **SHALL**¹⁴ be documented and identify the approved configuration, status, proposed changes to the configuration, status of approved changes, and information to support the functions of the configuration identification, and configuration control.

The responsibility for ensuring software QA resides with the individual company or department that maintains the software. Specific activities and responsibilities for complying with these requirements are to be detailed in each individual company's software QA Compliance Procedure(s) or Software QA Plan(s).

Actions to meet Specific Additional Requirements

None

6.2.2.4 Criterion 6 (Design) – Implementing Documents

- 1-MAN-004-CSMM, Computer Software Management Manual
- 1-V51-COEM-DES-210, Site Engineering Process Procedure
- MAN-027-SERM, Site Engineering Requirements Manual
- 1-MAN-018-NSM, Nuclear Safety Manual

6.2.3 Criterion 7 – Procurement

6 2.3.1 Criterion 7 (Procurement) - General Requirements

REQUIREMENT SOURCE 10 CFR 830.122 (g)

"(1) Procure items and services that meet established requirements and perform as specified

(2) Evaluate and select prospective suppliers on the basis of specified criteria

(3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services "

REQUIREMENT SOURCE DOE O 414 1A, Section 2.b (3)

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

REQUIREMENT SOURCE DOE 440.1, Attachment II, Section 22

"Implement Suspect and Counterfeit Item (S/CI) controls as part of the contractor's Quality Assurance Program to the extent commensurate with the risks posed by the facility and ensure that the controls contribute to a hazard-free workplace "

6 2.3 2 Criterion 7 (Procurement) - Specific Additional Requirements

None

6 2 3.3 Criterion 7 (Procurement) – Program Description

Actions to meet General Requirements

K-H maintains a Procurement System for the acquisition of commodities, items, and services The Site procurement process provides a planned and controlled approach to procurement activities to ensure procured items and services conform to specified requirements Procurement documents contain the technical, quality, and acceptance requirements for the procurement of items and services The procurement process ensures that prospective suppliers are evaluated and selected on the basis of specified criteria

K-H may have specific contracts with subcontractors that identify their QA program requirements

The procurement process also contains controls for technical, quality, and acceptance requirements to flow down to suppliers and lower-tier contractors Included in this flow down are applicable Price-Anderson Amendments Act requirements K-H Procurement Quality Assurance (PQA) evaluates suppliers, maintains the Site Evaluated Subcontractors List, investigates supplier issues leading to resolution, and represents the Site to the DOE contractor's Supplier Quality Information Group

Procurement specifications for equipment, commodities, and services are developed in accordance MAN-134-PPM, Procurement Program Manual and PRO-1034-PEQA, Procurement Engineering and Quality Assurance, while procurement for items supporting engineering design packages are controlled in accordance with 1-V51-COEM-DES-210, Site Engineering Process Procedure The documents specify the application of technical and quality requirements to be included in the procurement specifications including product specifications and controls to preclude the procurement

of suspect/counterfeit material Procurement requisitions in support of work packages are initiated through the IWCP

K-H is responsible for evaluating suppliers' QA programs and maintaining the K-H Evaluated Subcontractors List in accordance with 1-J55-ADM-08 10 K-H Analytical Program Office is responsible for evaluating suppliers of analytical services K-H PQA is responsible for evaluating suppliers of commodities and services other than analytical services

Receipt inspection and certification activities for procured items are conducted to verify compliance with the procurement documents These activities include selected inspections, review of required documentation, selected testing, and ensuring the appropriate generation and closure of nonconformance documents

The Waste Requirements Group (WRG) functions as the subject matter expert for procurement of all waste commodities In this role, WRG ensures that related designs are reviewed by subject matter experts in the TRU and LLW Projects for conformance with WIPP, NTS and other waste repository site waste acceptance criteria They also ensure that commodities are used for the correct application depending on the type of waste The WRG coordinates with the Material Stewardship Quality Assurance organization to ensure that the appropriate quality requirements are incorporated into procurement documents

Actions to meet Specific Requirements

None

6.2.3.4 Criterion 7 (Procurement) – Implementing Documents

- Kaiser-Hill Company, L L C , Procurement Systems Volume I, II, and III
- MAN-134-PPM, Procurement Program Manual
- PRO-1034-PEQA, Procurement Engineering and Quality Assurance
- 1-V51-COEM-DES-210, Site Engineering Process Procedure

6 2 4 Criterion 8 – Inspection & Acceptance Testing

6.2.4.1 Criterion 8 (Inspection & Acceptance Testing) - General Requirements

REQUIREMENT SOURCE 10 CFR 830.122 (h)

"(1) Inspect and test specified items services and processes using established acceptance and performance criteria

(2) Calibrate and maintain equipment used for inspections and tests "

REQUIREMENT SOURCE DOE 440.1, Attachment II, Section 22

"Implement Suspect and Counterfeit Item (S/C) controls as part of the contractor's Quality Assurance Program to the extent commensurate with the risks posed by the facility and ensure that the controls contribute to a hazard-free workplace "

6 2 4 2 Criterion 8 (Inspection & Acceptance Testing) - Specific Additional Requirements

REQUIREMENT SOURCE ANSI/NCSL Z540-1-1994

The contents of ANSI/NCSL Z540-1-1994, Part I, General Requirements for the Competence of Calibration Laboratories, and Part II, Quality Assurance Requirements for Measuring and Test Equipment (M&TE), are established as requirements The associated handbook, which is an informational guide, is not included as requirements

6.2.4.3 Criterion 8 (Inspection & Acceptance Testing) – Program Description

Actions to meet General Requirements

Site infrastructure programs provide for inspection, testing, and calibration of specified items, services, and processes to demonstrate that items and processes perform as intended. Procedure 1-PRO-072-001 specifies inspection and test requirements applicable to the Site. The procedure provides a graded approach for determining when inspections and tests are required. Inspection, testing, and calibration are conducted using established acceptance and performance criteria. Equipment used for inspections and tests is calibrated and maintained. Inspections, testing, and calibration to verify conformance of an item to specified requirements and/or demonstrate satisfactory performance for service will be planned, documented, performed, and evaluated using a graded approach according to risk.

Controls are established and provide for documented methods to communicate the status of operations, equipment, and systems to affected personnel. The work package planning process specifies lockout and tag-out situations and utilizes methods to convey the status of pre-operational and post-maintenance activities to promote the safe operation of equipment and systems. A formal return to service process following successful post-maintenance testing is established.

The Site Metrology Program includes process, inline instruments as well as the standard Measuring and Test Equipment. Controls are provided so that inspection and acceptance testing, identified in the technical documents, are performed and documented as required and in accordance with procedures.

Actions to meet Specific Additional Requirements

Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality **SHALL**¹⁵ be controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits.

The content of ANSI/NCSL Z540-1-1994, Part I, General Requirements for the Competence of Calibration Laboratories, and Part II, Quality Assurance Requirements for M&TE, **SHALL**¹⁶ be considered requirements for this Program. The associated handbook, which is an informational guide, is not included as requirements.

6.2.4.4 Criterion 8 (Inspection & Acceptance Testing) – Implementing Documents

- 1-PRO-072-001, Inspection and Acceptance Testing Process
- MAN-027-SERM, Site Engineering Requirements Manual
- 1-V51-COEM-DES-210, Site Engineering Process Procedure
- Integrated Work Control Program
MAN-071-IWCP, Integrated Work Control Program Manual
- Control of Measuring and Test Equipment Program
MAN-092-M&TEM, Measuring and Test Equipment Management Manual
- Procurement Program
MAN-134-PPM, Procurement Program Manual
1-V51-COEM-DES-210, Site Engineering Process Procedure

6.3 ASSESSMENT

6.3.1 Criterion 9 – Management Assessment

6.3.1.1 Criterion 9 (Management Assessment) - General Requirements

- 1. REQUIREMENT SOURCE 10 CFR 830.122 (i)

Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives "

REQUIREMENT SOURCE DOE O 414.1A, Section 2.c.(1)

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

6.3.1.2 Criterion 9 (Management Assessment) - Specific Additional Requirements

None

6 3.1.3 Criterion 9 (Management Assessment) – Program Description

Actions to meet General Requirements

Management assessment places emphasis on the use of human and material resources to achieve Site goals and objectives Management assessments include an introspective evaluation to determine if the entire integrated management system effectively focuses on meeting Site and company goals Self-evaluations or self-assessments are a preferred form of management assessment Other forms of management assessment include, but are not limited to, critiques, reviews, walkdowns, and appraisals

K-H management retains the overall responsibility for management assessments Direct participation by managers is essential to assure that effective programs have been established and implemented Managers conduct assessments of their processes to identify problems that may prevent the organization from achieving its goals and objectives Problems detected by management assessments are documented and corrected in accordance with 3-X31-CAP-001

Actions to meet Specific Additional Requirements

None

6 3.1 4 Criterion 9 (Management Assessment) – Implementing Documents

- Management Assessment
3-W24-MA-002, Kaiser-Hill Management Assessment Program
PRO-1576-SAP-001, Self Assessment Program

6 3 2 Criterion 10 – Independent Assessment

6 3 2 1 Criterion 10 (Independent Assessment) - General Requirements

REQUIREMENT SOURCE 10 CFR 830.122 (j)

"(1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement

(2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments

(3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed "

REQUIREMENT SOURCE DOE O 414.1A, Section 2.c.(2)

"Independent assessments must 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 must have sufficient authority and freedom from the line to carry out its responsibilities Persons conducting

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independent assessments must be technically qualified and knowledgeable in the areas assessed "

6.3 2.2 Criterion 10 (Independent Assessment) - Specific Additional Requirements

None

6.3.2 3 Criterion 10 (Independent Assessment) – Program Description

Actions to meet General Requirements

K-H is responsible for establishing direction and guidance for the Independent Assessment Program and performing independent oversight and assessments within K-H and subcontractor organizations. Independent assessment activities are used to evaluate the performance of work processes with regard to requirements, expectations of the customer, and progress toward achieving the Site mission and goals. Independent assessment activities are conducted to assure the appropriate QA requirements are incorporated into Site work control processes and documents and are included in Site daily activities. Independent assessment activities evaluate program and floor level compliance with Site infrastructure programs and procedures. Independent assessment activities are documented and reports are provided to appropriate levels of management. Findings are used to evaluate effectiveness of the processes and identify needed improvements. Independent assessment concerns are tracked and follow-up actions taken to verify that corrective action is accomplished as scheduled in accordance with the 3-X31-CAP-001.

Those performing independent assessment activities **SHALL**¹⁷ have sufficient authority and freedom to carry out their responsibilities. Persons performing independent assessment activities are technically qualified, knowledgeable in the areas assessed, and do not have direct responsibility in the areas assessed.

DOE requires that all contractors and their subcontractors allow access to all facility areas for the purpose of conducting assessment activities. To enhance the performance and efficiency of assessments, all employees, to the level of their knowledge and authority, provide requested information and documentation during the assessment process. For effective communication and where corrective action is necessary, management of the assessed organization(s) **Should** participate in the assessment process.

Actions to meet Specific Additional Requirements

None

6.3 2 4 Criterion 10 (Independent Assessment) – Implementing Documents

- MAN-040-RDM, Readiness Determination Manual
- 3-B52-IA-003, Conduct of Independent Assessment Activities
- 1-W37-IA-002, Integrated Planning and Scheduling of Independent Assessment Activities
- 1-N92-ADM-02 03, Training Qualification and Certification of Independent Auditors and Assessors

7. RECORDS

7.1 DOCUMENTS DERIVED FROM THIS MANUAL

Other Site QA documents **SHALL**¹⁸ be consistent with the requirements of this Manual. In cases where this Manual provides sufficiently detailed information and direction, as concurred with by the K-H Quality Program Manager, procedures and instructions **may** incorporate such information by reference to this Manual.

7.2 MAINTENANCE OF THIS MANUAL

This manual serves as the vehicle for annual submission of the updated QA program to DOE

7.3 RECORDS PROCESSING

The records of this Program **SHALL**¹⁹ be identified, prepared, reserved, and preserved as quality records. In addition, any records that are "records which furnish documentary evidence of the quality of activities affecting quality" **SHALL**²⁰ be prepared, preserved, and maintained to meet the requirements of procedure 1-V41-RM-001. This **SHALL**²¹ be accomplished in compliance with this Manual and the QAPP recordkeeping requirements developed by each cognizant organization.

8. REFERENCES

Federal Regulations

10 CFR 71, *Packaging and Transportation of Radioactive Material, Subpart H, Quality Assurance*

10 CFR 820, *Procedural Rules for DOE Nuclear Activities*

10 CFR 830 122, *Quality Assurance Criteria*

10 CFR 830 3, *Definitions*

40 CFR 194, *Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations*

DOE Orders

DOE Order 1324 2, *Records Disposition (referenced within DOE Guide 830 120)*

DOE Order 414 1A, *Quality Assurance*

DOE Order 425 1A, *Startup and Restart of Nuclear Facilities*

DOE Order 440 1, *Worker Protection Management for DOE Federal and Contractor Employees*

DOE Order 5480 20A, *Personnel Selection, Qualification and Training Requirements for DOE Nuclear Facilities*

DOE Order 5480 23, *Safety Analysis Reports*

DOE Standards & Other DOE Documents

WIPP Hazardous Waste Permit US EPA No NM 4890139088

CAO-94-1012, Rev 3, *U S Department of Energy Carlsbad Area Office (CAO), Quality Assurance Program Document*

Defense Nuclear Facilities Safety Board (DNFSB) Recommendations 90-2 and 91-1

DOE Environment, Safety and Health Configuration Guide

DOE Guide 830 120, Rev 0, *Implementation Guide for Use with 10 CFR Part 830 120, Quality Assurance Requirements*

DOE Memorandum from Richard L. Black, dated June 6, 1997, re hazard categorization

DOE Office of the Assistance Secretary for Environment, Safety and Health, *Enforcement Manual*

DOE/AL 57XA, *Standards and Calibration Program*

DOE/NV-325, *Nevada Test Site Waste Acceptance Criteria*

DOE-STD-1027-92, *Guidance on Preliminary Hazardous Classification and Accident Analysis Technique for Compliance with DOE Order 5480 23, Safety Analysis Reports*

DOE-STD-1082-94, *Preparation, Review, and Approval of Implementation Plans for Nuclear Safety Requirements*

DOE-STD-3009-94, *Preparation Guide for USDOE Non-Reactor Nuclear Facility Safety Analysis Reports*

Industry Criteria and Guidance

ASME NQA-1-1989, *Quality Assurance Requirements for Nuclear Facility Applications.*

ASME NQA-3-1989, *Quality Assurance Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories*

ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*

ANSI/NCSL Z540-1-1994, *Calibration Laboratories and Measuring and Test Equipment - General Requirements*

ANSI/ASQC Z1 4-1993, *Sampling Procedures and Tables for Inspection by Attributes*

ASTM-C-1009-89, *Standard Guide for Establishing a Quality Assurance Program for Analytical Chemistry Laboratories Within the Nuclear Industry*

NFPA 232-1986 & NFPA 232AM-1986

SNT-TC-1A, *American Society of Nondestructive Testing (ASNT) Recommended Practice, and supplements*

Site Policy, Directives, and Implementing Documents

See Appendix 2

Rocky Flats Closure Contract

Rocky Flats Closure Contract between Kaiser-Hill Company, LLC and the United States Department of Energy, Contract No DE-AC34-00RFO1904

9. SHALL STATEMENT INDEX

"SHALL" statements within this Manual are accompanied by a superscripted number
This number corresponds below with a particular reference to a requirements document

- 1 DOE Carlsbad Area Office (CAO) Quality Assurance Program Document and WIPP Hazardous Waste Permit US EPA No NM 4890139088
- 2 Nevada Test Site Waste Acceptance Criteria
- 3 Best Management Practice
- 4 CAO RCRA Part B Permit and CAO QAPD (CAO-94-1012)
- 5 10 CFR 820, General Requirements and 10 CFR 830 122
- 6 10 CFR 820, General Requirements and 10 CFR 830 122
- 7 10 CFR 830 7
- 8 10 CFR 830 Part 121 (C) 4
- 9 10 CFR 830 Part 121 (C) 4
- 10 CAO RCRA Part B Permit and CAO QAPD (CAO-94-1012)
- 11 Kaiser-Hill Training Program Manual (MAN-094-TPM) and Training Implementation Matrix
- 12 Kaiser-Hill Computer Software Management Manual (1-MAN-004-CSMM)
- 13 Kaiser-Hill Computer Software Management Manual (1-MAN-004-CSMM)
- 14 Kaiser-Hill Configuration Change Control Program and Design Process Requirements (1-V51-COEM-DES-210)
- 15 10 CFR 830 Part 122 (g)
- 16 Kaiser-Hill Control of Measuring and Test Equipment Program (MAN-092-M&TEM)
- 17 10 CFR 830 Part 122 (i)
- 18 10 CFR 830 Part 121 (b)
- 19 Kaiser-Hill Site Documents Requirements Manual (MAN-001-SDRM)
- 20 Records Management Guidance for Records Sources (1-V41-RM-001)
- 21 Kaiser-Hill Site Documents Requirements Manual (MAN-001-SDRM)

APPENDIX 1
DEFINITIONS AND ACRONYMS
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1.1 **SHALL, Should, and May Statements**

The **SHALL** identifies those requirements that **SHALL** be considered mandatory. The word **Should** indicates a recommendation that is based on standards, and good safety and business practices. The word **may** indicates when permission is granted. It is neither a requirement nor a recommendation. **May** statements often provide a suggested or possible course of action. For emphasis, these terms are presented in boldface text throughout this Manual.

1.2 **Definitions**

Definitions apply to Site Quality Assurance Program (QAP) documents developed to formally institutionalize the QAP, and any subsequent documents associated with the QAP and its implementation. In cases of conflict between the definitions contained herein and as contained in other Site documents, the definitions contained herein take precedence where pertaining to quality and the QAP.

Some definitions given in this document contain more detail than is normally associated with "definition of terms". Additional guidance is purposefully provided to facilitate greater understanding of these terms, and associated concepts, among users and implementers of the QAP. The following documents may further illuminate the definitions provided here, they are provided for information.

- 1 10 CFR 830.122, *Quality Assurance Requirements*
- 2 DOE 414.1A, *Quality Assurance*
- 3 10 CFR 830.3, *Definitions*
- 4 ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*
- 5 ASME NQA-1, *Quality Assurance Program Requirements for Nuclear Facility Applications, including Basic Requirements and Supplements*,
- 6 ASTM C1009, *Standard Guide for Establishing A Quality Assurance Program for Analytical Chemistry Laboratories Within the Nuclear Industry*
- 7 DOE/AL 57XA, *Standards and Calibration Program*
- 8 10 CFR 820, *Procedural Rules for DOE Nuclear Activities*
- 9 DOE Office of the Assistant Secretary for Environment, Safety and Health, *Enforcement Manual*

APPENDIX 1
DEFINITIONS AND ACRONYMS
(Page 2 of 15)

Acceptance Criteria Specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other requirement documents

Accuracy The closeness of a measured value to a true value

Activity An all-inclusive term describing a specific set of operations or related tasks to be performed serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication) that result in a product or service

Administrative Controls Provisions relating to organization and management, procedures, recordkeeping, assessment, and reporting necessary to ensure safe operation of a facility [DOE 5480 23]

Adverse Trend A series of data inputs or observations that indicates attention is required to resolve or avoid a problem

Assessment An all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection, or surveillance

Assessor/Auditor/Appraiser An individual who is qualified to participate in audit functions under the direction of a lead auditor, an auditor **may** not perform audits independently nor serve as an audit team leader (See **Lead Auditor**)

Audit (Quality) A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements, and whether these arrangements are implemented effectively and suitable to achieve objectives

Authorization Basis. Those aspects of the facility design basis and operational requirements relied on by DOE to authorize operation. These aspects are considered to be important to the safety of facility operations. The Authorization Basis is described in documents such as the Final Safety Analysis Report (FSAR) and other safety analyses, Hazard Classification Documents, Technical Safety Requirements (TSRs), DOE-issued safety evaluation reports, and facility specific commitments made to comply with DOE Orders and policies

Bias A systematic error that remains constant over a series of replicated measurements

Calibration To adjust and/or determine either (i) The response or reading of an instrument relative to a standard (e.g., primary, secondary, or tertiary) or to a series of conventionally true values, or (ii) The strength of a radiation source relative to a standard (e.g., primary, secondary, or tertiary) or conventionally true value [10 CFR 835.2]

Certificate of Conformance A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements

Certification The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements

APPENDIX 1
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Characteristic Any property or attribute of a datum, item, process, or service that is distinct, describable, and/or measurable

Commercial Grade Item An item satisfying the following

- Not subject to design or specification requirements that are unique to nuclear facilities,
- Used in applications other than nuclear facilities,
- Is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., catalog)

Compensatory Measures An interim action taken in response to a deficiency in order to reduce environmental, safety or health risk to an acceptable level until the deficiency is resolved

Controlled Document Written information that is prepared, reviewed, approved, distributed, and maintained in accordance with established procedures

Corrective Action Action taken to resolve a deficiency. Corrective action may include both short-term immediate responses and longer-term activities to investigate the deficiency, determine and address underlying causes, and preclude recurrence

Customers(s) Those individuals or organizations for whom items or services are furnished or work performed in response to defined expectations and specifications, or who will use or are affected by the output of one's work

Data Quality Objectives Qualitative and quantitative statements derived from the Data Quality Objectives Process that clarify/study technical and quality objectives, define the appropriate type of data and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions

Data Quality Objectives Process A systematic strategic planning tool based on the scientific method that identifies and defines the type, quality, and quantity of data needed to satisfy a specified use. The key elements of the process include

- Concisely defining the problem,
- Identifying the decision to be made,
- Identifying the key inputs to that decision,
- Defining the boundaries of the study,
- Developing the decision rule,
- Specifying tolerable limits on potential decision errors, and
- Selecting the most resource efficient data collection design

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Data quality objectives are the qualitative and quantitative outputs from the Data Quality Objectives (DQO) process. The DQO process was developed originally by the U S Environmental Protection Agency, but has been adapted for use by other organizations to meet their specific planning requirements.

Deficiency A generic term which denotes the characteristics of an item, activity, process, or document that depart from a specified requirement, render it unfit for its intended use, or render its compliance or safety status indeterminate.

Design Change Any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

Design Input Those criteria, parameters, bases, or other design requirements upon which detailed final design is based.

Design Output Drawings, specifications, and other documents used to define technical requirements of structures, systems, components, and computer programs.

Design Process Technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.

Document Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record.

Environmental Conditions The description of a physical medium (e.g., air, water, soil, sediment) or biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.

Environmental Technology A term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be added to process discharges (e.g., emissions, effluents) or utilized in the ambient environment to remove pollutants or contaminants from or prevent them from entering the environment. Examples of discharge controls include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems, however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification, or vitrification, and biological treatment.

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Evaluated Subcontractors List A listing of subcontractors that have demonstrated through quality system evaluations the capability to provide items and services in accordance with established requirements

Exemption Written release from applicable requirement(s) of DOE Orders, Notices, and Manuals, granted to a DOE Element of Contractor, by an appropriate official

Generic Implications Potential of a deficiency to affect or exist in other buildings, useful to others

Good Practice Observed policies, management approaches, work processes, or activities which clearly contribute to safety, efficiency, effectiveness, and/or productivity

Graded Approach A process by which the level of detail in analysis, documentation, and actions necessary to comply with requirements is commensurate with

- Relative importance to safety, environment, safeguards, and security,
- Magnitude of any hazard involved,
- Complexity of the facility and/or systems being relied on to maintain an acceptable level of risk,
- Life-cycle stage of a facility or activity,
- Programmatic mission of a facility or activity,
- Particular characteristics of a facility or activity, and
- Any other relevant factors

Guideline/Guidance A suggested practice that is not mandatory in programs intended to comply with a standard. The word **Should** denotes a guideline, the word **SHALL** denotes a requirement

Hazard A source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to personnel or damage to a facility or to the environment (without regard to the likelihood or credibility of accident scenarios or consequence mitigation)

Implementation Plan A document prepared by a contractor that sets forth

- When and how the actions appropriate to comply with the requirements of a section of this Part, including the requirements of a plan or program required by this section, **SHALL** be taken, and
- What relief will be sought if a contractor cannot attain full compliance with a requirement in a reasonable manner

Indeterminate Having a condition where an item's functional capabilities are in question or the ability of the item to meet the applicable acceptance criteria or to perform to the governing design requirement is unknown

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Independent Assessment Formally conducted and documented evaluations performed by qualified individuals, groups, or organizations not part of the organizations directly performing or accountable for the work being assessed. The independent assessment or organization designation does not apply to the following oversight organizations

- Internal audit organizations that use accepted industry practices to perform financial audits,
- Technical evaluation groups that implement the requirements of 10CFR 830.122, Criterion 6, Design,
- Program, project, line management, operations, compliance, and other organizations that perform evaluations to ensure compliance with performance expectations, DOE Orders, Federal Regulations, and Laws other than 10 CFR 830.120 and DOE Order 414.1A

Independent (Personnel) A condition characterizing an individual or group of individuals qualified to analyze, review, inspect, test, audit, or otherwise evaluate activities and work results because

- They had no direct responsibility or involvement in performing the activity or work,
- They are not accountable for the activity or work result,
- They do not report directly to the immediate supervisors who are responsible for performing the activity or work being evaluated

Indoctrination Act of instructing in fundamentals so as to provide an understanding of principles involved

Inspection An activity such as measuring, examining, testing or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformance is achieved for each characteristic

Inspector A person who performs inspection activities to verify whether an item or activity conforms to specified requirements

Internal Audit An audit of those portions of an organization's QAP retained under its direct control and within its organizational structure

Item An all-inclusive term used in place of any of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part, product, structure, subassembly, subsystem, system, unit, documented concepts or data

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Lead Auditor/Audit Team Leader/Lead Assessor An individual who is qualified to organize and direct audits, report findings, and evaluate corrective actions

Level of Concern. A numerical designation assigned to a condition or event that denotes its significance. The level of concern is designated using a five-point scale, defined as follows

- (1) Minor concern
- (2) Concern
- (3) Significant concern
- (4) Serious concern
- (5) Major concern

Management Individuals directly responsible and accountable for planning, implementing, and assessing work

Management Assessment Assessment performed by management that focuses on how well the manager's area of responsibility is performing and **Should** identify problems that hamper the organization from meeting its objectives

Management Systems Review. The qualitative assessment of data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained

Measuring and Test Equipment Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements

Nonconformance A hardware deficiency. For WIPP purposes, this also includes deficiencies in characteristic or record that render the quality of a WIPP-related item or sample unacceptable or indeterminate

Nonreactor Nuclear Facility Facility in which activities or operations that involve radioactive and/or fissionable materials in such form and quantity that a nuclear hazard potentially exists to the employees or the general public. Included are activities or operations that

- Produce, process, or store radioactive liquid or solid waste, fissionable materials, or tritium,
- Conduct separations operations,
- Conduct irradiated materials inspection, fuel fabrication, decontamination, or recovery operations,
- Conduct fuel enrichment operations,
- Perform environmental remediation or waste management activities involving radioactive materials

Incidental use and generation of radioactive materials in a facility operation (e.g., check and calibration sources, use of radioactive sources in research and experimental and machines) would not ordinarily require the facility to be included in this definition. Accelerators and reactors and their operations are not included

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Objective Evidence Any statement of fact, information, or record, either quantitative or qualitative, pertaining to the quality of an item or service based on observations, measurements, or tests, which can be verified (such as an approved Document Change Form (DCF), training roster, or completed Work Control Form)

Opportunity for Improvement. An item, activity, process, or document which, if subjected to quality improvement actions, would make an increased contribution to factors such as safety, efficiency, effectiveness, and/or productivity

Owner Person, group, company, agency, or corporation who has or will have title to the nuclear facility

Peer Review A documented critical review of work generally beyond the state of the art or characterized by the existence of potential uncertainty. The peer review is conducted by qualified individuals (or organization) who equivalent in technical expertise (i.e., peers) to those who performed the original work. The peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them. Peer reviews provide an evaluation of a subject where quantitative methods of analysis or measures of success are unavailable or undefined, such as in research and development.

Performance Evaluation Audit A type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

Precision Repeatability of a measurement

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Process. Orderly system or series of actions that achieves a desired end or result

Procurement Document Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase

Product Result of activities and processes

Purchaser Organization responsible for establishment of procurement requirements and for issuance, administration, or both, of procurement documents

Qualification (Personnel) Characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests that qualify an individual to perform a required function

Quality Condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations

Quality Assurance All those planned and systematic actions necessary to provide adequate confidence that quality is achieved and that a structure, system, component, product, or service will perform satisfactorily in service and satisfy given needs

Quality Assurance Overview An organized set of activities performed as independent functions. Its purpose is to assure that all aspects of quality-related activities at the program, project, and contractor level of management are adequately addressed

Quality Assurance Program. The overall program established by an organization to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work

Quality Assurance Project Plan Formal document describing in comprehensive detail the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria

Quality Assurance Record. Completed document that furnishes evidence of the quality of items and/or activities affecting quality

Quality Audit Systematic, independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives

Quality Management Plan Formal document or manual, usually prepared once for an organization, that describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted

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Quality Management System Compilation of quality documents which identifies the Site quality requirements, expresses management's philosophy regarding quality, describes the Site quality program, defines quality terms, and provides a list of Site administrative procedures for controlling and managing quality work

Quality System Structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services The Quality System provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance and quality control

Quality Control. Overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer, operational techniques and activities that are used to fulfill requirements for quality

Quality Improvement Management program for improving the quality of operations Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation

Quality Indicators Measurable attributes of the attainment of the necessary quality for a particular environmental decision Indicators of quality include precision, bias, completeness, representativeness, reproducibility, comparability, and statistical confidence

Quality Related Composite of activities intended to achieve quality and those intended to assure the achievement of quality

Subcontractor Quality System Audit A systematic in-depth evaluation at a subcontractor's facility to determine the effectiveness of implementation of a quality system and process controls necessary to provide reasonable assurance that an item or service will meet established requirements and perform as expected [1-J55-ADM-08 10]

Radiological Facility Facilities that do not meet or exceed the Hazard Category 3 threshold quality values published in DOE Standard 1027-92, but still contain some quantity of radioactive material (above those discussed in Appendix B of 40 CFR 302)

Radioactive Waste Solid, liquid or gaseous material that contains radionuclides regulated under the Atomic Energy Act, as amended, and is of negligible economic value considering the cost of recovery

Reactor The entire nuclear reactor facility, including the housing, equipment, and associated areas devoted to the operation and maintenance of one or more reactor cores, unless it is modified by words such as containment, vessel, or core Any apparatus that is designed or used to sustain nuclear chain reactions in a controlled manner, including critical and pulsed assemblies and research, test, and power reactors, is defined as a reactor All assemblies designed to perform subcritical experiments that could potentially reach criticality are also to be considered reactors Critical assemblies are special nuclear devices designed and used to sustain nuclear reactions Critical

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assemblies **may** be subject to frequent core and lattice configuration change and **may** be used frequently as mockups of reactor configurations

Receiving Taking delivery of an item at a designated location

Record Completed document or other media that provides objective evidence of an item, service, or process

Record (Quality) Document that furnishes objective evidence of the quality of items or activities and that has been verified and authenticated as technically complete and correct. Records **may** include photographs, drawings, magnetic tape, and other data recording media

Recurrence Control Corrective Actions which if implemented properly, will address generic conditions and will reduce the likelihood or prevent a deficiency from recurring

Repair Process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement

Requirements Mandatory conditions, stipulations, or specifications that must be met during the performance of actions and activities. Requirements **SHALL** be derived from requirements documents and primarily address regulatory, safety, emergency, quality, legal, financial, and/or technical aspects of activities of facilities

Result Qualitative or quantitative description of a property obtained from an analysis and reported to a requester

Review Examination of a document or process prior to approval or concurrence to determine compliance with EM policies, DOE Orders, other government agency, program, project, and QA requirements, for potential impact on EM missions, policies, requirements, and objectives, and for agreement with professional judgment in an area of expertise

Rework Action taken on a nonconforming product so that it will fulfill the original specified requirements

Right of Access Right of a purchaser or designated representative to enter the premises of a supplier for the purpose of inspection, surveillance, or QA audit

Root Cause Most fundamental circumstances that are manifested by an observed deficiency (i.e., where the deficiency is but a symptom of a more basic problem)

Scrap Nonconforming item that is removed from service or rejected as being unacceptable for the intended quality-affecting purpose

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Selective Application Process to determine which elements or sub elements of the quality requirements apply to activities affecting quality, within a defined scope of work

Self-Assessment Process of evaluation of programs, activities and processes by responsible organizations to determine adherence to applicable requirements, achievement of performance objectives and the implementation of best management

Service Performance of work, such as design, construction, fabrication, inspection, nondestructive examination/testing, environmental qualification, repair, installation, or the like

Source Inspection Process of inspecting procured items or materials from a shipper or transfer agent at the point of origination before shipment to the Site for use

Special Process Process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product

Supplier Any individual or organization who furnishes items or services in accordance with a procurement document An all-inclusive term used in place of any of the following vendor, seller, contractor, subcontractor, fabricator, and consultant, and their sub-tier levels

Surveillance Act of monitoring or observing to verify whether an item or activity conforms to specified requirements

Technical Review Documented, traceable, in-depth, critical review, analysis, or evaluation of documents, materials, or data, that falls within the state of the art, conducted to verify and validate its applicability, correctness, adequacy, and completeness Technical reviews are performed by qualified personnel with technical expertise sufficient to render an informed opinion in the area under review and who are independent of those who conducted the work being reviewed

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

Traceability Ability to trace the history, application, or location of an item and like items or activities by means of recorded identification

Training Instruction, supervised performance or drill that prepares an individual to meet the performance requirements of the job

Trending Process of analyzing data to identify performance changes over time Typically trending is accomplished by examining the data in time sequence order, using statistically based rules to identify abnormalities, shifts, and changes in performance

Use-As-Is Disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use

Validation Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled In design and development, validation concerns the process of examining a product or result to determine conformance to user needs

Verification Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled

Waiver Documented authorization to depart from specified requirements

Work Process of performing a defined task or activity, e g , research and development, field sampling, analytical operations, equipment fabrication, operations, maintenance and repair, administration, software development and use, inspection, safeguards and security, data collection, and analysis

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1.3 Acronyms

AA	Authorization Agreement
AB	Authorization Basis
ALARA	As Low As Reasonably Achievable
ASNT	American Society of Nondestructive Testing
BFO	Basis for Operation
BIO	Basis for Interim Operation
CBFO	U S Department of Energy, Carlsbad Field Office
CPB	Closure Project Baseline
CMPM	Configuration Management Program Manual
COOP	Conduct of Operations Program
D&D	Decontamination and Decommissioning
DDCP	Decontamination and Decommissioning Characterization Protocol
DNFSB	Defense Nuclear Facilities Safety Board
DOE	Department of Energy
DPP	Decommissioning Program Plan
DQO	Data Quality Objective
EPA	Environmental Protection Agency
ES&H	Environment, Safety & Health
FDPM	Facility Disposition Program Manual
GET	General Employee Training
GRS	General Records Schedule
HASP	Health and Safety Plan
ISM	Integrated Safety Management
IWCP	Integrated Work Control Program
JHA	Job Hazards Analysis
JTB	Job Task Briefing
K-H	Kaiser-Hill Company, L L C
LLW	Low Level Waste
LLWMP	Low Level Waste Management Plan
M&TE	Measuring and Test Equipment
NARA	National Archives & Records Administration
NCR	Nonconformance Report
NCSM	Nuclear Criticality Safety Manual
NSM	Nuclear Safety Manual

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NTS	U S Department of Energy, Nevada Test Site
PAAA	Price-Anderson Amendments Act
PAM	Proposed Action Memoranda
PATS	Plant Action Tracking System
PBD	Project Baseline Description
PEB	Pre-Evolution Briefing
PEP	Project Execution Plan
PMP	Project Management Plan
QA	Quality Assurance
QAP	Quality Assurance Program
QAPjP	TRU Waste Characterization Program Quality Assurance Project Plan
QAPP	Quality Assurance Program Plan
RFCA	Rocky Flats Closure Agreement
RFCP	Rocky Flats Closure Project
RFFO	Rocky Flats Field Office
RWP	Radiological Work Permit
S/CI	Suspect and Counterfeit Items
SAR	Safety Analysis Report
SDRM	Site Document Requirements Manual
SERM	Site Engineering Requirements Manual
SRCM	Site Radiological Control Manual
SME	Subject Matter Expert
SNM	Special Nuclear Material
WEMS	Waste & Environmental Management System
TRU	Transuranic
TPM	Training Program Manual
WAC	Waste Acceptance Criteria
WAD	Work Authorization Document
WBS	Work Breakdown Structure
WIPP	U S Department of Energy, Waste Isolation Pilot Plant

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QAP Requirements	Implementation Program & Infrastructure Documents
<p>Management</p> <p>Criterion 1 – Program</p>	<p><u>Quality Assurance Program</u></p> <p>Quality Assurance (QA) Policy</p> <p>Quality Assurance Program Manual</p> <p>K-H QA Program Procedures Binder</p> <p>1-C40-QAP-02 01, Preparation of Quality Assurance Program Plans</p> <p>1-MAN-008-WM-001, TRU Waste Management Manual</p> <p>95-QAPJP-0050, RFETS TRU Waste Characterization Program Quality Assurance Program Project Plan</p> <p><u>Miscellaneous Infrastructure Documents</u></p> <p>MAN-016-ISM, Integrated Safety Management Manual</p> <p>MAN-075-DMM, Directives Management Manual</p> <p>1-MAN-022-PAAAPROG, Price-Anderson Amendments Act Program Manual</p> <p>MAN-001-SDRM, Site Document Requirements Manual</p>
<p>Management</p> <p>Criterion 2 – Personnel Training & Qualification</p>	<p><u>Training Program</u></p> <p>MAN-094-TPM, Training Program Manual</p> <p>PLN-97-007, TRU Waste Characterization Program Training Implementation Plan</p> <p>94-RWP/EWQA-0014, Low-Level/Low-Level Mixed Waste Management Plan</p> <p><u>Miscellaneous Infrastructure Documents</u></p> <p>MAN-066-COOP, Conduct of Operations Manual</p> <p>1-N92-ADM-02 03, Training, Qualification and Certification of Independent Auditors and Assessors</p>

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<p>Management</p> <p>Criterion 3 – Quality Improvement</p>	<p>Site Corrective Action Process</p> <p>3-X31-CAP-001, K-H Corrective Action Process</p> <p>MAN-062-CAUSEANALYSIS, Cause Analysis Requirements Manual</p> <p>Miscellaneous Infrastructure Documents</p> <p>1-A65-ADM-15 01, Control of Nonconforming Items</p> <p>2-U76-WC-4030, Control of Waste Nonconformances</p> <p>1-MAN-075-DMM, Directives Management Manual</p> <p>1-V10-ADM-15 02, Stop Work Action</p> <p>MAN-071-IWCP, Integrated Work Control Program Manual</p> <p>1-MAN-022-PAAAPROG, Price Anderson Amendments Act Program</p> <p>PRO-486-WIPP-006, TRU Waste Characterization Project Quality Assurance Grading</p>
<p>Management</p> <p>Criterion 4 – Documents and Records</p>	<p>Document Control Program</p> <p>Pro-815-DM-01, Developing, Maintaining, and Controlling Documents</p> <p>Site Procedures Program</p> <p>MAN-001-SDRM, Site Document Requirements Manual</p> <p>1-V51-COEM-DES-210, Site Engineering Process Procedure</p> <p>Records Management Program</p> <p>1-V41-RM-001, Records Management Guidance for Records Sources</p> <p>1-PRO-077-WIPP-005, Management of Waste Information Prior to Transmittal to the Waste Records Center</p> <p>PRO-1106-LLW-005, Low Level Quality Assurance Records Management</p> <p>Miscellaneous Infrastructure Documents</p> <p>MAN-010-NMS, Nuclear Materials Safeguards Manual</p> <p>1-MAN-026, K-H Security Manual, Chapter 6, Identification, Protection, and Control of Classified, Unclassified and Sensitive Information</p>

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<p><u>Performance</u></p> <p>Criterion 5 – Work Processes</p>	<p><u>Engineering</u></p> <p>MAN-027-SERM, Site Engineering Requirements Manual 1-V51-COEM-DES-210, Site Engineering Process Procedure</p> <p><u>Integrated Work Control Program</u></p> <p>MAN-071-IWCP Integrated Work Control Program Manual 1-MAN-016-ISM, Integrated Safety Management Manual</p> <p><u>Site Procedures Program</u></p> <p>MAN-001-SDRM, Site Document Requirements Manual</p> <p><u>Conduct of Operations Program</u></p> <p>MAN-066-COOP, Site Conduct of Operations Manual</p> <p><u>Environmental Management and Waste Management Program</u></p> <p>1-MAN-008-WM-001, TRU Waste Management Manual 94-RWP/EWQA-0014, Low-Level / Low-Level Mixed Waste Management Plan 1-PRO-079-WGI-001, Waste Characterization, Generation, and Packaging 1-PRO-X05-WC-4018, TRU Waste Certification 4-G83-WEM-WP-1209, WEMS Waste Package Verification and Certification 1-MAN-039-WEM-WP-1200, Waste & Environmental Management System (WEMS) Program Management Manual RCRA Part B Permit and Compliance Documents Site Quality Assurance Project Plan for CERCLA Remedial Investigations/Feasibility Studies & RCRA Facility Investigations/Corrective Measures Studies Activities (QAPJP) Pollution Prevention Program Plan 1-C80-WO1102-WRT, Waste/Residue Traveler Instructions 1-C88-WP1027-NONRAD, Nonradioactive Waste Packaging 1-M12-WO-4034, Solid Radioactive Waste Packaging Requirements 1-M60-WPC-001, Waste Process Control 1-PRO-Q11 WO-1221, Controls for Updating Waste Packaging Information in WEMS 1-MAN-036-EWQA-1 6 1, Waste Characterization Program Manual</p> <p><u>Testing, Surveillance, and Maintenance Management Program</u></p> <p>1-PRO-072-001, Inspection and Test Acceptance Process MAN-071-IWCP, Integrated Work Control Program Manual</p>

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<p>Performance</p> <p>Criterion 5 – Work Processes</p>	<p><u>Radiological Control Program</u></p> <p>Radiological Control Manual</p> <p>RPP-0001, Radiation Protection Program</p> <p><u>Nuclear Safety Program</u></p> <p>1-MAN-018-NSM, Nuclear Safety Manual</p> <p>1-MAN-010-S&A, Safeguards and Accountability Manual</p> <p><u>Nuclear Material Control and Accountability Program</u></p> <p>MAN-010-NMS, Nuclear Materials Safeguards Manual</p> <p>97-PLAN-MCA-002, Nuclear Material Control and Accountability Plan</p> <p><u>Emergency Preparedness Program</u></p> <p>EPLAN-99, Emergency Plan</p> <p>1-64000-QAP-01 03, Emergency Preparedness Quality Assurance Plan</p> <p><u>Procurement Program</u></p> <p>MAN-134-PPM, Procurement Program Manual</p> <p>PRO-1034-PEQA, Procurement Engineering and Quality Assurance</p> <p>K-H Procurement Systems, Volumes I, II, and III</p> <p>1-V51-COEM-DES-210, Design Process Requirements</p> <p><u>Control of Measuring and Test Equipment Program</u></p> <p>MAN-092-M&TEM, Measuring and Test Equipment Management Manual</p> <p>3-M76-SOP-107, Measuring and Test Equipment Control Program</p> <p><u>Miscellaneous Infrastructure Documents</u></p> <p>K-H Quality Assurance Program Procedures Binder</p> <p>1-A67-QAP-08 01, Identification and Control of Items</p> <p>1-C20-QAP-09 01, Control of Processes</p> <p>1-MAN-026, K-H Security Manual</p> <p>1-MAN-009-PMM, Property Management Manual</p> <p>MAN-T91 STSM-001, Site Transportation Safety Manual</p>

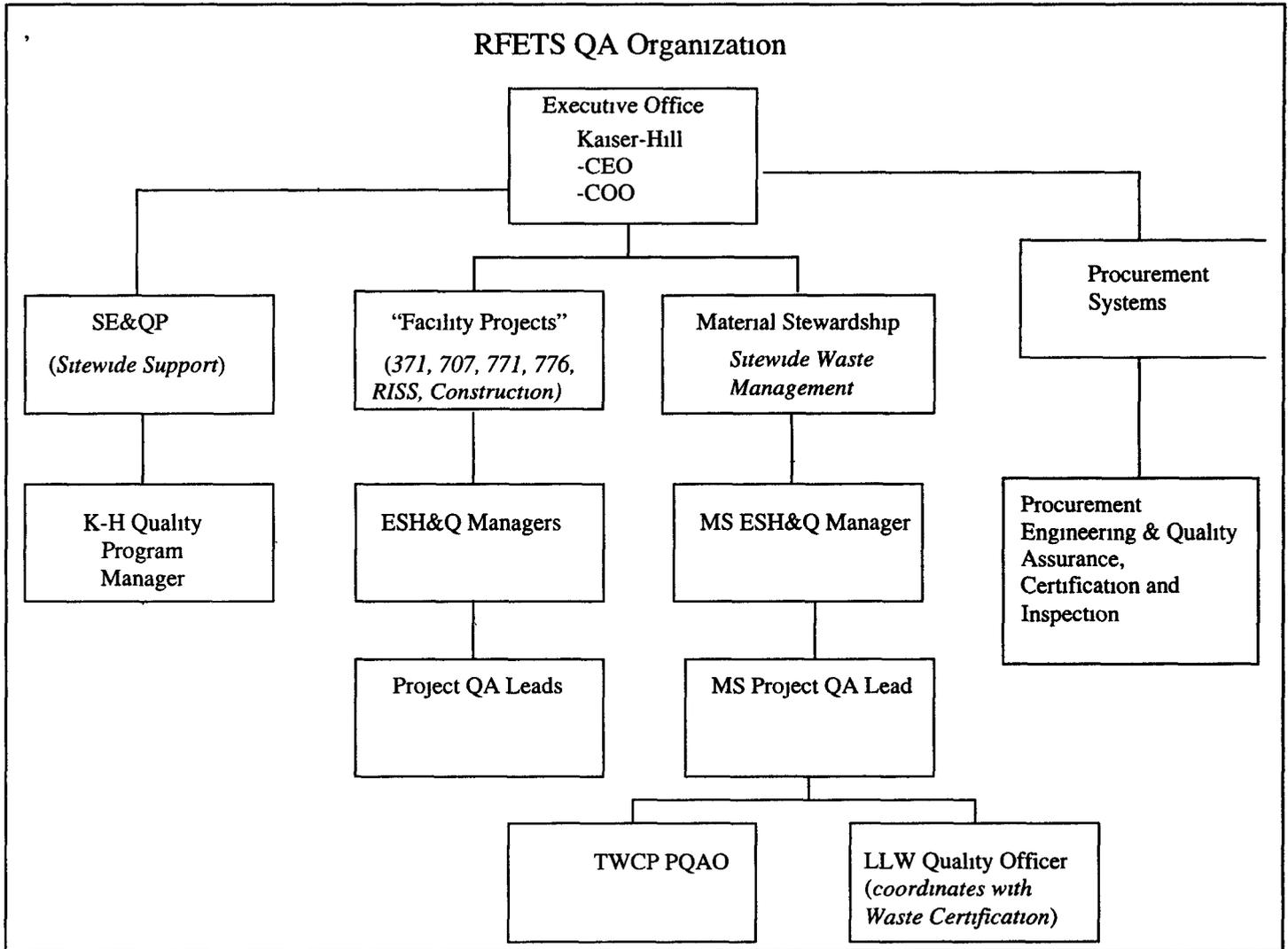
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QAP Requirements	Implementation Program & Infrastructure Documents
<p><u>Performance</u> Criterion 6 – Design</p>	<p>1-MAN-004-CSMM, Computer Software Management Manual 1-V51-COEM-DES-210, Design Process Requirements MAN-027-SERM, Site Engineering Requirements Manual MAN-018-NSM, Nuclear Safety Manual</p> <p><u>Miscellaneous Infrastructure Documents</u> MAN-010-NMS, Nuclear Materials Safeguards Manual PRO-664-NSP-USQP, Nuclear Safety Program Unreviewed Safety Question Process MAN-071-IWCP, Integrated Work Control Program Manual PRO-569-ADM-02 01, Operation Review Committee Requirements</p>
<p><u>Performance</u> Criterion 7 – Procurement</p>	<p><u>Procurement Program</u> K-H Procurement Systems, Volumes I, II, and III MAN-134-PPM, Procurement Program Manual MAN-955-099, Customer Service Organization Operations Manual PRO-1034-PEQA, Procurement Engineering and Quality Assurance</p> <p><u>Miscellaneous Infrastructure Documents</u> 1-V51-COEM-DES-210, Design Process Requirements MAN-027-SERM, Site Engineering Requirements Manual 1-PRO-453, Master Agreement Subcontract Procurement PRO-J44-RC&I-6600, Procured Items Inspection and Certification</p>
<p><u>Performance</u> Criterion 8 – Inspection & Acceptance Testing</p>	<p>1-PRO-072-001, Inspection and Acceptance Testing Process</p> <p><u>Configuration Change Control Program/Conduct of Engineering</u> 1-V51-COEM-DES-210, Design Process Requirements</p> <p><u>Integrated Work Control Program</u> MAN-071-IWCP, Integrated Work Control Program Manual</p> <p><u>Control of Measuring and Test Equipment Program</u> MAN-092-M&TEM, Measuring and Test Equipment Management Manual</p> <p><u>Procurement Program</u> MAN-134-PPM, Procurement Program Manual PRO-1034-PEQA, Procurement Engineering and Quality Assurance 1-J55-ADM-08 01, Subcontractor Quality Evaluations</p> <p><u>Miscellaneous Infrastructure Documents</u> MAN-010-NMS, Nuclear Materials Safeguards Manual MAN-066-COOP, Site Conduct of Operations Manual</p>

APPENDIX 2
QUALITY ASSURANCE PROGRAM (QAP)
INFRASTRUCTURE DOCUMENTS LIST
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QAP Requirements	Implementation Program & Infrastructure Documents
<p><u>Performance</u> Criterion 9 – Management Assessment</p>	<p><u>Management Assessment</u> 3-W24-MA-002, K-H Management Assessment Program</p> <p><u>Miscellaneous Infrastructure Documents</u> 97-PLAN-MCA-002, Nuclear Material Control and Accountability Plan MAN-040-RDM, Readiness Determination Manual</p>
<p><u>Performance</u> Criterion 10 – Independent Assessment</p>	<p><u>Assessment Program</u> MAN-040-RDM, Readiness Determination Manual 3-B52-IA-003, Conduct of Independent Assessment Activities 1-W37-IA-002, Integrated Planning and Scheduling of Independent Assessment Activities PRO-985-QA-SURV, Performance of Quality Assurance Surveillances and Monitoring Activities 1-N92-ADM-02 03, Training Qualification and Certification of Independent Auditors and Assessors</p> <p><u>Miscellaneous Infrastructure Documents</u> PRO569-ADM-02 01, Operations Review Committee Requirements</p>

APPENDIX 3
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APPENDIX 4

Deficiency and Corrective Action Tracking Systems

APPROVED SITE DEFICIENCY AND CORRECTIVE ACTION TRACKING SYSTEMS (DATABASES AS WELL AS SITE INFRASTRUCTURE ARE INCLUDED)

- A Plant Action Tracking System (PATS) [3-X31-CAP-001]
- B Waste and Environmental Management System (WEMS), Waste Nonconformance Report (NCR) Module [1-MAN-039-WEM-WP-1200]
- C Environmental Corrective Action Tracking System (ECATS) [PRO-455-ECATS]
- D Radiological Improvement Reporting System (RIRs) [PRO-998-RSP-13 01]
- E Occurrence Reporting and Processing System (ORPS)* [1-D97-ADM-16 01]
- F PAAA Noncompliance Tracking System (NTS)* and Price Anderson Screening System (PASS) [1-MAN-022-PAAAPROG]
- G Criticality Safety Deficiency Tracking Database [MAN-088-NCSM]

* DOE-controlled databases