



Department of Energy
 Albuquerque Operations
 Los Alamos Area Office
 Los Alamos, New Mexico 87544

JUL 0 1 1991

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Allyn M. Davis, Director
 Hazardous Waste Management Division
 U. S. Environmental Protection Agency, Region 6
 1445 Ross Avenue
 Dallas, Texas 75202

Dear Mr. Davis:

Please find enclosed two hard copies and one electronic copy of the Los Alamos National Laboratory Quality Program Plan for Environmental Restoration Activities. This document has been submitted in the past as Annex II of the Installation Work Plan. It is now being submitted separately for the approval of the Region 6 Quality Assurance Office.

Please address any questions concerning this submittal to Steve Slaten of the Los Alamos Area Office Environment, Safety and Health Branch at (505) 665-5050.

Sincerely,

Jerry L. Bellows
 Jerry L. Bellows
 Area Manager

LESH:2SS-009

Enclosures

cc:
 Allen J. Tiedman, ADO, LANL, MS-A120
 Tom Gunderson, HSE-DO, LANL, MS-K491



2749 General

Los Alamos National Laboratory
Environmental Restoration

A Department of Energy environmental clean-up program

**LOS ALAMOS NATIONAL LABORATORY
QUALITY PROGRAM PLAN**

FOR

ENVIRONMENTAL RESTORATION ACTIVITIES

June 1991

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QUALITY PROGRAM PLAN IDENTIFICATION FORM

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1.0	INTRODUCTION.....	1 of 2
1.1	Scope.....	1 of 2
1.2	Policy Statement.....	1 of 2
2.0	ORGANIZATION.....	1 of 8
2.1	Responsibilities of the Health, Safety, and Environment Deputy Division Leader.....	1 of 8
2.2	Responsibilities of the Environmental Restoration Program Manager.....	1 of 8
2.3	Responsibilities of the Deputy Group Leader.....	3 of 8
2.4	Responsibilities of Project Leaders.....	3 of 8
	2.4.1 Operable Unit Project Leaders.....	3 of 8
	2.4.2 Quality Program Project Leader.....	4 of 8
	2.4.3 Health and Safety Project Leader.....	4 of 8
	2.4.4 Community Relations Project Leader.....	5 of 8
	2.4.5 Project Leader for the Facility for Information Management and Display.....	6 of 8
	2.4.6 Project Leader for Records Management.....	6 of 8
	2.4.7 Project Leader for Resource Planning.....	7 of 8
2.4	Responsibilities of Technical Team Leaders.....	7 of 8
2.5	Quality Assurance Representative.....	8 of 8
3.0	QUALITY ASSURANCE PROGRAM.....	1 of 5
3.1	Personnel Qualifications and Training.....	1 of 5
	3.1.1 Qualifications of Environmental Restoration Program Personnel.....	1 of 5
	3.1.1.1 Documentation of Qualifications.....	3 of 5
	3.1.1.2 Evaluation of Personnel Qualifications.....	3 of 5
	3.1.2 Training.....	3 of 5
3.2	Assessment of Quality Program.....	3 of 5
3.3	Data Quality Objectives.....	3 of 5
3.4	Assessment of Data Quality.....	4 of 5
	3.4.1 Precision.....	4 of 5
	3.4.1.1 Standard Reference Materials.....	4 of 5
	3.4.1.2 Instrument Checks.....	4 of 5
	3.4.2 Accuracy.....	4 of 5
	3.4.2.1 Traceability of Instruments.....	5 of 5
	3.4.2.2 Traceability of Standards.....	5 of 5
	3.4.2.3 Traceability of Samples.....	5 of 5
	3.4.2.4 Traceability of Data.....	5 of 5
	3.4.2.5 Reference, Spiked, or Blind Samples.....	5 of 5

3.4.3	Representativeness, Comparability, and Completeness.....	5 of 5
4.0	DESIGN CONTROL.....	1 of 1
5.0	PROCUREMENT DOCUMENT CONTROL AND CONTROL OF PURCHASED ITEMS AND SERVICES.....	1 of 1
6.0	INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS.....	1 of 4
6.1	Quality Assurance Project Plans.....	1 of 4
6.2	Standard Operating Procedures.....	2 of 4
6.3	Quality Administrative Procedures.....	4 of 4
6.4	Administrative Procedures.....	4 of 4
7.0	DOCUMENT CONTROL.....	1 of 1
8.0	IDENTIFICATION AND CONTROL OF ITEMS AND SAMPLES.....	1 of 1
9.0	CONTROL OF PROCESSES.....	1 of 1
9.1	Data Collection.....	1 of 1
9.2	Validation.....	1 of 1
10.0	INSPECTION.....	1 of 1
11.0	TEST CONTROL.....	1 of 1
12.0	CONTROL OF MEASURING AND TEST EQUIPMENT.....	1 of 1
12.1	Identification of Equipment.....	1 of 1
12.2	Maintenance and Calibration of Measuring and Test Equipment.....	1 of 1
13.0	HANDLING, STORAGE, AND SHIPPING.....	1 of 1
14.0	INSPECTION, TEST, AND OPERATING STATUS.....	1 of 1
15.0	CONTROL OF NONCONFORMING ITEMS.....	1 of 1
16.0	CORRECTIVE ACTION.....	1 of 1
17.0	RECORDS.....	1 of 1
18.0	AUDITS AND SURVEYS.....	1 of 1
19.0	SOFTWARE QUALITY ASSURANCE.....	1 of 1
20.0	QUALITY IMPROVEMENT.....	1 of 1

REFERENCES

1.0 INTRODUCTION

The Environmental Restoration (ER) Program's Quality Program focuses on producing reports, environmental measurement data, and documentation of the quality controls used to implement the ER Program. Quality assurance (QA) serves both as a guideline and as a management tool to ensure that all activities are performed under the Quality Program Plan (QPP) in an appropriate, well-regulated manner that generates reliable, scientifically valid, and thoroughly documented data. This QPP describes how the University of California (UC) at Los Alamos National Laboratory (the Laboratory) will conduct the ER Quality Program at the Laboratory.

1.1 Scope

The scope of the Quality Program is broad because of the wide variety of activities involved in the ER Program. The requirements of this QPP apply to specific projects and activities managed by the ER Program Office. These projects and activities include, but are not limited to,

- Resource Conservation and Recovery (RCRA) facility investigations (RFIs) to identify, confirm, and quantify contamination; corrective measures studies (CMSs); and corrective action design/corrective action implementation (CMI);
- National Environmental Policy Act (NEPA) compliance documentation; and
- design, construction, and operation of the proposed Mixed Waste Storage and Disposal Facility.

The amount of QA applied to these activities varies according to the importance of the activity.

1.2 Policy Statement

It is the Laboratory's policy to conduct all ER activities in accordance with the QA standards or requirements specified by the Environmental Protection Agency (EPA) and US Department of Energy (DOE). The Laboratory is committed to providing the funding necessary to ensure development and implementation of the ER Quality Program. This funding is obtained from the DOE as part of the budgeting process for the DOE's ER Program. Management at all levels is responsible for quality.

The Laboratory's goals are to generate and produce data that are valid, complete, traceable, and defensible and to ensure that data quality objectives (DQOs) are met. The ER Program will conduct the QA practices necessary to achieve and maintain a clean, safe environment. Each person is responsible for the quality of his or her own work, which means knowing and understanding the requirements of each task undertaken, doing a job right the first time, and initiating action to change requirements that are inappropriate or unattainable.

2.0 ORGANIZATION

This section describes the structure of the ER Program and key QA responsibilities associated with the ER Quality Program. The organization of the ER Program is shown in Figure II-1.

QA personnel will have sufficient authority, access to work areas, and organizational freedom to identify quality-related problems; to recommend, initiate, or effect solutions through designated channels; and to verify implementation of the solutions to ensure that unsatisfactory conditions are corrected. These QA personnel will also have direct access to responsible management at a level where the appropriate authority and organizational freedom, including sufficient independence from cost and schedule, can effect an appropriate action.

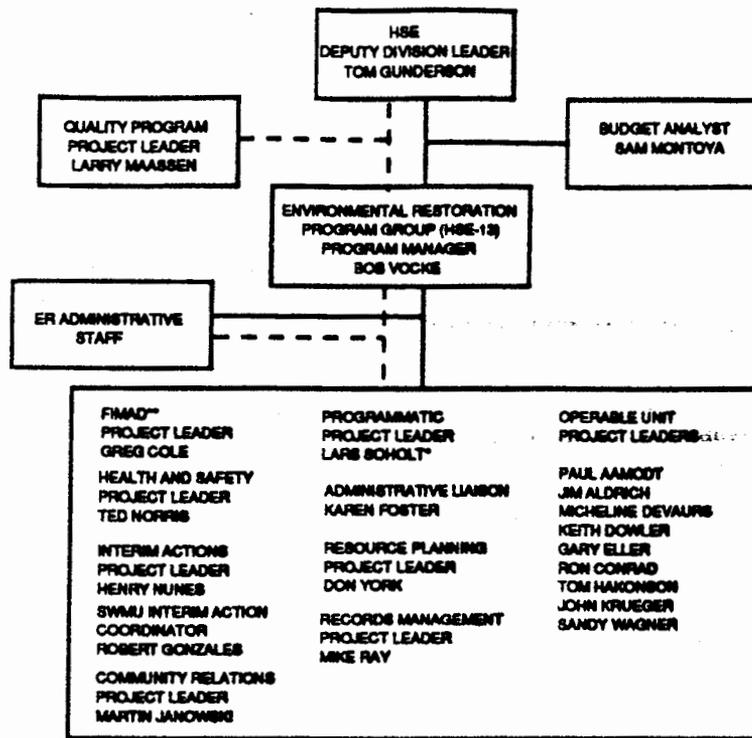
2.1 Responsibilities of the Health, Safety, and Environment Deputy Division Leader

The Deputy Division Leader is responsible for directing the organizations conducting the ER Program.

2.2 Responsibilities of the Environmental Restoration Program Manager

The Program Manager (PM) is responsible for the overall management of the ER Program, including

- ensuring that Laboratory ER activities are consistent with the goals and objectives of the Deputy Division Leader, DOE, EPA, and the New Mexico Environmental Improvement Division (NMEID);
- ensuring compliance with the Hazardous and Solid Waste Amendments (HSWA) Module of the Laboratory's permit to operate under RCRA;
- ensuring the preparation of procedures to administer the ER Program;
- costing, scheduling, and measuring performance;
- submitting monthly and quarterly reports to DOE;
- tracking deliverables and milestones established by the DOE, EPA, and NMEID; and



TECHNICAL TEAMS	GROUPS/DIVISIONS	TECHNICAL TEAM LEADER	QA REPRESENTATIVE	ER PROGRAM OFFICE TECHNICAL TEAM COORDINATOR
Analytical Chemistry/Sample Coordination	HSE-9***, CLS, INC	Chuck Reszutek	Reszutek	Wagner
Analytical Chemistry Instrumentation Dev.	HSE-9***, CLS, ERA, INC	Craig Lassure	Wagner	Wagner
Geochemistry	INC***, CLS, EES, HSE-6	Claresno Dully	Morgan	Wagner
Surface Geology, Geophysics	EES***, HSE	Bill Laughlin	Brosnan	Aldrich
Drilling/Logging	EES***, HSE	Sue Goff	Aamodt	Aamodt
Project Health & Safety	ER***, HSE-1, 2, 3, 5, 10, 11	Ted Norris	Norris	Norris
Community Relations	PA-3***, PA-1	Martin Janowski	Janowski	Janowski
FIMAD***	EES***, HSE-6	Greg Cole	Cole	Cole
Records Management	EES-1***	Mike Ray	Ray	Ray
Statistics	A-1***, EES-1, UCLA	Kathy Campbell	Campbell	Soholt
Decision Analysis	A-1***	Elizabeth Kelly	Campbell	Devaurs
Cost Benefit	A-4***	Linda Trochl	Trochl	Devaurs
Hydrology	EES***, HSE, N-4, MEE-13	Bruce Gellisher	Gellisher	Devaurs
Site Assess. and Remediation Tech. Devel.	HSE***, ERA	Henry Edinger	Aamodt	Aamodt
Document Preparation	IS-8, 11, 12, OS-6	Betsy Barnett	Foster	Soholt
Environmental Assessment	HSE-8, EES-8	Doris Garvey	Garvey	Aamodt
Corrective Action Imp. (Remediation)	ENG***, HSE-7	Chris Loggains	Soholt	Soholt
Mixed Waste/Storage Disposal Facility	MEE***, ENG, HSE-7	Dean Nelson	York	Aamodt
Engineering (Conceptual - Title II)	ENG***, MEE	Chris Loggains	Krueger	Krueger
Regulatory Compliance	HSE-8	Dave McInroy	McInroy	Krueger
Planning/Cost Estimating/Scheduling/Prog.	ER, HSE-00, MEE-4, ENG	Don York	York	Vodde
SWMU Intern Actions	HSE, EES-13, ENG	Henry Nunes	Salisbury	Gonzales
Air Quality	HSE-9***, EES-8	Craig Eberhart	Soholt	Soholt
Risk Assessment	ER***, EES, HSE-1, 5, 8, 10, 11, A, UCLA	Lars Scholtz (actg.)	Soholt	Soholt

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- - - - - QUALITY
 _____ TECHNICAL
 TBA = To Be Announced
 * Acting Program Manager (as needed)
 ** FIMAD = Facility for Information Management and Display
 *** Proposed Lead Group

Figure II-1. Organization of the Environmental Restoration Program at Los Alamos National Laboratory.

- ensuring the establishment, implementation, and support of the QA, health and safety (H&S), records management, and community relations programs.

2.3 Responsibilities of the Deputy Group Leader

The responsibilities of the Deputy Group leader are to

- serve as acting PM during the PM's absence;
- work with the PM and Deputy Division Leader to provide overall program planning coordination, oversight, and direction; and
- assist in interfacing with personnel and programs outside the ER Program Office, both inside and outside the Laboratory.

2.4 Responsibilities of Project Leaders

2.4.1 Operable Unit Project Leaders

Operable Unit (OU) Project Leaders (PLs) are responsible for

- overseeing day-to-day operations, including planning, scheduling, and reporting technical and related administrative activities;
- ensuring preparation of scientific investigation planning documents and procedures (e.g., QAPjP, RFI Work Plan);
- preparing monthly and quarterly reports for the PM;
- overseeing subcontractors, as appropriate;
- coordinating with technical team leaders;
- conducting technical reviews of the milestones and final reports;
- interfacing with the ER Quality Program Project Leader (QPPL) to resolve quality concerns and to coordinate audits with the QA staff;
- determining staffing needs, reviewing personnel qualifications, providing training, guidance, instruction, and supervision of staff;

- complying with the ER Program H&S, records management, and community relations plans; and
- complying with the ER Program's technical, administrative, and QA procedures.

2.4.2 Quality Program Project Leader

The QPPL is responsible for directing and managing the ER Quality Program, including

- ensuring that independent organizations adequately and effectively evaluate the quality program;
- verifying that ER Program personnel and subcontractors properly implement the ER Quality Program;
- resolving disputes regarding quality;
- overseeing a QA staff;
- reviewing and approving quality-related plans and implementing procedures;
- ensuring that QA audits are conducted;
- issuing stop-work orders;
- serving as liaison between the Laboratory's ER Quality Program and the EPA's Regional Office of Quality Assurance; and
- preparing monthly reports for the ER PM.

The QPPL will function and be funded independently from the technical projects undergoing QA review. The QPPL will not perform duties that preclude full attention to QA responsibilities or that conflict with the reporting and resolution of QA issues and problems. The QPPL reports directly to the ER PM on day-to-day activities and to the HSE Deputy Division Leader when necessary to resolve QA issues.

2.4.3 Health and Safety Project Leader

The H&S PL is responsible for

- preparing and ensuring implementation of the ER Program H&S plan;
- reviewing site-specific H&S plans prepared by subcontractor or Laboratory personnel;
- interfacing and coordinating with Laboratory personnel to use resources appropriate for the ER H&S Program;
- ensuring that the ER Program complies with applicable environmental regulations, DOE orders, UC and Laboratory policy, and applicable New Mexico laws and regulations;
- overseeing the maintenance of the H&S data base for the ER Program in such areas as worker training and medical surveillance; and
- preparing monthly reports for the ER PM.

2.4.4 Community Relations Project Leader

The community relations PL

- prepares the Community Relations Program Plan and implements its provisions;
- coordinates with program personnel to ensure resources for the community relations program;
- ensures that the community relations program meets the requirements of the HSWA Module;
- serves as the primary interface between the public and the ER Program Office; and
- prepares monthly reports for the ER PM.

2.4.5 Project Leader for the Facility for Information Management and Display

The Facility for Information Management and Display (FIMAD) supports all of the electronic information needs of the ER Program at Los Alamos. The PL for the FIMAD is responsible for

- developing and operating the FIMAD;
- conducting systems analyses of information-processing needs and incorporating analyses in the development of the FIMAD;
- testing, evaluating, and purchasing requisite hardware and software;
- determining staffing needs, reviewing personnel qualifications, and providing training, guidance, instruction, and supervision for the FIMAD;
- developing procedures for operation and configuration management of the FIMAD;
- initiating and maintaining an active collaborative effort with local universities; the National Center for Geographic Information and Analysis; industry; and other government organizations (foreign and domestic) in professional training, research, and applied technology;
- assisting in technical projects at the FIMAD, such as developing graphical user interfaces, system integration and networking; developing operating system tools for backup, security, and disaster recovery; and developing applications software to support two- and three-dimensional modeling, integration of raster and vector graphics, and still-video archival and retrieval capability across a network; and
- preparing monthly reports for the ER PM.

2.4.6 Project Leader for Records Management

The PL for records management will

- develop and implement a records management plan (RMP);
- serve as contact for project participants for matters regarding records and technical data;

- coordinate the flow of records to the FIMAD;
- ensure that records management procedures comply with regulatory guidelines and requirements;
- standardize documentation controls to ensure the integrity of data and records;
- initiate and oversee development of administrative procedures (APs) for implementing the RMP and Program Management Plan (PMP);
- assist with identifying reporting requirements (including reporting frequency, formats, and types of information);
- serve as primary interface with the Communications and Records Management Division to ensure compliance with Laboratory records policy;
- collaborate closely with key ER Program personnel on records management issues; and
- prepare monthly reports for the ER PM.

2.4.7 Project Leader for Resource Planning

The resource planning PL's responsibilities include

- developing a master logic network (schedule) for the ER Program,
- integrating the schedule with the work breakdown structure (WBS),
- projecting near- and long-term resource needs of the ER Program, and
- assisting other project leaders in resource planning and scheduling.

2.5 Responsibilities of Technical Team Leaders

Technical team leaders are responsible for

- coordinating team activities with PLs,
- issuing programmatic guidance to team members,
- ensuring independent reviews of team deliverables,

- ensuring development of Standard Operating Procedures (SOPs), as appropriate,
- ensuring the quality and completeness of deliverables, and
- designating QA representatives, as appropriate.

2.6 Quality Assurance Representative

The technical teams will be represented on the ER Program Quality Council (Section 20). The QA representative is the primary source of information on QA policy for the team and will serve as a member of the ER Program Quality Council. As appropriate, the QA representatives

- recommend and review proposals for improvements in QA policies and procedures,
- prepare and review quality-related procedures and plans,
- evaluate potential quality problem areas,
- consult on matters of QA specific to their organizations,
- serve as a source of information on QA matters and help to implement the ER Quality Program in their organization,
- help with the coordination of audits,
- participate in audits of other areas, and
- assist in preparing procurement requests.

3.0 QUALITY ASSURANCE PROGRAM

This QPP states the QA requirements applicable to the ER Program. Activities will be planned, implemented, and maintained as required by this QPP.

The requirements established in this QPP will be implemented by ER Program personnel through written documents such as QAPjPs, quality procedures (QPs), APs, and standard operating procedures (SOPs). The QPP describes what will be controlled and the planned approaches for implementing controls. The QPs, APs, QAPjPs, and SOPs describe in detail how controls will be implemented.

Figure II-1 identifies all of the major organizational units participating in the ER Quality Program. The figure also identifies the QA representative at each organizational level. ER Program subcontractors are accountable to PLs or organizational units and are subject to the same or equivalent QA requirements as those defined in this QPP.

This plan is prepared in accordance with the EPA guidelines for QPPs as outlined in QAMS-004/80, Interim Guidelines and Specifications for Preparing Quality Assurance Program Plans (EPA 1980) and NQA-1, Quality Assurance Requirements for Nuclear Facilities (ANSI/ASME 1989), as specified in DOE Order 5700.6B. Table II-1 is a matrix that lists the ER Quality Program control elements based on NQA-1 in the first column and on the QAMS-004/80 control elements in the second column.

Quality is defined as conformance to valid, mutually agreed-upon requirements. The intent of this QPP is to present a comprehensive, coherent, QA program compatible with QA standards of both DOE and EPA. The approach taken seeks to satisfy the QA requirements of both groups and to serve the basic intent of all quality programs; i.e., to ensure that appropriate controls are applied to a program, project, or activity; that the quality of the results is known and documented; and that the effectiveness of the controls, as implemented, can be evaluated.

3.1 Personnel Qualifications and Training

3.1.1 Qualifications of Environmental Restoration Program Personnel

3.1.1.1 Documentation of Qualifications

ER Program positions will be filled by qualified individuals. Documentation of personnel qualifications will include relevant education, experience, and training. A brief description of the education and relevant experience of ER Program staff is presented in Appendix R of the Installation Work Plan.

TABLE II-1

QUALITY ASSURANCE CONTROL ELEMENTS CROSS-REFERENCE MATRIX

<u>ER Quality Program Control Elements</u>	<u>QAMS 004/80 Control Elements</u>
Identification Form	1. Identification
1.0 Introduction	2. Introduction 3. Policy Statement
2.0 Organization	4. Quality Assurance Management
3.0 Quality Assurance Program	5. Personnel Qualifications 6. Data Quality Assessment
4.0 Design Control	7. Data Generation
5.0 Procurement Document Control and Control of Purchased Items and Services	6. Facilities, Equipment, and Services
6.0 Instructions, Procedures, Plans, and Drawings	7. Data Generation
7.0 Document Control	4. Quality Assurance Management
8.0 Identification and Control of Items and Samples	9. Data Quality Assessment
9.0 Control of Processes	8. Data Processing
10.0 Inspection	
11.0 Test Control	
12.0 Control of Measuring and Test Equipment	6. Facilities, Equipment, and Services
13.0 Handling, Storage, and Shipping	8. Data Processing
14.0 Inspection, Test, and Operating Status	
15.0 Control of Nonconforming Items	
16.0 Corrective Action	10. Corrective Action
17.0 Records	8. Data Processing
18.0 Audits and Surveillance	4. Quality Assurance Management
19.0 Software Quality Assurance	
20.0 Quality Improvement	

3.1.1.2 Evaluation of Qualifications

Supervisors will periodically review personnel qualifications to ensure that their qualifications are adequate to carry out their current responsibilities.

3.1.2 Training

Individuals assigned to perform activities affecting quality will receive, at a minimum, orientation to familiarize them with the purpose, scope, methods of implementation, and applicability of the following documents as they relate to the individual's work:

- QPPs;
- QAPjPs; and
- implementing procedures, SOPs, and work plans.

Training may consist of a mandatory reading list, classroom and video presentations, or other methods of instruction. Supervisors should review their employees' training needs at least annually.

3.2 Assessment of Quality Program

All projects and activities will be subject to periodic audits. Audits (systems audits) and surveys (performance audits) will be conducted as arranged by the PL, quality assurance representative, and QPPL. Audits assess the adequacy of, and adherence to, the ER QPP, QAPjPs, and implementing procedures. Audits (Section 18) will be performed in accordance with written plans and check lists.

3.3 Data Quality Objectives

Most, if not all, ER Program projects and activities rely on the ability to obtain environmental data of known and documented quality to meet objectives and to determine overall success. To ensure that adequate environmental data are obtained, DQOs must be established and documented at the onset of each project. To ensure that reliable data are obtained, tight quality controls must be built into project designs and are documented in QAPjPs and associated design documents.

DQOs for data collection describe the uncertainty that a decision maker is willing to accept in results derived from environmental data. This uncertainty is used to specify the quality of the measurement data required, usually in terms of precision, accuracy, representativeness, comparability, and completeness. The DQOs will be defined and approved by the Laboratory, DOE, and EPA before field and laboratory work is

initiated. The organizations performing the work must be aware of the DQOs so that they may make informed decisions about how to attain those DQOs during the course of the project. Development of DQOs is described in Data Quality Objectives for Remedial Response Activities (EPA 1987). DQOs are further discussed in QAPjPs.

Data quality should not be confused with data usability; the two are closely related, but only data users determine usability. In general, determining usability is a qualitative decision process, whereas determining data quality is a quantitative verification process.

3.4 Assessment of Data Quality

The quality of the measurement data generated and processed will be assessed to determine whether DQOs have been met. Aspects of data quality to be addressed are precision, accuracy, representativeness, completeness, and comparability. EPA-approved and/or the best available methodology will be used for assessing data quality. For many measurements and analyses conducted by the ER Program, suitable methodology must be developed and verified. Aspects of data quality to be addressed are discussed in the following subsections.

3.4.1 Precision

SOPs will contain a mechanism for demonstrating the reproducibility of each measurement process. Examples of activities used for assessing precision are listed below.

3.4.1.1 Standard Reference Materials

Analytical data from standard reference material will be within prescribed acceptance limits.

3.4.1.2 Instrument Checks

Each measurement device will be checked routinely to demonstrate that variables are within predetermined acceptance limits. Examples of checks include zero, noise level, drift, flow rate, linearity, and daily performance checks.

3.4.2 Accuracy

SOPs will contain mechanisms for demonstrating the relationship of the reported data compared with the "true" value(s).

3.4.2.1 Traceability of Instruments

A unique identification number will be assigned to each measurement device. Documentation will include the identification number, where and when the measurement device was used, description of maintenance performed, and the equipment and standards used for calibration.

3.4.2.2 Traceability of Standards

Each standard and measurement device will be calibrated against a standard of known and higher accuracy, when possible. All calibration standards will be traceable to National Institute of Standards and Technology (NIST) standards. If NIST standards do not exist, other validated (primary) standards will be used, or the basis for calibration will be documented.

3.4.2.3 Traceability of Samples

At the time each sample is collected, it will receive a unique identification number. Documentation will include sample number, time and place of sampling, and action taken on each sample in accordance with the procedure for sample chain of custody.

3.4.2.4 Traceability of Data

Data will be recorded in a manner that allows complete traceability from initial field records through retrieval from the data storage system.

3.4.2.5 Reference, Spiked, or Blind Samples

Recoveries of reference, spiked, or blind samples will be within predetermined acceptance limits.

3.4.3 Representativeness, Comparability, and Completeness

Where appropriate, statements on representativeness, comparability, and completeness will be included.

4.0 DESIGN CONTROL

Identifying and documenting design criteria for ER activities and projects involves establishing the performance and quality objectives that a project or activity must achieve. Selection and definition of appropriate functional criteria and other design parameters are necessary to ensure that correct bases are established for engineering design. Controls will be established for engineering design activities to ensure that engineering designs and design data comply with functional design criteria and other requirements.

Planning will be documented to provide early and adequate assurance that requirements can and will be met. Procedures will be developed for various design activities, including analyses, calculations, and the preparation and control of drawings and documents. Procedures will also be developed to verify that the products of engineering design comply with functional design criteria and meet applicable requirements.

Laboratory facilities that are designed, engineered, or constructed specifically for the ER of solid waste management units (SWMUs) are exempt from these design controls. Design control requirements for these facilities are addressed in the Laboratory Quality Manual for Engineering and Construction (Facilities Engineering Division).

5.0 CONTROL OF PROCUREMENT DOCUMENTS AND PURCHASED ITEMS AND SERVICES

Procurement of items and services will be controlled to ensure conformance with the requirements listed below. The extent to which controls are applied depends on the importance and complexity of the item or service and the need to control an activity to ensure the quality of the item or service. In general, commercial, off-the-shelf items and equipment are exempt from stringent procurement requirements.

Procurement documents will contain the following information, as appropriate:

- description of the scope of work,
- technical requirements for the work,
- Quality Program requirements,
- a right-of-access provision for audit purposes,
- subcontracting requirements (including having subcontractors pass through appropriate QA requirements),
- documentation requirements, and
- applicable design bases.

Acceptance of services performed requires documentation of audits, a technical review of data generated, or other objective evidence of satisfactory performance.

Methods of acceptance for items include

- supplier certificate of conformance,
- a source verification,
- an inspection performed upon receipt of the item,
- a post installation test of the item at the facility site, or
- a combination of the above.

6.0 INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS

A method for initiating, preparing, reviewing, and approving instructions, procedures, and drawings for ER Program QA, administrative, and technical activities will be established and maintained. Procedures will include or reference qualitative or quantitative acceptance criteria, if applicable, for determining that prescribed activities have been satisfactorily accomplished (e.g., that tolerances required for calibrating monitoring and test equipment have been met). Activities that typically require approved, detailed procedures include, but are not limited to, audits, records and document control, data assessment, and field and laboratory operations.

6.1 Quality Assurance Project Plans

All projects that generate environmental data mandated by the HSWA Module require a QAPjP. A generic QAPjP applicable to site investigation activities will be prepared.

Task-specific QAPjP must be prepared according to the Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans (EPA 1980). It should also reference approved SOPs whenever possible and incorporate the generic QAPjP by reference, as appropriate. The level of detail of a QAPjP will depend on the requirements of the OU work plan and other special considerations. Each QAPjP must address the 16 elements listed below. In instances in which specific QAPjP elements are addressed as an integral part of the OU work plan, it is only necessary to cite the location (section) in the work plan in the subsection designated for this purpose. If an element does not apply, an explanation must be included in the corresponding subsection of the QAPjP. It may be necessary to modify the plan during the course of the project.

Each QAPjP must include the following items:

- title page with provision for approval signatures;
- table of contents;
- project description;
- project organization and responsibility;
- DQOs for measuring the precision, accuracy, completeness, comparability, and representativeness of data;
- sampling procedures;

- chain-of-custody requirements;
- calibration procedures and their frequency;
- analytical procedures;
- data reduction, validation, and reporting;
- internal quality control checks and their frequency;
- performance and system audits and their frequency;
- QA reports to management;
- preventive maintenance procedures and schedules;
- specific routine procedures to assess precision, accuracy, representativeness, completeness, and comparability of data; and
- corrective action.

6.2 Standard Operating Procedures

SOPs describe standard operations, analyses, or actions commonly accepted as the usual method of conducting repetitive or routine work. They will be sufficiently complete and detailed to ensure that data of known quality are generated to meet measurement objectives and minimal loss of data results from out-of-control conditions.

SOPs will be

- adequate to establish traceability of standards, instrumentation, samples, and environmental data;
- consistent with sound scientific and engineering principles; and
- consistent with the instrument manufacturers' instruction manuals.

Documentation for SOPs will include

- a record of the performance of all tasks and their results,

- an explanation of the cause of missing data, and
- a validation of data each time they are recorded, calculated, or transcribed.

To accomplish these objectives, SOPs will address the following areas, as applicable:

- sampling and analytical methodology;
- special precautions, such as holding times and preservation;
- selection and use of instrumentation;
- calibration and standardization of instruments;
- preventive and remedial maintenance;
- replicate sampling and analysis;
- blind and spiked samples;
- quality control procedures such as inter- and intralaboratory or field activities;
- documentation;
- sample custody and handling procedures;
- sample transportation;
- data-handling and evaluation procedures; and
- precision, accuracy, completeness, representativeness, and comparability.

Measurement activities will adhere to established EPA regulations and guidelines and ER Program SOPs. Deviations from SOPs will be justified and documented in field and/or laboratory notebooks and/or logbooks and/or on the appropriate forms. Adherence to approved SOPs will be determined during audits. SOPs will be revised as necessary. SOPs covering H&S are covered in the ER Program Health and Safety Plan (Annex III of the IWP).

6.3 Quality Procedures

QPs will describe the methods for performing and implementing the quality requirements identified in this QPP (e.g., requirements for audits, corrective action, and stop work).

QPs will adhere to the following format:

Section 1	Purpose
Section 2	Scope
Section 3	Definitions
Section 4	Responsibilities
Section 5	Procedure
Section 6	References
Section 7	Records
Section 8	Attachments

QPs will be approved by the Program Manager and the QPPL.

6.4 Administrative Procedures

APs will describe the management controls for administrative controls such as records management, personnel qualification and training, document preparation and review, and document control.

7.0 DOCUMENT CONTROL

Documents that prescribe activities affecting quality (such as work plans, procedures, instructions, and directives) will be prepared, revised, reviewed, and issued in accordance with written procedures. These procedures will use logs, registers, transmittals, acknowledgments, and other controls to monitor the status of documents and to describe how documents, including changes thereto, are reviewed and coordinated before approval and issuance.

Changes to documents, other than those defined as minor changes, will be controlled by the same measures (or their equivalent) used to control the original document. They will be reviewed and approved by the organizations that originally reviewed the documents unless other organizations are specifically designated. The reviewing organization will have access to pertinent background information upon which to base its reviews.

Changes that do not alter a document's intent, objectives, or quality requirements will be considered minor and will not be subject to the requirements of this section. Minor changes that can be made or authorized by the preparer of the document include typographical errors, punctuation, and other minor editorial corrections.

8.0 IDENTIFICATION AND CONTROL OF ITEMS AND SAMPLES

Procedures for identifying and controlling samples, analytical standards, and data will be established to ensure that these items are accurately and correctly marked and traceable and that documentation is maintained. Field and laboratory procedures for sample identification and for chain of custody will be established to maintain the identity and integrity of all samples and sample data. Procedures for ensuring that working standards are traceable to primary reference materials will be developed. The specific methods used for identifying and controlling samples, standards, and data will be described in written procedures.

9.0 CONTROL OF PROCESSES

9.1 Data Collection

The QAPjP will address the methods to be used to eliminate or avoid errors during data collection. Data may be collected manually or electronically and may have many different sources ranging from historical sources to direct field measurements. Where field measurements or observations are made, the data collected will be entered on the appropriate forms. Bench records will be maintained for laboratory data. Data that may be collected include monitoring data, values, date and time of activity, site conditions, field calculations, and engineering analyses.

9.2 Validation

Data validation is defined as the process whereby data are filtered and accepted or rejected based on a set of predetermined criteria. Data validation consists of reviewing data for compliance with method acceptance criteria and then evaluating the usability and validity of the data. All calculations and records will be examined, quality control sample results will be checked, and the data set will be qualified.

The quality of sample analyses will be controlled and verified by established acceptance criteria to ensure that process parameters are controlled and that specified environmental measurement conditions are maintained. Acceptance criteria will be established for each analytical method. Acceptance criteria for analytical parameters are typically documented by maintaining control charts; however, records demonstrating that acceptance criteria have been achieved are an acceptable substitute.

Laboratories that analyze samples for the ER Program will maintain quality control charts. Analysts are responsible for documenting all process acceptance criteria and updating control charts in a timely and orderly manner. Separate control charts will be maintained for each instrument and analyst.

Data outside the upper and lower bounds for acceptance will be reported to the PL, who will decide whether data collection or analysis must be repeated. Validation of data collection and reduction is ensured through regular evaluations that include checking results for errors in computer entry, data transmission, and transcription during data processing. Data validation will follow established guidelines so that consistent reviews are obtained.

10.0 INSPECTION

Scientific investigations relating to site characterization do not ordinarily require that engineering inspections be made to verify conformance of an item or activity to specified requirements. Activities that do require inspection (such as acceptance of materials, technical reviews, document compliance, and project auditing) are covered elsewhere in this QPP.

All engineered/fabricated items used to contain hazardous and/or radioactive wastes and other means of remediation used for the ER Program will be inspected. Specialists who are independent of primary design activities will conduct the inspection. Any aspect of design activities can be inspected. Quality inspections of design efforts include a review of activities and independent verification performed as part of the design process.

Inspections related to construction will be conducted by the construction contractor or by Facilities Engineering Division staff at the Laboratory according to approved procedures. Before construction begins, the inspector will review design drawings and specifications. Materials inspections will include comparison with purchase requisitions and orders in a manner commensurate with the items' impact on quality.

11.0 TEST CONTROL

As defined by NQA-1, a test is a measurement against a known standard. In the scientific investigation process for site characterization, such tests are conducted only for calibrating equipment (Section 12).

Tests of all engineered and fabricated items used for containing hazardous and/or radioactive waste will be described in specific test plans. An independent specialist will review these plans to ensure that the tests are appropriate. The tests include soils tests for foundation suitability, strength, soil consistency, and unconfined compressive strength. Materials tests may also be needed to verify liner performance, the strength of concrete mixes, etc.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

General laboratory and field equipment must be appropriate for its intended use and must be available in sufficient quantities and condition to generate and process environmental data reliably and in a documentable manner.

12.1 Identification of Equipment

Each piece of analytical equipment will be uniquely identified, either by the manufacturer's model and serial number or by a Laboratory property number. A permanent record containing service, maintenance, and records of calibration and periods of use will be maintained for each piece of equipment.

12.2 Maintenance and Calibration of Measuring and Test Equipment

Permanent records of the maintenance histories of measuring and test equipment (including detailed descriptions of adjustments made and parts replaced) will be kept in bound notebooks or logbooks and will be signed and dated.

All equipment used for monitoring, measuring, or testing must have an established calibration and preventive maintenance procedure. This procedure will be outlined in an equipment-specific SOP. Equipment will be calibrated against known standards or with procedures outlined by the manufacturer. Where applicable, service agreements for the equipment may be obtained and used. Routine calibration services are provided by the Standards and Calibration Group (MEC-8) at the Laboratory.

If a piece of equipment is found to be out of calibration, previous measurements or test results will be reviewed. Equipment that is out of calibration will be immediately removed and will not be used again until it can be recalibrated. If calibration cannot be maintained, the equipment must be replaced or repaired.

Calibration and control measures may not be required for rulers, tape measures, levels, and other such devices if normal commercial equipment provides adequate accuracy.

13.0 HANDLING, STORAGE, AND SHIPPING

Procedures for handling, field storage, custody transfer, shipping, receiving, and laboratory storage of samples; laboratory identification and security of samples; tracking samples; and data file assembly for ER Program samples and associated analytical data will be specified and controlled to prevent contamination, damage, or loss and to minimize the deterioration of samples and standards. Personnel involved in handling, shipping, or storing samples will be trained in performing the specific procedures used, if not qualified by previous education or experience.

14.0 INSPECTION, TEST, AND OPERATING STATUS

The requirements of this section apply to engineered items. The requirements of this section do not apply to site characterization activities.

For engineered facilities that are used for hazardous and/or radioactive waste containment, this requirement applies to the operational readiness of the facility and to the operating status of support systems, such as environmental sampling and monitoring systems and waste inspection and handling systems. Activities demonstrating the operational readiness of such a facility will be identified. The facility's design and construction records will be reviewed. The results of tests, inspections, surveillances, audits, and corrective actions will be reviewed. All identified nonconformances will be resolved before determining that the construction task has been completed and that the facility is operable.

15.0 CONTROL OF NONCONFORMING ITEMS

Nonconforming items may include materials, operating equipment, test equipment, analytical equipment, unacceptable reports, or unacceptable construction work. In all cases, nonconforming items will be clearly identified (by label or by designation) and will be removed from service or otherwise controlled until a resolution has been completed and documented.

16.0 CORRECTIVE ACTION

A procedure will be developed to provide an effective method for identifying and correcting conditions that are adverse to quality. All personnel are responsible for identifying adverse conditions.

An effective corrective action program contains the following requirements:

- Conditions that adversely affect quality will be investigated promptly so that the cause can be determined and corrective action can be initiated to prevent recurrence.
- The cause of problems and the mitigative measures taken will be reported to the appropriate levels of management.
- Actions that must be taken to ensure the verification of corrective actions will be identified.

Corrective action procedures will have guidelines for determining when a corrective action is necessary, provisions to inform management of the need for a corrective action, and provisions for following up the corrective action to determine its success.

17.0 RECORDS

Adequate precautions will be taken during the reduction, manipulation, and storage of data to prevent the introduction of errors or the loss or misinterpretation of data. Data processing consists of collection, validation, storage, transfer, and reduction. The RMP (Annex IV of the IWP) addresses the programmatic needs for all stages of technical data, program records, technical literature, and other support documentation.

A records system to identify and classify project records will be established. The records system will be defined and implemented in accordance with written procedures, which will specify how records are identified, classified (lifetime or nonpermanent), indexed, reviewed (inspected), stored, protected, and retrieved.

Records that document evidence of quality will be specified, prepared, and maintained in accordance with appropriate APs and will comply with DOE Order 1324.2A, Records Disposition (DOE 1988). The records will be legible, identifiable, and retrievable and will be protected against damage, deterioration, or loss.

All records generated for the ER Program by the Laboratory and its subcontractors must be submitted to the ER Program in accordance with ER procedures.

18.0 AUDITS AND SURVEYS

Audits and surveys will be performed to verify that ER Program activities comply with all aspects of the Quality Program. Qualified audit staff will conduct audits in accordance with written plans and check lists. Audits will be scheduled to provide coverage of and coordination with ongoing QA activities and will be conducted at a frequency commensurate with the importance of the audited activity. If the activity to be audited is part of a scientific investigation activity, the audit team will include at least one individual who has technical expertise in the activity to be audited.

Surveys will be performed by ER Quality Program personnel, or their designated representatives, who have the qualifications, experience, training, or expertise relevant to the project or activity being surveyed. Surveys will be conducted on an *ad hoc* basis and will not require formal scheduling; however, written notification of an impending surveillance is normally provided to the affected organization(s).

The terms "systems audit" and "performance audit" as used in QA programs required by EPA for performing environmental measurements are roughly equivalent to the terms "audit" and "survey."

19.0 SOFTWARE QUALITY ASSURANCE

Controls will be established over the development, modification, acquisition, and use of software in accordance with DOE Order 1330.1C, Computer Software Management (DOE 1990). Newly developed or modified software will receive an independent technical review. Software will be verified, and validated when required, through testing. Records of software configuration will be maintained. Software will be protected against uncontrolled changes and against loss or damage. Software applications will be documented, and application problems will be documented and resolved.

20.0 QUALITY IMPROVEMENT

Processes will be established and implemented with the objective of preventing and identifying problems. Examples of planning and problem prevention activities include but are not limited to peer reviews, design reviews, audits, surveys, and deficiency reporting.

All personnel are to identify nonconforming items and processes. The extent of root cause analyses for nonconforming items and processes is to be commensurate with the importance or significance of the problem.

Management, at all levels, is to foster a "no-fault" attitude to encourage the identification of nonconforming items and processes. Management is to be involved in the quality improvement process to ensure that proper focus is given, adequate resources are allocated and difficult issues are resolved.

Processes are to be established and implemented to promote continuous improvement. A quality council will be formed consisting of representatives from the technical teams. This council will recommend and review proposals for improving the Quality Program. The council will focus on preventing problems and on continuously improving the program to produce results that meet or exceed requirements.

REFERENCES

ANSI/ASME (American National Standards Institute/American Society of Mechanical Engineers) 1989. "Quality Assurance Requirements for Nuclear Facilities," NQA-1-89, 345 East 47th Street, New York, New York.

DOE (US Department of Energy) 1986, "Quality Assurance." DOE Order 5700.6B, Washington, D.C.

DOE (US Department of Energy) 1988. "Records Deposition," DOE Order 1324.2A, Washington, DC.

DOE (US Department of Energy) 1990. "Computer Software Management," DOE Order 1330.1C, Washington, DC.

EPA (US Environmental Protection Agency) 1980. "Interim Guidelines and Specifications for Preparing Quality Assurance Program Plans," QAMS-004/80, Washington, DC.

EPA (US Environmental Protection Agency) 1985. "Regional Technical Assistance for Preparing Quality Assurance Project Plans," ROQA-005/85, Washington, DC.

EPA (Environmental Protection Agency) 1987. "Data Quality Objectives for Remedial Response Activities," EPA/540/G-87/1003, Washington, DC.