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Rev. 0

Environmental Restoration
Disposal Facility

Waste Disposal Operations

**Quality Assurance
Project Plan**

May 17, 1996

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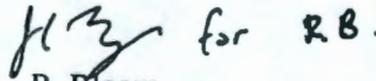
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List of Acronyms

ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing & Materials
ASQC	American Society of Quality Control
BHI	Bechtel Hanford, Inc.
CAR	Corrective Action Request
CERCLA	Comprehensive Environmental Response, Compensation, & Liability Act
DOE-RL	Department of Energy - Richland Operations Office
ERDF	Environmental Restoration Disposal Facility
EPA	Environmental Protection Agency
ER	Environmental Restoration
ES&H	Environment Safety & Health
LAN	Local Area Network
LMP	Leachate Management Plan
M&TE	Measuring & Test Equipment
NCR	Nonconformance Report
NIST	National Institute for Standards & Testing
NUREG	Nuclear Regulatory Guidance
OSHA	Occupational Safety & Health Administration
PCB	Polychlorinated Biphenyl
PQI	Productivity/Quality Improvement
QA	Quality Assurance
QAIs	Quality Assurance Instructions
QAPjP	Quality Assurance Project Plan
QC	Quality Control
RCRA	Resource Conservation & Recovery Act
WAC	Waste Acceptance Criteria
WAP	Waste Acceptance Plan
WMMP	Waste Materials Management Plan

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Introduction

Waste disposal operations at the Hanford Environmental Restoration Disposal Facility (ERDF) require adequate control of quality to ensure safe and environmentally compliant disposal of Hanford Environmental Restoration (ER) wastes. This Quality Assurance Project Plan (QAPjP) reflects both Quality Assurance policy and implementing instructions for the ERDF waste disposal operations. Rust Federal Services Inc. (Rust) is the waste disposal operations subcontractor for the ERDF and has overall responsibility for development, maintenance and implementation of this QAPjP. The plan, including its implementing instructions, are applicable to all personnel and operations associated with the ERDF waste disposal operations, including Rust, BHI (i.e. radiological controls personnel), and other subcontractor employees who assist in waste disposal operations at the ERDF site.

The Rust QA philosophy reflects the concept that work is a process that can be planned, performed, assessed, and improved. All work is accomplished using the resources of people, equipment, and procedures. Critical to the improvement of the work process is a continuous feedback obtained from employee input and management assessment systems. Application of a graded approach to Quality Assurance reflecting the risks involved in the work will also ensure that quality in performance of work is not diluted in the eyes of the employees. Specific requirements for the ERDF are documented in the ERDF plans and procedures including the operations manual, administrative procedures, and other implementing procedures.

Achievement of quality in all activities is an interdisciplinary function and the responsibility of all personnel, led by management. Senior management is responsible for establishing the culture and principles that integrate quality requirements into all work. All management is responsible for ensuring that individuals are provided with the information, tools, equipment, and procedures, along with the support and encouragement, to complete their work in a safe, efficient, and quality manner. Management is responsible for determining the needs and expectations of customers (both internal and external). Meeting these needs is a measure of quality and success.

This QAPjP is a combined policy manual and implementing instructions to minimize duplication of effort and maintain a centralized quality assurance focal point. The guidance document upon which this QAPjP is based is NUREG-1293, Rev. 1, Quality Assurance Guidance for a Low-Level Radioactive Waste Disposal Facility. Although the U.S. Nuclear Regulatory Commission has no jurisdiction over ERDF operations, this guidance was chosen as the most applicable to a commercial type disposal operation at ERDF for low-level, hazardous, and/or mixed ER wastes. Bechtel Hanford, Inc. (BHI) will serve as the oversight organization for quality assurance functions, similar to the "regulatory agency" authority that would be granted NRC in similar commercial operations under NUREG-1293. The Department of Energy - Richland Operations Office (RL) will provide oversight of the overall operation including BHI and Rust performance for waste disposal operations. Finally, the Environmental Protection Agency (EPA) has environmental regulatory jurisdiction over the ERDF and will provide appropriate oversight to ensure that the quality assurance requirements of 40 CFR are properly implemented at the facility.

The QAPjP is organized around the 18 Quality Assurance criteria described in NUREG-1293, with a section dedicated to each criterion. Each section contains the policy level guidance for the criterion, followed by any necessary Quality Assurance Instructions (QAIs) that describe specific application of that criterion at ERDF.

Criterion 1 - Organization

1.1 General Requirements - The organizational structure and assignment of responsibilities at ERDF have been established and shall be implemented in accordance with the following principles:

- Quality performance is achieved, verified, and maintained by the people who perform the work,
- Quality achievement is independently verified by the people or organizations who are not directly responsible for performing the work, and
- The level of inspection and degree of independence of inspections are based on the risk and complexity of the process or activity.

1.2 Standard Requirements

1.2.1 Description of Work Being Performed - The Hanford Environmental Restoration Disposal Facility (ERDF) is a waste repository for Environmental Restoration (ER) wastes generated from restoration of CERCLA past-practice sites at the Hanford Site. The ERDF is a two disposal cell RCRA compliant landfill that can be expanded to continue to meet Hanford Site ER needs. Waste Acceptance criteria are in place to ensure that the design criteria of the landfill are met, the landfill is protective of the environment, and worker health and safety can be ensured. Wastes will be received, placed, compacted, and covered with clean fill for long-term containment of the wastes. A final closure cap and long term monitoring will also be performed to ensure that the waste is properly maintained within the landfill structure.

The Waste Disposal Operations at the ERDF, for which this plan provides a quality assurance program, consist of the receipt, placement, compaction, compaction testing, placement and compaction of clean operating cover and environmental monitoring to allow safe and environmentally compliant disposal of radioactive, hazardous (dangerous), asbestos, PCB, and mixed wastes generated by the site ER activities. The plan does not address site characterization, facility design, facility construction, facility expansion through additional cells, closure, post-closure monitoring, groundwater monitoring, far field environmental monitoring, or remedial action waste acceptance program approval which are (or will be) covered under separate BHI or Hanford Site guidance.

1.2.2 Organizational Requirements - The project manager is responsible for developing and implementing an efficient organizational structure that clearly defines interfaces between parties/organizations, responsibilities, and authority. These lines of responsibility, authority and communication are established in administrative policy and designed to provide for safe, compliant and efficient waste disposal operations. If specific additional responsibilities, interfaces, and/or authorities apply due to changes or modification to facilities or operations, they will be established and documented during planning for the modifications. Responsibilities for achievement of quality shall be included in this planning and clearly documented early in the modification process.

Organizations who perform work (i.e. quality achieving functions) are responsible for controlling that work by developing, issuing, and complying with documented instructions and procedures. The need for specific instructions or procedures shall use a graded approach based upon the risk to safety, cost, schedule and the success of the program. Quality assurance requirements shall be built into the operational instructions to such a level as to ensure that operations are successful in ensuring safety and meeting environmental compliance requirements.

1.2.3 Management Requirements - Rust management is responsible for overall implementation of the ERDF QA Program as it relates to waste disposal operations. Personnel or organizations assigned by the project manager to verify achievement of quality shall have sufficient authority and freedom to take the following actions:

- Gain access to work areas and documents where related activities are occurring or work has been documented,
- Establish administrative controls and status indicators to preclude inadvertent bypassing of inspections or inadvertent operation of an item or performance of a process,
- Identify quality problems and have access to the levels of management necessary to resolve those problems,
- Initiate, recommend, or provide solutions to quality problems through designated channels,
- Verify the adequacy and implementation of solutions, and
- Ensure that further processing of items or activities is controlled until the proper disposition of a nonconformance or other unsatisfactory condition has occurred.

1.2.4 Corporate Quality Assurance Organization Support - The Rust corporate QA organization will provide the necessary support to assist the ERDF project manager and QA coordinators in developing and implementing the site specific QA Program. The corporate QA organization will provide this support through the ERDF QA Coordinators as the main point of contact. The level of support to be provided will be based upon the support requested by the QA Coordinators, Project Manager and corporate policy.

1.3 "Q"-Related Requirements - Quality (or "Q") Level requirements provide for application of higher level QA requirements in addition to Standard Level commercial business practices. The ERDF project manager and QA Coordinators jointly determine whether "Q"-Level requirements apply to work based on the importance and risk of the work. Examples of where "Q"-Level requirements may apply include items or activities that support regulatory compliance requirements. The basic group of "Q" level requirements for ERDF are discussed in QAI 1.1.

In addition to the organization and management regulations described under "Standard Requirements," the following requirements shall be applied when appropriate to work that has been designated as "Q"-related.

1.3.1 Procedural Control - Personnel or organizations must ensure that their assigned work is performed in accordance with established instructions, procedures, and standards. They must stop or correct work (1) when continuation will result in an obvious violation of requirements, or (2) until the procedures or instructions have been changed.

1.3.2 Personnel Training and Qualification - Personnel who verify quality assurance requirements must be evaluated and, where required, must be trained and qualified in keeping with defined instructions. When required, personnel must be certified for the performance of monitoring and verification.

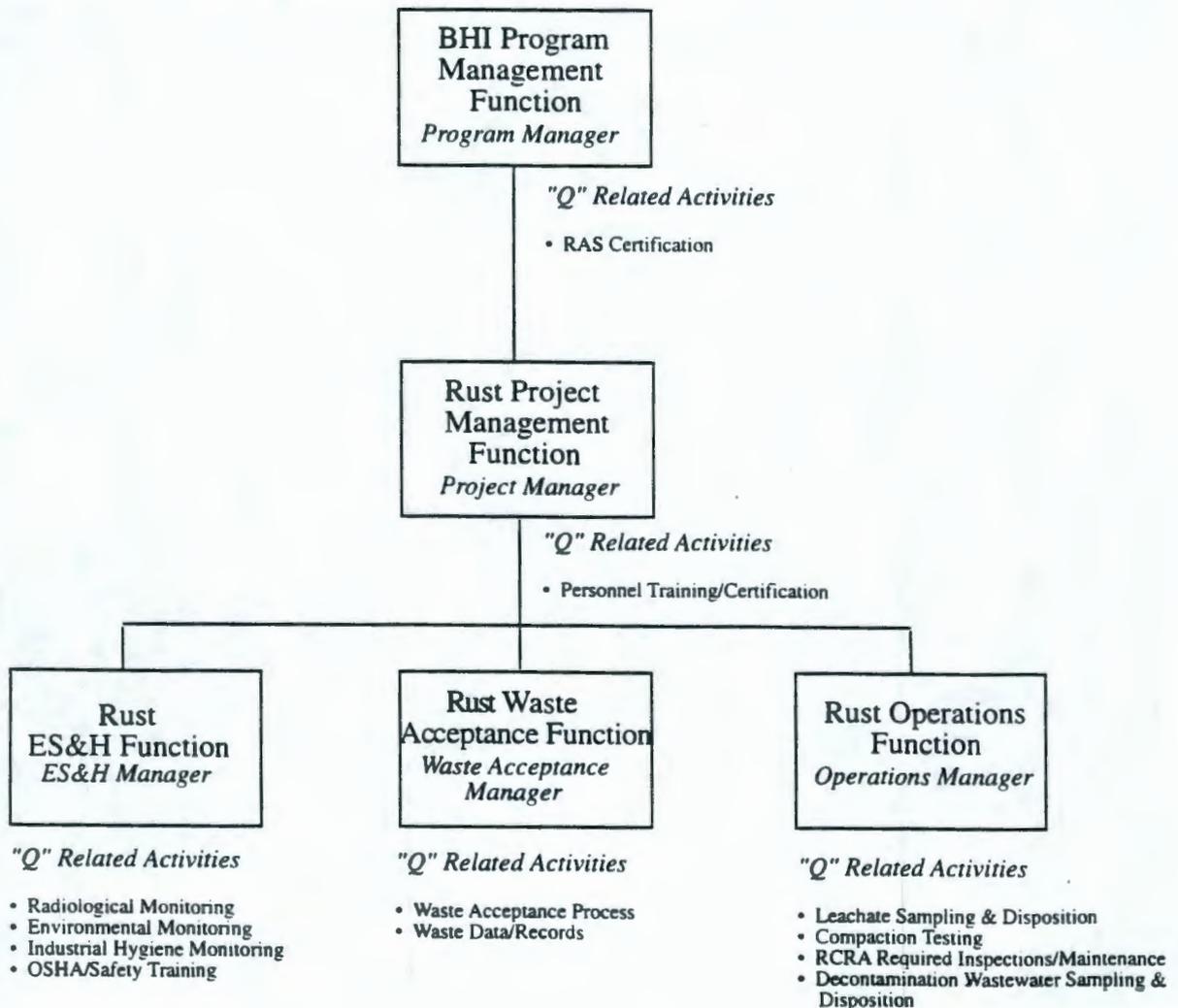
QAI 1.1 - ERDF QA Organizational Interfaces

This quality assurance instruction supplements **Criterion 1 - Organization** with specific definition of ERDF Waste Disposal Operations quality assurance organizations, interfaces and responsibilities. This instruction is aimed at defining the internal QA presence within the Rust organization and the external influences on the QA program implementation, including from BHI, DOE, and EPA. This QAI should be used in conjunction with ERDF administrative policy concerning organization and responsibility, which clearly defines roles and responsibilities within Rust for the performance of work.

Responsibilities and Instructions

QAI 1.1.1 Quality Achieving Functions - Achieving quality standards is the responsibility of those who perform the work. The need for verification, by methods such as reviews or inspections, must be determined as appropriate for individual activities by the project manager and key personnel. Figure 1 graphically describes for ERDF these quality achieving responsibilities which are further described in the following area specific descriptions:

Figure 1 - ERDF Quality Achieving Functional Organization



- **ERDF Project Management** - This function is headed by the Rust project manager and is responsible for performance of project management functions necessary to ensure safe, compliant, and efficient waste disposal operations at ERDF. A self-assessment function will be established by the project manager with key personnel assisting in periodic assessment of quality related activities. Most other work in this function is considered commercial type operations, with only the following activities as "Q" related activities: personnel training/certification.
- **ERDF Waste Acceptance** - This function is headed by the Rust waste acceptance manager and is responsible for ensuring acceptance of only wastes authorized for disposal by regulatory guidance. "Q" related activities in this function include implementation of the checks and balances required by the waste acceptance plan/procedures, record keeping associated with the waste acceptance process, and changes to the waste acceptance criteria which would effect implementation of the waste acceptance process. The third of these activities is controlled by BHI with DOE-RL and EPA approval.
- **ERDF Operations** - This function is headed by the Rust operations manager and is responsible for the proper placement of wastes, maintenance of the overall ERDF facility, and disposition of leachate. "Q" related activities in this function include leachate testing/disposal, compaction testing, and maintenance/inspections specifically required to meet regulatory requirements.
- **ERDF ES&H** - This function is headed by the Rust ES&H manager and is responsible for ensuring safe and environmental compliant waste disposal operations. "Q" related activities in this function include implementation of radiological controls monitoring, industrial hygiene monitoring, environmental compliance monitoring, and any associated training requirements. The radiological controls field work performed in this area will be accomplished by BHI employees under the direction of the Rust ES&H manager. These employees, and their management, are responsible for ensuring quality work and compliance with ERDF health and safety requirements, in exactly the same manner as Rust personnel and their management. The ES&H manager, however, retains overall responsibility for performance and documentation of the radiological controls work and must take necessary action with BHI management to ensure compliance in this area.

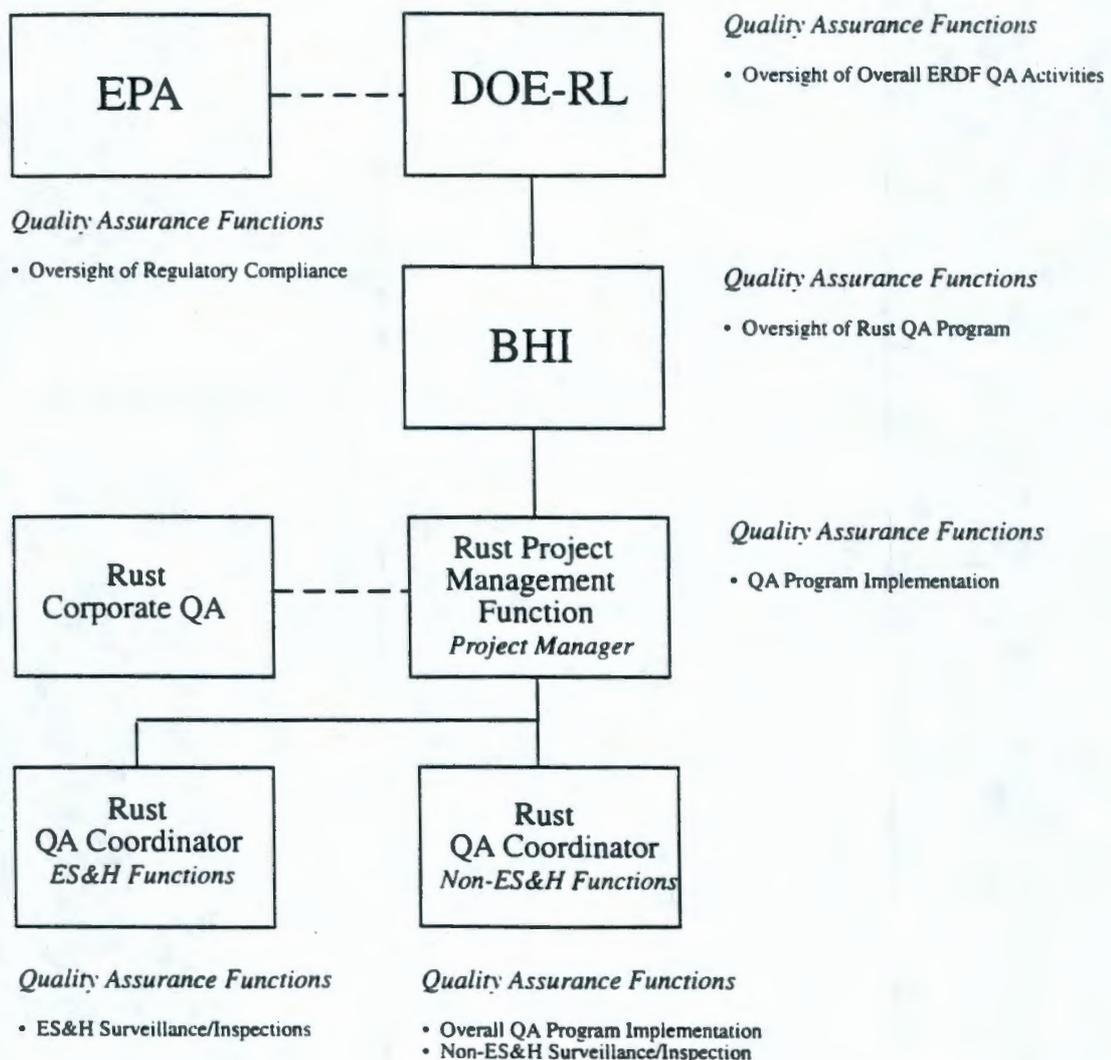
QAI 1.1.2 - Quality Assuring Functions - The quality assuring functions associated with ERDF are graphically displayed in Figure 2 and include the Rust ERDF Quality Assurance Coordinators, the Rust Corporate QA Organization, and BHI/DOE-RL/EPA project management/QA functions:

- **Rust ERDF QA Function** - The ERDF QA function is comprised of two QA coordinators who provide the Project Manager with overall QA support. The ES&H Manager is the "Non-ES&H QA Coordinator" and is the overall QA functional point of contact and responsible for non-ES&H QA activities. The Waste Acceptance Manager is the "ES&H QA Coordinator" and is responsible for ES&H QA activities. This organizational structure allows efficient use of personnel while maintaining verification responsibilities separated from those that actually perform the work.
- **Non-ES&H QA Coordinator** - The ES&H manager is responsible to the project manager for overall implementation of the ERDF QA program and also performing QA Coordinator functions for surveillance/inspection of non-ES&H site activities. His responsibilities also include overall maintenance and upkeep of the QAPjP and providing the main QA interface with BHI, DOE-RL and EPA. For quality functions,

the ES&H manager jointly reports to the Project Manger and the corporate QA manager to ensure independence and track resolution of quality concerns.

- **ES&H QA Coordinator** - The Waste Acceptance Manager also has QA responsibilities specific to QA Coordinator for surveillance/inspection of ES&H site activities. For quality functions, the waste acceptance manager jointly reports to the project manager and corporate QA manager. The waste acceptance manager will report completion of periodic surveillance/inspections to the ES&H manager but only for overall roll-up into the ERDF QA program record.

Figure 2 - ERDF Quality Assurance Functional Organization



- **Rust Corporate QA Organization** - The Rust corporate QA organization will provide overall guidance to the ERDF QA coordinators for development and implementation of the ERDF QA program. ERDF specific programs and implementation will be based upon overall corporate philosophy and programs. Support for surveillance and audits, including qualified auditors, will also be provided as determined to be necessary by the project manager and QA coordinators.
- **External QA Functions** - BHI, DOE-RL and EPA all have differing authority over ERDF waste disposal operations and will provide input through program monitoring, surveillance, and on-site inspections. The BHI QA function will revolve around overall Rust compliance at the ERDF site and implementation of this QAPjP. The DOE-RL QA function will provide necessary oversight of both the Rust and BHI activities at the site as deemed appropriate. Finally, the EPA oversight will revolve around ensuring implementation of the requirements of 40 CFR as the environmental regulatory authority for the ERDF.

QAI 1.1.3 Access to Activities and Documents - Individuals from Rust, BHI, DOE-RL, and EPA who have been identified as responsible for oversight of activities from a quality perspective shall be provided access to activities and documentation supporting those activities.

Criterion 2 - Quality Assurance Program

2.1 General Requirements - Waste disposal operations work performed by or for Rust at the ERDF site must comply with applicable requirements identified in this ERDF Quality Assurance Project Plan. This plan applies to only the operational portion of the ERDF life-cycle, with design, construction, expansion and closure to be covered under separate guidance by BHI. The ERDF QA Program outlined by this plan is designed to adopt and implement the cultural philosophy of both NUREG-1293, Rev. 1 and Rust management policies. In addition to these requirements, ERDF management has established and incorporated other sound business practices to ensure quality in all aspects of work performed.

2.2 Program Description - The QA Program applies to all waste disposal operations at ERDF, including operational, technical and administrative functions. When required to ensure quality achievement, all or portions of the ERDF QAPjP will be applied to Rust subcontractors and suppliers.

2.2.1 Program Basis - The QA Program is based on the concept that work performance is a process that can be planned, performed, assessed, and improved. Since all work is accomplished using the resources of people, equipment, and procedures as directed by management, management is responsible for fostering an attitude of support and encouraging personnel to complete their work in a quality manner. All employees are encouraged to identify noncompliant work or areas for improvement. Management is responsible for identifying (both internal and external) customer needs and expectations, meeting those needs and expectations, and using them as a measure of quality and success.

The achievement of quality in all activities is the responsibility of all employees as led by management. This is to be achieved by a multi-level system of quality verification and assessment:

- *First Level*—Self-checking, verification, and inspection by the individuals performing the work.
- *Second Level*—Internal Quality Control (QC) checks by other than those who performed the work.
- *Third Level*—Management Self-Assessment verifying and assessing the quality achieved in all work under their control.
- *Fourth Level*—Independent assessment by organizations other than those responsible for the work. This includes QA Coordinators and corporate QA support personnel.
- *Fifth Level*—Independent external assessments, performed by organizations external to Rust to assess management performance and achievement of quality.

This multi-level system is designed to ensure that quality is achieved in all work and to provide continuous feedback to management for improvement.

2.2.2 QA Program Levels - The QA Program is to be applied using a graded approach, allowing control over items and activities to be commensurate with their importance and level of risk. The importance assigned to an item or activity will be used to determine the QA Program requirements level assigned to that item or activity. The level must be assigned as early as possible during the planning of an activity or design of an item. The QA Program level will be determined by the manager of the responsible organization in consultation with the QA Coordinator. QA Program levels are as follows:

- **Standard Level**—The QA Program Standard Level is a base level of quality assurance that relies upon workers and project management personnel to perform work in a sound business fashion with quality as a way of life. The facility equipment, procedures, and policies are controlled based upon commercial models and good business practices. The depth of policy and oversight by management is determined by the project manager in order to maintain the facility operational and prudently protect corporate and government equipment.
- **Quality (or "Q") Level**—"Q"-Level requirements provide for application of higher level QA requirements in addition to Standard Level commercial business practices. The ERDF project manager and QA Coordinators jointly determine whether "Q"-Level requirements apply to work based on the importance and risk of the work. Examples of where "Q"-Level requirements may apply include items or activities that support regulatory compliance requirements. The basic group of "Q" level requirements for ERDF are discussed in QAI 1.1.

Application of the QA Program is to be graded. The graded approach provides a means of applying, in sufficient depth, the requirements appropriate to the item or activity

2.2.3 Manual Layout - The QA requirements in this manual are arranged as follows: The "General Requirements" section within a Criterion is a general summary of the requirements included in the Criterion and the scope/applicability. Specific requirements details are contained in the "Standard Requirements" and the "Q"-Related Requirements" sections within each criterion. Quality Assurance Instructions (QAIs) may be found after many Criteria to provide ERDF specific instructions, interpretations, or supplementary requirements.

2.3 Standard Requirements - The Standard Level of quality assurance requirements is a base QA Program that applies to all ERDF waste disposal operations activities. The QA Program level for all activities has been assigned in QAI-1.1 and shall be updated as early as possible by the responsible manager and the QA Coordinator during planning for any changes that impact "Q" level items. If the responsible management determines that the activity does not warrant assignment of a "Q" Level, then the activity is automatically assigned a Standard Level of quality assurance.

2.3.1 Program Implementation - Each organization performing activities covered by the QA Program must establish adequate instructions implementing the requirements of this manual that apply to the work. Implementing instructions shall provide for the following:

- Describe implementation of "Q"-Level quality specific requirements and when they apply,
- Identify organizational interfaces and responsibilities, as well as administrative, technical, and quality requirements,
- Initial release and revisions shall include a review and a documented resolution of comments by appropriate affected management before issuance, and
- Provisions for initial indoctrination and for any necessary continuing training of all employees performing activities affecting quality.

2.3.2 Quality Assurance Project Plan Maintenance - The Quality Assurance Project Plan will be revised whenever needed changes are identified. On an annual basis, normally in the first quarter, the Quality Assurance Project Plan will be reviewed by the project manager for significant changes in operations that may impact quality that may have evolved through a series of minor changes. Quality improvement principles, described in

QAI-2.3, should be considered throughout the performance of work and during maintenance activities for the QA program.

2.3.3 Planning - Programs and supporting activities must be planned, and plans must be reviewed and documented. The scope and the amount of detail in such plans will depend on the scope, complexity, and significance of the work being planned. Organizational responsibilities, interfaces, and implementing instructions must be identified during planning and must be maintained throughout the work. All organizations assigned responsibilities must be included in the review process, and their comments must be resolved.

2.3.4 Quality Assurance Instructions - Quality Assurance Instructions (QAIs) may be found after many Criteria in the Quality Assurance Project Plan. QAIs are intended to provide ERDF specific supplementary requirements and/or explanatory information for implementation of QA requirements that may change more frequently than the criterion.

2.3.5 Interfaces - Company organizations responsible for QA interfaces are specifically identified within the QAIs whenever possible. When the responsible organization is unknown, the assignment of responsibilities should be found in the administrative procedures or from the project manager.

2.3.6 QA Coordinators - QA Coordinators will be assigned by the project manager with the concurrence of the corporate QA manager. Expertise in the areas of activity as well as the complexity of the activity shall be considered when making the assignment. A QA Coordinator is a support resource to assist the project manager in implementing and complying with QA requirements in a cost-effective manner within allotted time schedules. QA Coordinators provide the following support:

- Assist in determining the correct QA Program level in the planning and modification phase of activities,
- Assist the project manager in applying QA requirements to activities during initial and subsequent phases,
- Instruct personnel in the QA requirements that apply to their activities and assist in implementing the requirements,
- Monitor changes to their assigned areas for changes that could impact quality, and ensuring that appropriate quality aspects are incorporated into the activity and this QA program,
- Assist the project manager during external QA audits by customer or other outside (external) organizations. This assistance may include providing responses to findings or formulating corrective actions,
- Conduct periodic reviews of documents and surveillance's of activities to verify compliance with procedures,
- Identify to the project manager areas of weakness or noncompliance,
- Act as the QA representative in the processing and disposition of Nonconformance Reports,
- Initiate Corrective Action Requests or Stop Work Orders, when appropriate per QAI-2.2, to prevent deterioration of quality when other measures have failed to provide correction of conditions adverse to quality,
- Maintain records documenting QA activities in support of the work,
- Assist the project manager in response to internal QA audits and related corrective action,

- Review project reports, computer program verifications, validation reports, procedures, documentation of design reviews, technical and procurement specifications, or other design output documents as required to ensure compliance with the QA requirements,
- Perform reviews of procurement requisitions, pre-award evaluations of suppliers, supplier source inspections, and supplier-generated QA records.
- Review plans for receiving inspections,
- Assist the project manager in applying the QA requirements to the work and, when appropriate, in obtaining changes to the QA program or to customer QA requirements, and
- Review subcontractor and supplier inspection plans as required for completeness and for inclusion of Quality Assurance Requirements, inspections, and required documentation.

2.3.7 Reviews - Originators of all documents are responsible for determining the need for review of those documents and selecting reviewers when necessary. Overall guidance on document control and reviews is found in the ERDF administrative policy. Review by the compliance organizations, such as QA and ES&H, should be considered. Reviewers should provide written comments in their areas of expertise to the originator. Concerns that are outside the area of responsibility of a reviewer may be provided to the originator as recommendations.

All review comments must be resolved by the author with the reviewer; if an impasse develops, the issue shall be escalated to the next level of management. The author will maintain documented evidence of review, including resolution or other disposition of comments. If the author or reviewer is dissatisfied with the resolution then the project manager should be contracted to resolve the technical disagreement.

2.3.8 Management Assessment - Managers will regularly assess the adequacy and implementation of the QA Program in areas for which they are responsible, including the use of the management assessment program described in QAI-2.1.

2.3.9 Personnel Training and Qualification - All employees must be provided indoctrination and training commensurate with their education, experience, and proficiency and with the complexity, scope, and nature of the work. Training needs must be evaluated and training must be provided whenever required to achieve initial proficiency or to adapt to changes in technology, methods, or job responsibilities. The ERDF training plans should address and stimulate professional development and should provide for maintenance of proficiency and continuous improvement. Training shall be subject to ongoing review to determine effectiveness. Training must be documented. (See QAI 2.3 for additional information.)

2.4 "Q"-Related Requirements

2.4.1 Quality Planning - "Q"-related activities must be planned at the earliest time possible during modifications to allow determining appropriate quality requirements commensurate with the change's importance.

2.4.2 Qualifications of Inspection or Verification Personnel - Personnel performing inspection or verification for acceptance of quality-related items or activities must be trained, qualified, and certified (when required) for the functions performed. Management will assess the maintenance of personnel proficiency on a periodic basis.

Requirements for the qualification and certification of personnel must be established and documented.

2.4.3 "Q" Related Procedures - Individual procedures support the QAPjP through the implementation of specific "Q" related activities, including environmental monitoring, waste acceptance, leachate management, waste placement efforts and records management. The following documents contain procedures which complete the "Q" related quality assurance requirements defined by this QAPjP:

- RFS-ERDF-002.3(a) - Waste Acceptance Procedures,
- RFS-ERDF-002.4(a) - Environmental Monitoring Procedures,
- RFS-ERDF-002.5(a) - Waste Materials Management Procedures,
- RFS-ERDF-002.6(a) - Leachate Management Procedures,
- RFS-ERDF-002.7(a) - Equipment Maintenance Procedures, and
- RFS-ERDF-005 - Administrative Procedures

QAI 2.1 - Management Assessment

This instruction is applicable as a Standard-Level QA Program requirement and provides direction for key ERDF personnel in performing and reporting self-assessments of effectiveness and implementation of the QA Program in their activities. The success and effectiveness of the QA Program depends on the personnel and management directly responsible for the work (i.e. quality achieving functions). The QA function provides support, monitors activities, reports compliance, provides management evaluation, and independently assesses implementation of the program.

Responsibilities and Instructions

QAI 2.1.1 Description of Self-Assessment - As used here, self-assessment refers to an evaluation by managers of the use and implementation of the QA Program requirements within their activities and the overall quality performance of those activities.

QAI 2.1.2 Who Performs Self-Assessments - The ERDF project manager will direct individual managers to perform self-assessments on an identified schedule. Self-assessment is intended to be independent of QA, but QA Coordinators may assist in areas such as planning of self-assessments.

QAI 2.1.3 Performance of Self-Assessment - The ERDF key personnel will evaluate the implementation, effectiveness, strengths, and weaknesses of the QA Program as a management tool. Implementation difficulties in applying the QA Program are to be included in this assessment. When appropriate, management planning for improvement should be completed with the assessment. The managers should determine whether the QA requirements are effectively applied. If the QA Program or any part of it is not applicable or is not implemented, the managers should say how it might be made more applicable or effective. Inclusion of quality improvements in organizational goals and their achievement should also be considered along with measurements of productivity. The following are examples of areas that might be considered in performing self-assessment:

- Quality of data or measurements produced,
- Adequacy of internal quality control checks, reviews, and procedures,
- Need for or adequacy of quality assessment procedures for monitoring the quality control procedures and evaluating their quality,
- Need for or adequacy of control of processes to achieve required quality,
- Adequacy of training and proficiency of staff personnel for assigned work,
- Need, accuracy, and availability of calibration standards for controlling quality,
- Adequacy and completeness of documentation, including traceability to samples and work represented,
- Adequacy of maintenance of equipment,
- Adequacy of planning and readiness reviews at the program level as well as for specific tasks (when appropriate),
- Need for and adequacy of internal self-assessments to ensure that internal quality performance is achieved as planned,
- Evaluation of the measurements of failure (rejected work) and the costs of redoing substandard work, and
- Use of internal performance audits, round-robins, and peer reviews to verify accuracy and repeatability of data.

QAI 2.1.4 Areas for ERDF Self-Assessment - The following are ERDF waste disposal operations specific areas that past performance records and current operations should be periodically assessed through the management assessment program:

- Personnel Training/Requalification
- Waste Acceptance Plan Implementation
- Waste Data Tracking System Implementation
- Leachate Sampling/Disposition
- Waste Placement Sequence Adherence
- Compaction Testing Periodicity and Performance
- Dust Control Utilization
- Working Face Size Control
- RCRA Required Inspection
- Radiological Surveys
- Environmental Monitoring
- Industrial Hygiene Monitoring
- OSHA/Safety Training

QAI-2.2 - Suspension of Activities

Rust policy is to conduct all work in accordance with appropriate safety, environmental, and quality standards. Furthermore, the Rust QA Program emphasizes the philosophy that those responsible for the work have primary responsibility for achieving quality in all aspects of their work. This QAI provides responsibilities, authorities, and instructions for suspension of activities to ensure that planning, scheduling and budgetary considerations do not override safety, quality, or environmental protection considerations.

This instruction is applicable to activities internal to Rust ERDF waste disposal operations. For external activities, such as for BHI personnel, suppliers or subcontractors, suspension of activities shall be issued through the project manager unless there are imminent safety concerns.

Responsibilities and Instructions

QAI 2.2.1 Suspension of Work by Employees/Line Management - All employees are responsible for the quality of the work that they perform, and it is expected that they will promptly stop work to correct deficiencies when they are detected. If, at any time, any employee becomes aware of an imminent safety, quality, or environmental condition that has the potential for injury, environmental impact, or a significant quality deficiency, the employee should take immediate action to mitigate the condition, including suspension of activities in the affected area. When the immediate and imminent hazard has been mitigated, the employee must notify the responsible management of prior conditions, actions taken to mitigate the hazard, and current conditions.

When deficiencies of a non-imminent nature are detected, the employee shall notify the responsible supervisor so corrective action can be taken.

Management is responsible for the safety, quality, and environmental compliance of areas and activities under their control. Managers are responsible for taking prompt corrective action when they become aware of deficiencies that may affect safety, quality, or environmental conditions. Managers are responsible for investigating the circumstances and conditions leading up to the condition. Managers are also responsible for establishing conditions under which suspended activities can resume, including rescheduling of work, revision of procedures, or other actions as appropriate.

QAI 2.2.2 Suspension of Activities by Oversight Organizations - It is expected that any safety, quality, or environmental compliance deficiencies detected and reported to responsible individuals will result in immediate resolution. Oversight organization members have the authority to request a formal suspension of activities when other measures to obtain corrective action have failed, and one or more of the following conditions exist:

- If work were to proceed, evidence of the safety, quality, or environmental problem would be covered; thus, a proper and complete investigation, inspection, or correction would be prevented.
- If work were to proceed, there would be a high probability of additional nonconformance, injury, or environmental noncompliance with the attendant rework, repair, or rejection costs of an existing unsatisfactory condition.
- If work were to proceed, irreplaceable data or data that would require significant effort to regenerate could be lost.
- If notification of those responsible has not resulted in corrective action for a significant condition adverse to safety, quality, or environmental compliance.

QAI 2.2.2 Issuance of a Stop Work Order

Imminent Danger Work Stoppage - Individuals identifying a condition requiring immediate work stoppage to protect personnel and/or the environment should stop work in the field and formally document and report the following stop work order information to the project manager:

- Stop work originator and date,
- Specific description of the condition or events leading to the order, including steps taken to resolve the issue before resorting to the formal Stop Work Order, and
- Specific description or limits of work activities stopped and conditions that should be corrected prior to resumption of work.

Non-Imminent Danger Work Stoppage - Individuals identifying a condition requiring work stoppage, but not imminent danger to personnel or the environment should document the following in a Stop Work Order and submit to the project manager for approval:

- Stop work originator and date,
- Specific description of the condition or events leading to the order, including steps taken to resolve the issue before resorting to the formal Stop Work Order, and
- Specific description or limits of work activities to be stopped and conditions that should be corrected prior to resumption of work.

The signature of either the QA Coordinator, the ES&H Manager, or the project manager is required to formally approve the Stop Work Order. Stop Work Orders must remain in effect until the cause of the condition and actions to correct it have been identified, and the order suspending activities has been rescinded. If appropriate or necessary, the activity area or equipment should be tagged, flagged, locked down, or barricaded to prevent inadvertent continuation of activities.

Correction of Condition and Lifting of Stop Work Orders - The project manager shall approve restart of work once corrective actions have been identified and closed, with the concurrence of the QA Coordinator or ES&H manager depending upon the expertise of the condition that caused work to be stopped.

QAI-2.3 - Certification of Personnel

This instruction provides ERDF specific requirements for certification of personnel for site testing requirements. QA audits on-site, as required, will be performed by qualified and certified auditors drawn from the Rust Corporate family of QA resources. Auditor certifications to ASME NQA-1, ASQC, or ISO-9000 in accordance with Rust Corporate QA Auditor Certification Requirements (QA/PAM 7, Rev 1) will be considered acceptable for participation in ERDF audits. No specific QA auditing certification will be required or normally held by on-site personnel.

Responsibilities and Instructions

QAI 2.3.1 ERDF Specific Test/Inspection Positions Requiring Certification

- **Compaction Testing Certification** - Personnel performing compaction testing shall be properly trained in accordance with the following ASTM Standard Test Methods:
 - ⇒ D1556 "Standard Test Method for Density and Unit Weight of Soil in Place by the Sandcone Method."
 - ⇒ D1557 "Test Methods for Moisture-Density Relations of Soils and Soil-Aggregate Mixtures Using 10-lb. Rammer and 18-in. Drop."
 - ⇒ D2216 "Standard Test Method for Laboratory Determination of Water (Moisture) Content of Soil and Rock."
 - ⇒ D3017 "Standard Test Method for Water Content of Soil and Rock in Place by Nuclear Methods."
- **RCRA Required Inspections** - 40 CFR 264.16, WAC - 173.303-330.
- **Sampling** - Personnel performing sampling of leachate, decontamination wastewaters, and environmental monitoring media shall be trained in accordance with approved sampling procedures that implement the requirements of SW-846, Test Methods for Evaluating Solid Waste, Physical/Chemical Methods.
- **Other Inspections/Quality Activities** - The size and type of operation at ERDF does not require an on-site force of personnel certified to perform many activities which are infrequent in nature (i.e. root cause analysis, source inspections, receipt inspections, etc.). Certified corporate personnel will be used if circumstances arise that require a certified inspector to perform such activities.

QAI 2.3.2 Inspection and Test Personnel Requirements

Qualifications — The ERDF training plan/procedures must identify the qualifications needed for identified positions requiring inspection and test certification. Experience and training of personnel are to be commensurate with the scope, complexity, or special nature of the activities. Evaluation methods must be defined to determine a candidate's initial and subsequent capability based upon education, experience, training, and test results or demonstrations of capability. The management personnel responsible for administering the certification process are to be identified.

Indoctrination and Training — The procedures must provide requirements for indoctrination of personnel in the technical objectives and requirements that apply to the

activities. The requirements include applicable codes, standards, specifications, or QA Program elements to be employed. Specific certification aspects for identified positions shall be discussed in the ERDF Training Plan. The program must include required reading or classroom training, along with appropriate on-the-job or test/inspection activities under simulated field conditions.

Determination of Initial Capability — The capabilities of candidates for certification must be determined by an evaluation of the education, training, and relevant experience of candidates, and test demonstration results (compaction testing) or on-the-job observed walkthrough (RCRA inspections).

Evaluation of Performance — The job performance of inspection and test personnel must be evaluated at intervals not to exceed 3 years. Reevaluation and recertification will be by evidence of continued satisfactory performance or a redetermination of capability. Individuals who have not performed inspection or test activities within an area of qualification for 1 year, or who are determined at any time not to have capabilities needed to satisfy requirements to qualify for the job, must be removed from performing inspections or tests until the required capabilities have been demonstrated.

Certificate of Qualification — Qualification of personnel will be certified in writing by an internal memorandum to file and will include the following information:

- Name and title of the individual being certified,
- Activities to which certification applies,
- Basis for certification, such as education, experience, and indoctrination; training; test results; and demonstration of capability,
- Signature of the designated individual who is responsible for certification,
- Date of certification, and
- Date of expiration of certification.

QAI-2.4 - Quality Improvement

This QAI provides information and guidance on the types of mechanisms and processes used at ERDF to continuously improve the quality of items and activities. This QAI is a standard level QA practice and is employed as appropriate to promote continuous improvement and efficient commercial type operations at the site.

Responsibilities and Instructions

QAI 2.4.1 General Quality Improvement Philosophy - The purpose of quality improvement is to prevent problems that may lead to decreased quality in our products and services. This includes identifying and correcting problems before the product or service is released from control of the waste disposal operations at ERDF. The ability to prevent or detect deficient items or services at all levels, particularly by quality achieving personnel, is a measure of success.

To continue to provide the highest quality goods and services to our customers (both internal and external), all employees are required to continuously seek to improve the quality of the work that they perform. Management at all levels is expected to foster and encourage an attitude of no-fault in identification of problems and an atmosphere of openness to suggestions for improvement. Management is responsible for identifying both the needs and expectations of their internal and external customers, communicating these to all individuals involved in the work, and encouraging and supporting their employees in exceeding the customer expectations whenever possible.

QAI 2.4.2 Implementation Mechanisms - Numerous mechanisms have been established within Rust to support quality improvement efforts. All organizations shall apply and support these mechanisms as deemed appropriate by management to prevent and detect problems and improve the quality of work:

- **Trend Analysis**—Measurement and analysis of quality and performance indicators to statistically detect changes over a period of time.
- **Planning**—The conscious effort of predetermining a course of action, establishing performance objectives, identifying opportunities for improvement, identifying and mitigating potential problems, and informing all participants. Planning is broad-based and may include peer reviews, trend analysis, risk assessments, safety analysis reports, and design reviews.
- **Root Cause Analysis**—The process of evaluating causal factors in an effort to identify the single most likely cause of a problem. Identification of the root cause is the goal of investigations, corrective actions, and trend analysis.
- **Performance Goals and Objectives**—Establishment of measurable performance indicators. These require determination of current performance and the actions required to improve the process or activities.
- **Nonconformance Reporting**—Systematic reporting, evaluating, and dispositioning of identified problems.
- **Tracking and Follow-up**—The recording and completion of actions required to resolve problems or improve the process, according to a planned schedule.
- **Corrective Action**—The formal process of determining causal and root causes; correcting specific, similarly affected items or activities; and taking necessary actions to preclude recurrence of the problem.
- **Productivity/Quality Improvement (PQI) System**—A method for all employees to identify areas for improvement in quality, productivity, safety, or environmental

compliance and to receive awards/rewards for improvements that reduce costs to Rust and the government.

- **Management Walkdowns**—The routine walkdown of work areas by all levels of management to observe first-hand the work in progress, communicate with those performing the work, and identify potential or current problems.

Use of these mechanisms shall be formally documented by the Project Manager through internal memorandum, report, or presentation to management depending upon the nature of the activity. Record copies of activities shall be maintained in the project files.

Criterion 3 - Design Control

3.1 General Requirements - Design control varies greatly for a low-level radioactive waste landfill based upon the stage in the life-cycle. Significant design control requirements must be in place and properly implemented during characterization, siting, preliminary design, and final design. Expansion of the landfill capacity and/or cell closure also require significant design control to ensure that the appropriate regulatory, engineering, and safety requirements are met and can be properly implemented through the design and appropriate construction specifications. All organizations that participate in preparation of such design documents must implement a design control system within its area of specific responsibility. The system must ensure that the design efforts are planned, controlled, and completed in an orderly manner and in accordance with the requirements of this Criterion. Design control applies to new designs and design changes, and to research and development that includes design activities. Design documents may include drawings, design inputs and criteria, specifications, design analysis, computer programs, system descriptions, procedures, and instructions.

The waste disposal operations at ERDF have limited impact on the facility design or maintenance of configuration control. The operations consist of leachate management, waste acceptance, waste placement, waste transportation shuttle service, and other support activities. These operations rely on an in-place, established, and operational landfill facility (including support systems). The design control standard requirements have been tailored to that minimal impact which is contained in appropriately developed, documented, and implemented plans and procedures. These plans and procedures implement the design characteristics for waste placement in the landfill cells and ensure operation of the facility within the design/safety envelope. Major civil upgrades to support waste disposal operations (i.e. trailer installation, scale installation, etc.) will be documented via red-line drawing changes or new electronic drawings and submitted for BHI approval. The actual ERDF configuration control is outside of the scope of this QAPjP and resides within BHI QA requirements. Design control for activities other than actual waste disposal operations (i.e. additional cell design, closure cover design, etc.) are also outside of the scope of this QAPjP and reside with BHI QA programs.

3.2 Standard Requirements

3.2.1 Operational Design - The organization preparing operational design documents must document controls and procedures that define the responsibilities and delineate the actions required to implement the requirements identified in appropriate design specifications. Adequate administrative procedures must be in place to ensure that original plans, along with modifications, are properly prepared, reviewed, and approved to implement design requirements. Specific design control guidance to be applied to the plans and procedures identified in Section 2.4.3 is provided in QAI 3.1. From an environmental compliance perspective, these procedures combined with this QAPjP must incorporate, implement, and verify quality of implementation of the following operational landfill requirements:

- 40 CFR 264.301(a)(2) - Leachate Collection and Removal - Maintenance and operation of an adequate system to ensure that is capable of maintaining leachate depth less than one foot over the liner.
- 40 CFR 264.303(b) - Monitoring and Inspection - Monitoring must be performed periodically and after certain events to ensure proper liner and leachate collection system operation.
- 40 CFR 264.304 - Response Actions - Planning and implementation of response actions based upon landfill conditions (i.e. leachate flow rates).

- 40 CFR 264.309 (b) - Waste Placement - The contents of each disposal cell must be maintained with the approximate location of each waste type in the cell.

3.2.2 Computer Software Design - The ERDF automation/waste acceptance process software shall be designed, developed, and tested to the requirements identified in the ERDF Automation Plan, RFS-ERDF-006. The Waste Acceptance Manager shall be responsible for development and implementation of the following controls on the automation software:

- **Software Design** - The ERDF Automation Plan shall constitute the design basis and functional specification for the ERDF software and be reviewed and approved by appropriate personnel.
- **Software Verification Testing** - Software shall be verification tested prior to initial operational use in accordance with QAI 3.2 and the requirements of the automation plan. Verification testing plans and reports shall be developed, documented and approved by the Waste Acceptance Manager as required by QAI 3.2. Verification tests must demonstrate the capability of the software to produce valid results for test problems over the range of operation of the program. Verification testing may range from a single test to a series of tests performed on individual modules, followed by an overall computer program test.
- **Software In-Use Testing** - Testing of the software shall also be performed whenever operating system changes are made or revisions to the base software are undertaken. All required testing shall be performed prior to placing the system on-line at the ERDF with actual waste data and systems. In-use testing plans and reports shall be developed, documented and approved by the Waste Acceptance Manager as required by QAI 3.2. Software testing shall ensure that both changes to specific portions of software, as well as the overall software package, are still valid over the range of operation of the program.
- **Software Control** - ERDF software shall be revision marked and controlled by the Waste Acceptance Manager to ensure use of only approved versions. Superseded software shall be destroyed except for one copy which shall be appropriately archived in accordance with records management policies. Appropriate in-use and verification testing shall be determined

3.2.3 Environmental Data Collection Design - The design of data collection programs to comply with environmental regulations for air, liquid, and solid medias requires a defined, controlled, and documented process to ensure validity of results. The ERDF specific requirements for design of environmental collection programs are further defined in QAI 3.3.

3.3 "Q" Related Requirements - No requirements beyond those identified in Standard Requirements apply.

QAI-3.1 - Design Control Implementation

This instruction and the requirements of Criterion 3 are applicable to the following ERDF requirements for waste disposal operations:

- Implementation of Safety Basis Commitments (i.e. waste acceptance requirements and inventory and working face restrictions),
- Compaction testing to ensure landfill structural stability, and
- RCRA compliance system integrity/operability (i.e. leachate collection)

Responsibilities and Instructions

Operational plans and procedures shall be prepared, reviewed, approved, and implemented to ensure that operational design control requirements are met during ERDF waste disposal operations. These plans and procedures shall be reviewed/approved by appropriate oversight organizations (BHI, DOE-RL, and EPA) as appropriate to the area of expertise required to implement the requirement. Changes to operational plans or procedures impacting these activities, as determined by the project manager, shall also receive appropriate review and approval to ensure that waste disposal operations remain in compliance.

Facility modifications to support waste disposal operations shall also be adequately documented and submitted to BHI for incorporation into the overall design configuration control. This includes the addition of major civil upgrades (i.e. trailers, facilities, etc.) or major modifications to existing facilities/systems. Appropriately approved as-built drawings shall be provided upon the completion of mechanical acceptance of the facilities/systems.

QAI-3.2 - Computer Software Testing

This instruction is applicable to testing and maintaining the ERDF waste acceptance/automation software.

Responsibilities and Instructions

QAI 3.2.1 Automation Responsibilities - The Waste Acceptance Manager is responsible for the development, testing, implementation, and maintenance of the ERDF waste acceptance/automation software and system.

QAI 3.2.2 Software Requirements - The automation system shall comply with the performance requirements identified in the ERDF Automation Plan, RFS-ERDF-006.

QAI 3.2.3 Overall Software Testing - Test requirements and acceptance criteria must be developed and approved by the Waste Acceptance Manager. Requirements for computer program tests, including verification and in-use tests must be controlled and documented. The test requirements and acceptance criteria must reflect the design or other technical requirements of the users.

QAI 3.2.4 Verification Testing - The automation software for the ERDF shall be verification tested prior to being placed into use, including a full system test involving the truck scale, data entry over the Bechtel LAN, and other local entry. Verification tests must demonstrate the capability of the computer program to produce valid results for test problems within the range of usage described in the program documentation. Acceptable test methods for verifying computer programs include the following:

- Hand calculators.
- Calculations using comparable, proven programs.
- Empirical data and information from technical literature.

Program verification must demonstrate required performance over the range of operation of the program. Verification testing shall include the full spectrum of data entry points, including: truck scale, waste profile, waste acceptance, and waste placement entries. The software shall then be verified to properly enter the data into the overall ERDF database, perform the proper waste acceptance verification and calculation functions, and print out accurate periodic reports.

QAI 3.2.5 In-Use Applications Tests - Test problems must be developed and documented to permit users to confirm acceptable performance of the computer program in operation. Test problems must be run whenever operating system configuration changes are made.

QAI 3.2.6 Test Procedures - Computer program test procedures will include the following applicable elements:

- Required tests and test sequence.
- Required ranges of input parameters.
- Identification of the points at which testing is required.
- Criteria for establishing test cases.
- Requirements for testing logic branches.
- Anticipated output values.

- Test problems.
- Reports, records, standard formatting, and conventions.

QAI 3.2.7 Test Results and Records - Test results must be documented and the results evaluated to ensure that computer program test requirements have been satisfied.

Verification test records must include the following:

- The computer hardware used,
- The version of the software,
- Date of the test,
- Tester or data recorder's name,
- Test problems,
- Results and acceptability,
- Action taken in connection with any deviations from the test requirements, and
- Name of person evaluating the test results.

In-use test results must include the following:

- The version of the software,
- Computer hardware used,
- Date of the test,
- Tester or data recorder's name, and
- Acceptability of test results.

QAI 3.3 - Design of ERDF Environmental Data Collection Programs

This instruction identifies supplemental requirements applicable to the design of ERDF specific environmental compliance data collection programs. It is applicable to data collection systems that will provide environmental data to be used in making regulatory decisions or demonstrate compliance with the ERDF ROD or implementing guidance.

Responsibilities and Instructions

QAI 3.3.1 Overall Requirements - Processes for the collection of environmental data will be defined, controlled, verified, and documented. The design process for a data collection program shall include establishment of field sampling methods, sample handling and custody, analytical test methods, techniques for assessing limitations on data use, and data reporting. The design of the data collection process shall be performed as part of the overall planning for environmental compliance samples. Some overall compliance instructions, such as sample labeling and chain-of-custody shall be implemented through overall ERDF guidance found in this QAPjP (QAI 13.1 and QAI 13.2). More specific detailed implementation instructions shall be found in specific operating procedures for each environmental compliance sampling event.

QAI 3.3.2 Design of Data Collection System - Design of a data collection program may be completed at one time or in stages depending on the nature of the work and the information known. The initial ERDF data collection design was performed as part of the ERDF mobilization process and will be modified as necessary to retain compliance with environmental regulations or as deficiencies are identified that require a modification of the program(s). Based on the intended uses of the data to be collected, the data collection system design, equipment, and data collection process are documented for the following environmental sampling types in operational planning identified below:

- Environmental Air Samples - ERDF Environmental Monitoring Plan
- Leachate Samples - ERDF Leachate and Washwater Management Plan
- Washwater Samples - ERDF Leachate and Washwater Management Plan

Design of data collection systems for ERDF shall be based upon identified data quality objectives that outline the data needs and determine an appropriate data collection system. The design of the data collection systems shall consider:

- Data quality needs, including precision, accuracy, detection limits, completeness, and comparability,
- Measurement/data acquisition methods,
- Data review, validation, and verification requirements and methods,
- Reconciliation of data with data quality objectives, and
- Sample types and sampling locations,
- Sampling equipment to be used,
- Sample identification, traceability, custody, and handling requirements from collection through analysis and disposal,
- Selection of analytical methods,
- Calibration of monitoring and sampling field equipment and instruments,
- QC samples including equipment blanks, spikes, and duplicates,
- Data reporting, review and documentation requirements, and
- Development, retention, protection, and disposition of records.

QAI 3.3.3 Assessment of Data Usability - Data that will be used to characterize environmental compliance and impact of ERDF operations shall be qualified according to the intended use of the data. Data that was not collected under known controlled conditions and plans must be qualified as such to ensure that such data will only be used as appropriate.

QAI 3.3.4 Documentation - Design of the environmental data collection programs must be documented in appropriate governing operational plans as identified in QAI 3.3.3. Such documentation shall be approved by the Project Manager, QA Coordinator, BHI, and regulatory agencies as appropriate.

QAI 3.3.5 Revision Control - Data collection planning changes, including field changes, shall be subject to the same review and approval process as the original documents as defined in the ERDF Administrative Procedures, RFS-ERDF-005.

Criterion 4 - Procurement Document Control

4.1 General Requirements - Procurement document control varies greatly for a low-level radioactive waste landfill based upon the stage in the life-cycle. Significant procurement document control requirements must be in place and properly implemented to procure characterization/siting, preliminary design, final design, and construction services and/or equipment. Expansion of the landfill capacity and/or cell closure also require significant procurement document control to ensure that the appropriate regulatory, engineering, and safety requirements are met and can be properly implemented.

The waste disposal operations at ERDF have limited impact in meeting facility design specifications through procurement actions. Crucial activities revolve around proper operations to place, compact, and test the compaction of the waste, rather than verifying/accepting the equipment that performs the activity. Waste disposal equipment, and support facilities, must be adequate to allow proper placement of the waste, but are commercial grade items that impact operability more than proper waste placement. ERDF project management shall ensure that equipment is capable of performing the types of services required, but shall place quality emphasis on the actual operation of the equipment and testing of the waste compaction rather than equipment procurement control.

Procurement documents for those quality impacting items identified in QAI 4.1 shall be controlled to ensure that design bases and other requirements, such as QA requirements, are included or identified in procurement of items or services, whether purchased directly or by subcontractors. Procurement of commercial grade services are not impacted by this criterion and shall be performed in a good business fashion and in accordance with company policies

4.2 Standard Requirements - Procedures shall be established for preparing and controlling procurement documents used to obtain quality related items and services from suppliers. This procedure is described in QAI 4.1 for ERDF.

4.3 "Q"-Related Requirements - In addition to the Standard Requirements previously described, the following requirements apply to procurements for activities that have been designated "Q" Level.

Supplier QA Program - Procurement documents may require that suppliers have a documented QA Program appropriate for the equipment being procured. Specific quality requirements shall be identified in the procurement documentation.

Approval - Procurement documents for "Q" related items or services shall be reviewed and approved by the appropriate QA Coordinator.

QAI-4.1 - Procurement Document Control Implementation

This instruction and the requirements of Criterion 4 are applicable to the following ERDF specific equipment/services for waste disposal operation procurements:

- Sampling equipment for leachate (including bottles, preservatives, etc.).
- Laboratory services for environmental samples,
- Compaction testing equipment designated M&TE by QAI 12.1,
- Replacements for installed ERDF environmental compliance components, as identified by the project manager and QA coordinator, and
- Other equipment/services identified by the QA Coordinator and approved by the project manager.

This instruction and the requirements of Criterion 4 are not applicable to commercially available equipment, which will be procured using good business practices. The following types of equipment/services are considered commercially available for ERDF waste disposal operations:

- Waste placement equipment,
- Support equipment and facilities,
- Transportation equipment (as appropriate),
- Fuel and maintenance services, and
- Support supplies not specifically identified as quality equipment above.

Responsibilities and Instructions

QAI 4.1.1 ERDF Procurement Document Preparation/Approval - Procurement documentation for quality items or services shall be prepared by the appropriate line management and approved by the project manager and QA coordinator. Replacement equipment for ERDF facilities purchased by Rust shall be reviewed with BHI to determine what, if any, quality requirements apply prior to preparing the procurement documents. Appropriate BHI approvals shall also be pursued for replacement of government furnished systems/equipment.

QAI 4.1.2 Content of Procurement Documents - Quality related procurement documents shall contain the following:

- **Scope of Work**—A clear, concise statement of the scope of the work to be performed by the supplier.
- **Technical Requirements**— Appropriate technical requirements must be specified, with potential sources of information: drawings, specifications, environmental regulations, codes, standards, procedures, or instructions (including revisions) that describe the items or services to be furnished. The procurement documents must also include identification of any required tests, inspections, and acceptance requirements to be used in monitoring and evaluating the supplier's performance.
- **Rights of Access**—Provisions may be made in the procurement documents for access to the supplier's and sub-tier supplier's facilities and records for inspection or audit by ERDF personnel if determined by the project manager to be necessary.

Criterion 5 - Instructions, Procedures, and Drawings

5.1 General Requirements - Instructions, procedures, and drawings appropriate to the circumstances shall be developed for control of all work performed to achieve the required quality.

5.2 Standard Requirements - Organizations shall develop appropriate procedures and instructions for control of their activities and processes. Managers are responsible for the following actions:

- Identifying procedures and instructions that are needed,
- Ensuring that the procedures and instructions adequately describe the work, and
- Ensuring that personnel are trained in the use of the procedures and instructions.

5.2.1 Content of Procedures - The procedures and instructions controlling operations work should include the following as appropriate to the type of work and associated risk:

- Responsibilities and interfaces in performing the work,
- The method and sequence by which an activity will be performed,
- The records to be generated, including standard forms for recording data, and
- Acceptance criteria in both qualitative (such as samples or standards of workmanship) or quantitative (such as dimensions, tolerances, or limits) forms.

5.2.2 Development, Review, Use, and Control of Procedures - Procedures shall be adequately controlled from development through obsolescence to ensure operations are properly carried out, including:

- Personnel technically competent in the field shall prepare and validate, as necessary, the work procedures and instructions,
- Procedures shall be reviewed and approved prior to use in the field,
- Controlled copies of procedures shall be clearly marked and removed when superseded, and
- Personnel shall be familiar with procedures and subsequent changes through training, briefings, or required reading as appropriate.

5.3 "Q"-Related Requirements - Initial release of "Q" related procedures identified in Section 2.4.3 shall be submitted to BHI, DOE-RL, and EPA, as appropriate, for review and approval prior to implementation. Changes to "Q" related procedures shall be approved in accordance with the ERDF Administrative Procedures prior to implementation based upon the significance of the change.

Criterion 6 - Document Control

6.1 General Requirements - Preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality must be controlled to ensure that current and correct documents are being employed by those performing the work. Such documents (instructions, procedures, and drawings), including changes, shall be reviewed for adequacy by and approved for release by authorized personnel.

6.2 Standard Requirements

6.2.1 Document Control - A system must be established and implemented for the control of documents. The system shall ensure that current and correct documents are available to personnel where the work is performed and must provide for the following:

- Identification of documents to be controlled,
- Methods of distribution,
- Assignment of responsibilities for preparing, reviewing, approving, issuing, and controlling documents,
- Review of documents for adequacy, completeness, and correctness before approval and issue, and
- Identification of controls applied to unapproved, uncontrolled, or superseded documents to prevent their inadvertent use.

6.2.2 Change Control - Document changes must be reviewed and approved by the same organizations that performed the original review and approval (unless other organizations have been specifically designated). The reviewing organizations shall have access to pertinent data and background information upon which to base their approval. Minor changes, such as inconsequential editorial or typographical corrections, do not require the same review and approval as the original document. To prevent the omission of a required review, the document control system must identify personnel who may authorize minor changes that do not require additional reviews.

6.3 "Q"-Related Requirements - No requirements beyond those identified in Standard Requirements apply.

Criterion 7 - Control of Purchased Material, Equipment and Services

7.1 General Requirements - Procedures must be established for the control of purchased items and services to ensure conformance to procurement documents and specifications. These procedures must address the following subjects and the extent of applicability:

- Planning of procurement activities.
- Evaluation and selection of suppliers.
- Source inspection and audits.
- Assessment of supplier Quality-related activities.
- Inspection of purchased items at receipt.
- Documented evidence of conformance of purchased items or services to procurement

7.2 Standard Requirements - Procurement of most major equipment will occur through the Rust corporate offices and will use standard corporate procurement practices. Procurement of any quality related equipment >\$5,000 will be managed and approved through the Rust corporate offices. A procurement specific quality assurance package that includes the applicable items from Section 7.1 above shall be developed based upon corporate policy and submitted to the following personnel for review and approval:

- Corporate equipment used on the ERDF site - ERDF Project Manager, appropriate ERDF QA Coordinator, and Corporate Personnel (as identified in administrative procedures based upon capital outlay).
- Replacement government equipment - Same as corporate equipment above plus BHI Project Management and BHI QA.

Small quality equipment procurement (i.e. items discussed in QAI 4.1) shall be performed in accordance with the following requirements:

7.2.1 Planning of Procurement Activities - Procurement activities shall be planned and documented in accordance with Criterion 4 to ensure a systematic approach to the procurement process. The planning process must clearly identify the actions to be taken to ensure quality of procured items or services and the responsibilities of impacted personnel.

7.2.2 Supplier Evaluation and Selection - The selection of suppliers for award of a procurement must be based on evaluation of the supplier's capability to provide items or services in accordance with the requirements of the procurement documents. Management determining selection shall document the process and criteria for evaluation and selection of suppliers.

7.2.3 Evaluation of Supplier Performance - The manager purchasing the items or services shall establish with the suppliers the means and interfaces necessary to verify supplier performance. These means shall be specifically documented as requirements in the procurement documents, as required. Measures may include the following as appropriate to the individual procurement:

- Document the understanding concerning supplier performance as provisions and requirements of the procurement documents,
- Review supplier-generated or supplier-processed documentation for compliance with requirements,
- Identify agreed upon changes and process information about changes,
- Ensure efficient document exchange or transmittal with the supplier, and

- Establish the frequency and scope of any necessary inspections or surveillance.

The extent of verification of supplier performance is a function of the importance, complexity, and quantity of the item or service procured. Verification must be conducted as early as possible by qualified people assigned to check, inspect, or witness the activities of the supplier. Technical activities for which the responsible manager is deemed qualified by the ERDF Project Manager will be verified by that responsible individual. Appropriately trained and qualified corporate resources will be used for verification when the Project Manager deems necessary. Verification is not normally planned for ERDF procurements and use of corporate assets will be considered if such activity is required. Purchase of equipment for BHI to replace existing ERDF systems or equipment shall be performed in accordance with the same specifications as the original purchase (including evaluation of supplier performance), unless deviation is desired by BHI.

7.2.4 Acceptance of Items - Methods must be established in procurement documents for the acceptance of quality related items furnished by a supplier. Before offering an item for acceptance, the supplier quality system shall verify that the item furnished complies with procurement requirements. Procurement specifications and inspection and test requirements shall be satisfied and any nonconformances dispositioned before the procured item is used or put into service. In cases where there are indications or evidence that suppliers knowingly supplied items or services of substandard quality, the project manager shall be notified. This information will be investigated, and, if substantiated, reported to the appropriate corporate personnel. The information will also be reported through the DOE occurrence reporting system if replacement of government equipment was being pursued.

7.2.5 Commercially Available Items - A vast majority of the equipment and supplies at the ERDF are considered commercial items and may be accepted for use by the cognizant management. A receipt inspection for item conformance with procurement documents and operability (as necessary) should be accomplished by the cognizant manager to ensure that the item is of an acceptable quality for ERDF waste disposal operations. Appropriate action should be taken with the supplier if:

- The item is damaged/unusable,
- The item is different than the item procured,
- The item was not properly calibrated or otherwise tested as required in the procurement documents, or
- Applicable documentation requested by the procurement documents was not received or is incomplete.

7.2.6 Commercially Available Services - Acceptance of commercial grade services, such as maintenance, engineering or consulting services, that cannot be based on physical inspection or testing will be based on one or more of the following:

- Technical verification of the data produced.
- Surveillance and/or audit of the activity.
- Review of objective evidence for conformance to the requirements of the procurement documents (such as certifications or design reports).

Cognizant management should ensure that services are properly performed before accepting completion of the activity from the supplier and authorizing payment.

7.3 "Q"-Related Requirements - In addition to the Standard requirements identified above, the following requirements apply to procurement documents that have been designated "Q"-related.

7.3.1 Methods of Acceptance - Acceptance of a "Q" related item or service shall be based on one or more of the following methods, as appropriate to the procurement.

- *Receiving Inspection*—Inspections upon receipt of items or services shall be performed in accordance with established procedures. Inspections must obtain objective evidence to verify features such as configuration; identification; and dimensional, physical, or other characteristics. When procurement documents require supplier documentation to be furnished before the receipt inspection is performed, the inspection must be coordinated with the review of the documentation.
- *Source Verification*—Source verification that is identified as required must be performed at the earliest time practical after award so deficiencies may be detected and corrected before subsequent work precludes verification. Audits may be conducted, when applicable, to determine supplier conformance with specified requirements of the QA Program. All verifications at the source shall be arranged through corporate procurement personnel and shall include personnel appropriately qualified to ASME NQA-1, ASQC or ISO-9000.
- *Post-Installation Testing*—Before post-installation testing is performed, test requirements and acceptance documentation shall be mutually established by Rust and the supplier.

7.3.2 Control of Supplier Nonconformances - The purchaser and the supplier must establish and implement methods for disposition of items and services that do not meet the requirements of procurement documents. These methods must contain as a minimum provisions for the following:

- Evaluation of nonconforming items,
- Submittal of nonconformance notices to the purchaser by the supplier, defining the nonconformance (including a disposition recommended by the supplier) and supporting technical justification for "accept as is" or "repair" dispositions,
- Disposition by Rust of the supplier's recommendation,
- Verification of the implementation of the disposition, and
- Maintenance of records of nonconformances submitted by the supplier.

7.3.3 Analytical Services Requirements - Procurements for analytical services of environmental compliance samples shall be accomplished such that laboratories are required to meet applicable requirements for testing and data reporting. The statement of work shall require:

- Specific SW-846 methods shall be called out for each sample and those methods shall be included within the procurement statement of work as required to be performed in accordance with the requirements of SW-846.
- The laboratory shall implement internal chain-of-custody procedures that interface with the ERDF specific chain-of-custody instructions identified in QAI 13.2.
- The laboratory shall be required to be approved:
 - ◆ The WMX Technologies laboratory verification program and continue to stay certified based upon periodic surveillance through the WMX program or

- ◆ Be under contract to other Hanford Operating Contractors (i.e. WHC, BHI or PNNL) and continue to stay certified based upon periodic surveillance through the appropriate contractor program.

The use of duplicates, blanks, and/or spikes (as appropriate) will also be included in the design of data collection systems (per QAI 3.3) and documented in the appropriate operational plans. These additional quality checks will be used by ERDF management personnel to periodically assess the quality of data provided by the laboratory and determine if additional monitoring or evaluation is required.

QAI - 7.1 - Supplier Selection

This instruction describes interfaces applicable to selection of suppliers for "Q"-Level procurement of ERDF items and services.

Responsibilities and Instructions

QAI 7.1.1 Applicability - QA involvement in the selection of suppliers is limited to procurements for which requisitions require supplier pre-award evaluation or other procurements in which QA assistance is requested by project management.

QAI 7.1.2 Supplier Evaluation - Any required technical review of suppliers should be completed before the QA evaluation is performed. The QA Coordinator will then determine if supplier submittals comply with the specified QA requirements. When the results of the evaluation are indeterminate and implementation of the supplier's QA Program cannot be determined by other means, or when the importance of the quality of the procured items or services justifies further evaluation, the QA organization must perform an audit or pre-award survey at the supplier's facilities. This audit may be performed through use of Rust corporate resources in accordance with Criterion 18 and QAI 18.1.

Suppliers found unacceptable must be identified, along with detailed information concerning their areas of deficiencies. Acceptable suppliers must be identified to the procuring manager for final negotiations and selection.

QAI 7.1.3 Records - When the supplier is required to maintain specific records, the retention times, disposition, or submittal requirements must be specified in the procurement documents. The decision process and justification for supplier selection will also be documented and retained in the project record files.

QAI 7.1.4 Analytical Services - The Waste Acceptance Manager shall act as the main contact for interface with contracted off-site laboratories. Laboratory services shall be procured and monitored in accordance with the requirements of Section 7.3.3. The Waste Acceptance Manager shall perform a quarterly surveillance of laboratory performance through review of results of blanks, spikes, and duplicates submitted to the contracted laboratory during the period to evaluate supplier performance. The results of this surveillance shall be used in determining the ongoing use of the laboratory and compliance with the analytical services statement of work. On-site evaluation of the laboratory is not considered necessary based upon the limited quantity of samples, the requirement for CLP participation, and the use of ongoing blanks, duplicates, and/or spikes as necessary to support the individual environmental data collection programs.

QAI - 7.2 - Procurement Planning Acceptance

This instruction identifies the requirements and interfaces applicable to the planning for acceptance of procured items and services. It is applicable when requested or when "Q"-Level procurements are performed.

Responsibilities and Instructions

QAI 7.2.1 Prerequisites - Pre-procurement planning and the requisition review process shall establish one or more of the following methods for accepting items or services: receiving inspection, source inspection, functional testing, or review of supplier-generated documentation. When acceptance is by functional testing or source inspection, the procurement documents must include the appropriate requirements.

QAI 7.2.2 Non-"Q" Related Acceptance Planning - For Standard Level procurements, the requisitioner is responsible for planning and making arrangements for acceptance of items or services.

QAI 7.2.3 "Q" Related Acceptance Planning - For "Q"-Level procurements, the assigned QA Coordinator assists the requisitioner and appropriate corporate procurement personnel with the planning and performance of acceptance activities. They shall jointly plan the following activities:

- *Receipt Inspection*—Physical inspection for compliance with technical requirements must be performed by the requisitioner responsible for these requirements and does not include the activities of commercial inspection, such as count, damage, matching, or stock numbers. Review of supplier-submitted documents must be performed by technical personnel, assisted by the QA Coordinator as necessary
- *Functional Testing*—When acceptance is to be based upon functional testing performed after receipt, technical planning shall include development and approval of a test plan. The test plan must refer to or include the actual test procedures, acceptance criteria, and data recording requirements and be approved by Project Manager and appropriate QA Coordinator prior to performance.
- *Source Inspection*—Source inspection activities must be planned, including verification and implementation of QA requirements. Inspection Hold and Notification points identified in the procurement documents must be planned to support the supplier's schedule. When the requisition requires inspection or tests utilizing the supplier's procedures, the test procedures must be reviewed and accepted by Rust technical personnel before use.
- *Supplier Documentation*—When acceptance planning requires that either complete or partial acceptance is based upon documents provided by the supplier, the acceptance plan shall include provisions to track the status of required submittals, dates of review, acceptance status, and dates. Documents shall be transmitted for review by both technical personnel and QA Coordinators for acceptability.

QAI 7.2.4 Nonconformances - Items that have been physically received and found to have deficiencies in documentation, in physical attributes, or during functional testing must be segregated. A Rust NCR shall be prepared in accordance with QAI 15.1 and appropriate actions to resolve the NCR taken as outlined in that instruction. The project manager and/or corporate procurement must be contacted to assist in resolution with the supplier. Nonconformances to requirements of procurement documents, which have been identified by a supplier nonconformance report, shall be forwarded to the QA Coordinator for initiation of an internal NCR, if appropriate per QAI 15.1, and acceptance or rejection of the supplier's proposed actions.

Criterion 8 - Identification and Control of Material, Parts, and Components

8.1 General Requirements - A system shall be established and implemented to ensure that only correct and accepted items are installed or used, and that only correctly identified and traceable samples are utilized for the generation of data. Commercially available material, parts, and components, as discussed in Criteria 4 and 7 are exempt from these requirements.

8.2 Standard Requirements

8.2.1 Standards for Items - The procedures must ensure that the following are addressed:

- Identification is maintained either on the item or by records traceable to the item. Physical identification must be used to the maximum extent possible,
- Identification does not affect the use or function of the item, and
- Items having limited calendar or operating life are identified and controlled to preclude the use of items with expired shelf or operating lives.

8.2.2 Standard Requirements for Samples - Environmental compliance samples shall be specifically identified, controlled, and a clear line of traceability shall be maintained in accordance with operational procedures and the instructions provided in QAI 13.1. Specific requirements include:

- *Identification* - Samples must be clearly identified through markings either on or with the sample or in documents that can be traced to the sample. Identification must be accomplished through either physical identification on the sample container, procedural controls/separation from other samples or markings on the sample itself when it will not detrimentally affect the sample.
- *Traceability* - Procedures shall include provisions to ensure that samples are identified to allow traceability and clear association with the sampling location and activity. The procedures shall also include organizational responsibilities for maintaining traceability.
- *Chain-of-Custody* - Samples shall be controlled by appropriate procedures at all times and a clear chain-of-custody in accordance with QAI 13.2 established to ensure that a sample can be tracked from origination to the laboratory for analysis and finally to a data report.

Individual implementing procedures for sampling of leachate, decontamination wastewaters, and air samples shall comply with the requirements of SW-846 and shall fully document methods for taking samples, identifying samples, maintaining traceability of samples, and documentation of chain-of-custody from the field through the return of data.

8.3 "Q"-Related Requirements - No requirements beyond those identified in Standard Requirements apply.

Criterion 9 - Control of Processes

9.1 General Requirements - Process control must be achieved and maintained by employment of qualified personnel, as required by Criterion 2, and the use of instructions, procedures, and drawings, as required by Criterion 5.

9.2 Standard Requirements - Special Processes (a process in which the specified quality cannot be readily determined by inspection or test of the product and the results of which are highly dependent on the control of the process and/or skill of the operator) will be developed, controlled and performed in accordance with approved procedures that include or refer to acceptance criteria and qualifications of personnel, equipment, and procedures.

The only special process currently identified associated with ERDF waste disposal operations is the sampling operation for environmental compliance samples, including the follow media: air, leachate, and decontamination washwaters. Personnel performing the sampling of these media shall be appropriately trained and qualified to perform the collection of these samples. The requirements that must be adequately understood by these personnel include baseline requirements (i.e. sampling methods to support compliance with SW-846), overall data collection program planning requirements (i.e. air monitoring basis and requirements from the data collection system design outlined in the Environmental Monitoring Plan), sample collection and handling requirements outlined in this QAPjP, and sampling specific activities required by specific operational procedures for the sampling event in question.

If other Special Processes are identified, the management responsible for the work shall establish the appropriate procedures or other controls and documentation. Organizations responsible for Special Processes shall ensure that procedures are prepared and approved to meet QA requirements. The QA Coordinator shall ensure that these requirements are incorporated into QA Project Plan and shall perform audits and surveillance to ensure that controls of Special Processes are implemented.

9.3 "Q"-Related Requirements - No requirements beyond those identified in Standard Requirements apply.

Criterion 10 - Inspection

10.1 General Requirements - Organizations responsible for inspections that determine acceptability of work or items or surveillance that verify conformance must establish and implement procedures for the control of the work or items. The requirements within this Criterion, although stated as requirements for inspection, apply to both inspections and surveillance. This section is intended to apply to "oversight" of quality related inspections and surveillance. It is not the intent that this section applies to the performance of RCRA related surveillance and inspections.

Inspections and surveillance at ERDF will incorporate the following principles:

- Personnel who perform inspections must have reporting independence. They must not report to supervisors below the project manager who are responsible for the work, and they must not themselves be responsible for directing or performing the work or activity that is being inspected.
- Personnel who perform inspections for acceptance must be qualified to perform the assigned inspection tasks.
- Provision must be made for inclusion of any notification points and for mandatory hold points in operations procedures beyond which the work cannot proceed until specified actions are taken.
- Planning and documentation for inspections or surveillance must describe the characteristics of the item or activity, methods utilized, acceptance criteria, and results of the inspection or surveillance.
- Inspection, surveillance, or monitoring must be included in planning to verify that in-process performance satisfies quality requirements.
- Items and activities must undergo final inspection and acceptance, including acceptance of documentation and records, and
- Information required and the records generated must be specified.

10.2 Standard Requirements

10.2.1 Planning of Inspections - Inspections that verify and ensure conformance to specified requirements shall be planned, performed, and documented in accordance with written instructions, procedures, or checklists. Inspection planning encompasses in-process and final-acceptance inspection. When direct inspection is not possible or is inadequate to fully verify conformance, plans must provide for systematic monitoring and surveillance of the activities to ensure that the processes are controlled and specified quality is achieved throughout the work.

Inspection planning must establish inspection Hold and Notification points, when appropriate, and provide for overall assignment of coordination and sequencing of inspection activities. When appropriate, Hold and Notification points must be included in control documents such as schedules, procurement documents, and specifications. When sampling is used to determine the acceptability of a group of items or data, the sampling procedures must be based on recognized standard practices.

Inspection plans, instructions, procedures, or checklists should include the following:

- Required procedures, drawings, or specifications.
- Characteristics or activities to be inspected.
- Description of the method of inspection (i.e., visual, non-destructive, or destructive).

- Measuring or test equipment, or special tools required, and the requirements for accuracy of the equipment or tools.
- Acceptance criteria.
- Recording of the inspection results.
- Identification of inspectors who perform the inspection.
- Date of the inspection.
- Results or acceptability of the inspection. For items or activities found unacceptable, follow-up and reinspection must be provided.

10.2.2 Independence and Qualification of Inspection Personnel -

Acceptance inspections must be performed by individuals other than those who performed or directly supervised the activity or work being inspected. Inspection personnel must be trained and qualified to perform assigned inspection tasks. Documented qualifications of personnel who perform inspections must be maintained and correct. The level and depth of inspection and the degree of inspection personnel independence should be based on the complexity and risk involved.

10.2.3 In-Process Inspections - Inspections of items or activities that are in process will be performed according to documented plans and as necessary to verify that quality requirements have been fulfilled. Surveillance and monitoring, by direct or indirect methods, will be utilized when in-process inspection is not possible or appropriate.

10.2.4 Final Inspections - Completed items and activities shall be inspected as required to verify conformance to specified requirements. Final inspections must include a review and examination of records for adequacy and completeness, if not previously examined. A review of all inspection records, the results, and the resolution of nonconformances must be included. Final acceptance shall be documented and approved by authorized personnel.

10.2.5 Recognition of Hold Points - When mandatory Hold or Notification points are identified in pertinent documents, work must not proceed beyond those points without the consent of the organization that established the Hold points.

10.3 "Q"-Related Requirements - In addition to the General and Standard Requirements identified above, the following requirements apply to inspections performed on items or activities that have been designated "Q"-related:

- Documents that define or contain plans for acceptance inspection of "Q" related items/services must be reviewed and approved by the QA Coordinator before the inspection is performed.
- In addition to being trained and qualified, personnel who perform inspections must be evaluated and certified to perform their assigned inspections. Inspection personnel must be qualified in accordance with approved procedures.
- Personnel who are authorized to perform final acceptance and documentation must be designated during the inspection planning process.

Rust corporate resources will generally be used for "Q" related inspections and personnel will be certified appropriately per NQA-1, ASQC, or ISO-9000.

QAI - 10.1 - Surveillance

This instruction describes general activities performed during a QA surveillance, organizational interfaces, and requirements for reporting and follow-up. Surveillance verify compliance of activities with QA or other requirements. Although auditing techniques are used, surveillance are less formal than audits and may be performed in response to needs on shorter notice. Surveillance may be broad in scope or narrow with great depth. Surveillance are intended to verify compliance with procedures, practices, and the like. They are not intended to address the adequacy of a system or process.

Responsibilities and Instructions

QAI 10.1.1 Planning - The QA Coordinators shall submit a list of prospective surveillance that are suggested for a three month rolling period to the project manager. This list is a plan, not a firm schedule, and it is maintained only to keep management informed of potential upcoming surveillance. When possible, the individual who performs the surveillance should notify the affected organization about 1 week in advance to confirm the actual scheduled date. Although unscheduled surveillance may be performed, to do so is not the normal practice.

QAI 10.1.2 Access and Assistance - The management of organizations under surveillance must provide access and assistance to the people who perform the surveillance. Besides providing advance notification, surveillance personnel must announce their presence to appropriate supervisory or management personnel when entering work areas or buildings. Access to records requires the permission and assistance of designated individuals who are responsible for control of access to records.

QAI 10.1.3 Performance of the Surveillance - A specific checklist or plan for surveillance shall be prepared by the person who will perform the surveillance and used during actual performance. The checklist is intended to provide value to the specific surveillance process and not to be of a specific form or content. The results of the surveillance should be based on objective evidence drawn from observations of activities and conditions, and the analysis of documentation, rather than statements by people who were contacted. Whenever possible, the specific activities observed or the documents analyzed should be identified for later follow-up.

A conditions or action noted during the surveillance that does not comply with the requirements may be immediately identified to the personnel responsible to allow them to correct the conditions. Corrections that are made immediately should be reported as such in the surveillance report. At the completion of the surveillance, the responsible manager should be notified of the results of the surveillance. If deficient areas were found, they should be identified and compliance should be obtained or a statement of planned actions and a date for completion should be requested. An exit meeting may be held if requested or if the results seem to need more explanation than a written report can easily provide.

QAI 10.1.4 Surveillance Reporting - A surveillance report must be prepared and issued by the person performing the surveillance. The report will normally be in the form of an internal memorandum and should include a copy of any checklist/plan used, major positive aspects and discrepancies identified, and any recommended corrective actions to resolve discrepancies noted. The following is the standard information that shall be provided:

- Surveillance Number and Title,
- Date(s) performed,
- Summary of results,
- Activities observed,

- Surveillance of compliance with (list the area and requirements documents).
- Persons contacted/observed, and
- Actions required.

A surveillance can be immediately closed if conditions were in accordance with requirements or if non-compliant conditions were corrected immediately. A surveillance must be held open if conditions were found that did not comply with requirements and could not be corrected immediately. In this case, a finding report (Figure 10.1-1) will be prepared for each significant uncorrected condition. The report will be sent to the responsible management with a request for corrective action to bring the activities into compliance with requirements, including a schedule/date for completion of corrective actions.

Adverse conditions that would have been reported as findings but were corrected during the surveillance must be identified in the report as having been potential findings. This information is needed by the Project Manager and QA function to assist in understanding operational trends.

QAI 10.1.5 Follow-up For Open Findings - The person performing the surveillance is responsible for evaluating the completeness and adequacy of proposed corrective actions to open findings. Responses shall be considered adequate when actions are planned to bring the activities and supporting documentation into compliance with existing procedural requirements, or procedural requirements will be changed and approved by required personnel to modify procedural requirements with current practices/conditions. Responses found inadequate will be returned to the responsible manager with an attached memo of explanation and a request for a second response. Acceptance of a response shall be by indication of the Finding Report form. Continued failure to develop a satisfactory response to a finding will be escalated to the Project Manager and/or the Corporate QA Director as necessary.

For open surveillance reports where a proposal for corrective action was received and a commitment date established, the surveillant will follow the progress of the commitment. When the proposed action appears to have been completed, the surveillant will verify the completion. If the corrective action has been completed as proposed, the surveillant will sign on the finding closed by line of the Finding Report. When all surveillance findings have been closed for an open surveillance report, the surveillance report shall be closed by an internal memorandum to supplement the original surveillance report. This memorandum shall indicate the actions taken and include copies of completed Finding Reports.

Figure 10.1-1 (con't) - Finding Report, Page 2

Finding Report - Page 2	Finding #
What was the root cause of the deficiency?	
Has any completed work been affected or do similar problems exist in other areas of work?	
What actions have been or will be taken to correct the problem(s) and prevent recurrence?	
When will the corrective actions be completed?	
Responsible Manager (Signature & Date)	

Criterion 11 - Test Control

11.1 General Requirements - The following requirements apply to tests that verify conformance to specified requirements or demonstrate that items will perform satisfactorily in service. Test specific controls shall be documented that address any of the following that apply:

- Test requirements and acceptance criteria must be standard nationally accepted test methods (i.e. ASTM) or be provided/approved by technically competent members of the organization requiring the test,
- Test procedures must include or refer to test objectives, prerequisites, instrumentation required, and environmental conditions that must be maintained,
- Test control elements must include calibrated or standardized instrumentation and equipment, procedures, trained personnel, specimen or sample condition, and environmental conditions that must be maintained,
- Test results must be documented and evaluated to ensure that test requirements have been met, and
- Test records that include information and data on specific items and activities must be maintained.

11.2 Standard Requirements

11.2.1 Test Requirements - A procedure, plan or instruction shall be established and implemented for individual test activities, including test requirements and test acceptance criteria. Test requirements and acceptance criteria shall be based on specified requirements contained in operating specifications, design or other pertinent technical documents. Test plans shall be approved by the Project Manager and the Appropriate QA Coordinator. Environmental compliance data collection programs shall be designed, approved, and controlled in accordance with requirements of Criterion 3 and QAI 3.3 as defined in the appropriate operational plans and procedures.

11.2.2 Test Procedures - Organizations that perform tests shall either develop procedures or adopt existing procedures (i.e. nationally accepted procedures such as ASTM) for controlling test processes. Test control procedures shall be approved by the Project Manager and appropriate QA Coordinator before use. Test control procedures shall include or refer to test objectives and provisions for ensuring that prerequisites for a test have been met. Tests include the following, when applicable:

- Use of calibrated or standardized instruments,
- Use of appropriate equipment,
- Personnel trained in the procedure,
- Condition of the test equipment and the samples or specimens to be tested,
- Any restrictive environmental conditions, and
- Provisions for data acquisition and recording.

In lieu of specially prepared written test procedures, appropriate sections of related documents and standards, such as ASTM methods, supplier manuals, or approved drawings or process-control travelers may be used, provided that adequate instructions are included to ensure the required quality of work.

11.2.3 Test Results - Test results must be documented and evaluated by designated individuals to ensure completeness and accuracy of the data and that test requirements have been satisfied. Environmental data collection results shall be

documented in accordance with applicable operational plans to ensure data can be adequately evaluated and transferred to appropriate personnel/agencies through established reporting.

11.2.4 Test Reports - Test reports must include the following, as a minimum:

- Items, specimens, or samples tested,
- Identification of the individual performing the test, or the serial number or ID number of the data recorder, if any,
- Date of test,
- Type of observation,
- Test results and acceptability,
- Deviations noted during the test and actions taken in connection with them, and
- Individual evaluating the results.

Reporting of environmental compliance data shall be performed in accordance with the applicable requirements identified in the operational plan that defines the data collection system (i.e. EMP, HASP, LMP, etc.).

11.3 "Q"-Related Requirements - No requirements beyond those identified in Standard Requirements apply.

QAI 11.1 ERDF Compaction Testing

This instruction describes specific requirements for performance and documentation of compaction tests at ERDF. The instruction applies to the following tests deemed as "Q" related for ERDF waste disposal operations:

- Compaction Testing in accordance with ASTM Standard Test Method for Density and Unit Weight of Soil in Place by the Sand-Cone Method (ASTM D1556)
- Test Methods for Moisture-Density Relations of Soils and Soil-Aggregate Mixtures using 10-lb. Rammer and 18-in. Drop (ASTM D1557)
- Standard Test Method for Laboratory Determination of Water (Moisture) Content of Soil and Rock (ASTM D2216)
- Water content testing in accordance with ASTM Standard Test Method for Water Content of Soil and Rock in Place by Nuclear Methods (ASTM D3017)

Responsibilities and Instructions

QAI 11.1.1 Compaction Test Instructions - Adequate test instructions shall be documented in the Waste Materials Management Plan (WMMP) to perform the necessary compaction testing, maximum dry density and moisture content. The instructions will incorporate either in whole or by reference the requirements outlined in ASTM D1556, D1557, D2216, and D3017.

QAI 11.1.2 Test Frequency - Testing shall be performed on a minimum of every 1,000 yd³ placed on the working face and at least one test must be performed in each active placement area every operating shift.

QAI 11.1.3 Test Equipment - Test equipment shall be identified in the WMMP and shall be controlled in accordance with Criterion 12 and QAI 12.1. Test equipment identified as "Q" related shall be procured in accordance with the requirements of Criterion 4 and QAI 4.1.

QAI 11.1.4 Test Results Comparison - Compaction shall be deemed adequate if test results show compaction to a minimum of 90% of Modified Proctor (ASTM D1557) maximum dry density in accordance with the requirements of the WMMP. Moisture shall be maintained to assist in achieving the 90% of maximum density. ERDF will utilize information on maximum dry density from the Remedial Action characterization activities (if available) or determine the maximum dry density at the ERDF per ASTM D1557. If testing indicates unacceptable results, then the operations manager will be notified and additional compaction operations and testing requirements shall be repeated until acceptable compaction results are obtained in that area

QAI 11.1.5 Test Reports - Compaction test results shall be documented and reported in accordance with the data form from the WMMP and shall incorporate the standard requirements of Criterion 11. Test reports shall be retained as quality records in accordance with the requirements of Criterion 17 and QAI 17.1 and the ERDF Administrative Procedures (RFS-ERDF-005).

QAI 11.2 ERDF Environmental Testing

This instruction describes specific requirements for performance and documentation of environmental tests at ERDF. The instruction applies to the following environmental sampling and monitoring activities deemed as "Q" related for ERDF waste disposal operations:

- Leachate sampling as identified in the ERDF Leachate & Washwater Management Plan and implementing procedures,
- Washwater sampling as identified in the ERDF Leachate & Washwater Management Plan and implementing procedures,
- Air sampling as identified in the ERDF Environmental Monitoring Plan and implementing procedures, and
- Other environmental compliance sampling as identified in appropriately approved and controlled procedures.

Responsibilities and Instructions

QAI 11.2.1 Environmental Testing Instructions - Adequate test instructions shall be documented and approved in the appropriate ERDF plans and procedures to control the performance of environmental testing. Environmental testing instructions shall properly implement the data collection system design for the media in question as identified in the appropriate plan (i.e. ERDF Leachate & Washwater Management Plan or Environmental Monitoring Plan) to ensure that the objectives of testing can be adequately met through field performance outlined in the instructions.

QAI 11.2.2 Test Frequency - Testing shall be performed as required for the individual environmental sample:

- *Leachate* - As necessary based on leachate volume and the need to maintain surge capacity in the leachate storage tanks required by the ERDF Leachate & Washwater Management Plan,
- *Washwater* - As necessary based on washwater volume and the need to maintain surge capacity in the washwater storage tank required by the ERDF Leachate & Washwater Management Plan, and
- *Air* - Samples shall be collected every two weeks as identified in the ERDF Environmental Monitoring Plan. Air flow shall be tested when collecting sample papers using BHI-SH-04, Instruction 7.29.

QAI 11.2.3 Test Equipment - Test equipment shall be identified in the ERDF Leachate & Washwater Management Plan or ERDF Environmental Monitoring Plan and shall be controlled in accordance with Criterion 12 and QAI 12.1. Test equipment identified as "Q" related shall be procured in accordance with the requirements of Criterion 4 and QAI 4.1.

QAI 11.2.4 Test Reports - Results of environmental testing shall be documented and reported in accordance with applicable regulatory requirements and shall incorporate the standard requirements of Criterion 11. Test reports shall be retained as quality records in accordance with the requirements of Criterion 17 and QAI 17.1 and the ERDF Administrative Procedures (RFS-ERDF-005). The following dispositions of test reports shall be used for environmental testing:

- *Leachate* - Leachate analytical results shall be maintained as part of the facility records as required to show reason for disposal choices for individual batches of leachate. No specific reporting requirements have been identified for leachate.

- *Washwater* - Washwater analytical results shall be maintained as part of the facility records as required to show reason for disposal choices for individual batches of washwater. No specific reporting requirements have been identified for washwater.
- *Air* - Air sampling results shall be reported quarterly and annually, as identified in the ERDF Environmental Monitoring Plan, to allow inclusion in the overall Hanford Site required reporting.

Criterion 12 - Control of Measuring and Test Equipment

12.1 General Requirements - Control systems must be established and implemented to ensure that tools, gauges, instruments, and other measuring and test devices used that affect or evaluate the quality of activities are controlled, calibrated, and adjusted at specific intervals so that necessary accuracies are maintained. Included in this scope are those instruments used to monitor or collect environmental, health, and safety data.

A calibration and control system is not required for rulers, tape measures, levels, or other devices where normal commercial standards provide adequate accuracy. Also, the system might not apply to test equipment used for preliminary checks, or when data obtained will not be used to determine acceptability or be the basis for design, engineering, or other acceptance evaluation.

This Criterion does not apply to equipment standardization, operating checks, or other comparisons on installed operational equipment not specifically used as Measuring and Test Equipment. This equipment is controlled through periodic calibration as identified in the ERDF Equipment Maintenance Plan and through specific operations, start-up, or test procedures.

12.2 Standard Requirements - A documented program must be established, implemented, and maintained for calibration and control of measuring and test equipment (M&TE) and of measurement reference standards. The program must be designed to determine and ensure the accuracy of M&TE and measurement reference standards and will allow prompt detection of inaccuracies for timely corrective action. The program will include the following elements, as a minimum.

12.2.1 Identification of M&TE - A list of M&TE and measurement reference standards and their assigned locations or custodians will be prepared to identify specifically those items that are within the calibration program.

12.2.2 Calibration Procedures - Documented procedures for calibrating M&TE and measurement reference standards will be used. Procedures such as published standard practices, written instructions that accompany purchased equipment, or other acceptable instructions may be used. Calibration procedures must contain the following minimum information:

- Identity of the item calibrated,
- Calibration equipment and measurement reference standards to be used, including required parameter, range, and accuracies required,
- Checks, tests, measurements, and acceptance tolerances of each instrument characteristic being calibrated,
- Frequency of calibration,
- Sequence of operations, and
- Special instructions, safety precautions, or other information.

12.2.3 Records - Records must be maintained for each piece of equipment to show that established schedules and procedures for calibration of M&TE and measurement reference standards have been followed. The records will contain a history of calibration and other means of control, showing calibration interval, date of last calibration, when next calibration is due, conformance or nonconformance to required tolerances before and after adjustments, and any limits on use or corrections to be applied. Each record must identify the equipment to which it applies, procedure or instructions followed in performing the calibration, calibration data, relevant environmental conditions, traceability to the referenced

standard used, the person performing the calibration, and the calibration date. Other pertinent information related to the equipment, such as operational failure or erratic behavior that could affect the quality of data, should be included in the record.

12.2.4 Adequacy of Measurement Reference Standards - Measurement reference standards used for calibrating M&TE must be traceable and have calibration ranges, precision, accuracies, and environmental conditions documented so that the M&TE can be calibrated and maintained within the required tolerances. When practical and possible, the bias or uncertainty of the measurement reference standard should contribute no more than one-quarter of the allowable M&TE tolerance for each characteristic being calibrated. Certificates or reports of measurement reference standards will include the following minimum information:

- Identification or serial number,
- Identification of the calibration source and report number,
- Date of calibration,
- Calibration values assigned, with statement of accuracy (uncertainties),
- Relevant environmental conditions (temperature, gravity, air buoyancy, etc.) under which the calibration was performed for which the assigned accuracies are valid,
- Correction that must be applied if standard conditions (temperature, gravity, buoyancy, etc.) are not met or differ from those during calibration, and
- Statement that the standards used are traceable, if the laboratory is other than the National Institute of Standards and Technology (NIST).

12.2.5 Environmental Controls - M&TE and measurement reference standards must be transported, stored, and calibrated in environments that will not adversely affect their accuracy. Environmental factors that must be considered include heat, humidity, vibration, radio frequency interference, electrostatic discharge, dust, cleanliness, and fumes. When inaccuracy of M&TE caused by systematic environmental effects cannot be avoided, compensating corrections must be determined and applied.

12.2.6 Intervals of Calibration - The calibration and control program must require that all M&TE and measurement reference standards needing recalibration be recalled at prescribed intervals. The intervals may either be expressed as calendar time or related to usage. Factors to consider when selecting calibration intervals include past experience, inherent stability, purpose of use, manufacturer's recommendations, characteristics of the equipment, and accuracy required. Historical records that contain experience data for evaluating and adjusting calibration intervals should be maintained.

12.2.7 Traceability - M&TE must be calibrated using measurement reference standards with calibrations traceable to nationally recognized standards, if such standards exist, or to accepted values of natural physical constants. When no national standard exists, the basis for calibration must be documented. Measurement reference standards shall be identified on calibration data records and supported by certificates, reports, or data sheets attesting to the calibration data, calibration facility, environmental conditions, and data that show compliance with requirements for accuracy.

12.2.8 Labeling - M&TE and measurement reference standards must be labeled to indicate their calibration status. The label must include the date of last calibration and the due date for the next calibration. When size or functional characteristics prevent the application of a label, an identifying code may be used or the label may be affixed to the

instrument container. When neither labeling nor coding is practical, the procedures must provide for monitoring of records to ensure control. M&TE whose use must be limited will be identified and controlled (such as a multi-scale instrument for which only one scale was calibrated). Items not calibrated or that have calibration limitations shall be labeled as to their status and/or limitations.

12.2.9 Precalibration Checks - M&TE and measurement reference standards submitted for calibration must be checked and the as-found results will be recorded before any adjustments, repairs, or modifications are made.

12.2.10 Out-of-Tolerance Control - M&TE and measurement reference standards found to be out of tolerance, past due (out of calibration), improperly maintained or calibrated, or subjected to possible damage must be identified and removed from service until corrective measures can be taken. The equipment must be tagged or segregated to prevent inadvertent use. An evaluation of all equipment tested or calibrated since the last calibration must be performed to establish acceptability of the equipment and the work or to confirm a nonconformance. Results of the investigation must be documented. The Quality Assurance function must be notified for any M&TE or measurement reference standards used in an out-of-tolerance condition. When equipment is calibrated and controlled for another organization, the User Organization must be notified of the nonconformance so that it may then initiate corrective action and investigation of the condition. When appropriate to the specific M&TE, the use of trending should be considered.

12.2.11 Out-of-Service and Retired M&TE and Measurement Reference Standards - Before placing M&TE and measurement reference standards in inactive, out-of-service, or retired status, the M&TE and measurement reference standards must be calibrated to verify accuracy and to close the calibration cycle. The calibration and labeling must indicate the status of the equipment.

12.2.12 Subcontracted Calibration Services - Subcontracted calibration services suppliers, other than NIST or government laboratories, must be evaluated through the quality audit program to determine their capability to perform calibrations in accordance with this Criterion. Evidence of compliance with these requirements must be included in the procurement documents. The procurement documents must be provided to QA and Property Management for review prior to procurement.

12.2.13 Control of M&TE and Measurement Reference Standards - Organizations using M&TE and measurement reference standards should consider and apply the following controls to ensure consistent results of acceptable accuracy:

- Provide environmental and handling controls,
- Train and qualify personnel in the use and calibration requirements of M&TE,
- Verify calibration or standardization before use,
- Perform interim checks between calibrations,
- Document and recalibrate damaged M&TE and measurement reference standards, and
- Limit use of M&TE to authorized personnel.

12.3 "Q"-Related Requirements - No requirements beyond those identified in Standard Requirements apply.

QAI - 12.1 - ERDF MT&E Controls

This instruction describes specific requirements for identification and calibration control of measurement and test equipment (M&TE) at the ERDF. The instruction applies to "Q" related equipment used to perform compaction testing for ERDF waste disposal operations. Table 1 is a list of "Q" related M&TE and the reference ASTM standard.

Table 1 - ERDF M&TE	
M&TE Description	Procurement Standard
Nuclear Density Gauges	ASTM D2922, Section 5 ASTM D3017, Section 5
Sand-Cone Density Apparatus	ASTM D1556, Section 6.1
Standard Masses	ASTM E617 - Must be NIST traceable
Balance or Scale	ASTM D1556, Section 6.3 ASTM D2216, Section 6.2
Drying Oven	ASTM D2216, Section 6.1
Thermometer	ASTM E1 - Must be NIST traceable
Molds	ASTM D1557, Section 6.1
Manual Rammer	ASTM D1557, Section 6.2
Sieves	ASTM E11
Air Monitor Vacuum Pumps	Initial calibration must be NIST traceable with 5% accuracy

Responsibilities and Instructions

QAI 12.1.1 Equipment Identification - All "Q" related measurement and test equipment will have a unique identifier marked on or attached to the equipment. The identifier will have the following format: "ERDF-XX-YY." XX will be the last two digits of the year in which the equipment was received and YY will be a sequential number assigned from the "Q" related M&TE logbook.

QAI 12.1.2 Calibration/Verification Procedures and Frequency - Table 2 lists the calibration/verification procedures and the associated frequencies for ERDF M&TE.

Table 2 -M&TE Calibration/Verification Procedure and Frequency		
M&TE Description	Calibration/Verification Standard	Frequency
Nuclear Density Gauges	ASTM D2922, Annex A1 ASTM D3017, Annex A1	yearly
Sand-Cone Density Apparatus	ASTM D1556, Annex A1	quarterly
Standard Masses	N/A	one-time only - initial procurement
Balance or Scale	ASTM D4753, Section 7.4.3	quarterly
Drying Oven	Daily temperature check with certified thermometer below when in use drying samples	daily
Thermometer	N/A	one-time only - initial procurement
Molds	ASTM D1557, Section 9.1.3	quarterly
Manual Rammer	ASTM D1557, Section 9.1.4	quarterly
Sieves	N/A	one-time only - initial procurement
Air Sample Vacuum Pump	BHI-SH-04, Instruction 7.29	At sample collection, every 14 days

Criterion 13 - Handling, Storage, and Shipping

13.1 General Requirements - Cleaning, handling (including lifting and rigging), storing, packaging, shipping, and preserving of items shall be accomplished to prevent damage, loss, or deterioration from environmental conditions. "Item," as used in this Criterion, includes test specimens and samples, materials, equipment, and components designated as "Q" related. Other waste disposal operations handling, storage, and shipping should be carried out in commercial standard fashions applying good business practices.

13.2 Standard Requirements - User organizations must establish procedures appropriate to their work for shipping, handling, and storing items to preclude deterioration or damage to the item or the environment. Specific requirements for environmental compliance samples are outlined in QAI 13.1, while the following standard requirements apply to handling, storage, and shipping of other ERDF items:

13.2.1 Packaging - For critical, sensitive, perishable, or high-value items, the need for special equipment or protective environments (such as containers, shock absorbers, accelerometers, inert gas atmosphere, and specific humidity or temperature levels) must be specified and provided for, and their use should be verified.

13.2.2 Tools and Equipment - When appropriate, special handling tools and equipment must be used to ensure safe and adequate handling. Tools and handling equipment must be inspected and tested to verify that they are adequately maintained. Operators of special handling and lifting equipment must be experienced and trained in the use of the equipment.

13.2.3 Markings - Instructions for marking, labeling, packaging, shipping, and storing items and specimens shall be established as necessary. Markings required to identify, maintain, and preserve the item, such as a requirement for protective atmosphere, must be applied to the package and maintained as those items or samples are handled, transported, or transferred from one organization or location to another.

13.2.4 Shipping and Handling Procedures - When appropriate for critical, sensitive, perishable, or high-value items, procedures or instructions must be developed for the packaging, markings, tools, and equipment to be used. These instructions must require documentation that the packaging, tooling, and markings were provided, utilized, and verified. When multiple organizations are involved, procedures or instructions should describe interface or custody responsibilities.

13.2.5 Storage Procedures - When appropriate, procedures must be developed and maintained for the storage and preservation of items or protection of the environment. The procedures must include considerations for maintaining markings, preserving special environmental conditions, and inspecting storage arrangements. Provisions for the receipt and protective storage of accompanying documents, such as manuals or logs, as well as a need for a documented inventory or verification of receipt, must be considered.

13.3 "Q"-Related Requirements - No requirements beyond those identified in Standard Requirements apply.

QAI - 13.1 - Sample Handling

This instruction provides additional details and information for implementation of requirements identified in Criterion 13. This instruction is applicable only to environmental compliance samples, including leachate samples, decontamination washwater samples, air samples, and other appropriate environmental media.

Responsibilities and Instructions

QAI 13.1.1 Sampling Method - Environmental compliance sampling methods shall be used to ensure that samples are properly taken, using the proper equipment, environmental conditions and controls. The sampling methods shall be developed in accordance with the media specific data collection system design as outlined in QAI 3.3. These methods shall be documented in implementing operational procedures and implemented through approved operational procedures. The following methods have been identified for environmental compliance samples:

- **Leachate Samples** - A representative sample shall be drawn by compositing a total of 3000 ml of leachate taken at the centerpoint of 1 foot increments in the respective leachate storage tank with one sample biased to within 3" of the surface. In other words, if the leachate tank has 3 feet of leachate, then 1000 ml will be drawn from the 6" level, 1000 ml will be drawn from the 18" level, and 1000 ml will be drawn from within 3" of the surface (36" level). If the respective leachate storage tank has less than 1 foot of liquid, then two samples will be taken and composited - one from within 3" of the bottom and one from within 3" of the surface.
- **Washwater Samples** - A representative sample shall be drawn by compositing a total of 3000 ml of washwater taken at the centerpoint of 1 foot increments in the washwater storage tank with one sample biased to within 3" of the surface. In other words, if the washwater storage tank has 3 feet of leachate, then 1000 ml will be drawn from the 6" level, 1000 ml will be drawn from the 18" level, and 1000 ml will be drawn from the surface (36" level). If the washwater storage tank has less than 1 foot of liquid, then two samples will be taken and composited - one from within 3" of the bottom and one from within 3" of the surface.
- **Air Filter Samples** - Air shall be passed through a 47mm 5 micron filter paper for a two-week period at which time the sample shall be collected for analysis.

QAI 13.1.2 Sampling Equipment - Equipment used shall also be defined in accordance with the media specific data collection system design as outlined in QAI 3.3. Equipment requiring calibration shall be verified to have a valid calibration label and be within periodic calibration requirements. Verification checks will be documented in the operations daily log.

- **Leachate Sampling Equipment** - Leachate shall be sampled from the tank level standpipe (for the inner liner) using a peristaltic pump, Teflon tubing, a COLIWASA, a 3 liter compositing bottle and appropriate compositing sample bottles. The individual leachate level samples will be pumped from the various tank levels into a 3 liter compositing bottle. The COLIWASA will then be used to take samples from that bottle and place composited liquid into individual bottles compliant with the analytical methods to be used for various radionuclide, organic, and inorganic analyses.
- **Washwater Sampling Equipment** - Washwater shall be sampled from the tank level standpipe (for the inner liner) using a peristaltic pump, Teflon tubing, a COLIWASA, a 3 liter compositing bottle and appropriate sample bottles. The individual washwater level samples will be pumped from the various tank levels into the 3 liter bottle. The COLIWASA will then be used to take samples from that bottle and place composited liquid into individual bottles compliant with the analytical methods to be used for various radionuclide, organic, and inorganic analyses.

- **Air Filter Sampling Equipment** - Environmental monitoring air samples will be collected using a Hanford standard air sampler.

QAI 13.1.3 Preservative Usage - Samples requiring the use of a preservative shall be properly identified as part of the media specific data collection system design as outlined in QAI 3.3. The sample bottles prepared in accordance with operating instructions and the appropriate preservative shall be used based upon the types of analysis requested. Shelf-life of preservatives shall be verified prior to use to ensure that the materials are within manufacturer's recommended useful life.

QAI 13.1.4 Sample Numbering and Tracking - A unique number will be assigned to each environmental compliance sample by the Waste Acceptance Manager. This number will be a two part number of the form "96-001". The first part of the number is the last two digits of the calendar year the sample was taken. The second part of the number is a sequential number unique to the sample in question starting at 1 for the first sample of each calendar year. The Waste Acceptance Manager shall maintain a sample tracking log that identifies sample numbers assigned, types of sample, sample destination for analysis, data receipt from laboratory, and sample disposal.

QAI 13.1.5 Sample Labeling - Identification must be maintained either on or with the sample or in documents that can be traced to the sample. Identification must be accomplished through one or more of the following guidelines or requirements:

- Physical identification must be used to the maximum extent possible.
- Procedural controls, physical separation, or other appropriate means shall be used to maintain identification when physical identification on the sample is either impractical or insufficient.
- Identification markings applied to the samples shall not detrimentally affect the sample and shall be clear and legible.

When samples are subdivided, identification markings must be transferred to the divided samples. Subdivided samples shall be assigned the identification while maintaining association with the original samples. When possible, identification should be accomplished before physical separation. Identification markings must not be hidden or obliterated by surface treatments, packaging, or storage containers unless other means of identification are substituted.

An example of a standard ERDF sample label is shown in Figure 13.1-1 and will be used to the maximum extent possible to ensure consistency of labeling. Waterproof, reproducible ink shall be used to complete the required information on the label. The sampler shall initial the label to ensure that the person who collected the sample can be identified. A sample seal shall also be installed across the container/lid gap to allow identification of any samples that have been tampered with.

QAI 13.1.6 Sampling Documentation - The sampler performing environmental compliance samples shall maintain a log of the sampling activity. The log shall contain the same information contained on the sample label: Sample Number, Sample Type (& Location as appropriate), Analysis Required, Preservatives, and Comments. The log shall also identify the conditions during the sampling event, the serial number of equipment used to perform the sampling, and any additional information deemed pertinent to the validity of the sample. Unusual conditions, such as duplicates, spikes, or splits shall also be identified in the log.

QAI 13.1.7 Control of Samples - Personnel performing sampling or involved in the transfer of samples to the appropriate laboratory shall comply with chain-of-custody requirements identified in QAI 13.2. Samples shall either be maintained within the personal custody of the responsible

individual, or locked in an appropriate container/cabinet/room that will allow certainty that the sample is as labeled and has not been tampered with.

Figure 13.1-1 - Example of an ERDF Environmental Compliance Sample Label

RUST Federal Services Inc. ERDF Waste Disposal Operations Sample # _____ Date: _____ Time: _____ Sample Type: <input type="checkbox"/> Air Filter (#___) <input type="checkbox"/> Leachate (Tank #___) <input type="checkbox"/> Washwater <input type="checkbox"/> Other _____ Sampler: _____ Analysis: _____ Handling: <input type="checkbox"/> Filtered <input type="checkbox"/> Cooled <input type="checkbox"/> Other _____ Preservatives: <input type="checkbox"/> HCl <input type="checkbox"/> H2SO4 <input type="checkbox"/> HNO3 pH _____ Comments: _____

QAI 13.1.8 Sample Storage - Samples will not normally be stored, but rather field conditioned to meet transport requirements and shipped directly to the laboratory. Prior to temporary storage, hold times and/or environmental condition requirements (i.e. temperature, humidity, etc.) shall be reviewed to ensure that the sample can be temporarily stored and still provide quality data upon analysis. Acceptable storage times shall be identified in the data collection design portion of the appropriate operational plan. Temporary storage shall be approved by the Waste Acceptance Manager who will also determine a temporary storage location.

QAI 13.1.9 Handling, Storing, and Shipping of Samples - Environmental compliance samples shall be transported in a manner protective of sample integrity. The shipper is responsible for the correct hazard class designation (49 CFR 173) of the sample and ultimately the packaging used. The person making the shipment is also responsible for ensuring that any samples presented for transportation comply with the appropriate shipping regulations.

QAI 13.1.10 Disposition of Samples Received That Exhibit Evidence of Tampering - The Waste Acceptance Manager shall be the central point of contact with the laboratory and will resolve any discrepancies identified with the sample upon receipt at the laboratory. The following steps shall be taken if the laboratory identifies to the Waste Acceptance Manager that a samples has been tampered with:

- Discuss with the laboratory the extent of evidence of tampering and physical condition of the sample,
- Review the status with the shipper of the sample to determine if conditions have changed from the status when shipped to the laboratory,
- If conditions have changed, arrange for the sample to be returned without analysis,
- Arrange for another sample to be taken to replace the sample that was tampered with, and
- Document the actions taken in the sampling log and the fact that the sample was not considered acceptable for analysis due to the potential for tampering.

QAI 13.2 - ERDF Chain-of-Custody Instructions

Each sample obtained for environmental compliance shall be maintained in accordance with the chain-of-custody requirements of this instruction to ensure traceability from the collection of the sample through data return from the laboratory.

Responsibilities and Instructions

QAI 13.2.1 Requirements to Ensure Custody - The custodian of an environmental compliance sample shall maintain custody of samples to ensure that the sample can be traced from its origination. The custodian shall maintain positive control through either personal possession of the sample or possession through placing under lock in an area approved by the Waste Acceptance or ES&H Manager.

QAI 13.2.2 Sample Collector Responsibilities - The sample collector is responsible to take custody of the sample(s) as soon as the samples are collected. The sample collector shall maintain custody of the sample until the proper transfer of custody is properly accomplished using Figure 13.2-1.

QAI 13.2.3 Relinquishing Party in Transfer of Custody - The relinquishing party in a transfer of custody shall present the samples and chain-of-custody documentation to the sample recipient for transfer of custody. The relinquishing party shall:

- Resolve any discrepancies identified during the transfer of custody by the receiving party,
- Sign the "Relinquished by" block on the chain-of-custody form including other appropriate information (date, time, name, etc.) when the receiving party is prepared to accept custody of the samples and effect the transfer. (Note: The sample collector is the first person to sign the "Relinquished by" block on the form).

QAI 13.2.4 Receiving Party in Transfer of Custody - The receiving party shall examine the sample containers and the accompanying chain-of-custody documentation. A comparison shall be made of the sample containers and the label information against the chain-of-custody documentation, including the following:

- Container types and sizes,
- Sample numbers,
- Sample collectors,
- Date and time collected,
- Analytes of interest,
- Selected laboratory,
- Preservation method.

If discrepancies exist between the samples and the chain-of-custody documentation, the receiving party shall refuse to accept custody of the samples until the discrepancies are resolved. If no discrepancies exist or after discrepancies are resolved, the receiving party will sign the "Received by" block of the chain-of-custody form including other appropriate information (date, time, name, etc.) and take custody of the samples.

QAI 13.2.5 Transfer to Offsite Laboratory - The sample custodian shall package and ship the samples as required by the data collection program for the type of samples in question. The packaging, holding-time, and shipment requirements of Criterion 13 shall be followed.

QAI 13.2.6 Receipt at Offsite Laboratory - The offsite laboratory shall inspect the received samples for the following items:

- Ensure the seals are intact,
- Ensure that labels are affixed and legible,
- Sample analysis is specified for each sample or discrete set of samples,
- The physical condition of the samples is acceptable, and
- The samples being transferred are those identified in the form.

The offsite laboratory shall then notify the ERDF Waste Acceptance Manager or ES&H Manager of any problems resulting from the inspection in accordance with the Statement of Work for laboratory services. The person receiving the samples shall sign, date, and record the time of sample custody transfer and retain the original until sample analysis is complete and appropriate data and chain-of-custody documentation can be returned to the ERDF organization. The offsite laboratory shall also implement appropriate laboratory chain-of-custody procedures upon the transfer of custody until return of any samples for disposal by the ERDF project.

13.2.7 Sample Return for ERDF Disposal - If a sample has been collected and subsequently a portion or all of the sample needs to be returned for appropriate disposal, the offsite laboratory will properly ship the sample back to the ERDF site. The Waste Acceptance Manager or ES&H Manager shall arrange for final disposal of the samples in the ERDF and complete the "Final Sample Disposition" block at the bottom of the chain-of-custody form.

Figure 13.2-1 ERDF Chain-of-Custody Form

Criterion 14 - Inspection, Test, and Operating Status

14.1 General Requirements - A system shall be established to ensure that the inspection and test status of items will be identified throughout manufacture, installation, testing, and operation. The system must ensure that only those items that have passed the required inspections and tests are used. The system is applicable only when specified within work or planning documents.

The word item is used as a general term that includes any of the following that apply in a particular situation: assembly, component, equipment, material, module, part, sample, structure, subassembly, system, unit, technical data, documents, computer codes, samples, or work performed to specified requirements.

14.2 Standard Requirements - There are no standard level requirements identified for inspection, test, and operating status.

14.3 "Q"-Related Requirements - The following requirements apply when acceptance status and status controls for items are designated as part of "Q"-Level activities and when planning documents or procedures specify the use of status indicators.

14.3.1 Procedures for Status Indicators - Procedures must be established by line management for the use of status indicators to indicate the acceptance status of items inspected or tested. These procedures must provide for the following:

- Description of the status indicators to be used.
- Authorities and responsibilities for the application and removal of status indicators.
- Establishment of a system of status indicators and, when appropriate, inclusion of those indicators within work instructions.

14.3.2 Status Identification - The acceptance status of items must be identified by the use of status indicators, such as tags, labels, physical separation, markings, or stamps. When direct indication of status is not appropriate, documents traceable to the item, such as inspection records, test plans, or other documents, may be used to indicate status.

14.3.3 Inspection Status - The following indicators must be used to identify the acceptance status of inspections and tests:

- *Acceptable*—Items, materials, components, or systems that have satisfactorily passed required inspections and tests.
- *Hold*—Items, materials, components, or systems that are in process, or the acceptance status of which is undetermined (items awaiting receiving inspection, in fabrication, or controlled by a Nonconformance Report for repair or rework).
- *Nonconforming*—Items, materials, or components that have been inspected or tested and found to deviate from established requirements.

QAI - 14.1 - Acceptance Status Indicators

This instruction provides additional details and information for implementation of requirements identified in Criterion 14. This instruction is applicable only on "Q"-Level work when specified within work or other planning documents.

Responsibilities and Instructions

QAI 14.1.1 Use of Status Indicators - Status indicators shall be used only to indicate the status of inspection or acceptance test of an item and shall not be used to identify items. When status tagging or labeling is specified and used, the indicators shall be changed with corresponding changes of status.

QAI 14.1.2 Responsibilities - The QA Coordinators shall develop and provide standardized status indicator tags and labels for ERDF use. If other types of status indicators (such as ink or metal stamps or colored tape) are required, the QA organization shall be notified for assistance. User organizations shall identify the individuals who may apply status indicators and the conditions under which the indicators may be placed or removed. Individuals who place status indicators are responsible for ensuring that supporting documentation exists and is complete to substantiate the status indicators.

QAI 14.1.3 Status Indicator Procedures - When status tagging is required for an activity, the organization using the tags shall develop the details for complying with Criterion 14 or include the details in inspection or test procedures. The implementing instruction or procedure must be provided to QA for review and comment before use.

QAI 14.1.4 Description of Status Indicators - Colored tags or adhesive labels shall be used as visual aids to identify the current status of acceptance of inspection and test. The colors to be used for status indicators are as follows:

- Green — Acceptable
- Yellow — Hold
- Red — Reject.

The status (Acceptable, Hold, or Reject) shall be printed in bold type to facilitate status identification. Other specialized tags or labels may be developed and used for indicating status, with concurrence of the QA Coordinator.

Criterion 15 - Nonconforming Materials, Parts, or Components

15.1 General Requirements - A system must be established for the control of items or activities that do not conform to written requirements. The purpose is to prevent inadvertent use or installation of items or the acceptance of data or other products that were obtained by a process that was not in accordance with written requirements. The controls must provide for identification, documentation, evaluation, segregation (when practical), and disposition of nonconforming items and notification of organizations that might be affected. This Criterion applies to items, data, and activities that affect the quality of the work performed. It does not normally apply to occurrences that have no element of noncompliance with written requirements.

15.2 Standard Requirements - A documented system must be established, implemented, and maintained by organizations to provide for identification, control, and correction of nonconforming items and activities. The system must include the elements of control of nonconformances that are described in this Criterion. QAI 15.1 is provided as a way of implementing the requirements of Criterion 15. If another mechanism is preferred, it must be described in writing and must meet the requirements of Criterion 15.

A nonconformance is a deficiency in a characteristic, procedure, or documentation that renders the quality of an item unacceptable or indeterminate. Nonconformances may include design changes that are not properly controlled and items or activities that have been found out of compliance with requirements specified in procurement documents, specifications, drawings, test procedures, or other documents that contain acceptance criteria. Items may also be considered nonconforming if their quality is unacceptable or indeterminate because of a deficiency in characteristic, documentation, or compliance with procedure.

The word item is used as a general term that includes any of the following that apply in a particular situation: assembly, component, equipment, material, module, part, sample, structure, subassembly, system, unit, technical data, documents, computer codes, samples, or work performed to specified requirements.

A Nonconformance Report is a standard way to issue a report that describes a nonconformance and provides a record of action taken to deal with the nonconforming condition.

15.2.1 Reporting - Nonconforming items or data that have been delivered or transmitted to other organizations must be reported and evaluated. Nonconforming items or data that have not gone beyond the organization must be documented and evaluated internally, but formal reporting, such as described in QAI 15.1, is not required.

For activities in progress within an organization, any items or conditions that do not comply with program requirements must be reported and evaluated within that organization. The organization's mechanism for process control (recording and review of results) shall provide adequate documentation of these items or conditions. However, managers of activities are responsible for evaluating the consequence of nonconformances and formally reporting nonconformances that have significant adverse effects on quality of the work performed outside their organizations.

15.2.2 Identification - Nonconforming items will be identified and acceptability status will be indicated by marking, tagging, or other methods that will not adversely affect the end use of the items. Nonconforming items that cannot be marked may be identified on the container or package, or they may be moved into a segregated, identified storage area. Prompt notification of the nonconforming items must be provided to organizations that are affected. Nonconforming activities (such as actions that do not comply with written

procedures) or data must be identified to prevent further use and included in the Nonconformance Report.

15.2.3 Segregation of Items - Nonconforming items must be segregated, whenever practical, in a clearly identified holding area where they will be kept until the disposition of the items is determined. If physical segregation is impractical or impossible because of physical conditions (such as size, weight, or requirement for controlled environment), other administrative steps may be taken to prevent inadvertent use of nonconforming items.

15.2.4 Disposition Control and Authority - Written documentation must be provided by organizations to describe the evaluation and disposition of nonconformances. Further processing or installation of items, or continuation of activities must be controlled until the nonconformance has been evaluated and the disposition has been approved.

The evaluation of a nonconformance must be performed by people who have demonstrated competence in the area being evaluated, have access to pertinent background information, and understand the requirements that apply to the items or activities. Managers who are responsible for the items or activities must be included in evaluation of a nonconformance.

15.2.5 Disposition - Designated individuals must evaluate nonconformances and determine the disposition. Determination of other work affected and action to be taken must be included; for example, repetition of work of unacceptable or indeterminate quality, revision of procedures, or steps to ensure compliance with existing procedures. Acceptance of nonconforming activities or items without further work must include a technical justification.

15.2.6 Closure - Procedures for controlling nonconformances must provide for completion of the disposition by designated individuals. Reinspections or examinations for items reworked or repaired must be documented.

15.2.7 Status - If status indicators are used, individuals who verify completion of the disposition are responsible for ensuring that the correct status indicator is maintained.

15.3 "Q"-Related Requirements - No requirements beyond those identified under Standard Requirements apply.

QAI - 15.1 - Nonconformance Reporting, Disposition, and Closure

This instruction provides a system for reporting and disposition of ERDF nonconformances and closure of reportable nonconformances. It also identifies the responsibilities, interfaces, and actions between the QA Coordinator and other organizations.

Nonconformances within the scope of this instruction shall be reported by means of a Nonconformance Report. The QA Coordinator should be called on for advice or assistance in evaluation of conditions and subsequent treatment of identified nonconformances.

Actions or conditions that are or might be adverse to quality but that do not represent noncompliance with written requirements are not within the scope of this instruction, nor are nonconforming items, data that have not been reported or transmitted beyond the organization. Such conditions are to be identified in routine records of work performed, along with documentation of evaluation of the conditions and a description of the actions taken.

Responsibilities and Instructions

QAI 15.1.1 Responsibilities for Reporting Nonconformances - Any individual who identifies an apparent nonconformance (beyond the scope of normal internal reporting) should follow the standard reviews described in administrative procedures. If the condition is judged to be reportable, a Nonconformance Report (NCR) will be initiated and transmitted to the QA Coordinator, or the QA Coordinator will be asked to prepare the NCR. When appropriate, the individual must segregate nonconforming items, apply a "Hold" tag, or otherwise indicate the indeterminate status to prevent use before evaluation of the condition and disposition of any NCR.

The QA Coordinator further evaluates the information and processes it. Individuals identified by the QA Coordinator as action parties are responsible for investigating the nonconforming item or activity, assisting in the disposition process, effecting the disposition, and, whenever possible, identifying and correcting the root cause of the condition. These individuals must ensure that the disposition is correct and appropriate.

The QA Coordinator assists by administering and coordinating the NCR process. The QA Coordinator prepares NCRs or reviews submitted NCRs for completeness monitors them to completion. The QA Coordinator consults with appropriate individuals to identify technical and management individuals for the evaluation and disposition of NCRs. The QA Coordinator also has the overall responsibility to monitor the NCR process, including maintaining a log of NCRs, responsible individuals, status, and closure documentation.

The QA Coordinator must work actively toward the disposition of NCRs and must meet formally or informally with technical and management personnel to obtain disposition consensus, justification, or instruction. Responsible technical and management personnel must assist the QA Coordinator in determining an appropriate disposition. When additional testing, inspection, or evaluation is required, the individuals responsible for disposition must request the performance of these activities.

QAI 15.1.2 Nonconformance Reporting - An individual who recognizes a nonconformance must provide the following information:

- Identification of the nonconforming item, data, or activity. For test procedures or other activities,
- The test procedure or activity affected must be identified.

- Design document, plan, procedure, or other document that contains technical requirements.
- Project, program, or work activity area affected.
- Quantity and the location of affected items, if applicable.
- Description of the nonconforming item or activity and the item affected, presented in "Required" and "Is" format, as in the following examples:
 - Required: Use of calibrated equipment.
 - Is: Equipment "xyz" was used past calibration due date.
 - Required: Equipment voltage set at 2.50 V dc + 0.10 V dc.
 - Is: Test "xxx" performed with setting of 2.90 V dc.
 - Required: Computer programs must be verified.
 - Is: Unverified program was used.
- Name or signature of the individual identifying the nonconforming condition and date signed.

Items or activities that lack requirements but that are deemed to be of indeterminate quality may be reported in the NCR system to obtain an evaluation of the condition and, if appropriate, to establish requirements or obtain other corrective action. The individual who reports the nonconforming condition may also include a statement of the probable cause of the condition and a recommendation for the disposition of the condition.

The QA Coordinator must ensure that the information is complete, obtain and add an identification number, determine the appropriate distribution and action parties (normally the responsible manager of the activity and other technical personnel), and sign, date, and distribute the NCR. If an NCR is originated by a QA Coordinator, another QA Coordinator or the project manager will administer and coordinate the NCR

QAI 15.1.3 Disposition of Nonconformances - The QA Coordinator must contact the action parties for their assistance in evaluating the nonconforming condition. The need for additional inspection, testing, or investigation must be stated on the NCR. All information obtained must be evaluated jointly by the QA Coordinator and the action parties. When a consensus decision has been reached, the disposition must be described on the NCR. Disposition normally consists of one of the following:

- *Accept As Is*—Used when the nonconforming condition is judged to have no adverse effect on quality, and the item or activity will continue to meet all functional requirements. No additional work or actions are required. A justification must be included.
- *Rework*—Used when additional work will bring a nonconforming item into compliance with original requirements. If tests are involved, they may need to be repeated.
- *Repair*—Used when a nonconforming item can be returned to an acceptable condition but not according to the original requirements. New requirements must be established, and the repaired items must be inspected or evaluated on the basis of the requirements. A justification must be included.
- *Reject*—Used when a nonconforming item cannot meet its intended function. This disposition may include scrapping, returning to the supplier for correction or replacement, or disposition otherwise as determined by the action parties.

Justification Statement — Disposition "Accept As Is" or "Repair" must be justified by a statement of the technical basis or other bases. Appropriate supporting information, such as calculations,

must be included or attached. Changes to design documents must be submitted to the design organization for approval. When the disposition of an NCR is "Accept As Is" or "Repair" for government furnished equipment, then BHI Project Management and QA must review and approve the disposition prior to closure of the report.

Instruction Statement - When items are reworked or repaired to conform to other than existing requirements, detailed instructions must be cited or provided. Inspection or test criteria must be included when a change from an original requirement is made. When items are rejected, any special instructions must be included.

The action parties must also evaluate the cause of the nonconforming condition and evaluate actions to prevent recurrence. Examples of such actions include revision of a requirements document, revision of procedures, training of personnel, or disciplinary action.

QAI 15.1.4 Closure of NCRs - When disposition has been completed, the originator or the QA Coordinator closes the NCR. Any Hold tags or other status indicators that were placed on items must be removed by the person who placed them (or a designated representative). If verification of disposition reveals a result other than the one required by the disposition statement, the NCR must be closed and a new NCR issued to address the noncompliance with the requirement for disposition.

Copies of closed NCRs (or notification of closure) are sent by the QA Coordinator to everyone on the original distribution and any other individuals who have become involved since the distribution.

QAI 15.1.5 Instructions for Completion of the NCR Form - The individual who identifies a nonconforming item or activity must enter the following information on the appropriate line within the heavy border on the NCR form (see Figure 15.1-1) or provide the information to the QA Coordinator:

- Purchase Order or Subcontract Number of the item, if applicable.
- Brief descriptive title that identifies the nonconformance.
- Title, number, and revision number of the document containing the requirements.
- Project, program, or activity affected by or responsible for the item or activity.
- Name of the supplier or subcontractor, when applicable.
- Any unique identification number for items, or a job number or other reference (such as report number, test number, or sample number).
- Item (line) number of each condition when more than one condition affects a specific item or activity.
- Description of the condition in a "Required" and "Is" format (see examples in QAI 15.1).
- Most probable cause of the condition, if known.
- Recommendations for actions (when appropriate) to correct the condition and related conditions.
- Signature of the person who has entered the information and the date signed.

QA Coordinator - The QA Coordinator enters the information in boxes 1 through 11 of the NCR form when notified by others. When the information has been entered, the QA Coordinator determines whether the information is adequate. The QA Coordinator may print the originator's name in box 11 of the form if the originator did not sign and is not available. The QA Coordinator signs and dates box 12 and enters the NCR number in box 13. The responsible administrative and

technical personnel must be identified as action parties in box 20, and anyone else who should know about the NCR must be designated for information copies.

Disposition of the NCR - The QA Coordinator and the action parties evaluate the nonconformance and determine what disposition is proper. When consensus has been reached, the disposition statement, the justification, and any instructions are entered in box 14 or on a continuation sheet. If consensus cannot be reached between the QA coordinator and the action parties, the Project Manager shall be contacted to determine the appropriate disposition. Boxes 15 through 17 must be marked to show whether a design change is involved, the nonconformance should be referred to ES&H manager for possible. Required corrective action will normally be described in box 14, or a Corrective Action Request will be issued. When agreement on disposition has been reached, the QA Coordinator and the action parties must sign and date the approvals in box 18.

Closeout of NCR - When disposition has been completed, the originator (or other designated individual) or the QA Coordinator signs and dates box 19 to show that disposition has been completed as directed or that some other disposition has been agreed to. If the disposition is other than that previously agreed upon, the NCR must be closed and a new NCR issued as described in QAI 15.1. The QA Coordinator distributes copies of the closed NCR (or notice of closure) to the action parties and to anyone else who is affected.

Figure 15.1-1. Nonconformance Report

RUST Federal Services		Nonconformance Report		13. NCR No.
				Page 1 of _____
1. Purchase Order Number		2. Title or Subject		3. Document No., Title, or Revision
4. Project, Program, or Activity		5. Supplier Name/Address		6. Job No. or ID No.
7. Item		8. Description of Nonconformance		
		14. Disposition/Justification Instructions		
9. Probable Cause of Condition				
10. Recommended Action to Correct				
11. Originator's Signature of Name Date				
12. QA Signature Date				
15. Design Document Change Request? <input type="checkbox"/> Yes (Document No. _____) <input type="checkbox"/> No		16. Reportable as an Event? <input type="checkbox"/> Yes (Report No. _____) <input type="checkbox"/> No		17. Corrective Action Required? <input type="checkbox"/> Yes (specify _____) <input type="checkbox"/> Yes (CAR No. _____) <input type="checkbox"/> No
18. Technical Representative Date		Signature Date		Signature Date
QA Coordinator Date		Signature Date		Signature Date
19. <input type="checkbox"/> Disposition Completed as Directed				
<input type="checkbox"/> Other (Specify): _____				
_____ Originator or QA Coordinator				
20. Action		Information Copies		

QAI - 15.2 - Procurement Related Nonconformances

This QAI provides instruction and requirements for the administration of nonconformances identified during the procurement process. This QAI is applicable as a part of the Standard-Level QA Program requirements. Activities to procure replacements for government furnished ERDF equipment shall be performed in conjunction with BHI Project Management and QA organizations to ensure that NCR performance and resolution is acceptable.

Responsibilities and Instructions

QAI 15.2.1 Authority to Contract Subcontractors - Nonconformances to procurement document requirements may be detected at any of several points in the procurement process. While any individual can initiate a Nonconformance Report (NCR), those related to procurement are normally initiated by individuals who are familiar with the specific procurement. A contractual agreement exists between Rust and its suppliers; consequently, it is mandatory that the cognizant project management be informed of all supplier nonconformances. Any information requested or provided must be through the appropriate contract representatives with the subcontractor in question.

A minimum of three entities are normally involved in the processing of procurement-related NCRs: the procurement representative (i.e. project manager and/or corporate purchasing), the QA Coordinator, and a technical representative. The designated procurement representative is the only individual authorized to communicate with the supplier.

The QA Coordinator is responsible for administration of Nonconformance Reports. In this capacity, the QA Coordinator will track the NCR, assist in coordinating the disposition, verify (if necessary) that the disposition has been completed, close the NCR, and distribute copies of NCR to all involved parties.

QAI 15.2.2 Initiation and Handling - Procurement-related NCRs are handled differently, depending on the time and location of discovery and the contract requirements. Following are general classifications of common NCR situations.

- *Discovery at Receipt* (or other point of acceptance)—These NCRs are identified during the acceptance inspection. QA requirements and/or government requirements prohibit the acceptance of items or services that do not meet procurement document requirements. The deficiencies must be noted on the receiver or other receipt inspection documentation and provided to the procurement representative. The procurement representative will expedite the disposition with Rust technical/QA personnel and work with subcontractor/supplier to implement the corrective action. In cases where it may be beneficial to Rust to accept the items or materials, an NCR may be initiated and dispositioned "accept-as-is" with a supporting technical justification. Depending on the contract type and costs, procurement or project management may require an alteration to the original requisition changing the requirements to accept the items or materials as provided.
- *Discovery After Receipt*—This case applies to items, materials, or services that were accepted at receipt and later found to be deficient, either due to latent defects or oversight during the receiving inspection. An NCR should be initiated in accordance with QAI 15.1 with the procurement representative immediately involved. Depending on the type of contract, costs involved, time of discovery, and warranty, the items or materials may be returned and replaced. If the procurement representative determines

that the items or materials cannot be returned, the NCR will be dispositioned in accordance with QAI 15.1 as an internal NCR.

- *Discovery Prior to Receipt*—Actions to be taken when nonconforming conditions are identified prior to receipt or presentation for acceptance are specified in the contract.

For contracts where the supplier is not required to have a QA program with an NCR reporting requirement, the procurement representative should be notified of the discovery along with pertinent facts. The procurement representative will inform the supplier of the identified condition so it can be corrected prior to presentation for acceptance. An NCR is not required and receipt inspection will be used to ensure acceptability of the corrective action.

For contracts where QA requirements have been applied and the supplier has an internal NCR program, any deficiencies should be reported to the supplier. The supplier is expected to initiate an NCR. For dispositions of accept-as-is and repair, the supplier is usually required to obtain concurrence from Rust. This shall be accomplished by initiating a Rust NCR in accordance with QA 15.1 with the supplier's NCR attached. After evaluating the impact on design, function, or other aspects of usage, the Rust NCR should be dispositioned indicating agreement with the supplier's proposed disposition. A copy of both NCRs should be provided to procurement for forwarding to the supplier.

- *Supplier Notification of Defective Materials*—Suppliers providing items, materials, and services must inform those potentially affected if, at a later date, the supplier should discover that it manufactured or provided defective items, materials, or services. When such notifications are received, the procurement and QA functions must be notified so that a determination of the presence and impact of the defective materials or services can be made. If defective materials or services are discovered, an NCR will be initiated in accordance with QAI 15.1 and handled in the same manner as if it were discovered after receipt.

QAI 15.2.3 Substandard Items, Materials, or Services - Where there are indications that suppliers knowingly supplied items, materials, or services of substandard quality, including counterfeit, defective, improperly marked or graded, fraudulent or falsified data, the corporate procurement and QA managers must be promptly notified. If the substandard equipment relates to ERDF replacement equipment, an investigation of the information will be completed and, if substantiated, the information shall be forwarded to the DOE Office of the Inspector General. Reporting will also be performed in accordance with the applicable requirements of DOE Order 5000.3B.

QAI 15.2.4 Documentation - In addition to the normal distribution, copies of the completed NCR will be provided to the procurement representative for inclusion in the supplier history files.

Criterion 16 - Corrective Actions

16.1 General Requirements - A system shall be established that provides for promptly identifying conditions adverse to quality, determining the cause of the conditions, and obtaining corrective action. The Project Manager is responsible for maintaining the corrective action system and ensuring timely action to closure CARs.

16.2 Standard Requirements - Procedures must be established and implemented for identifying and correcting conditions adverse to quality, such as system failures, malfunctions, deficiencies, defective material and equipment, nonconformance to requirements of design or procurement documents, or noncompliance with procedures.

When significant conditions adverse to quality have been identified and when other methods of obtaining corrective action have failed or have been ineffective, management must formally request corrective action. The procedure for requesting corrective action must provide for the following:

- Notification of the appropriate personnel of the adverse condition.
- Determination of the cause of the condition.
- Prompt identification and implementation of actions to correct the condition and prevent recurrence of similar conditions.
- Documentation of the adverse condition, the cause, and the corrective actions taken; and reporting to the appropriate levels of management for review and assessment.
- Verification of the implementation of the corrective action.

Information pertaining to an adverse condition must be periodically evaluated to determine whether trends are present that indicate the need for additional corrective action.

16.3 "Q"-Related Requirements - No requirements beyond those identified under Standard Requirements apply.

QAI - 16.1 - Corrective Action Request System

Conditions adverse to quality may be identified as the result of an event or found during an audit, surveillance, inspection, or random observation. These conditions are documented in Nonconformance, Audit, and Surveillance Reports, as well as in Unusual Occurrence and Unusual Event Reports. Each of these reports includes a determination of the cause and actions to correct the condition. This instruction defines the Corrective Action Request (CAR) system for achieving corrective action when earlier action taken in response to identified deficiencies has been inadequate, an adverse quality trend has developed, or a significant condition adverse to quality is identified.

Responsibilities and Instructions

The QA Coordinator is responsible for issuing Corrective Action Requests (CARs) to request corrective action from management when significant quality problems have not been effectively addressed by other mechanisms. CARs must be written and issued in accordance with this QAI.

The managers of an organization receiving a CAR are responsible for evaluating and investigating the adverse conditions, documenting the proposed corrections, and completing the corrections in a timely and effective manner. The responses to CARs must be evaluated and the corrective actions verified in accordance with this QAI.

QAI 16.1.1 Issuance of CARs - A CAR may be initiated by any member of the QA function who identifies a condition adverse to quality. The CAR shall be identified with a unique number for tracking and closure purposes.

The QA Coordinator reviews the draft CAR and the information relating to it. Draft CARs identifying conditions that are not significantly adverse, that may be resolved by other systems, or for which corrective action is already under way might not be approved by the QA Coordinator for issue.

When a CAR is appropriate, the QA Coordinator approves the CAR and notifies the management of the responsible organization of the intent to issue a CAR. The CAR is forwarded under a covering memo to the responsible management for action. Response to CARs is normally requested within 10 working days of issue.

QAI 16.1.2 Response to CARs - Upon notification or receipt of a CAR, the responsible management must take the necessary actions to bring the adverse condition under control and to investigate the causes of the condition. The management controls may include (1) suspension of all or part of the work, (2) management and supervisory reviews of work in progress, or (3) other actions deemed appropriate by the management of the organization.

The responsible organization shall review and investigate to determine the root cause of the conditions that led to the issuance of a CAR. After causes have been determined, the management shall propose (1) corrective action for current and past work that is affected, and (2) management action to prevent recurrence of the condition. Dates or schedules of completion shall be identified for each action. The QA Coordinator shall track CARs and issue a monthly report to the Project Manager on CAR status.

QAI 16.1.3 Review of Proposed Action - Upon receipt of the proposal for corrective action, the QA Coordinator and others who were consulted evaluate the information from the investigation and the proposed corrective actions to correct the condition and its causes. The evaluation of the response is to be timely, normally within 5 working days after receipt of the

corrective action proposal. The acceptability of the proposal shall be determined and documented, or the organization shall be contacted and concurrence on an alternate solution shall be obtained. If agreement cannot be reached, the condition shall be referred to the project manager.

The organization shall be notified when the proposal has been accepted. Other organizations involved or affected by the proposed actions shall be informed by the proposing organization of the plans and any required actions. Corrective action may be undertaken at the option of the responsible organization before the proposal for corrective action has been accepted.

QAI 16.1.4 Verification of Action - The progress of corrective action is tracked by the QA Coordinator to the scheduled completion dates. Upon completion of corrective action, the QA Coordinator verifies implementation of the action. The effectiveness of corrective action must be verified by surveillance, audit, trend analysis, or other reviews.

Arrangements for protective storage of records shall provide for the following:

- Storage of records in predetermined locations.
- Rules governing access to and control of the records files.
- Methods for maintaining control of records and accountability for records removed from the storage area.

Provision must be established to maintain control of access to records and to allow for planned retrievals.

17.2.6 Records Disposition - Retention times are specified by various regulatory agencies and customers. The most stringent retention period must be observed. Records to be released to customers or inactive storage must be inventoried by the records custodian and transmitted, and an acknowledgment of receipt must be requested. Records maintained by suppliers or others under the control of Rust at their facilities or other locations must be maintained and protected in accordance with this Criterion.

17.3 "Q"-Related Requirements - No requirements beyond those identified under Standard Requirements apply.

Criterion 18 - Audits, Surveillance, and Managerial Controls

18.1 General Requirements - Planned and scheduled QA audits must be performed to verify compliance with all aspects of the QA Program and to determine the effectiveness of the QA Program. Audits must be performed in accordance with written procedures and checklists by certified personnel who do not have direct responsibility for performing the activities being audited. Audit results must be documented and reported to responsible management, and follow-up action must be taken when necessary. Audit personnel shall be used from corporate resources and certified to NQA-1, ASQC or ISO-9000.

18.2 Standard Requirements - Procedures are developed and implemented by the QA Coordinator with assistance from the corporate QA organization for scheduling, preparation, performance, and reporting of QA audits.

18.2.1 Scheduling of Audits - Internal and external audits must be conducted at a frequency commensurate with the status and importance of the activity. Regularly scheduled programmatic audits are supplemented by additional audits of specific subjects when appropriate. Previous audit findings, nonconformance reports, or other independent sources of information are considered.

18.2.2 Audit Preparation - The QA organization develops and documents an audit plan for each audit. The plan must address the following elements:

- Scope of the audit.
- Requirements to be audited.
- Audit personnel.
- Organizations to be notified.
- Applicable documents.
- Audit schedule.
- Written audit procedures and checklists.

18.2.3 Audit Personnel - Personnel who are independent of the activities to be audited are selected and assigned as auditors. Personnel having direct responsibility for an activity must not be involved in selection of the auditors. Auditing personnel must have sufficient authority and organizational freedom to make the audit process meaningful and effective. Individuals who perform audits must be qualified in accordance with procedures.

The audit team must be identified during audit planning. The team consists of one or more auditors and a Lead Auditor. The Lead Auditor directs and organizes the audit, coordinates preparation and issuance of the audit report, and evaluates responses. The Lead Auditor ensures that the audit team has been trained and is aware of the audit scope, goals, and objectives before the start of the audit.

18.2.4 Audit Performance - Activity areas selected for audit must be evaluated against specified requirements. Objective evidence is examined to the depth necessary to determine whether the requirements are being satisfactorily documented. Results must be provided to management of the areas being audited.

Management of the audited organization or activity must investigate adverse audit findings, schedule corrective action (including measures to prevent recurrence of identified problems), and notify the Lead Auditor in writing of action planned or taken. The Lead

Auditor then evaluates the adequacy of the response. The audit team must then follow up to verify that corrective action has been taken.

18.2.5 Reporting of Audits - The audit report is issued by the Lead Auditor. It will include audit scope, names of the auditors, individuals contacted, summary of the results (including effectiveness of the elements of the QA Program that were audited), and a description of each reported adverse finding. Each finding must be described in enough detail to allow corrective action to be taken by the audited organization or activity.

18.2.6 Audit Records - Audit records must include audit plans, reports, written responses, and records of completion of corrective actions.

18.3 "Q"-Related Requirements - No requirements beyond those identified in Standard Requirements apply.

QAI - 18.1 - Performance and Reporting of Audits

This instruction defines the interfaces and responsibilities of organizations and management during the performance of a QA audit

Responsibilities and Instructions

QAI 18.1.1 Audit Planning and Scheduling - The corporate QA Director is responsible for the overall scheduling and planning of audits. Audit planning includes both long- and near-term planning. Near-term planning is reviewed at least quarterly for final scheduling. The planning remains flexible to allow response to factors such as special requests and changes in scope of work, and to allow the audits to provide the most useful information for management.

Audit planning includes consideration of the following:

- Complexity, scope of work, and schedules.
- Customer requests.
- Audit requirements established in program plans.
- Length of time since the last audit.
- Supplementary surveillance's that have been performed.
- Past quality performance by the program or organization.
- Number and results of audits of organizations that provide support to the program.
- Seasonal variation in work on a program.
- Availability of auditors and Lead Auditors.

The organizations to be audited are contacted to establish firm dates for the audits. Unscheduled audits may be performed when appropriate. Audit scheduling and planning must take into account current areas of work and the workloads, areas with past QA problems, and time since specific elements of the QA Program were audited.

Audit scheduling shall include assignment of a Lead Auditor from the QA organization who is independent of the activity that will be audited. Assistance from other organizations may be requested by QA. Scheduling of ERDF audits shall be forwarded to BHI Project Management and QA to allow appropriate oversight of audits as deemed necessary.

QAI 18.1.2 Audit Performance - The Lead Auditor schedules a pre-audit meeting with the organizations that will be audited. The pre-audit meeting must provide an introduction and outline of the scope of the audit. The audited organizations must provide the audit team with assistance and access to records and activities being audited.

At the completion of the investigative part of the audit, the audit team evaluates the information obtained and drafts a report of the results. A post-audit meeting is scheduled with managers of the audited organizations to present the results of the audit in the form of findings, observations, and commendations. The managers of the audited organization are permitted to present additional information or describe proposed or completed actions that are relevant to the audit. The managers are encouraged to propose or complete corrective actions to allow closure of findings at the post-audit meeting.

QAI 18.1.3 Audit Reporting - Following the post-audit meeting, the audit team shall prepare the audit report and supporting documentation. The report provides information on the areas and organizations audited, specifics investigated, observations, commendations, details supporting

findings, and agreements reached during the post-audit meeting. Findings shall be reported individually and directed to the responsible organizations for their response and proposed corrective action.

QAI 18.1.4 Audit Tracking and Status - The Lead Auditor tracks the responses and corrective actions of the audit. Where necessary, the organizations are notified of overdue responses, acceptance of proposed actions, or the closure of a finding. The corporate QA Director shall ensure that audits are properly tracked program wide, including ERDF specific audits.

QAI 18.1.5 Findings Closeout - After the Lead Auditor is notified that the proposed corrective actions have been completed for a specific finding, a verification of completion will be performed and documented. The verification may consist of reviews, surveillance, additional follow-up auditing, or other actions depending on the type, complexity, and importance of the activity.

QUALITY ASSURANCE PROCEDURE

QA AUDITOR CERTIFICATION

Approved By:

R. B. Millward

Director, Quality Assurance

11-15-93

Date

FOR INFORMATION
ONLY

1.0 Purpose

The purpose of this procedure is to describe the qualification and certification for QA Auditors and Lead Auditors. It applies to personnel who perform Quality Assurance system audits, both internal to the company and external (e.g., suppliers or subcontractors).

2.0 Responsibilities

2.1 Facility/Project QA Manager

The facility/project QA Managers are responsible for the implementation of this procedure. The QA Manager will ensure that audit personnel receive adequate training for their duties and will maintain documentation, in accordance with this procedure, of the training, qualification, and certification of Auditors and Lead Auditors.

2.2 Lead Auditors

Personnel assigned as Lead Auditors are responsible for ensuring that audit team members receive adequate training and orientation before the performance of audits. Lead Auditors will evaluate the performance of and assist in the professional development of the personnel assigned to them. Lead auditors will exercise judgement and control during audits. Lead Auditors are expected to be professional and ethical in their duties at all time.

2.3 Auditors

Auditors are responsible for assisting Lead Auditors in assigned areas. Auditors are responsible for their own professional development, utilizing the training and guidance provided to them by Lead Auditors and management personnel.

3.0 Requirements

Only personnel who have been qualified and certified in accordance with this procedure may be assigned to perform Quality Assurance audits (internal or external). Each audit must be performed under the direction of an individual certified as a Lead Auditor.

3.1 Qualification of Auditors

Anyone who is assigned to assist in the performance of an audit will be considered an auditor, and must receive orientation and training before performing any audit function (see Attachment 1, flowchart). This requirement does not apply to individuals whose only function in an audit is to provide technical advice. Lead Auditors will ensure that the assigned Auditors have the following minimum training:

Orientation - Auditors must be provided a working knowledge of corporate and facility/project QA Program requirements. For external audits, the Auditors must have a working knowledge of applicable nationally recognized QA systems, such as ISO-9000, ASME NQA -1, Mil-Q-9858A, Mil-I-45208, IEEE-323 or others that apply to the organization being audited.

Training - Knowledge of the general conduct of audits is required. The training must include establishing auditing objectives, audit preparation, entrance meetings, audit investigative methods, organization of information, determination of findings and observation, exit meetings, preparation of reports, evaluation of responses, and followup and closeout of findings.

On-The-Job Training - Guidance and counseling under the direct supervision of a Lead Auditor shall be provided. This training must include all aspects of an audit from the initial planning through the completion and closeout of an audit. Attendance at formal training will be documented by the trainer. A copy of the attendance record will be provided to the individual receiving the training.

3.2 Qualification of Lead Auditors

A candidate for Lead Auditor must have been certified under one or more of the following quality systems;

- 1) ASQC Certified Quality Auditor (CQA); or
- 2) ISO-9000 Certified Lead Auditor; or
- 3) must have verifiable evidence that a minimum of 10 credits under the following scoring system has been accumulated:

Education (4 Credits Maximum) - Associate degree from an accredited institution: score 1 credit, or if the degree is in engineering, physical sciences, mathematics, or quality assurance, score 2 credits. A Bachelor's degree from an accredited institution: score 2 credits, or if the degree is in engineering, physical sciences, mathematics, or quality assurance, score 3 credits. In addition score 1 credit for a masters degree in engineering, physical sciences, business management, or quality assurance from an accredited institution:

Experience (9 Credits Maximum) - Technical experience, such as engineering, science, manufacturing, construction, operation, or maintenance: score 1 credit for each full year, with a maximum of 5 credits for this aspect of experience. If 2 years of this experience have been in the nuclear or waste management fields, score 1 additional credit; or if 2 years of this experience have been in quality assurance, score 2 additional credits; or if 2 years of this experience have been in auditing, score 3 additional credits; or if 2 years of this experience have been in nuclear or waste management quality assurance, score 4 additional credits.

Other Credentials of Professional Competence (2 Credits Maximum) - The facility/project QA Manager may grant up to 2 credits for other performance factors applicable to auditing that may not be explicitly identified previously. Examples of these factors include leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and quality assurance training courses.

Qualification of Lead Auditors will be documented using a form, such as Attachment 2.

3.3 Evaluation For Lead Auditor Certification (Internal)

Lead Auditor candidates who have met the qualification requirements identified above will be evaluated by the facility/project QA Manager for the following capabilities:

Communication Skills - The candidate will be evaluated for communication skills and the ability to

communicate clearly, both in writing and verbally. These skills should include clear expression, receptive listening to gain understanding, and the ability to communicate in a firm but non-demeaning manner. The evaluation of communication skills shall be documented by the facility/project QA Manager.

Training - In addition to the training received as an Auditor, candidate Lead Auditors must have training to assure their competence in auditing skills. Training in the following areas will be given based upon a needs evaluation for each candidate by the facility/project QA Manager:

- Knowledge and understanding of national consensus standards and other nuclear or regulatory related codes, standards, regulations, and guides related to quality assurance.
- General structures of Quality Assurance Programs as a whole, and the elements of the QA Program as they apply to sound business management practices.
- Knowledge of the QA Program auditing activities. Auditing techniques of examining, questioning, sampling, evaluating, and reporting. Also, methods and techniques to identify and followup on corrective actions and close audit findings.
- Audit planning in quality related activities such as design, procurement, fabrication, handling, shipping, storage, inspection, testing, statistics, maintenance, repairs, operations, safety, or modifications.
- On-the-job training in the elements of auditing.

Audit Participation - The prospective candidate for certification as a Lead Auditor must have participated in a minimum of 5 quality assurance audits within 3 years before the date of qualification; one of the audits must have been a full quality assurance system audit within a year before the date of qualification.

Examination - The candidate for Lead Auditor must have passed an examination that tests comprehension and evaluates the ability to apply the knowledge and skills of a Lead Auditor.

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3.4 Certification of Lead Auditors (Internal)

Candidates who satisfy the requirements for qualification, and who have been evaluated by the facility/project QA Manager, may be certified as Lead Auditors for internal audits.

3.5 Certification of Lead Auditors (External)

Candidates for certification as Lead Auditors for external audits must satisfy the qualification and evaluation requirements for internal auditing and the additional following evaluation requirements:

3.5.1 A working knowledge of other industry QA Programs and codes that apply to a particular audit. Examples of standards and organizations that produce standards include: Department of Defense (DOD), Environmental Protection Agency (EPA), American Petroleum Institute (API), American Welding Society (AWS), American Society of Mechanical Engineers (ASME), Institute of Electrical and Electronics Engineers (IEEE), National Fire Protection Association (NFPA), American National Standards Institute (ANSI), and American Society for Testing and Materials (ASTM).

3.5.2 Knowledge of the contractual relationship between the audited and auditing organization, including knowledge of contracting procedures. Included is an understanding of the intercompany interface requirements, and a working knowledge of procurement requirements and the requirements of the Federal Acquisition Regulation (FAR).

3.5.3 Participation in at least one external quality program audit during the previous 3 years.

The facility/project QA Manager will evaluate candidates for external Lead Auditor on the above attributes. The evaluation may be based on direct observation of the individual during external auditing activities; evaluations by other certified external Lead Auditors, procurement, or management personnel; evaluation of reports; or oral interviews. The evaluation will be documented using a form, such as Attachment 3.

3.6 Maintenance of Lead Auditor Qualification

Lead Auditors (Internal and External) must maintain their proficiency through one or more of the following:

- Regular and active participation in the auditing process.
- Review and study of codes, standards, procedures, instructions, and other documents related to Quality Assurance Programs and program auditing.
- Participation in training programs.

3.7 Requalification

Proficiency will be assessed annually by the facility/project QA Manager. The assessment will include an evaluation and determination to extend the qualification or to require requalification. The assessment will be documented using forms, such as Attachments 2 and 3.

3.8 Administration of Auditor Qualifications

Training needs of Lead Auditors will be assessed by the facility/project QA Manager. Training may be conducted in-house or by outside groups.

The development and administration of the Lead Auditor examination is the responsibility of the facility/project QA Manager. The facility/project QA Manager may elect to have outside groups (e.g., ASQC CQA Program) develop or administer the examination or both. The examination should address all significant aspects of the auditing process.

The integrity of a written examination will be maintained by proctoring and by appropriate confidentiality of the examination files. A grade of 90 percent on the examination shall be considered satisfactory. Any questions answered incorrectly will be discussed with the prospective Lead Auditor by the facility/project QA Manager to assure complete understanding of the auditing process.

4.0 Records

All records generated by activities described in this procedure are nonpermanent and are to be retained until the next recertification or three years, whichever is longer. The following records will be generated:

- Record of Lead Auditor qualification
- Evaluation of External Lead Auditors
- Evaluation of Lead Auditor Qualification.

Examinations and results will be maintained and destroyed at the discretion of the facility/project QA Manager.

5.0 References

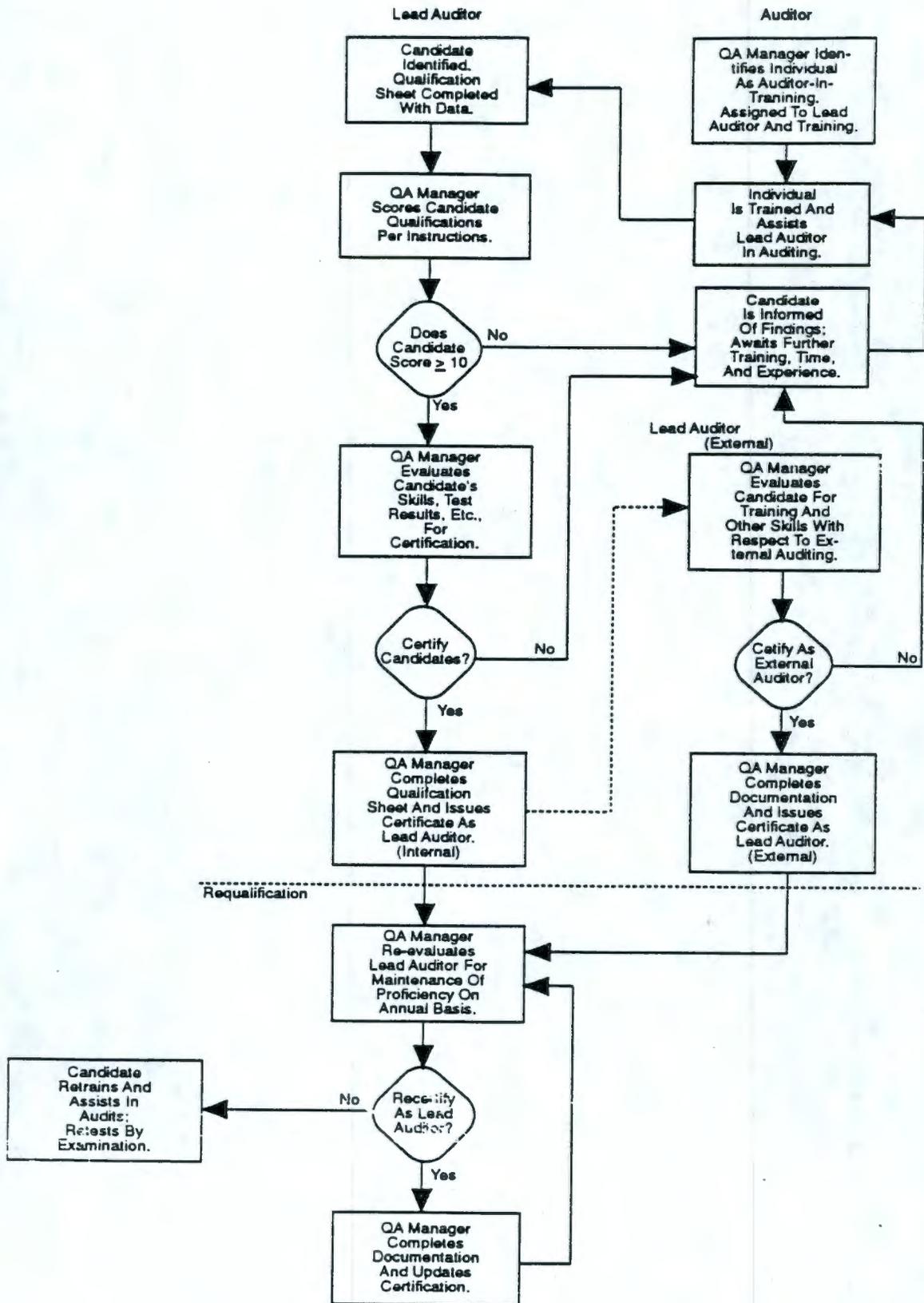
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ATTACHMENTS

1. **Qualification and Certification of Auditors (Flowchart)**
2. **Record of Lead Auditor Qualification**
3. **Evaluation of External Lead Auditors**

ATTACHMENT 1
 Qualification And Certification Of Auditors



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Record of Lead Auditor Qualification

Name _____ Date _____

Employer _____

Qualification Point Requirements **Credits**

Education—University/Degree Date 4 Credits Max. _____

- 1. Undergraduate Level
- 2. Graduate Level

Experience—Company/Dates 9 Credits Max. _____

Technical (0-5 credits) and
Nuclear Industry (0-1 credit), or
Quality Assurance (0-2 credits), or
Auditing (0-4 credits)

Professional Accomplishment—Certificate/Date 2 Credits Max. _____

- 1. P.E.
- 2. Society

Management—Justification/Evaluator/Date 2 Credits Max. _____

Explain:

Total Credits: _____

Evaluated by _____ Date _____
(Name and Title)

Audit Communication Skills

Evaluated by _____ Date _____
(Name and Title)

Audit Training Courses

Course Title or Topic Date _____

- 1. _____
- 2. _____

Audit Participation

	Location	Audit	Date
1.			
2.			
3.			
4.			
5.			

Examination _____ Passed _____ Date _____

Auditor Qualification
Certified by _____ Date Certified _____
(Signature and Title)

Annual	Signature		
Evaluation	Date		

Evaluation of External Lead Auditors

Name _____ Date _____
 Certified as Lead Auditor by _____ Date _____

Knowledge	Satisfactory	Unsatisfactory
Familiarity With Industry QA Programs	_____	_____
Knowledge of Codes and Standards and Their Application	_____	_____
Knowledge of Contracting Procedures and Interfaces	_____	_____
Working Knowledge of the FAR and Other Contracting Regulations	_____	_____
Experience		
Experience or Training on Application of QA Requirements for External Organizations	_____	_____
External Audit Planning and Performance (1 audit minimum)	_____	_____
Professionalism		
Knowledge of Duties and Requirements as a Company Representative	_____	_____
Image (Demeanor, Manner, Dress, and Conduct)	_____	_____
Business Ethics	_____	_____
Other	_____	_____

Evaluated by _____ Date _____
(Signature)

External Audit Participation			
Company/Location	Criteria	Date	Remarks
1. _____			
2. _____			
3. _____			
4. _____			

Certified External Lead Auditor by _____ Date _____
(Signature and Title)

Annual	Signature		
Evaluation	Date		

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