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Quality Management Plan for the Los Alamos National Laboratory Risk Reduction and Environmental Stewardship – Remediation Services Project

Prepared by: Signature on original — **Date:** 4/15/04

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Approved by: Signature on original — **Date:** 4/20/04

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REVISION LOG

Revision No.	***Effective Date***	***Prepared By***	***Description of Changes***	***Affected Pages***
R0	6/10/98	John L. Day	Initial Issue. Replaces Quality Program Plan for Environmental Restoration Activities, June 1991.	All
R1	04/30/01	Andrew E. Gallegos	Complete rewrite to address LANL LPR 308-00-00.1, "Institutional Quality Management," PAAA and 10 CFR 830 Subpart A, "Quality Assurance Requirements."	All
R2	08/25/03	Andrew E. Gallegos	Revised to address ER Program title change, clarify quality requirement implementation processes and methods, and incorporate Appendix A, in accordance with DOE comments. Added a preface section that includes statements addressing graded approach and PAAA. Added a list of acronyms and definitions.	All
R3	4/20/04	Larry Maassen	Revised to reflect new organizational structure, delete Appendix A, and to correct references to 10 CFR 830 Subpart A. This revision also incorporates DOE comments regarding management commitment to resources, training, suspect/counterfeit item identification, M&TE verification, and expansion and clarification of criterion objectives. Personnel trained to Revision 2 of this document do not require retraining to Revision 3.	All

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TABLE OF CONTENTS

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RRES-RS PROJECT DEPUTY DIRECTOR'S QUALITY POLICY STATEMENT

"The Quality Management Plan [QMP] for the Los Alamos National Laboratory [LANL or the Laboratory] Risk Reduction and Environmental Stewardship – Remediation Services [RRES-RS] Project" establishes the principles, requirements, and practices necessary to implement an effective quality assurance program. The QMP is based on the ten criteria of 10 Code of Federal Regulations (CFR) 830 Subpart A, "Quality Assurance Requirements" and US Department of Energy (DOE) Order 414.1, "Quality Assurance," as directed by Laboratory Performance Requirement (LPR) 308-00-00, "Institutional Quality Management."

The QMP establishes the RRES-RS Project's quality management system objectives, ensuring that the goal of the RRES-RS Project—to perform work in a quality manner while minimizing potential hazards to the environment, public, or facility workers—is achieved or surpassed. This quality management system integrates the Laboratory's safety management system, as described in the Laboratory document, "Integrated Safety Management" (LA-UR-98-2837), and the Price-Anderson Amendments Act (PAAA), as codified in 10 CFR 820, "Procedural Rules for Department of Energy Nuclear Activities." All RRES-RS Project work is performed by using approved instructions, procedures, and other appropriate means that implement regulatory or contractual requirements for technical standards, administrative controls, and other hazard controls. The scope, depth, and rigor of implementing the QMP criteria for a specific activity are determined by the use of a graded approach.

Each RRES-RS Project participant is responsible for the quality of his or her own work. Quality specialists are available to help RRES-RS Project participants determine the applicability of requirements to program activities. However, it is the responsibility of each person to be aware of the RRES-RS Project's quality requirements and to perform all activities in accordance with current and approved procedures.

The RRES-RS Project upholds the principle of continuous improvement. All personnel are encouraged, expected, and required to identify and report opportunities for improvement as well as any deficiencies or conditions that do not conform to the requirements of the QMP. The improvement process has the objective of preventing problems and improving the quality of products and services. RRES-RS Project managers are committed to fostering a "no-fault" attitude to encourage the identification of nonconforming items and processes, the implementation of this QMP, and dedication to the concept of continuous quality improvement.

Signature on original 4/19/04

Dave McInroy, RRES-RS Deputy Project Director Date

PREFACE

Introduction

This QMP details the 10 mandatory criteria upon which the RRES-RS Project's quality management system is built. Each section of the QMP presents one criterion, provides a description of the criterion objective for the RRES-RS Project, and presents program-specific direction for its implementation. Because the quality assurance requirements of 10 CFR 830 Subpart A and DOE Order 414.1 are very similar, only the CFR criteria are cited. The objectives and implementation provided are applicable to both sets of criteria. The QMP defines the "what" of the quality management system (i.e., quality program). The "how" shall be detailed in one or more implementing procedures for each criterion.

The QMP requirements shall be implemented according to a graded approach. Work activities shall be managed through systems that are adequate and commensurate with the quality requirements, risk, and hazards involved in the activity. The term "risk" includes the potential for impact to human health and safety, threat to the environment, noncompliance with quality and safety requirements, and impact to cost. Quality and safety noncompliances may be subject to enforcement actions under the PAAA, as codified in 10 CFR 820.

Graded Approach

The RRES-RS Project Deputy Director has determined that a selective approach to the application of codes, standards, procedural controls, verification activities, and documentation requirements, as well as a formalized maintenance program are appropriate for RRES-RS Project activities (refer to Laboratory Implementation Requirement 230-01-02, "Graded Approach for Facility Work," available at http://labreq.lanl.gov/pdfs/ops/01_operations/lir2300102.pdf). Such a selective approach allows for the application of extensive controls to certain elements of activities and limited controls to others. The selective approach shall not be used to obtain exemptions from QMP requirements.

The control measures to be applied to any particular activity (e.g., the procurement of items or services, conducting a field sampling campaign, or training), are covered in documents such as procedures, statements of work, project-specific work plans, and procurement contracts associated with the activity.

Price-Anderson Amendments Act

The PAAA of 1988 is the legislative foundation for the regulation and enforcement of nuclear safety standards. The PAAA is based upon provisions established by the Atomic Energy Act of 1954 (AEA). The AEA, as amended, provided for the indemnification and limitation of public liability arising from nuclear incidents. In 1988, the PAAA was signed into law to renew DOE's authority to indemnify contractors **and** to ensure that contractor performance was consistent with prescribed standards as a condition of indemnification. Congress also mandated a new program, separate and apart from contractual award fees, to subject contractors to potential civil and criminal penalties for violations of DOE rules, regulations, and orders relating to nuclear safety. The PAAA program is now being carried out by DOE and the Laboratory and is applicable to certain RRES-RS Project activities.

CRITERION 1—PROGRAM

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.** (10 CFR 830 Subpart A, §830.122, "Criterion 1—Management/Program")

Criterion Objective

The principal factor representing the performance of an organization is the quality of its products and services. The quality management system describes methods for planning, performing, and assessing the adequacy of work, including work assigned to parties outside the organization. Management at all levels shall ensure that sufficient resources are available for performance of work in accordance with this QMP. Management is responsible for leadership and commitment to quality achievement and improvement within a framework of public, worker, and environmental safety. Management retains the primary responsibility and accountability for the scope and implementation of the management system. However, every individual in the organization is responsible for achieving quality in his or her activities. Management shall require and cultivate the achievement and improvement of quality at all levels of the organization and ensure that this QMP is understood and implemented.

Objective Implementation

This objective shall be achieved by implementing documents and/or processes that effectively manage quality and safety controls for RRES-RS Project activities (e.g., planning, personnel training, worker qualification and staffing, quality improvement, document control and records management, work process management, design development and implementation, procurement processes, inspection and acceptance testing, management and independent assessment).

Chapter 3 of the "RRES-RS Project Installation Work Plan [IWP]," "Quality Assurance Project Plan [QAPP]," establishes how the RRES-RS Project conducts Resource Conservation and Recovery Act corrective actions. The QAPP follows the requirements of DOE Order 414.1, "Quality Assurance," and 10 CFR 830 Subpart A, "Quality Assurance Requirements," as implemented in this QMP and is subordinate to the QMP. The RRES-RS Project management system, the organizational structure, the functional responsibilities, the levels of authority, the authorization basis for field activities, and the interfaces for those managing, performing, and assessing the adequacy of work are addressed in Chapter 1 of the IWP. All work conducted under and on behalf of the RRES-RS Project is conducted in accordance with this QMP and administrative controls such as those described in RRES implementing procedures (e.g., quality procedures (QPs) and/or standard operating procedures (SOPs)). Other RRES-RS Project documents (the IWP, sampling and analysis plans, statements of work, etc.) govern the programmatic aspects of RRES-RS work, including planning, scheduling, and cost.

CRITERION 2—PERSONNEL TRAINING AND QUALIFICATION

1) **Train and qualify personnel to be capable of performing their assigned work.**

2) **Provide continuing training to personnel to maintain their job proficiency.** **(**10 CFR 830 Subpart A, §830.122, "Criterion 2—Management/Personnel Training and Qualification")

Criterion Objective

A fundamental requirement for effective accomplishment of any mission is that all personnel be capable of performing their assigned tasks. The RRES-RS Project training program is designed to ensure that both University of California employees and subcontractor personnel perform proficiently in their assigned tasks and that this level of proficiency is maintained. Line management, including program and project team leaders, is responsible for identifying orientation and training requirements. The extent of orientation and training is commensurate with the scope, complexity, and nature of the activity, as well as the educational level, experience, and proficiency of the employee. Implementing procedures (i.e., QPs and SOPs) specify the degree of training and documentation required.

Objective Implementation

RRES-RS personnel shall develop and utilize RRES-RS Project procedures and/or establish and implement methods for

- performing, documenting, and tracking personnel training and education;
- providing initial and continuing training to ensure that personnel have and maintain the qualifications (e.g., education and experience) necessary to perform assigned work;
- ensuring that personnel receive RRES-RS Project QMP orientation;
- ensuring that personnel attend and complete all necessary training provided by organizations outside of the RRES-RS Project (e.g., Laboratory general employee, hazardous worker, radiation worker, and emergency response training); and
- ensuring that personnel are certified to perform assigned work if certification is required and that such certification is documented and maintained.

CRITERION 3—QUALITY IMPROVEMENT

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 recurrences 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.**
(10 CFR 830 Subpart A, §830.122, "Criterion 3—Management/Quality Improvement")

Criterion Objective

Quality improvement is a management process that is carried out to improve an item, service, or process. All aspects of work activities and the management system are subject to continuous improvement through an assessment and feedback process. The objective of the RRES-RS Project quality improvement process is to continuously strive to provide a better product to RRES-RS Project customers by constantly seeking a better approach in the initiation, implementation, completion, and closeout of activities, tasks, and/or projects.

RRES-RS Project employee involvement and ownership of the quality improvement process is based on the premise that all work can be planned, performed, measured, and improved. Managers and supervisors have a responsibility to regularly assess the performance of those portions of the quality program for which they have direct responsibility. They also have a responsibility to support RRES-RS Project employees in the implementation of the quality improvement process without displaying or manifesting any suggestion of reluctance or retribution.

Objective Implementation

1. RRES-RS personnel shall perform periodic assessments to verify the appropriate implementation of the RRES-RS Project QMP.

2. RRES-RS personnel shall review item characteristics and process implementation documents to identify items and processes needing improvement.

3. RRES-RS personnel shall develop and utilize procedures and/or establish and implement methods for

   - reporting and evaluating nonconforming conditions, deficiencies, noncompliances, conditions adverse to quality, conditions adverse to the environment, conditions adverse to the health and welfare of personnel, and identifying and reporting potential noncompliance with the PAAA;
   - controlling nonconformance and deficiency reports, identifying and implementing appropriate corrective actions and verifying closure, and preventing the recurrence of nonconformances, noncompliances, and deficiencies;
   - determining the levels of control and types of corrections required, identifying health and safety issues and work-related environmental impacts;

- addressing the development and implementation of a nonconformance, deficiency, and corrective action tracking system;
- ensuring that a corrective action follow-up is conducted to verify timely and proper implementation of corrective actions;
- ensuring that nonconforming items are labeled with legible and easily recognizable markings and tags or that other methods (e.g., segregation) are employed to prevent the use of nonconforming items;
- ensuring that authorized personnel control further processing, delivery, installation, or use of a nonconforming item pending an evaluation and an approved disposition;
- ensuring that technical justification for the acceptability of nonconforming items with a disposition of use-as-is or repair is performed and documented by qualified personnel;
- ensuring that repair/replacement items and processes are inspected and tested according to the original requirements or the specified/documented alternatives;
- ensuring that performance data analyses consider internal and external failure costs, prevention costs, and other implementing information when identifying trends that adversely impact quality and opportunities to improve items and processes;
- describing the processes for addressing stop work and restart; and
- describing the processes for utilizing the Laboratory Lessons Learned system to develop and create reports for the RRES-RS Project Lessons Learned program.

CRITERION 4—DOCUMENTS AND RECORDS

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.** (10 CFR 830 Subpart A, §830.122, "Criterion 4—Management/Documents and Records")

Criterion Objective

Documents and records are required to effectively manage, perform, and assess work. Documents are required to control policy, administrative, and/or technical information. This criterion helps ensure that documents, such as procedures, plans, specifications, instructions, and drawings, as well as changes to documents, are properly controlled.

A record contains information that is retained for its expected future value. Records should be of sufficient detail to support technical and regulatory decisions. This criterion implements records management process controls such as the identification, processing, storage, and protection of records.

Objective Implementation

RRES-RS personnel shall develop and utilize RRES-RS Project procedures and/or establish and implement methods for

- describing the processes for the preparation, review, approval, issuance, and revision of all RRES-RS Project documents;
- prescribing work processes;
- specifying requirements;
- implementing and maintaining information management processes;
- describing the processes for identifying record-keeping requirements;
- preparing, reviewing, approving, and submitting records, including data, to the RRES-RS Project Records Processing Facility;
- ensuring the authentication of records through stamping, initialing, signing, dating, and other approved means;
- ensuring that records are protected to prevent the loss of information and to address security requirements;
- ensuring that records are indexed, retained, and retrievable; and
- ensuring that records that require special processing are controlled and useable (e.g., computer codes or information on high-density media or optical disks are compatible with the hardware and software required to maintain and access records).

CRITERION 5—WORK PROCESSES

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.** (10 CFR 830 Subpart A, §830.122, "Criterion 5—Performance/Work Processes")

Criterion Objective

All work should be regarded as a process. Each work process consists of a series of actions planned and carried out by qualified workers using specified work processes and equipment under administrative, technical, and environmental controls established by management to achieve an end result. This criterion helps management ensure that the requirements necessary to perform work activities are planned and completed under controlled conditions by qualified personnel in accordance with safe work practices. Processes affecting safety and the quality of items, samples, or services are controlled by instructions, procedures, plans, drawings, or other appropriate methods.

Objective Implementation

1. RRES-RS personnel shall perform work using established engineering, scientific, and/or administrative practices that are described in the implementation documents for the RRES-RS Project (e.g., the IWP, QPs, SOPs, design documentation, technical standards, and desk instructions) and which are managed in accordance with Criterion 4.

2. RRES-RS personnel shall develop and utilize RRES-RS Project procedures and/or establish and implement methods for

   - ensuring that before the start of work, planning is completed to determine task requirements, design requirements, specifications, and appropriate codes and standards, and that processes that are required to perform the work are assessed and verified;
   - ensuring that safety management is planned, implemented, and continually improved through active participation by personnel at every level of the organization (see the Laboratory publication, "Integrated Safety Management");
   - providing guidance to address and implement PAAA requirements;
   - ensuring that items, data, and samples are identified and used properly in work performance and that their use is documented and traceable (e.g., by using a chain-of-custody form for samples);
   - maintaining items, samples, and measuring and test equipment (M&TE) to prevent their damage, loss, or deterioration;
   - ensuring that M&TE and monitoring, data collection, and analytical equipment are calibrated, adjusted, and maintained at prescribed intervals (or before use) by using certified equipment that is compliant with nationally recognized standards;

- ensuring that a process is established and implemented to control the calibration, maintenance, accountability, and use of equipment;
- ensuring that equipment found to be out of tolerance during the calibration process is identified and controlled and that the responsible organization is notified;
- describing the process for addressing any special handling, storage, or shipping requirements for items and samples;
- describing the process for the control of special processes and/or unique operations such as but not limited to welding, leak testing, radioactive waste tracking, nondestructive examination, waste characterization, waste isolation, and compliance verification;
- ensuring that measures are established and implemented to control consumables, items, and samples with limited shelf lives as well as to prevent the use of incorrect, outdated, or defective items and samples; and
- describing the requirements for preventing the use of incorrect or defective items, identifying and controlling suspect/counterfeit items, and providing for the control and maintenance of such items.

CRITERION 6—DESIGN

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.** (10 CFR 830 Subpart A, §830.122, "Criterion 6—Performance/Design")

Criterion Objective

The objective of the RRES-RS Project design process is to define the appropriate management controls for developing, reviewing, approving, and verifying the implementation of design requirements associated with environmental restoration activities. A formal design process shall be established that provides control of design inputs, outputs, verification, configuration, and revisions, as well as the technical and administrative interfaces appropriate to the importance of the design.

Objective Implementation

RRES-RS personnel shall develop and utilize RRES-RS Project procedures and/or establish and implement methods for

- ensuring that a design control process (i.e., control of design inputs and outputs) is developed and implemented that controls specifications, drawings, design criteria, and component performance, including experimental hardware and software;
- ensuring that design inputs are correctly translated into design outputs such as specifications, drawings, procedures, and instructions;
- ensuring that the responsible design organization prescribes and documents the design activities to the level of detail necessary to carry out the design process correctly and verifies that the design meets requirements;
- ensuring that documentation is sufficient in detail to permit verification that the final design, including approved design output and approved changes, incorporates the design input;
- ensuring that alterations to final designs, field changes, modifications to operating facilities, and the reasons for such changes are technically justified and documented;
- ensuring that changes to approved designs are controlled in the same manner as the original design;
- ensuring that dispositions of use-as-is or repair for nonconforming items are technically justified and documented;
- ensuring that the design process for any item that requires significant design change is reviewed, verified and, as necessary, modified;

- ensuring that design interfaces are identified and controlled and that the design efforts are coordinated among the participating organizational units or organizations;
- ensuring that interface controls include the assignment of responsibility and the establishment of procedures among participating design units for the design review, approval, release, distribution, and revision;
- ensuring that design information transmitted across design interfaces (i.e., design engineering, design field changes, as-builts etc.) is documented and controlled;
- ensuring that when design information is transmitted informally, the transmittal is confirmed promptly by a controlled document;
- ensuring that the design verifications are completed before relying on the component, system, structure, or computer program to perform its function and before installation;
- ensuring that qualified personnel who are not participants in the design process verify the acceptability and adequacy of design work and documents, including design inputs, reviews, processes, outputs, alternate calculations, changes, or qualification tests; and
- ensuring that design documentation and records, which provide evidence that the design and design verification processes have been performed in accordance with the QMP, are managed as records according to approved procedures.

CRITERION 7—PROCUREMENT

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 processesto ensure that approved suppliers continue to provide acceptable items and services** (10 CFR 830 Subpart A, §830.122, "Criterion 7—Performance/Procurement")

Criterion Objective

The procurement process ensures that items and/or services provided by suppliers meet the requirements and expectations of the end-user. This criterion defines the extent and nature of the controls that must be applied to the procurement of structures, systems, components, items, and services. These controls should be commensurate with the uniqueness, complexity, and importance to public and operational safety of the system or item to which they are applied. Purchased items and services must meet established requirements and performance expectations.

Objective Implementation

RRES-RS personnel shall develop and utilize RRES-RS Project procedures and/or establish and implement methods for

- ensuring that procurement documents are prepared, reviewed, approved, and controlled;
- ensuring that the technical requirements and acceptance criteria (i.e., inspection and acceptance testing) are specified, as applicable;
- ensuring that procurement documents invoke the applicable requirements specified in the QMP and/or a need for a documented and approved quality plan or program;
- ensuring that procurement documents require suppliers to incorporate appropriate quality requirements in sub tier procurement documents;
- ensuring that the procurement documents identify the documentation required for submittal by the supplier for information, review, approval, and/or retention;
- ensuring that the procurement documents provide for the right-of-access to a supplier's and supplier's subcontractors facilities and quality records and, as appropriate, the rights of RRES-RS Project authorized representatives to conduct surveillance of and/or audit the provision of services and to inspect any items provided;
- ensuring that all procurement documents require suppliers to identify appropriate spare parts and provide the technical and quality data required to order such parts;
- ensuring that the quality organization (i.e., RRES-RS Quality Integration and Improvement) reviews and approves designated purchase requisitions (PRs), PR change notices, and referenced documents according to established procedures, thereby ensuring the incorporation of QMP requirements;

- ensuring that RRES-RS Project procurement policies are commensurate with other Laboratory procurement policies and procedures and address the procurement requirements of the RRES Division and Supply Chain Management Division;
- ensuring that suppliers are evaluated, qualified, and selected in accordance with methods and/or specified criteria appropriate to the importance and complexity of the item or service;
- ensuring that an approved supplier list is developed and maintained;
- ensuring that PAAA applicability requirements are specified in subcontracts, as appropriate;
- ensuring that suppliers are evaluated on a periodic basis to verify that items and services are provided in a manner that is acceptable and meets the criteria of the QMP and other applicable documents and requirements;
- ensuring that the purchase of a commercial-grade item is based upon the intended use of the item and determined by using the graded approach; and
- ensuring that purchases of commercial-grade materials are evaluated to prevent the procurement of suspect/counterfeit items and, if such items are purchased, to identify them and prevent their release for use.

CRITERION 8—INSPECTION AND ACCEPTANCE TESTING

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.** (10 CFR 830 Subpart A, §830.122, "Criterion 8—Performance/ Inspection and Acceptance Testing")

Criterion Objective

Inspections and tests are conducted to verify that the physical and/or functional aspects of items, services, and processes meet requirements and are acceptable for use. Implementation of this criterion fulfills the requirements for the planning and execution of inspections of items to verify conformance with specified criteria (e.g., criteria for the source, receipt, acceptance, maintenance, in-service use, and control of start-up, operational, computational, and analytical (i.e., computer program) testing and testing equipment; the provision, function, and execution of analytical services; and the qualification and/or certification of inspection personnel).

Objective Implementation

RRES-RS personnel shall develop and utilize RRES-RS Project procedures and/or establish and implement methods for

- describing the criteria for inspection and testing and the performance of inspection and testing for items or services that are designed, purchased, tested, installed, and operated;
- describing the identification and tracking of items to applicable drawings, specifications, or other documents through stages of production, delivery, acquisition, and installation;
- describing the controls to be applied to products, items, materials, or systems to be inspected and/or tested;
- describing the methods for identifying, verifying, labeling, operating, and controlling calibrated equipment used for monitoring, data collection, inspection, and testing;
- describing the maintenance requirements for items or services that are designed and/or purchased;
- describing any applicable mandatory inspection points, i.e., points at which inspection is required to proceed with work and without which work will not proceed unless the specific consent of a designated representative is given;
- ensuring that inspections and acceptance tests are performed according to specified acceptance criteria;
- ensuring that inspection and test criteria that are not met are documented and reported;
- ensuring that authorized personnel document and approve the acceptance of items or activities;
- ensuring that items that have been modified, repaired, or replaced are inspected and/or tested according to specified criteria;
- ensuring that test results are evaluated to verify that testing requirements have been satisfied;

- ensuring that testing processes to demonstrate that items and systems will perform as intended are established and implemented;
- ensuring that testing is structured so that proving the acceptability of designs is not confused with verifying the adequacy of work;
- ensuring that testing is performed by qualified personnel who are independent of the work performed;
- ensuring that test plans and procedures are reviewed and controlled according to established procedures;
- ensuring that testing of computer programs is accomplished according to written test plans or procedures;
- ensuring that, unless specified otherwise, test requirements and acceptance criteria are provided and approved by the RRES-RS Project organizational unit responsible for the design or use of the program to be tested;
- ensuring that required tests, including verification, hardware integration, and in-use tests as appropriate, are controlled;
- ensuring that test requirements and acceptance criteria are based upon applicable design or other pertinent technical documents;
- ensuring that, in accordance with requirements specified the procurement document, suppliers or subcontractors submit test plans and procedures; and
- ensuring that, in accordance with the specifications of the procurement document, RRES-RS Project representatives monitor supplier or subcontractor test activities.

CRITERION 9—MANAGEMENT ASSESSMENT

> **Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.** (10 CFR 830 Subpart A, §830.122, "Criterion 9—Assessment/Management Assessment")

Criterion Objective

Managers at every level must periodically assess the performance and function of their organization to evaluate the organization's ability to satisfy customer requirements and expectations, its success in accomplishing its mission, and the need for organizational improvement. Managers shall assess the organization's use of human and material resources to achieve the organization's goals and objectives. Managers shall also conduct introspective evaluations of their management programs to ensure that they sufficiently integrate customer requirements and strategic goals.

Objective Implementation

Managers perform management assessments. Delegating management assessment to a consultant or internal audit group is inconsistent with the requirement and will diminish the value of the assessment. Managers will conduct management assessments in accordance with a procedure or procedures developed by following the guidance provided in DOE G 414.1-1A, "Management Assessment and Independent Assessment Guide."

CRITERION 10—INDEPENDENT ASSESSMENT

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**. (10 CFR 830 Subpart A, §830.122, "Criterion 10, Assessment/Independent Assessment")

Criterion Objective

The objective of the independent assessment process is to obtain impartial evaluations of RRES-RS Project and supplier management systems and work processes. To ensure impartiality, the evaluations are performed by qualified and/or certified personnel who are not participants in the systems or processes being evaluated. These evaluations are conducted to determine the effectiveness of systems and to identify needed improvements to quality and safety. RRES-RS Project quality assurance support personnel shall be responsible for planning, scheduling, and conducting independent assessments.

For the purposes of the QMP, the term "independent assessment " used in this criterion is commensurate with the terms "audit" and "surveillance."

Objective Implementation

RRES-RS personnel shall develop and utilize RRES-RS Project procedures and/or methods for

- describing the processes for planning, implementing, and managing an independent assessment program;
- ensuring that periodic independent assessments are conducted to verify the implementation of the RRES-RS Project QMP, to identify the degree of compliance with RRES-RS Project documents, to measure item and service quality, to measure the adequacy of work performance, the degree of compliance to work control documents, and to promote quality and safety improvement;
- ensuring that personnel performing independent assessments possess sufficient authority and independence from line management and the assessed area and are free of cost and schedule constraints; and,
- ensuring that personnel conducting independent assessments are technically qualified and/or certified and are knowledgeable in the activities they assess.

LIST OF ACRONYMS

AEA	Atomic Energy Act
CFR	Code of Federal Regulations
DOE	US Department of Energy
IWP	installation work plan
LANL	Los Alamos National Laboratory
LPR	lab performance requirement
M&TE	measuring and test equipment
PAAA	Price-Anderson Amendments Act
PR	purchase requisition
QAPP	Quality Assurance Project Plan
QMP	Quality Management Plan
QP	quality procedure
RRES-RS	Risk Reduction and Environmental Stewardship – Remediation Services Project
SOP	standard operating procedure

LIST OF TERMS

accuracy — The degree of agreement of a measurement with an accepted reference or true value.

approval — Formal or official documented acceptance.

authentication — The act of attesting that the information contained within a document is accurate, complete, legible, and appropriate to the work accomplished by stamping, signing, or initialing and dating a document.

assessment/verification — The act of reviewing, inspecting, testing, checking, conducting surveillances, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements.

audit — A planned and documented evaluation of objective evidence to determine the adequacy of and compliance with established implementing documents and the effectiveness of implementation.

commercial-grade item — An item satisfying each of the following criteria:

- The item is not subject to design or specification requirements that are unique to nuclear facilities.

- The item is used in applications that are not performed for the nuclear industry.
- The item is to be ordered from the manufacturer or supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., catalog).

completed document — An authenticated document.

configuration — The functional and/or physical characteristics of an item, as set forth in technical documentation and achieved in a product.

design input — Criteria, parameters, bases, or other design requirements upon which detailed final design is based.

design output — Drawings, specifications, and other documents used to define the technical requirements of structures, systems, components, and computer programs.

document — Recorded information that describes, defines, specifies, reports, certifies, requires, or provides data or results.

graded approach — A method that provides for the application of management controls commensurate with criteria such as probability and consequence of failure, complexity of design or fabrication uniqueness, end-use for data generated, ability to demonstrate functional compliance, quality history, degree of standardization, and impacts to cost or schedule.

independent assessment — Audit, surveillance, or inspection carried out by a third party with no involvement in the work or investment in the object being inspected.

inspection — An examination or measurement to verify that an item or process meets specified requirements.

inspection point — A procedural step that requires the performance of an inspection (e.g., hold or witness points).

item — An all-inclusive term used in place of any of the following: assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

measuring and test equipment (M&TE) — Devices or systems used to calibrate, measure, gage, test, or inspect for the purposes of controlling or acquiring data to verify conformance to specified requirements.

method — A systematic way, process, and/or technique employed by RRES-RS personnel to accomplish a task (e.g., soil, water, or air sampling; surveillance; and assessment).

monitor — To observe a process or activity for the purpose of verifying conformance to specified requirements.

monitoring, data collection, and analytical equipment — Devices, systems, or equipment used to collect data, control processes, and perform analyses.

nonconformance — A deficiency in characteristic or record that renders the quality of an item or sample unacceptable or indeterminate.

objective evidence — Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item, sample, or activity based on measurements, tests, or observations that can be verified.

Price-Anderson Amendments Act (PAAA) — A legal framework for the regulation and enforcement of nuclear safety standards.

procedure — An approved and documented set of instructions for performing or effecting a process or for achieving an established objective.

procurement document — PRs, purchase orders, drawings, contracts, specifications, or instructions used to define technical and quality requirements for the procurement of items.

process — A series of actions that achieve an end or result or accomplish work.

project plan — Sub tier implementation documents that are limited in scope and usually contain more detail than a QMP. The RRES-RS Project QAPP (Chapter 3 of the RRES-RS Project IWP) is an example of a project plan.

quality — The degree to which an item or process meets or exceeds the user's requirements and expectations.

quality assurance — The planned and systematic performance of actions necessary to provide confidence that a structure, system, or component will perform satisfactorily in service.

quality control — Action taken to control and measure the quality of the physical characteristics of components, systems, structures or processes in relation to predetermined requirements.

quality assurance project plan (QAPP) — A document that sets forth the plans, organization, and system that those responsible for managing a specific activity and/or project shall utilize. The content and extent of detail of the plan will vary in accordance with the size and type of project and stage of project execution.

quality management plan — A structured and documented management system describing the policies, objectives, principles, organizational authorities, responsibilities, accountability, and implementation plan of an organization for ensuring the quality of its work processes, items, and services. The QMP provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance and quality control processes.

record — A completed document that furnishes objective evidence of the quality of items, samples, or activities.

records processing facility — Facility designed for keeping records in a manner that minimizes the risk of damage or destruction (also known as records holding facility).

records management — The systematic control of the creation, maintenance, retention, protection, and preservation of records.

repair — The process of restoring reliable and safe functionality to a nonconforming item independent of original conformance requirements.

rework — The process by which an item is made to conform to original requirements by completion or correction.

risk — The possibility or degree of probability of financial/facility loss or personal/environmental injury due to a work-process weakness/failure.

service — The performance of work, such as design, fabrication, inspection, repair, installation, or analysis that does not involve delivering an item to the purchaser.

special process — A process that is highly dependent upon control and/or operator skill to achieve results and that produces items or services the quality of which cannot be readily determined by inspection or test.

supplier — An all-inclusive term used to represent an organization, vendor, seller, contractor, fabricator, consultant, and/or subtier individual or organization that furnishes items or services according to the terms of a procurement document.

surveillance — The act of observing real-time activities and/or reviewing documentation to verify conformance with specified requirements.

technical review — An in-depth analysis and evaluation of documents, activities, materials, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

testing — An element of verification for the determination of the capability of an item or process to meet specified requirements by subjecting it to a set of physical, chemical, environmental, or operating conditions.

use-as-is — A disposition permitted for a nonconforming item when it can be established and documented that the item is satisfactory for its intended use.

validation — An activity that demonstrates that items, processes, or sets of data satisfy specified requirements of the user.

Using a CRYPOCard, click here to record "self-study" training to this procedure.

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